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Dossier zur Nutzenbewertung gemäß § 35a SGB V

Obinutuzumab (Gazyvaro®)

Roche Pharma AG

Modul 4 C - Anhang G

Patienten mit nicht vorbehandeltem fortgeschrittenem follikulärem Lymphom (FL), außer Grad 3B

Medizinischer Nutzen und medizinischer Zusatznutzen, Patientengruppen mit therapeutisch bedeutsamem Zusatznutzen

Stand: 10.05.2021

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1 (Anhang): Ergebnisse für OS Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel – Datenschnitt 01.01.2016

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
ENDPOINT: Overall Survival
MODEL: Unstratified Analysis STUDY: BO21223
Time to Event Analysis by Subgroups (Efficacy)

		G-chemo (N=601)												R-chemo (N=601)												G-chemo vs. R-chemo						
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	601	100,0	35	5,8	566	94,2	NE	NE	NE	NE	NE	NE	601	100,0	46	7,7	555	92,3	NE	NE	NE	NE	NE	NE	0,2011	0,75	0,48	1,17		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	283	47,1	23	8,1	260	91,9	NE	NE	NE	NE	NE	NE	280	46,6	26	9,3	254	90,7	NE	NE	NE	NE	NE	NE	0,5522	0,84	0,48	1,48		Convergence criterion (GCONV=1E-8) satisfied.	0,4767
	Female	318	52,9	12	3,8	306	96,2	NE	NE	NE	NE	NE	NE	321	53,4	20	6,2	301	93,8	NE	NE	NE	NE	NE	NE	0,1681	0,61	0,30	1,24		Convergence criterion (GCONV=1E-8) satisfied.	
Age	< 60 years	298	49,6	8	2,7	290	97,3	NE	NE	NE	NE	NE	NE	323	53,7	15	4,6	308	95,4	NE	NE	NE	NE	NE	NE	0,1895	0,57	0,24	1,34		Convergence criterion (GCONV=1E-8) satisfied.	0,5219
	>= 60 years	303	50,4	27	8,9	276	91,1	NE	48,7	NE	NE	NE	NE	278	46,3	31	11,2	247	88,8	NE	NE	NE	NE	NE	NE	0,3712	0,79	0,47	1,32		Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	487	81,0	30	6,2	457	93,8	NE	NE	NE	NE	NE	NE	481	80,0	41	8,5	440	91,5	NE	NE	NE	NE	NE	NE	0,1526	0,71	0,44	1,14		Convergence criterion (GCONV=1E-8) satisfied.	0,5457
	Other	114	19,0	5	4,4	109	95,6	NE	NE	NE	NE	NE	NE	120	20,0	5	4,2	115	95,8	NE	NE	NE	NE	NE	NE	0,8858	1,10	0,32	3,79		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	North America	75	12,5	6	8,0	69	92,0	NE	48,7	NE	NE	NE	NE	77	12,8	5	6,5	72	93,5	NE	NE	NE	NE	NE	NE	0,6374	1,33	0,40	4,37		Convergence criterion (GCONV=1E-8) satisfied.	0,6850
	Western Europe	294	48,9	17	5,8	277	94,2	NE	NE	NE	NE	NE	NE	286	47,6	24	8,4	262	91,6	NE	NE	NE	NE	NE	NE	0,2016	0,67	0,36	1,25		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia-Pacific	152	25,3	8	5,3	144	94,7	NE	NE	NE	NE	NE	NE	155	25,8	9	5,8	146	94,2	NE	NE	NE	NE	NE	NE	0,8086	0,89	0,34	2,31		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	80	13,3	4	5,0	76	95,0	NE	NE	NE	NE	NE	NE	83	13,8	8	9,6	75	90,4	NE	NE	NE	NE	NE	NE	0,2737	0,52	0,16	1,72		Convergence criterion (GCONV=1E-8) satisfied.	
Baseline ECOG Performance Status score	0-1	585	97,3	31	5,3	554	94,7	NE	NE	NE	NE	NE	NE	576	95,8	39	6,8	537	93,2	NE	NE	NE	NE	NE	NE	0,2774	0,77	0,48	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,5772
	2	15	2,5	4	26,7	11	73,3	24,4	12,0	NE	NE	25,5	NE	23	3,8	7	30,4	16	69,6	20,4	9,7	NE	NE	NE	NE	0,9390	1,05	0,31	3,59		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	2	0,3			2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Independence status (Katz ADL)	Independent (5-6)	459	76,4	20	4,4	439	95,6	NE	NE	NE	NE	NE	NE	462	76,9	37	8,0	425	92,0	NE	NE	NE	NE	NE	NE	0,0208	0,53	0,31	0,92		Convergence criterion (GCONV=1E-8) satisfied.	0,0155
	Some dependence (3-4)	4	0,7			4	100,0	NE	NE	NE	NE	NE	NE	5	0,8	3	60,0	2	40,0	5,9	0,6	NE	39,7	0,6	NE	0,1319	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Very dependent (0-2)	3	0,5			3	100,0	NE	NE	NE	NE	NE	NE	7	1,2			7	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Outside valid range	52	8,7	4	7,7	48	92,3	NE	NE	NE	NE	NE	NE	47	7,8	1	2,1	46	97,9	NE	NE	NE	NE	NE	NE	0,2290	3,53	0,39	31,64		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	83	13,8	11	13,3	72	86,7	NE	48,7	NE	NE	NE	NE	80	13,3	5	6,3	75	93,8	NE	NE	NE	NE	NE	NE	0,1612	2,10	0,73	8,04		Convergence criterion (GCONV=1E-8) satisfied.	
Independence status (Katz IADL)	Independent (5-8)	504	83,9	28	5,6	476	94,4	NE	NE	NE	NE	NE	NE	501	83,4	36	7,2	465	92,8	NE	NE	NE	NE	NE	NE	0,2747	0,76	0,46	1,25		Convergence criterion (GCONV=1E-8) satisfied.	0,9680
	Some dependence (1-4)	9	1,5	1	11,1	8	88,9	NE	0,8	NE	NE	NE	NE	14	2,3	4	28,6	10	71,4	39,7	16,1	NE	NE	39,7	NE	0,4938	0,47	0,05	4,26		Convergence criterion (GCONV=1E-8) satisfied.	

	Very dependent (0)	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Outside valid range	16	2,7			16	100,0	NE	NE	NE	NE	NE	NE	11	1,8			11	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	71	11,8	6	8,5	65	91,5	NE	48,7	NE	NE	NE	NE	74	12,3	6	8,1	68	91,9	NE	NE	NE	NE	NE	NE	0,9619	0,97	0,31	3,03	Convergence criterion (GCONV=1E-8) satisfied.	
Chemotherapy regimen	CHOP	195	32,4	7	3,6	188	96,4	NE	NE	NE	NE	NE	NE	203	33,8	9	4,4	194	95,6	NE	NE	NE	NE	NE	NE	0,6609	0,80	0,30	2,15	Convergence criterion (GCONV=1E-8) satisfied.	0,6296
	CVP	61	10,1	2	3,3	59	96,7	NE	NE	NE	NE	NE	NE	57	9,5	5	8,8	52	91,2	NE	43,5	NE	NE	NE	NE	0,2125	0,37	0,07	1,90	Convergence criterion (GCONV=1E-8) satisfied.	
	Bendamustine	345	57,4	26	7,5	319	92,5	NE	NE	NE	NE	NE	NE	341	56,7	32	9,4	309	90,6	NE	NE	NE	NE	NE	NE	0,3862	0,80	0,47	1,34	Convergence criterion (GCONV=1E-8) satisfied.	
Histologic grade	1	242	40,3	12	5,0	230	95,0	NE	NE	NE	NE	NE	NE	219	36,4	16	7,3	203	92,7	NE	NE	NE	NE	NE	NE	0,2747	0,66	0,31	1,40	Convergence criterion (GCONV=1E-8) satisfied.	0,6951
	2	267	44,4	13	4,9	254	95,1	NE	NE	NE	NE	NE	NE	289	48,1	20	6,9	269	93,1	NE	NE	NE	NE	NE	NE	0,3093	0,70	0,35	1,40	Convergence criterion (GCONV=1E-8) satisfied.	
	3	4	0,7			4	100,0	NE	NE	NE	NE	NE	NE	3	0,5	1	33,3	2	66,7	9,2	0,2	NE	NE	0,2	NE	0,2482	<0.01	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	3a	82	13,6	9	11,0	73	89,0	NE	NE	NE	NE	NE	NE	85	14,1	9	10,6	76	89,4	NE	NE	NE	NE	NE	NE	0,9262	1,04	0,41	2,63	Convergence criterion (GCONV=1E-8) satisfied.	
	Other	2	0,3			2	100,0	NE	NE	NE	NE	NE	NE	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	4	0,7	1	25,0	3	75,0	30,9	30,9	NE	NE	30,9	NE	4	0,7			4	100,0	NE	NE	NE	NE	NE	NE	0,1573	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
FLIPI	Low (0-1)	128	21,3	6	4,7	122	95,3	NE	NE	NE	NE	NE	NE	125	20,8	4	3,2	121	96,8	NE	NE	NE	NE	NE	NE	0,5924	1,41	0,40	5,00	Convergence criterion (GCONV=1E-8) satisfied.	0,5732
	Intermediate (2)	224	37,3	9	4,0	215	96,0	NE	NE	NE	NE	NE	NE	223	37,1	12	5,4	211	94,6	NE	NE	NE	NE	NE	NE	0,4900	0,74	0,31	1,75	Convergence criterion (GCONV=1E-8) satisfied.	
	High (>=3)	249	41,4	20	8,0	229	92,0	NE	48,7	NE	NE	NE	NE	253	42,1	30	11,9	223	88,1	NE	NE	NE	NE	NE	NE	0,1736	0,68	0,38	1,19	Convergence criterion (GCONV=1E-8) satisfied.	
FC Gamma Receptor IIa	131HH	182	30,3	6	3,3	176	96,7	NE	NE	NE	NE	NE	NE	184	30,6	11	6,0	173	94,0	NE	NE	NE	NE	NE	NE	0,2455	0,56	0,21	1,51	Convergence criterion (GCONV=1E-8) satisfied.	0,2586
	131HR	277	46,1	21	7,6	256	92,4	NE	NE	NE	NE	NE	NE	270	44,9	23	8,5	247	91,5	NE	NE	NE	NE	NE	NE	0,6392	0,87	0,48	1,57	Convergence criterion (GCONV=1E-8) satisfied.	
	131RR	114	19,0	4	3,5	110	96,5	NE	NE	NE	NE	NE	NE	117	19,5	12	10,3	105	89,7	NE	NE	NE	NE	NE	NE	0,0398	0,32	0,10	1,01	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	28	4,7	4	14,3	24	85,7	48,7	23,5	NE	NE	48,7	NE	30	5,0			30	100,0	NE	NE	NE	NE	NE	NE	0,0507	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
FC Gamma Receptor IIIa	158VV	67	11,1	3	4,5	64	95,5	NE	NE	NE	NE	NE	NE	77	12,8	7	9,1	70	90,9	NE	NE	NE	NE	NE	NE	0,3328	0,52	0,13	2,01	Convergence criterion (GCONV=1E-8) satisfied.	0,7189
	158VF	283	47,1	13	4,6	270	95,4	NE	NE	NE	NE	NE	NE	238	39,6	18	7,6	220	92,4	NE	NE	NE	NE	NE	NE	0,1332	0,58	0,29	1,19	Convergence criterion (GCONV=1E-8) satisfied.	
	158FF	223	37,1	15	6,7	208	93,3	NE	NE	NE	NE	NE	NE	256	42,6	21	8,2	235	91,8	NE	NE	NE	NE	NE	NE	0,5568	0,82	0,42	1,59	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	28	4,7	4	14,3	24	85,7	48,7	23,5	NE	NE	48,7	NE	30	5,0			30	100,0	NE	NE	NE	NE	NE	NE	0,0507	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
FC Gamma Receptor IIb/IIc	232II	417	69,4	26	6,2	391	93,8	NE	NE	NE	NE	NE	NE	406	67,6	33	8,1	373	91,9	NE	NE	NE	NE	NE	NE	0,2808	0,75	0,45	1,26	Convergence criterion (GCONV=1E-8) satisfied.	0,5500
	232IT	104	17,3	4	3,8	100	96,2	NE	NE	NE	NE	NE	NE	116	19,3	8	6,9	108	93,1	NE	NE	NE	NE	NE	NE	0,3332	0,56	0,17	1,85	Convergence criterion (GCONV=1E-8) satisfied.	
	232TT	9	1,5			9	100,0	NE	NE	NE	NE	NE	NE	10	1,7	1	10,0	9	90,0	NE	16,1	NE	NE	NE	NE	0,3711	<0.01	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	71	11,8	5	7,0	66	93,0	48,7	48,7	NE	NE	48,7	NE	69	11,5	4	5,8	65	94,2	NE	NE	NE	NE	NE	NE	0,8956	1,09	0,29	4,11	Convergence criterion (GCONV=1E-8) satisfied.	
Time from initial FL diagnosis to randomization	< 6 months	490	81,5	25	5,1	465	94,9	NE	NE	NE	NE	NE	NE	474	78,9	34	7,2	440	92,8	NE	NE	NE	NE	NE	NE	0,1672	0,70	0,42	1,17	Convergence criterion (GCONV=1E-8) satisfied.	0,7978
	6-12 months	35	5,8	1	2,9	34	97,1	NE	NE	NE	NE	NE	NE	32	5,3	1	3,1	31	96,9	NE	NE	NE	NE	NE	NE	0,8306	0,74	0,05	11,99	Convergence criterion (GCONV=1E-8) satisfied.	
	> 12 months	73	12,1	8	11,0	65	89,0	NE	NE	NE	NE	NE	NE	95	15,8	11	11,6	84	88,4	NE	43,5	NE	NE	NE	NE	0,9815	0,99	0,40	2,46	Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,5	1	33,3	2	66,7	8,2	8,2	NE	NE	8,2	NE														NE					
Ann Arbor Stage 2	Stage I	10	1,7	1	10,0	9	90,0	NE	30,9	NE	NE	NE	NE	8	1,3			8	100,0	NE	NE	NE	NE	NE	NE	0,3613	>999.99	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	0,4305
	Stage II (w/o bulky disease)	14	2,3			14	100,0	NE	NE	NE	NE	NE	NE	14	2,3	2	14,3	12	85,7	NE	34,4	NE	NE	NE	NE	0,1918	<0.01	0,00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
	Stage II (with bulky disease)	27	4,5	1	3,7	26	96,3	NE	NE	NE	NE	NE	NE	30	5,0	2	6,7	28	93,3	NE	NE	NE	NE	NE	NE	0,5177	0,46	0,04	5,12	Convergence criterion (GCONV=1E-8) satisfied.	

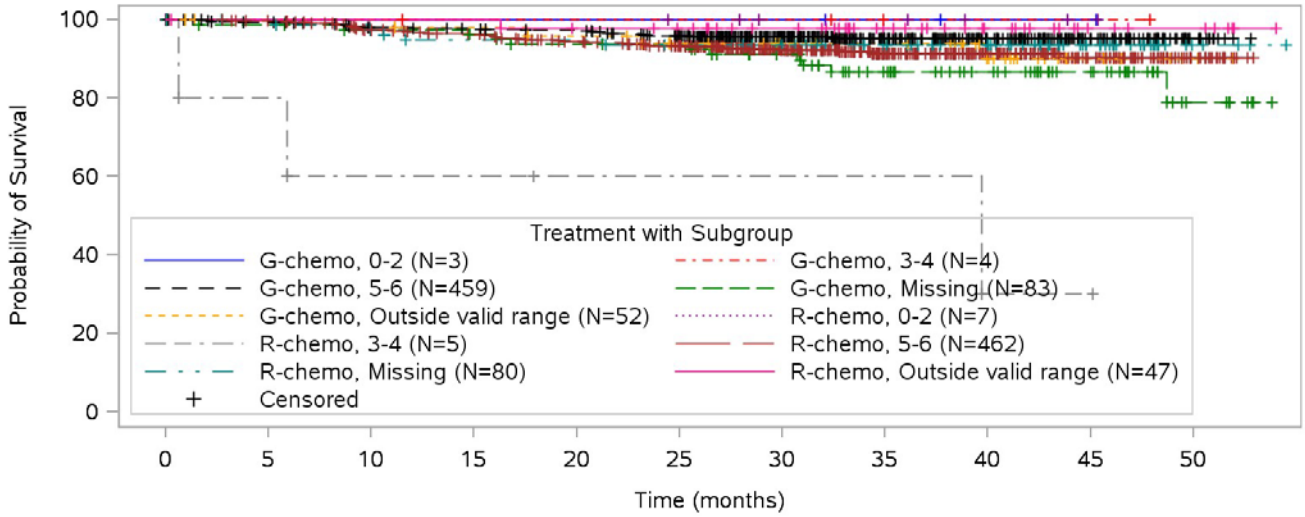
	Stage III	208	34,6	12	5,8	196	94,2	NE	NE	NE	NE	NE	NE	209	34,8	16	7,7	193	92,3	NE	NE	NE	NE	NE	NE	0,4130	0,73	0,35	1,55		Convergence criterion (GCONV=1E-8) satisfied.	
	Stage IV	339	56,4	21	6,2	318	93,8	NE	NE	NE	NE	NE	NE	336	55,9	26	7,7	310	92,3	NE	NE	NE	NE	NE	NE	0,4513	0,80	0,45	1,43		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,5			3	100,0	NE	NE	NE	NE	NE	NE	4	0,7			4	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable. Clinical cut-off:
31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/t_eff_tte.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/t_eff_tte_sg_OS_FOLY_IT.xls 01OCT2019 13:13

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
ENDPOINT: Overall Survival
STUDY: BO21223

Independence status (Katz ADL) (N=1202)



Patients at risk

G-chemo, 0-2	3	3	3	3	3	3	3	2	1	1	
G-chemo, 3-4	4	4	4	3	3	3	3	1	1	1	
G-chemo, 5-6	459	450	440	437	434	416	310	205	131	66	13
G-chemo, Missing	83	80	78	77	75	74	66	50	39	26	7
G-chemo, Outside valid range	52	50	50	49	48	44	34	32	23	10	2
R-chemo, 0-2	7	7	7	7	7	6	4	4	2	1	
R-chemo, 3-4	5	4	3	3	2	2	2	2	1	1	
R-chemo, 5-6	462	457	440	431	416	396	292	195	129	71	20
R-chemo, Missing	80	78	76	74	74	72	65	55	44	24	4
R-chemo, Outside valid range	47	46	46	46	44	42	36	25	17	8	6

Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_km_sg.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_km_sg_OS_FOLY_IT.pdf
01OCT2019 13:30

2 (Anhang): Ergebnisse für OS Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel – Datenschnitt 03.03.2017

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
ENDPOINT: Overall Survival
MODEL: Unstratified Analysis STUDY:

B021223
Time to Event Analysis by Subgroups (Efficacy)

		G-chemo (N=601)												R-chemo (N=601)												G-chemo vs. R-chemo						
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	601	100,0	48	8,0	553	92,0	NE	NE	NE	NE	NE	NE	601	100,0	56	9,3	545	90,7	NE	NE	NE	NE	NE	NE	0,3792	0,84	0,57	1,24		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	283	47,1	30	10,6	253	89,4	NE	NE	NE	NE	NE	NE	280	46,6	33	11,8	247	88,2	NE	NE	NE	NE	NE	NE	0,5842	0,87	0,53	1,43		Convergence criterion (GCONV=1E-8) satisfied.	0,7889
	Female	318	52,9	18	5,7	300	94,3	NE	NE	NE	NE	NE	NE	321	53,4	23	7,2	298	92,8	NE	NE	NE	NE	NE	NE	0,4396	0,78	0,42	1,45		Convergence criterion (GCONV=1E-8) satisfied.	
Age	< 60 years	298	49,6	11	3,7	287	96,3	NE	NE	NE	NE	NE	NE	323	53,7	17	5,3	306	94,7	NE	NE	NE	NE	NE	NE	0,3277	0,69	0,32	1,47		Convergence criterion (GCONV=1E-8) satisfied.	0,6318
	>= 60 years	303	50,4	37	12,2	266	87,8	NE	NE	NE	NE	NE	NE	278	46,3	39	14,0	239	86,0	NE	NE	NE	NE	NE	NE	0,4896	0,85	0,54	1,34		Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	487	81,0	42	8,6	445	91,4	NE	NE	NE	NE	NE	NE	481	80,0	51	10,6	430	89,4	NE	NE	NE	NE	NE	NE	0,2644	0,79	0,53	1,19		Convergence criterion (GCONV=1E-8) satisfied.	0,4554
	Other	114	19,0	6	5,3	108	94,7	NE	NE	NE	NE	NE	NE	120	20,0	5	4,2	115	95,8	NE	NE	NE	NE	NE	NE	0,6902	1,27	0,39	4,17		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	North America	75	12,5	6	8,0	69	92,0	NE	NE	NE	NE	NE	NE	77	12,8	10	13,0	67	87,0	NE	NE	NE	NE	NE	NE	0,3898	0,64	0,23	1,77		Convergence criterion (GCONV=1E-8) satisfied.	0,8718
	Western Europe	294	48,9	23	7,8	271	92,2	NE	NE	NE	NE	NE	NE	287	47,8	27	9,4	260	90,6	NE	NE	NE	NE	NE	NE	0,4375	0,80	0,46	1,40		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia-Pacific	152	25,3	10	6,6	142	93,4	NE	NE	NE	NE	NE	NE	154	25,6	9	5,8	145	94,2	NE	NE	NE	NE	NE	NE	0,8437	1,09	0,44	2,69		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	80	13,3	9	11,3	71	88,8	NE	NE	NE	NE	NE	NE	83	13,8	10	12,0	73	88,0	NE	NE	NE	NE	NE	NE	0,8801	0,93	0,38	2,30		Convergence criterion (GCONV=1E-8) satisfied.	
Baseline ECOG Performance Status score	0-1	585	97,3	43	7,4	542	92,6	NE	NE	NE	NE	NE	NE	576	95,8	49	8,5	527	91,5	NE	NE	NE	NE	NE	NE	0,4204	0,85	0,56	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,4282
	2	15	2,5	5	33,3	10	66,7	24,4	12,0	NE	NE	25,5	NE	23	3,8	7	30,4	16	69,6	20,4	9,7	NE	NE	NE	NE	0,6387	1,32	0,42	4,15		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	2	0,3			2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Independence status (Katz ADL)	Independent (5-6)	459	76,4	27	5,9	432	94,1	NE	NE	NE	NE	NE	NE	462	76,9	43	9,3	419	90,7	NE	NE	NE	NE	NE	NE	0,0449	0,61	0,38	0,99		Convergence criterion (GCONV=1E-8) satisfied.	0,0071
	Some dependence (3-4)	4	0,7			4	100,0	NE	NE	NE	NE	NE	NE	5	0,8	3	60,0	2	40,0	5,9	0,6	NE	39,7	0,6	NE	0,0720	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Very dependent (0-2)	3	0,5			3	100,0	NE	NE	NE	NE	NE	NE	7	1,2	1	14,3	6	85,7	NE	37,0	NE	NE	NE	NE	0,5127	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Outside valid range	52	8,7	6	11,5	46	88,5	NE	NE	NE	NE	NE	NE	47	7,8	2	4,3	45	95,7	NE	NE	NE	NE	NE	NE	0,1728	2,89	0,58	14,34		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	83	13,8	15	18,1	68	81,9	NE	52,4	NE	NE	NE	NE	80	13,3	7	8,8	73	91,3	NE	NE	NE	NE	NE	NE	0,0902	2,13	0,87	5,23		Convergence criterion (GCONV=1E-8) satisfied.	
Independence status (Katz IADL)	Independent (5-8)	504	83,9	38	7,5	466	92,5	NE	NE	NE	NE	NE	NE	501	83,4	46	9,2	455	90,8	NE	NE	NE	NE	NE	NE	0,3244	0,81	0,52	1,24		Convergence criterion (GCONV=1E-8) satisfied.	0,7760
	Some dependence (1-4)	9	1,5	1	11,1	8	88,9	NE	3,8	NE	NE	NE	NE	14	2,3	4	28,6	10	71,4	39,7	16,1	NE	NE	39,7	NE	0,4317	0,43	0,05	3,81		Convergence criterion (GCONV=1E-8) satisfied.	
	Very dependent (0)	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Outside valid range	16	2,7			16	100,0	NE	NE	NE	NE	NE	NE	11	1,8			11	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	71	11,8	9	12,7	62	87,3	NE	NE	NE	NE	NE	NE	74	12,3	6	8,1	68	91,9	NE	NE	NE	NE	NE	NE	0,4048	1,55	0,55	4,35		Convergence criterion (GCONV=1E-8) satisfied.	
Chemotherapy regimen	CHOP	196	32,6	12	6,1	184	93,9	NE	NE	NE	NE	NE	NE	203	33,8	9	4,4	194	95,6	NE	NE	NE	NE	NE	NE	0,4607	1,38	0,58	3,28		Convergence criterion (GCONV=1E-8) satisfied.	0,3473
	CVP	60	10,0	4	6,7	56	93,3	NE	NE	NE	NE	NE	NE	57	9,5	7	12,3	50	87,7	NE	NE	NE	NE	NE	NE	0,2594	0,50	0,15	1,71		Convergence criterion (GCONV=1E-8) satisfied.	
	Bendamustine	345	57,4	32	9,3	313	90,7	NE	NE	NE	NE	NE	NE	341	56,7	40	11,7	301	88,3	NE	NE	NE	NE	NE	NE	0,2912	0,78	0,49	1,24		Convergence criterion (GCONV=1E-8) satisfied.	
Histologic grade	1	242	40,3	17	7,0	225	93,0	NE	NE	NE	NE	NE	NE	219	36,4	20	9,1	199	90,9	NE	NE	NE	NE	NE	NE	0,3663	0,74	0,39	1,42		Convergence criterion (GCONV=1E-8) satisfied.	0,4311

	2	266	44,3	16	6,0	250	94,0	NE	NE	NE	NE	NE	NE	289	48,1	25	8,7	264	91,3	NE	NE	NE	NE	NE	NE	0,2261	0,68	0,36	1,27		Convergence criterion (GCONV=1E-8) satisfied.	
	3	4	0,7			4	100,0	NE	NE	NE	NE	NE	NE	3	0,5	1	33,3	2	66,7	9,2	9,2	NE	NE	0,2	NE	0,2482	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	3a	82	13,6	13	15,9	69	84,1	NE	45,7	NE	NE	NE	NE	85	14,1	10	11,8	75	88,2	NE	NE	NE	NE	NE	NE	0,4429	1,38	0,60	3,15		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	2	0,3			2	100,0	NE	NE	NE	NE	NE	NE	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	5	0,8	2	40,0	3	60,0	30,9	2,2	NE	NE	2,2	NE	4	0,7			4	100,0	NE	NE	NE	NE	NE	NE	0,1475	>999.99	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
FLIPI	Low (0-1)	127	21,1	7	5,5	120	94,5	NE	NE	NE	NE	NE	NE	125	20,8	4	3,2	121	96,8	NE	NE	NE	NE	NE	NE	0,4167	1,65	0,48	5,65		Convergence criterion (GCONV=1E-8) satisfied.	0,5141
	Intermediate (2)	225	37,4	12	5,3	213	94,7	NE	NE	NE	NE	NE	NE	222	36,9	14	6,3	208	93,7	NE	NE	NE	NE	NE	NE	0,6290	0,83	0,38	1,79		Convergence criterion (GCONV=1E-8) satisfied.	
	High (>=3)	249	41,4	29	11,6	220	88,4	NE	NE	NE	NE	NE	NE	254	42,3	38	15,0	216	85,0	NE	NE	NE	NE	NE	NE	0,2939	0,77	0,48	1,25		Convergence criterion (GCONV=1E-8) satisfied.	
FC Gamma Receptor IIa	131HH	182	30,3	9	4,9	173	95,1	NE	NE	NE	NE	NE	NE	184	30,6	14	7,6	170	92,4	NE	NE	NE	NE	NE	NE	0,3093	0,65	0,28	1,50		Convergence criterion (GCONV=1E-8) satisfied.	0,2157
	131HR	277	46,1	27	9,7	250	90,3	NE	NE	NE	NE	NE	NE	270	44,9	28	10,4	242	89,6	NE	NE	NE	NE	NE	NE	0,7426	0,92	0,54	1,55		Convergence criterion (GCONV=1E-8) satisfied.	
	131RR	114	19,0	5	4,4	109	95,6	NE	NE	NE	NE	NE	NE	117	19,5	14	12,0	103	88,0	NE	NE	NE	NE	NE	NE	0,0337	0,35	0,13	0,96		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	28	4,7	7	25,0	21	75,0	45,7	23,5	NE	NE	48,7	NE	30	5,0			30	100,0	NE	NE	NE	NE	NE	NE	0,0029	>999.99	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
FC Gamma Receptor IIIa	158VV	67	11,1	5	7,5	62	92,5	NE	NE	NE	NE	NE	NE	77	12,8	9	11,7	68	88,3	NE	NE	NE	NE	NE	NE	0,4200	0,64	0,21	1,91		Convergence criterion (GCONV=1E-8) satisfied.	0,9657
	158VF	283	47,1	20	7,1	263	92,9	NE	NE	NE	NE	NE	NE	238	39,6	23	9,7	215	90,3	NE	NE	NE	NE	NE	NE	0,2520	0,71	0,39	1,28		Convergence criterion (GCONV=1E-8) satisfied.	
	158FF	223	37,1	16	7,2	207	92,8	NE	NE	NE	NE	NE	NE	256	42,6	24	9,4	232	90,6	NE	NE	NE	NE	NE	NE	0,3887	0,76	0,40	1,43		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	28	4,7	7	25,0	21	75,0	45,7	23,5	NE	NE	48,7	NE	30	5,0			30	100,0	NE	NE	NE	NE	NE	NE	0,0029	>999.99	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
FC Gamma Receptor IIb/IIc	232II	417	69,4	33	7,9	384	92,1	NE	NE	NE	NE	NE	NE	406	67,6	42	10,3	364	89,7	NE	NE	NE	NE	NE	NE	0,2153	0,75	0,48	1,18		Convergence criterion (GCONV=1E-8) satisfied.	0,4524
	232IT	104	17,3	4	3,8	100	96,2	NE	NE	NE	NE	NE	NE	116	19,3	9	7,8	107	92,2	NE	NE	NE	NE	NE	NE	0,2185	0,49	0,15	1,58		Convergence criterion (GCONV=1E-8) satisfied.	
	232TT	9	1,5	2	22,2	7	77,8	NE	29,1	NE	NE	52,5	NE	10	1,7	1	10,0	9	90,0	NE	16,1	NE	NE	NE	NE	0,4523	2,44	0,22	26,91		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	71	11,8	9	12,7	62	87,3	NE	NE	NE	NE	NE	NE	69	11,5	4	5,8	65	94,2	NE	NE	NE	NE	NE	NE	0,1923	2,15	0,66	6,98		Convergence criterion (GCONV=1E-8) satisfied.	
Time from initial FL diagnosis to randomization	< 6 months	490	81,5	37	7,6	453	92,4	NE	NE	NE	NE	NE	NE	474	78,9	43	9,1	431	90,9	NE	NE	NE	NE	NE	NE	0,3493	0,81	0,52	1,26		Convergence criterion (GCONV=1E-8) satisfied.	0,8017
	6-12 months	35	5,8	2	5,7	33	94,3	NE	NE	NE	NE	NE	NE	32	5,3	1	3,1	31	96,9	NE	NE	NE	NE	NE	NE	0,6338	1,78	0,16	19,62		Convergence criterion (GCONV=1E-8) satisfied.	
	> 12 months	73	12,1	8	11,0	65	89,0	NE	NE	NE	NE	NE	NE	95	15,8	12	12,6	83	87,4	NE	NE	NE	NE	NE	NE	0,8168	0,90	0,37	2,20		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,5	1	33,3	2	66,7	8,2	0,2	NE	NE	8,2	NE													NE						
Ann Arbor Stage 2	Stage I	10	1,7	1	10,0	9	90,0	NE	30,9	NE	NE	NE	NE	8	1,3			8	100,0	NE	NE	NE	NE	NE	NE	0,3711	>999.99	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0,3954
	Stage II (w/o bulky disease)	14	2,3			14	100,0	NE	NE	NE	NE	NE	NE	15	2,5	2	13,3	13	86,7	NE	34,4	NE	NE	NE	NE	0,1892	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Stage II (with bulky disease)	27	4,5	1	3,7	26	96,3	NE	NE	NE	NE	NE	NE	29	4,8	2	6,9	27	93,1	NE	NE	NE	NE	NE	NE	0,5322	0,47	0,04	5,23		Convergence criterion (GCONV=1E-8) satisfied.	
	Stage III	209	34,8	15	7,2	194	92,8	NE	NE	NE	NE	NE	NE	208	34,6	19	9,1	189	90,9	NE	NE	NE	NE	NE	NE	0,4692	0,78	0,40	1,53		Convergence criterion (GCONV=1E-8) satisfied.	
	Stage IV	338	56,2	31	9,2	307	90,8	NE	NE	NE	NE	NE	NE	337	56,1	33	9,8	304	90,2	NE	NE	NE	NE	NE	NE	0,7483	0,92	0,57	1,51		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,5			3	100,0	NE	NE	NE	NE	NE	NE	4	0,7			4	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_ASH2018/qa/program/t_eff_tte.sas
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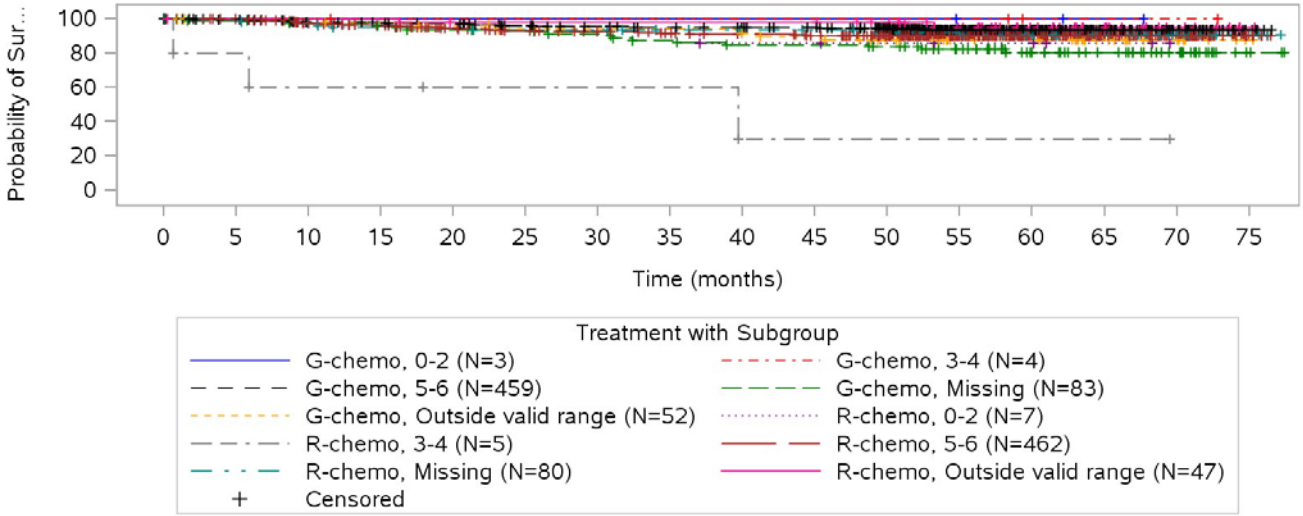
POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
ENDPOINT: Overall Survival
STUDY: BO21223

Independence status (Katz ADL) (N=1202)



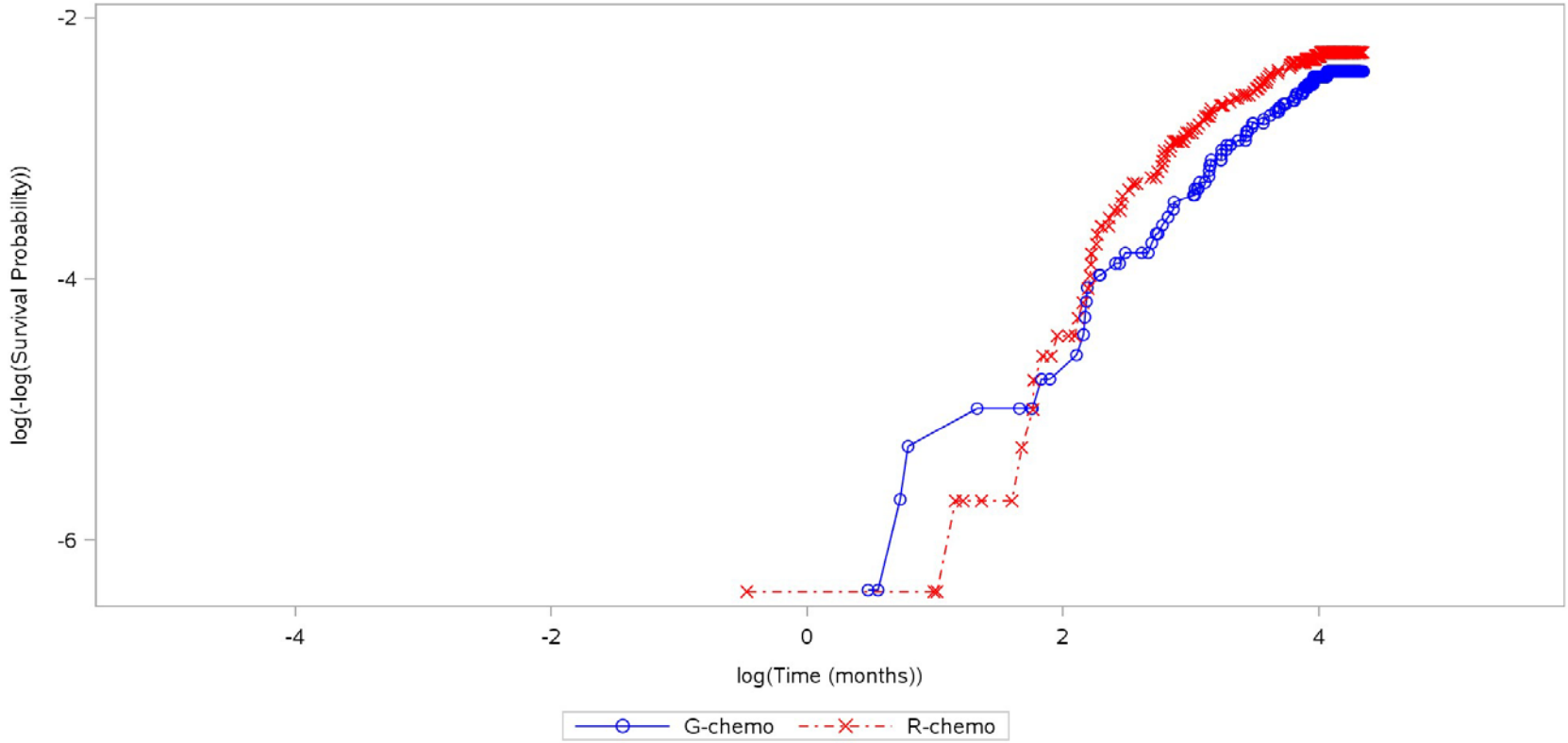
Patients at risk

G-chemo, 0-2	3	3	3	3	3	3	3	3	3	3	3	2	2	1		
G-chemo, 3-4	4	4	4	3	3	3	3	3	3	3	3	3	1	1	1	
G-chemo, 5-6	459	450	440	437	434	425	419	415	411	406	380	269	179	99	50	5
G-chemo, Missing	83	80	78	77	75	74	72	69	67	67	65	56	40	31	20	3
G-chemo, Outside valid range	52	50	50	49	48	46	45	45	44	43	38	29	28	17	9	1
R-chemo, 0-2	7	7	7	7	7	7	7	7	6	6	5	4	4	2		
R-chemo, 3-4	5	4	3	3	2	2	2	2	1	1	1	1	1	1		
R-chemo, 5-6	462	457	440	431	416	407	400	395	390	385	355	261	172	97	57	7
R-chemo, Missing	80	78	76	74	74	73	73	70	68	67	65	56	46	31	16	4
R-chemo, Outside valid range	47	46	46	46	44	44	44	44	44	44	41	34	23	15	7	1

Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_ASH2018/qa/program/g_km_sg.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_ASH2018/qa/output/g_km_sg_OS_FOLY_IT_03MAR2017_21223.pdf
02OCT2019 18:50

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
ENDPOINT: Overall Survival
STUDY: BO21223
Check of Proportional Hazards Assumption, Stratified Analysis by Chemotherapy regimen, FLIPI
Log of Negative Log of Estimated Survivor Functions



Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_ASH2018/qa/program/g_phchk.sas
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08OCT2019 17:47

3 (Anhang): Ergebnisse für PFS (Bewertung durch IRC) Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
aENDPOINT: Progression-Free Survival (PFS) IRC
MODEL: Unstratified Analysis STUDY: BO21223
Time to Event Analysis by Subgroups (Efficacy)

		G-chemo (N=601)											R-chemo (N=601)												G-chemo vs. R-chemo						
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	601	100,0	93	15,5	508	84,5	48,7	43,3	NE	NE	NE	NE	601	100,0	125	20,8	476	79,2	40,3	34,6	47,1	51,2	47,1	NE	0,0131	0,71	0,55	0,93		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	283	47,1	55	19,4	228	80,6	43,3	31,0	NE	NE	48,7	NE	280	46,6	63	22,5	217	77,5	35,5	27,7	47,1	47,1	47,0	NE	0,2368	0,80	0,56	1,15		Convergence criterion (GCONV=1E-8) satisfied.	0,3504
	Female	318	52,9	38	11,9	280	88,1	NE	NE	NE	NE	NE	NE	321	53,4	62	19,3	259	80,7	43,5	38,2	NE	51,2	51,2	NE	0,0204	0,62	0,41	0,93		Convergence criterion (GCONV=1E-8) satisfied.	
Age	< 60 years	298	49,6	39	13,1	259	86,9	NE	43,3	NE	NE	NE	NE	323	53,7	63	19,5	260	80,5	41,5	33,5	NE	NE	NE	NE	0,0209	0,63	0,42	0,94		Convergence criterion (GCONV=1E-8) satisfied.	0,4497
	>= 60 years	303	50,4	54	17,8	249	82,2	48,7	33,2	NE	NE	48,7	NE	278	46,3	62	22,3	216	77,7	40,0	32,1	47,0	51,2	46,1	51,2	0,1779	0,78	0,54	1,12		Convergence criterion (GCONV=1E-8) satisfied.	
Race/ethnicity	White	487	81,0	82	16,8	405	83,2	48,7	40,0	NE	NE	48,7	NE	481	80,0	100	20,8	381	79,2	41,5	34,6	47,1	51,2	47,1	NE	0,1011	0,78	0,59	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,1123
	Other	114	19,0	11	9,6	103	90,4	NE	34,1	NE	NE	NE	NE	120	20,0	25	20,8	95	79,2	32,1	28,0	NE	NE	39,7	NE	0,0175	0,43	0,21	0,88		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	North America	75	12,5	12	16,0	63	84,0	48,7	27,9	NE	48,7	48,7	NE	77	12,8	16	20,8	61	79,2	46,1	16,7	NE	51,2	46,1	NE	0,4956	0,77	0,36	1,63		Convergence criterion (GCONV=1E-8) satisfied.	0,6461
	Western Europe	294	48,9	50	17,0	244	83,0	NE	34,0	NE	NE	NE	NE	286	47,6	62	21,7	224	78,3	39,7	33,5	47,1	47,1	47,0	NE	0,1021	0,73	0,51	1,07		Convergence criterion (GCONV=1E-8) satisfied.	
	Asia-Pacific	152	25,3	15	9,9	137	90,1	NE	36,4	NE	NE	NE	NE	155	25,8	28	18,1	127	81,9	NE	27,7	NE	NE	NE	NE	0,0324	0,51	0,27	0,96		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	80	13,3	16	20,0	64	80,0	43,3	16,4	NE	NE	NE	NE	83	13,8	19	22,9	64	77,1	40,6	19,1	NE	NE	NE	NE	0,7981	0,92	0,47	1,78		Convergence criterion (GCONV=1E-8) satisfied.	
Baseline ECOG Performance Status score	0-1	585	97,3	88	15,0	497	85,0	48,7	43,3	NE	NE	NE	NE	576	95,8	116	20,1	460	79,9	40,6	35,5	47,1	51,2	47,1	NE	0,0168	0,71	0,54	0,94		Convergence criterion (GCONV=1E-8) satisfied.	0,4562
	2	15	2,5	5	33,3	10	66,7	16,5	6,1	NE	25,5	16,5	NE	23	3,8	9	39,1	14	60,9	12,9	6,1	NE	NE	16,1	NE	0,8126	1,14	0,38	3,42		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	2	0,3			2	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Independence status (Katz ADL)	Independent (5-6)	459	76,4	62	13,5	397	86,5	NE	NE	NE	NE	NE	NE	462	76,9	93	20,1	369	79,9	41,5	34,4	47,1	NE	47,1	NE	0,0079	0,65	0,47	0,89		Convergence criterion (GCONV=1E-8) satisfied.	0,2242
	Some dependence (3-4)	4	0,7	1	25,0	3	75,0	16,2	16,2	NE	NE	16,2	NE	5	0,8	3	60,0	2	40,0	5,9	0,6	NE	39,7	0,6	NE	0,6071	0,54	0,05	5,95		Convergence criterion (GCONV=1E-8) satisfied.	

	Very dependent (0-2)	3	0,5			3	100,0	NE	NE	NE	NE	NE	NE	7	1,2	2	28,6	5	71,4	33,5	8,3	NE	NE	33,5	NE	0,3354	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Outside valid range	52	8,7	13	25,0	39	75,0	32,7	23,2	NE	NE	40,0	NE	47	7,8	7	14,9	40	85,1	51,2	19,6	51,2	51,2	NE	NE	0,1643	1,97	0,74	5,20		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	83	13,8	17	20,5	66	79,5	48,7	29,0	NE	NE	48,7	NE	80	13,3	20	25,0	60	75,0	38,2	16,5	NE	NE	40,6	NE	0,3615	0,74	0,38	1,42		Convergence criterion (GCONV=1E-8) satisfied.	
Independence status (Katz IADL)	Independent (5-8)	504	83,9	79	15,7	425	84,3	NE	40,0	NE	NE	NE	NE	501	83,4	98	19,6	403	80,4	43,5	34,6	NE	51,2	47,1	NE	0,1034	0,78	0,58	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,0879
	Some dependence (1-4)	9	1,5	2	22,2	7	77,8	16,2	3,8	NE	NE	16,2	NE	14	2,3	6	42,9	8	57,1	16,1	6,2	NE	39,7	16,1	NE	0,7742	0,78	0,15	4,14		Convergence criterion (GCONV=1E-8) satisfied.	
	Very dependent (0)	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Outside valid range	16	2,7			16	100,0	NE	NE	NE	NE	NE	NE	11	1,8	4	36,4	7	63,6	16,2	9,0	NE	NE	16,2	NE	0,0071	<0.01	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	71	11,8	12	16,9	59	83,1	48,7	31,0	NE	NE	48,7	NE	74	12,3	17	23,0	57	77,0	40,3	20,6	NE	NE	NE	NE	0,2432	0,64	0,30	1,36		Convergence criterion (GCONV=1E-8) satisfied.	
Chemotherapy regimen	CHOP	195	32,4	30	15,4	165	84,6	NE	NE	NE	NE	NE	NE	203	33,8	41	20,2	162	79,8	40,3	28,0	NE	NE	NE	NE	0,2632	0,76	0,48	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,8151
	CVP	61	10,1	14	23,0	47	77,0	33,2	17,9	NE	NE	NE	NE	57	9,5	14	24,6	43	75,4	39,0	8,9	NE	NE	43,5	NE	0,6717	0,85	0,41	1,79		Convergence criterion (GCONV=1E-8) satisfied.	
	Bendamustine	345	57,4	49	14,2	296	85,8	48,7	43,3	NE	NE	48,7	NE	341	56,7	70	20,5	271	79,5	40,6	34,4	47,1	51,2	47,1	NE	0,0259	0,66	0,46	0,95		Convergence criterion (GCONV=1E-8) satisfied.	
Histologic grade	1	242	40,3	38	15,7	204	84,3	NE	37,6	NE	NE	NE	NE	219	36,4	42	19,2	177	80,8	47,0	29,7	NE	NE	47,0	NE	0,2888	0,79	0,51	1,22		Convergence criterion (GCONV=1E-8) satisfied.	0,9773
	2	267	44,4	38	14,2	229	85,8	48,7	43,3	NE	NE	48,7	NE	289	48,1	61	21,1	228	78,9	40,6	33,1	47,1	51,2	47,1	NE	0,0308	0,64	0,43	0,96		Convergence criterion (GCONV=1E-8) satisfied.	
	3	4	0,7	1	25,0	3	75,0	NE	16,2	NE	NE	16,2	NE	3	0,5	1	33,3	2	66,7	6,0	6,0	NE	NE	6,0	NE	0,7276	0,61	0,04	0,93		Convergence criterion (GCONV=1E-8) satisfied.	
	3a	82	13,6	15	18,3	67	81,7	NE	21,5	NE	NE	NE	NE	85	14,1	21	24,7	64	75,3	34,6	13,1	NE	NE	39,7	NE	0,3445	0,73	0,37	1,41		Convergence criterion (GCONV=1E-8) satisfied.	
	Other	2	0,3			2	100,0	NE	NE	NE	NE	NE	NE	1	0,2			1	100,0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	4	0,7	1	25,0	3	75,0	30,9	30,9	NE	NE	30,9	NE	4	0,7			4	100,0	NE	NE	NE	NE	NE	NE	0,2207	>999.99	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
FLIPI	Low (0-1)	128	21,3	20	15,6	108	84,4	NE	33,2	NE	NE	NE	NE	125	20,8	13	10,4	112	89,6	NE	39,0	NE	NE	NE	NE	0,3250	1,42	0,71	2,85		Convergence criterion (GCONV=1E-8) satisfied.	0,0941
	Intermediate (2)	224	37,3	26	11,6	198	88,4	NE	43,3	NE	NE	NE	NE	223	37,1	40	17,9	183	82,1	47,0	29,7	NE	NE	47,0	NE	0,0500	0,61	0,37	1,00		Convergence criterion (GCONV=1E-8) satisfied.	
	High (>=3)	249	41,4	47	18,9	202	81,1	48,7	29,2	NE	NE	48,7	NE	253	42,1	72	28,5	181	71,5	32,1	16,9	40,6	47,1	46,1	51,2	0,0151	0,64	0,44	0,92		Convergence criterion (GCONV=1E-8) satisfied.	
FC Gamma Receptor IIa	131HH	182	30,3	23	12,6	159	87,4	NE	40,0	NE	NE	NE	NE	184	30,6	36	19,6	148	80,4	47,1	32,1	NE	NE	47,1	NE	0,0689	0,62	0,37	1,04		Convergence criterion (GCONV=1E-8) satisfied.	0,9100

	131HR	277	46,1	46	16,6	231	83,4	NE	36,4	NE	NE	NE	NE	270	44,9	60	22,2	210	77,8	40,0	27,7	NE	51,2	51,2	NE	0,0905	0,72	0,49	1,06		Convergence criterion (GCONV=1E-8) satisfied.	
	131RR	114	19,0	17	14,9	97	85,1	43,3	34,1	NE	NE	NE	NE	117	19,5	24	20,5	93	79,5	43,5	28,0	NE	NE	47,0	NE	0,3036	0,72	0,39	1,35		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	28	4,7	7	25,0	21	75,0	17,6	9,2	48,7	48,7	NE	NE	30	5,0	5	16,7	25	83,3	41,5	12,0	NE	NE	41,5	NE	0,4281	1,59	0,50	5,00		Convergence criterion (GCONV=1E-8) satisfied.	
FC Gamma Receptor IIIa	158VV	67	11,1	8	11,9	59	88,1	NE	40,0	NE	NE	NE	NE	77	12,8	18	23,4	59	76,6	40,3	21,2	NE	47,1	46,1	NE	0,0900	0,49	0,21	1,14		Convergence criterion (GCONV=1E-8) satisfied.	0,5691
	158VF	283	47,1	46	16,3	237	83,7	NE	36,4	NE	NE	NE	NE	238	39,6	48	20,2	190	79,8	40,0	33,5	NE	NE	47,0	NE	0,2231	0,78	0,52	1,17		Convergence criterion (GCONV=1E-8) satisfied.	
	158FF	223	37,1	32	14,3	191	85,7	NE	43,3	NE	NE	NE	NE	256	42,6	54	21,1	202	78,9	39,7	27,7	NE	51,2	51,2	NE	0,0563	0,66	0,42	1,01		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	28	4,7	7	25,0	21	75,0	17,6	9,2	48,7	48,7	NE	NE	30	5,0	5	16,7	25	83,3	41,5	12,0	NE	NE	41,5	NE	0,4281	1,59	0,50	5,00		Convergence criterion (GCONV=1E-8) satisfied.	
FC Gamma Receptor IIb/IIc	232II	417	69,4	67	16,1	350	83,9	NE	40,0	NE	NE	NE	NE	406	67,6	86	21,2	320	78,8	40,3	33,5	51,2	51,2	47,1	NE	0,0461	0,72	0,53	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,2003
	232IT	104	17,3	11	10,6	93	89,4	NE	NE	NE	NE	NE	NE	116	19,3	22	19,0	94	81,0	NE	32,1	NE	NE	NE	NE	0,0748	0,52	0,25	1,08		Convergence criterion (GCONV=1E-8) satisfied.	
	232TT	9	1,5	3	33,3	6	66,7	16,2	6,5	NE	NE	16,2	NE	10	1,7	2	20,0	8	80,0	47,0	16,1	47,0	47,0	NE	NE	0,1444	4,64	0,48	44,77		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	71	11,8	12	16,9	59	83,1	37,6	30,9	48,7	48,7	NE	NE	69	11,5	15	21,7	54	78,3	28,6	19,4	NE	NE	41,5	NE	0,4040	0,72	0,34	1,55		Convergence criterion (GCONV=1E-8) satisfied.	
Time from initial FL diagnosis to randomization	< 6 months	490	81,5	70	14,3	420	85,7	48,7	48,7	NE	NE	NE	NE	474	78,9	98	20,7	376	79,3	40,6	34,6	47,1	51,2	47,0	NE	0,0073	0,66	0,48	0,90		Convergence criterion (GCONV=1E-8) satisfied.	0,5240
	6-12 months	35	5,8	6	17,1	29	82,9	40,0	34,0	NE	NE	40,0	NE	32	5,3	5	15,6	27	84,4	NE	19,8	NE	NE	NE	NE	0,8858	1,09	0,33	3,61		Convergence criterion (GCONV=1E-8) satisfied.	
	> 12 months	73	12,1	16	21,9	57	78,1	36,4	20,7	NE	NE	NE	NE	95	15,8	22	23,2	73	76,8	32,1	21,2	NE	NE	43,5	NE	0,6179	0,85	0,44	1,62		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,5	1	33,3	2	66,7	3,8	3,8	NE	NE	3,8	NE													NE						
Ann Arbor Stage 2	Stage I	10	1,7	3	30,0	7	70,0	30,9	17,9	NE	NE	30,9	NE	8	1,3	1	12,5	7	87,5	NE	9,9	NE	NE	NE	NE	0,6464	1,70	0,17	16,91		Convergence criterion (GCONV=1E-8) satisfied.	0,7703
	Stage II (w/o bulky disease)	14	2,3	2	14,3	12	85,7	32,3	32,3	NE	NE	32,3	NE	14	2,3	4	28,6	10	71,4	27,5	7,9	NE	NE	34,4	NE	0,4103	0,50	0,09	2,72		Convergence criterion (GCONV=1E-8) satisfied.	
	Stage II (with bulky disease)	27	4,5	3	11,1	24	88,9	NE	33,2	NE	NE	NE	NE	30	5,0	3	10,0	27	90,0	NE	28,6	NE	NE	NE	NE	0,9590	1,04	0,21	5,18		Convergence criterion (GCONV=1E-8) satisfied.	
	Stage III	208	34,6	29	13,9	179	86,1	NE	40,0	NE	NE	NE	NE	209	34,8	37	17,7	172	82,3	43,5	38,2	NE	51,2	46,1	NE	0,3331	0,79	0,48	1,28		Convergence criterion (GCONV=1E-8) satisfied.	
	Stage IV	339	56,4	55	16,2	284	83,8	48,7	43,3	NE	NE	48,7	NE	336	55,9	80	23,8	256	76,2	34,6	22,7	47,1	NE	47,0	NE	0,0118	0,65	0,46	0,91		Convergence criterion (GCONV=1E-8) satisfied.	
	Missing	3	0,5	1	33,3	2	66,7	21,5	21,5	NE	NE	21,5	NE	4	0,7			4	100,0	NE	NE	NE	NE	NE	NE	0,3173	>999.99	0,00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/t_eff_tte.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/t_eff_tte_sg_PFSRAD1_FOLY_IT.xls 01OCT2019 13:18

4 (Anhang): Ergebnisse für FACT-G - Verbesserung der Gesundheitsbezogenen Lebensqualität um MID sechs - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients, Patients with Baseline and post Baseline FACT-G Total result
ENDPOINT: FACT-G Total - Responder (MID=6), improvement
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Efficacy)

			G-chemo (N=547)				R-chemo (N=547)				G-Chemo vs. R-Chemo															R-Chemo vs. G-Chemo			
			Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk							Relative Risk			
Analysis Visit Window	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Follow Up Month 12	All	n/a	398	72,8	162	40,7	360	65,8	150	41,7	0,96	Convergence criterion (GCONV=1E-8) satisfied.	0,72	1,28	-0,010	Algorithm converged.	-0,080	0,061	0,98	Algorithm converged.	0,82	1,16	0,7878		1,02	Algorithm converged.	0,86	1,21
	Sex	Male	187	34,2	75	40,1	167	30,5	74	44,3	0,84	Convergence criterion (GCONV=1E-8) satisfied.	0,55	1,28	-0,042	Algorithm converged.	-0,145	0,061	0,91	Algorithm converged.	0,71	1,16	0,4234	0,4019	1,10	Algorithm converged.	0,87	1,41
		Female	211	38,6	87	41,2	193	35,3	76	39,4	1,08	Convergence criterion (GCONV=1E-8) satisfied.	0,73	1,61	0,019	Algorithm converged.	-0,077	0,114	1,05	Algorithm converged.	0,83	1,33	0,7047		0,96	Algorithm converged.	0,75	1,21
	Age	< 60 years	210	38,4	87	41,4	198	36,2	81	40,9	1,02	Convergence criterion (GCONV=1E-8) satisfied.	0,69	1,52	0,005	Algorithm converged.	-0,090	0,101	1,01	Algorithm converged.	0,80	1,28	0,9152	0,6541	0,99	Algorithm converged.	0,78	1,25
		>= 60 years	188	34,4	75	39,9	162	29,6	69	42,6	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,58	1,37	-0,027	Algorithm converged.	-0,130	0,076	0,94	Algorithm converged.	0,73	1,20	0,6085		1,07	Algorithm converged.	0,83	1,37
	Race/ethnicity	White	304	55,6	125	41,1	278	50,8	111	39,9	1,05	Convergence criterion (GCONV=1E-8) satisfied.	0,75	1,46	0,012	Algorithm converged.	-0,068	0,092	1,03	Algorithm converged.	0,85	1,25	0,7703	0,2738	0,97	Algorithm converged.	0,80	1,18
		Other	94	17,2	37	39,4	82	15,0	39	47,6	0,72	Convergence criterion (GCONV=1E-8) satisfied.	0,39	1,30	-0,082	Algorithm converged.	-0,228	0,064	0,83	Algorithm converged.	0,59	1,16	0,2733		1,21	Algorithm converged.	0,86	1,70
	Geographic region	North America	55	10,1	28	50,9	52	9,5	22	42,3	1,41	Convergence criterion (GCONV=1E-8) satisfied.	0,66	3,03	0,086	Algorithm converged.	-0,102	0,274	1,20	Algorithm converged.	0,80	1,81	0,3763	0,6496	0,83	Algorithm converged.	0,55	1,25
		Western Europe	173	31,6	73	42,2	138	25,2	63	45,7	0,87	Convergence criterion (GCONV=1E-8) satisfied.	0,55	1,36	-0,035	Algorithm converged.	-0,146	0,076	0,92	Algorithm converged.	0,72	1,19	0,5406		1,08	Algorithm converged.	0,84	1,39
		Asia-Pacific	112	20,5	45	40,2	111	20,3	50	45,0	0,82	Convergence criterion (GCONV=1E-8) satisfied.	0,48	1,39	-0,049	Algorithm converged.	-0,178	0,081	0,89	Algorithm converged.	0,66	1,21	0,4632		1,12	Algorithm converged.	0,83	1,52
		Other	58	10,6	16	27,6	59	10,8	15	25,4	1,12	Convergence criterion (GCONV=1E-8) satisfied.	0,49	2,54	0,022	Algorithm converged.	-0,138	0,182	1,09	Algorithm converged.	0,59	1,99	0,7911		0,92	Algorithm converged.	0,50	1,69
	Baseline ECOG Performance Status score	0-1	390	71,3	156	40,0	351	64,2	146	41,6	0,94	Convergence criterion (GCONV=1E-8) satisfied.	0,70	1,26	-0,016	Algorithm converged.	-0,087	0,055	0,96	Algorithm converged.	0,81	1,14	0,6588	0,1175	1,04	Algorithm converged.	0,87	1,24
		2	7	1,3	6	85,7	8	1,5	4	50,0	6,00	Convergence criterion (GCONV=1E-8) satisfied.	0,48	75,33	0,357	Algorithm converged.	-0,076	0,790	1,71	Algorithm converged.	0,80	3,65	0,1623		0,58	Algorithm converged.	0,27	1,24
		Missing	1	0,2			1	0,2																				
	Independence status (Katz ADL)	Independent (5-6)	317	58,0	127	40,1	282	51,6	117	41,5	0,94	Convergence criterion (GCONV=1E-8) satisfied.	0,68	1,31	-0,014	Algorithm converged.	-0,093	0,065	0,97	Algorithm converged.	0,80	1,17	0,7227		1,04	Algorithm converged.	0,85	1,26
		Some dependence (3-4)	1	0,2	1	100,0																						
		Very dependent (0-2)	2	0,4	1	50,0	6	1,1	5	83,3	0,20	Convergence criterion (GCONV=1E-8) satisfied.	<0.01	6,66	-0,333	Algorithm converged.	-1,088	0,421	0,60	Algorithm converged.	0,14	2,51	0,4843		1,67	Algorithm converged.	0,40	6,97
		Outside valid range	33	6,0	14	42,4	32	5,9	17	53,1	0,65	Convergence criterion (GCONV=1E-8) satisfied.	0,24	1,73	-0,107	Algorithm converged.	-0,349	0,135	0,80	Algorithm converged.	0,48	1,33	0,3908		1,25	Algorithm converged.	0,75	2,09
		Missing	45	8,2	19	42,2	40	7,3	11	27,5	1,93	Convergence criterion (GCONV=1E-8) satisfied.	0,77	4,79	0,147	Algorithm converged.	-0,053	0,347	1,54	Algorithm converged.	0,84	2,82	0,1671		0,65	Algorithm converged.	0,35	1,20
	Independence status (Katz IADL)	Independent (5-8)	346	63,3	138	39,9	312	57,0	134	42,9	0,88	Convergence criterion (GCONV=1E-8) satisfied.	0,65	1,20	-0,031	Algorithm converged.	-0,106	0,045	0,93	Algorithm converged.	0,77	1,11	0,4251	0,3005	1,08	Algorithm converged.	0,90	1,29
		Some dependence (1-4)	3	0,5	2	66,7	4	0,7	3	75,0	0,67	Convergence criterion (GCONV=1E-8) satisfied.	0,02	18,06	-0,083	Algorithm converged.	-0,765	0,598	0,89	Algorithm converged.	0,33	2,37	0,8138		1,12	Algorithm converged.	0,42	3,00
		Outside valid range	11	2,0	4	36,4	5	0,9	2	40,0	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,10	7,51	-0,036	Algorithm converged.	-0,551	0,479	0,91	Algorithm converged.	0,24	3,43	0,8881		1,10	Algorithm converged.	0,29	4,15
		Missing	38	6,9	18	47,4	39	7,1	11	28,2	2,29	Convergence criterion (GCONV=1E-8) satisfied.	0,89	5,89	0,192	Algorithm converged.	-0,021	0,404	1,68	Algorithm converged.	0,92	3,07	0,0917		0,60	Algorithm converged.	0,33	1,09
	Chemotherapy regimen	CHOP	142	26,0	53	37,3	142	26,0	53	37,3	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,62	1,62	0,000	Algorithm converged.	-0,113	0,113	1,00	Algorithm converged.	0,74	1,35	1,0000	0,8397	1,00	Algorithm converged.	0,74	1,35
		CVP	41	7,5	15	36,6	27	4,9	12	44,4	0,72	Convergence criterion (GCONV=1E-8) satisfied.	0,27	1,94	-0,079	Algorithm converged.	-0,317	0,160	0,82	Algorithm converged.	0,46	1,48	0,5132		1,21	Algorithm converged.	0,68	2,18
		Bendamustine	215	39,3	94	43,7	191	34,9	85	44,5	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,65	1,43	-0,008	Algorithm converged.	-0,105	0,089	0,98	Algorithm converged.	0,79	1,22	0,8741		1,02	Algorithm converged.	0,82	1,27
	Histologic grade	1	159	29,1	73	45,9	133	24,3	51	38,3	1,36	Convergence criterion (GCONV=1E-8) satisfied.	0,85	2,18	0,076	Algorithm converged.	-0,038	0,189	1,20	Algorithm converged.	0,91	1,57	0,1972		0,84	Algorithm converged.	0,64	1,10
		2	184	33,6	72	39,1	174	31,8	74	42,5	0,87	Convergence criterion (GCONV=1E-8) satisfied.	0,57	1,32	-0,034	Algorithm converged.	-0,136	0,068	0,92	Algorithm converged.	0,72	1,18	0,5132		1,09	Algorithm converged.	0,85	1,40
		3	3	0,5	1	33,3	2	0,4			*	Quasi-complete separation of data points detected.			*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
		3a	50	9,1	16	32,0	47	8,6	23	48,9	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,22	1,12	-0,169	Algorithm converged.	-0,362	0,023	0,65	Algorithm converged.	0,40	1,08	0,0949		1,53	Algorithm converged.	0,93	2,52
		Other					1	0,2	1	100,0																		

		Missing	2	0,4			3	0,5	1	33,3		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01		Algorithm converged.	0,00	NE	1,0000		>999.99		Algorithm converged.	0,00	NE
	FLIPI	Low (0-1)	96	17,6	37	38,5	83	15,2	36	43,4	0,82		Convergence criterion (GCONV=1E-8) satisfied.	0,45	1,49	-0,048		Algorithm converged.	-0,193	0,096	0,89		Algorithm converged.	0,62	1,26	0,5113	0,4807	1,13		Algorithm converged.	0,79	1,60
		Intermediate (2)	151	27,6	53	35,1	131	23,9	51	38,9	0,85		Convergence criterion (GCONV=1E-8) satisfied.	0,52	1,38	-0,038		Algorithm converged.	-0,151	0,075	0,90		Algorithm converged.	0,66	1,22	0,5055		1,11		Algorithm converged.	0,82	1,50
		High (>=3)	151	27,6	72	47,7	146	26,7	63	43,2	1,20		Convergence criterion (GCONV=1E-8) satisfied.	0,76	1,90	0,045		Algorithm converged.	-0,068	0,158	1,11		Algorithm converged.	0,86	1,42	0,4340		0,90		Algorithm converged.	0,70	1,16
	FC Gamma Receptor IIa	131HH	128	23,4	40	31,3	118	21,6	48	40,7	0,66		Convergence criterion (GCONV=1E-8) satisfied.	0,39	1,12	-0,094		Algorithm converged.	-0,214	0,025	0,77		Algorithm converged.	0,55	1,08	0,1250	0,2704	1,30		Algorithm converged.	0,93	1,82
		131HR	182	33,3	86	47,3	160	29,3	71	44,4	1,12		Convergence criterion (GCONV=1E-8) satisfied.	0,73	1,72	0,029		Algorithm converged.	-0,077	0,135	1,06		Algorithm converged.	0,84	1,34	0,5950		0,94		Algorithm converged.	0,74	1,18
		131RR	75	13,7	30	40,0	68	12,4	26	38,2	1,08		Convergence criterion (GCONV=1E-8) satisfied.	0,55	2,11	0,018		Algorithm converged.	-0,142	0,178	1,05		Algorithm converged.	0,69	1,58	0,8292		0,96		Algorithm converged.	0,63	1,44
		Missing	13	2,4	6	46,2	14	2,6	5	35,7	1,54		Convergence criterion (GCONV=1E-8) satisfied.	0,33	7,23	0,104		Algorithm converged.	-0,265	0,474	1,29		Algorithm converged.	0,52	3,23	0,5831		0,77		Algorithm converged.	0,31	1,93
	FC Gamma Receptor IIIa	158VV	46	8,4	15	32,6	42	7,7	14	33,3	0,97		Convergence criterion (GCONV=1E-8) satisfied.	0,40	2,36	-0,007		Algorithm converged.	-0,204	0,189	0,98		Algorithm converged.	0,54	1,78	0,9424	0,3631	1,02		Algorithm converged.	0,56	1,86
		158VF	190	34,7	71	37,4	146	26,7	64	43,8	0,76		Convergence criterion (GCONV=1E-8) satisfied.	0,49	1,19	-0,065		Algorithm converged.	-0,171	0,041	0,85		Algorithm converged.	0,66	1,11	0,2289		1,17		Algorithm converged.	0,90	1,52
		158FF	149	27,2	70	47,0	158	28,9	67	42,4	1,20		Convergence criterion (GCONV=1E-8) satisfied.	0,77	1,89	0,046		Algorithm converged.	-0,065	0,157	1,11		Algorithm converged.	0,86	1,42	0,4204		0,90		Algorithm converged.	0,70	1,16
		Missing	13	2,4	6	46,2	14	2,6	5	35,7	1,54		Convergence criterion (GCONV=1E-8) satisfied.	0,33	7,23	0,104		Algorithm converged.	-0,265	0,474	1,29		Algorithm converged.	0,52	3,23	0,5831		0,77		Algorithm converged.	0,31	1,93
	FC Gamma Receptor IIb/IIc	232II	278	50,8	111	39,9	248	45,3	109	44,0	0,85		Convergence criterion (GCONV=1E-8) satisfied.	0,60	1,20	-0,040		Algorithm converged.	-0,125	0,044	0,91		Algorithm converged.	0,74	1,11	0,3500	0,3433	1,10		Algorithm converged.	0,90	1,35
		232IT	74	13,5	31	41,9	67	12,2	22	32,8	1,47		Convergence criterion (GCONV=1E-8) satisfied.	0,74	2,93	0,091		Algorithm converged.	-0,068	0,250	1,28		Algorithm converged.	0,83	1,97	0,2725		0,78		Algorithm converged.	0,51	1,21
		232TT	5	0,9	3	60,0	8	1,5	4	50,0	1,50		Convergence criterion (GCONV=1E-8) satisfied.	0,16	14,42	0,100		Algorithm converged.	-0,452	0,652	1,20		Algorithm converged.	0,44	3,25	0,7198		0,83		Algorithm converged.	0,31	2,26
		Missing	41	7,5	17	41,5	37	6,8	15	40,5	1,04		Convergence criterion (GCONV=1E-8) satisfied.	0,42	2,56	0,009		Algorithm converged.	-0,209	0,228	1,02		Algorithm converged.	0,60	1,74	0,9341		0,98		Algorithm converged.	0,57	1,67
	Time from initial FL diagnosis to randomization	< 6 months	326	59,6	139	42,6	290	53,0	118	40,7	1,08		Convergence criterion (GCONV=1E-8) satisfied.	0,79	1,49	0,019		Algorithm converged.	-0,058	0,097	1,05		Algorithm converged.	0,87	1,26	0,6249	0,1059	0,95		Algorithm converged.	0,79	1,15
		6-12 months	26	4,8	11	42,3	19	3,5	8	42,1	1,01		Convergence criterion (GCONV=1E-8) satisfied.	0,30	3,34	0,002		Algorithm converged.	-0,290	0,294	1,00		Algorithm converged.	0,50	2,01	0,9892		1,00		Algorithm converged.	0,50	1,99
		> 12 months	45	8,2	12	26,7	51	9,3	24	47,1	0,41		Convergence criterion (GCONV=1E-8) satisfied.	0,17	0,97	-0,204		Algorithm converged.	-0,392	-0,016	0,57		Algorithm converged.	0,32	1,00	0,0489		1,76		Algorithm converged.	1,00	3,11
		Missing	1	0,2																													
	Ann Arbor Stage 2	Stage I	9	1,6	4	44,4	4	0,7	3	75,0	0,27		Convergence criterion (GCONV=1E-8) satisfied.	0,02	3,65	-0,306		Algorithm converged.	-0,840	0,229	0,59		Algorithm converged.	0,24	1,49	0,2670	0,1750	1,69		Algorithm converged.	0,67	4,25
		Stage II (w/o bulky disease)	7	1,3	2	28,6	7	1,3	2	28,6	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,10	10,17	0,000		Algorithm converged.	-0,473	0,473	1,00		Algorithm converged.	0,19	5,24	1,0000		1,00		Algorithm converged.	0,19	5,24
		Stage II (with bulky disease)	21	3,8	10	47,6	16	2,9	8	50,0	0,91		Convergence criterion (GCONV=1E-8) satisfied.	0,25	3,34	-0,024		Algorithm converged.	-0,349	0,301	0,95		Algorithm converged.	0,49	1,85	0,8855		1,05		Algorithm converged.	0,54	2,04
		Stage III	135	24,7	45	33,3	132	24,1	59	44,7	0,62		Convergence criterion (GCONV=1E-8) satisfied.	0,38	1,02	-0,114		Algorithm converged.	-0,230	0,003	0,75		Algorithm converged.	0,55	1,01	0,0593		1,34		Algorithm converged.	0,99	1,82
		Stage IV	224	41,0	100	44,6	198	36,2	76	38,4	1,29		Convergence criterion (GCONV=1E-8) satisfied.	0,88	1,91	0,063		Algorithm converged.	-0,031	0,157	1,16		Algorithm converged.	0,93	1,46	0,1959		0,86		Algorithm converged.	0,68	1,08
		Missing	2	0,4	1	50,0	3	0,5	2	66,7	0,50		Convergence criterion (GCONV=1E-8) satisfied.	0,01	19,56	-0,167		Algorithm converged.	-1,041	0,708	0,75		Algorithm converged.	0,15	3,72	0,7246		1,33		Algorithm converged.	0,27	6,61

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_base/qa/program/t_eff_resp2.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/t_eff_resp2_sg_PFGT6I_FACTGpop_FOLY_IT.xls
10AUG2020 10:38

5 (Anhang): Ergebnisse für FACT-G - Verschlechterung der Gesundheitsbezogenen Lebensqualität um MID sechs - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients, Patients with Baseline and post Baseline FACT-G Total result
ENDPOINT: FACT-G Total - Responder (MID=6), worsening
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Efficacy)

			G-chemo (N=547)				R-chemo (N=547)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
			Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk										Relative Risk				
Analysis Visit Window	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Follow Up Month 12	All	n/a	398	72,8	86	21,6	360	65,8	67	18,6	1,21	Convergence criterion (GCONV=1E-8) satisfied.	0,84	1,72	0,030	Algorithm converged.	-0,027	0,087	1,10	Algorithm converged.	0,87	1,55	0,3059		0,80	Algorithm converged.	0,65	1,15
	Sex	Male	187	34,2	43	23,0	167	30,5	28	16,8	1,48	Convergence criterion (GCONV=1E-8) satisfied.	0,87	2,52	0,062	Algorithm converged.	-0,020	0,145	1,37	Algorithm converged.	0,89	2,10	0,1478	0,2947	0,73	Algorithm converged.	0,48	1,12
		Female	211	38,6	43	20,4	193	35,3	39	20,2	1,01	Convergence criterion (GCONV=1E-8) satisfied.	0,62	1,64	0,002	Algorithm converged.	-0,077	0,080	1,01	Algorithm converged.	0,68	1,48	0,9658		0,99	Algorithm converged.	0,67	1,46
	Age	< 60 years	210	38,4	45	21,4	198	36,2	41	20,7	1,04	Convergence criterion (GCONV=1E-8) satisfied.	0,65	1,68	0,007	Algorithm converged.	-0,072	0,086	1,03	Algorithm converged.	0,71	1,51	0,8583	0,3572	0,97	Algorithm converged.	0,66	1,41
		>= 60 years	188	34,4	41	21,8	162	29,6	26	16,0	1,46	Convergence criterion (GCONV=1E-8) satisfied.	0,85	2,51	0,058	Algorithm converged.	-0,024	0,139	1,36	Algorithm converged.	0,87	2,12	0,1761		0,74	Algorithm converged.	0,47	1,15
	Race/ethnicity	White	384	55,6	50	19,4	278	50,8	48	17,3	1,15	Convergence criterion (GCONV=1E-8) satisfied.	0,76	1,76	0,021	Algorithm converged.	-0,041	0,084	1,12	Algorithm converged.	0,80	1,59	0,5059	0,7537	0,89	Algorithm converged.	0,63	1,26
		Other	94	17,2	27	28,7	82	15,0	19	23,2	1,34	Convergence criterion (GCONV=1E-8) satisfied.	0,68	2,64	0,056	Algorithm converged.	-0,074	0,185	1,24	Algorithm converged.	0,75	2,06	0,4060		0,81	Algorithm converged.	0,49	1,34
	Geographic region	North America	55	10,1	9	16,4	52	9,5	9	17,3	0,93	Convergence criterion (GCONV=1E-8) satisfied.	0,34	2,57	-0,009	Algorithm converged.	-0,151	0,132	0,95	Algorithm converged.	0,41	2,20	0,8962	0,7454	1,06	Algorithm converged.	0,46	2,46
		Western Europe	173	31,6	30	17,3	138	25,2	19	13,8	1,31	Convergence criterion (GCONV=1E-8) satisfied.	0,70	2,45	0,036	Algorithm converged.	-0,045	0,116	1,26	Algorithm converged.	0,74	2,14	0,3929		0,79	Algorithm converged.	0,47	1,35
		Asia-Pacific	112	20,5	32	28,6	111	20,3	23	20,7	1,53	Convergence criterion (GCONV=1E-8) satisfied.	0,83	2,83	0,079	Algorithm converged.	-0,034	0,191	1,38	Algorithm converged.	0,86	2,20	0,1776		0,73	Algorithm converged.	0,45	1,16
		Other	58	10,6	15	25,9	59	10,8	16	27,1	0,94	Convergence criterion (GCONV=1E-8) satisfied.	0,41	2,13	-0,013	Algorithm converged.	-0,172	0,147	0,95	Algorithm converged.	0,52	1,74	0,8777		1,05	Algorithm converged.	0,57	1,92
	Baseline ECOG Performance Status score	0-1	390	71,3	85	21,8	351	64,2	65	18,5	1,23	Convergence criterion (GCONV=1E-8) satisfied.	0,85	1,76	0,033	Algorithm converged.	-0,025	0,090	1,18	Algorithm converged.	0,88	1,57	0,2692	0,0774	0,85	Algorithm converged.	0,64	1,13
		2	7	1,3			8	1,5	2	25,0		* Quasi-complete separation of data points detected.				* ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE
		Missing	1	0,2	1	100,0	1	0,2				* Complete separation of data points detected.				* ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		
	Independence status (Katz ADL)	Independent (5-6)	317	58,0	76	24,0	282	51,6	52	18,4	1,39	Convergence criterion (GCONV=1E-8) satisfied.	0,94	2,07	0,055	Algorithm converged.	-0,010	0,121	1,30	Algorithm converged.	0,95	1,78	0,1015	0,1701	0,77	Algorithm converged.	0,56	1,05
		Some dependence (3-4)	1	0,2																								
		Very dependent (0-2)	2	0,4	1	50,0	6	1,1	1	16,7	5,00	Convergence criterion (GCONV=1E-8) satisfied.	0,15	166,59	0,333	Algorithm converged.	-0,421	1,088	3,00	Algorithm converged.	0,31	28,84	0,3414		0,33	Algorithm converged.	0,03	3,20
		Outside valid range	33	6,0	5	15,2	32	6,9	5	15,6	0,96	Convergence criterion (GCONV=1E-8) satisfied.	0,25	3,71	-0,005	Algorithm converged.	-0,180	0,171	0,97	Algorithm converged.	0,31	3,03	0,9578		1,03	Algorithm converged.	0,33	3,23
		Missing	45	8,2	4	8,9	40	7,3	9	22,5	0,34	Convergence criterion (GCONV=1E-8) satisfied.	0,09	1,19	-0,136	Algorithm converged.	-0,290	0,018	0,40	Algorithm converged.	0,13	1,18	0,0974		2,53	Algorithm converged.	0,84	7,59
	Independence status (Katz IADL)	Independent (5-8)	346	63,3	80	23,1	312	57,0	58	18,6	1,32	Convergence criterion (GCONV=1E-8) satisfied.	0,90	1,92	0,045	Algorithm converged.	-0,017	0,107	1,24	Algorithm converged.	0,92	1,68	0,1560	0,0465	0,80	Algorithm converged.	0,50	1,09
		Some dependence (1-4)	3	0,5	1	33,3	4	0,7				* Quasi-complete separation of data points detected.				* ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
		Outside valid range	11	2,0	2	18,2	5	0,9				* Quasi-complete separation of data points detected.				* ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
		Missing	38	6,9	3	7,9	39	7,1	9	23,1	0,29	Convergence criterion (GCONV=1E-8) satisfied.	0,07	1,15	-0,152	Algorithm converged.	-0,309	0,006	0,34	Algorithm converged.	0,10	1,17	0,0869		2,92	Algorithm converged.	0,86	9,98
	Chemotherapy regimen	CHOP	142	26,0	34	23,9	142	26,0	33	23,2	1,04	Convergence criterion (GCONV=1E-8) satisfied.	0,60	1,80	0,007	Algorithm converged.	-0,092	0,106	1,03	Algorithm converged.	0,68	1,57	0,8889	0,6858	0,97	Algorithm converged.	0,64	1,48
		CVP	41	7,5	7	17,1	27	4,9	3	11,1	1,65	Convergence criterion (GCONV=1E-8) satisfied.	0,39	7,02	0,060	Algorithm converged.	-0,106	0,225	1,54	Algorithm converged.	0,43	5,43	0,5048		0,65	Algorithm converged.	0,18	2,30
		Bendamustine	215	39,3	45	20,9	191	34,9	31	16,2	1,37	Convergence criterion (GCONV=1E-8) satisfied.	0,82	2,27	0,047	Algorithm converged.	-0,028	0,122	1,29	Algorithm converged.	0,85	1,95	0,2285		0,78	Algorithm converged.	0,51	1,17
	Histologic grade	1	159	29,1	26	16,4	133	24,3	33	24,8	0,59	Convergence criterion (GCONV=1E-8) satisfied.	0,33	1,05	-0,085	Algorithm converged.	-0,178	0,009	0,66	Algorithm converged.	0,42	1,04	0,0753	0,0243	1,52	Algorithm converged.	0,96	2,40
		2	184	33,6	47	25,5	174	31,8	28	16,1	1,79	Convergence criterion (GCONV=1E-8) satisfied.	1,06	3,02	0,095	Algorithm converged.	0,011	0,178	1,59	Algorithm converged.	1,04	2,41	0,0309		0,63	Algorithm converged.	0,41	0,96
		3	3	0,5	1	33,3	2	0,4				* Quasi-complete separation of data points detected.				* WARNING: The relative Hessian convergence criterion of 1.8475907089 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
		4a	50	9,1	12	24,0	47	8,6	5	10,6	2,65	Convergence criterion (GCONV=1E-8) satisfied.	0,86	8,23	0,134	Algorithm converged.	-0,014	0,281	2,20	Algorithm converged.	0,86	5,92	0,0982		0,44	Algorithm converged.	0,17	1,16
		Other					1	0,2																				
		Missing	2	0,4			1	0,5	1	33,3		* Quasi-complete separation of data points detected.				* ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01	Algorithm converged.	0,00	NE	1,0000		>999.99	Algorithm converged.	0,00	NE
	FLIPI	Low (0-1)	96	17,6	23	24,0	83	15,2	17	20,5	1,22	Convergence criterion (GCONV=1E-8) satisfied.	0,60	2,49	0,035	Algorithm converged.	-0,087	0,157	1,17	Algorithm converged.	0,67	2,04	0,5790	0,7985	0,85	Algorithm converged.	0,49	1,49
		Intermediate (2)	151	27,6	38	25,2	131	23,9	26	19,8	1,36	Convergence criterion (GCONV=1E-8) satisfied.	0,77	2,39	0,053	Algorithm converged.	-0,044	0,150	1,27	Algorithm converged.	0,82	1,97	0,2909		0,79	Algorithm converged.	0,51	1,23
		High (>=3)	151	27,6	25	16,6	146	26,7	24	16,4	1,01	Convergence criterion (GCONV=1E-8) satisfied.	0,55	1,86	0,001	Algorithm converged.	-0,083	0,086	1,01	Algorithm converged.	0,60	1,68	0,9782		0,99	Algorithm converged.	0,60	1,66
	FC Gamma Receptor IIa	I31HH	128	23,4	36	28,1	118	21,6	23	19,5	1,62	Convergence criterion (GCONV=1E-8) satisfied.	0,89	2,93	0,086	Algorithm converged.	-0,019	0,192	1,44	Algorithm converged.	0,91	2,28	0,1178	0,0822	0,69	Algorithm converged.	0,44	1,10
		I31HR	182	33,3	36	19,8	160	29,3	25	15,6	1,33	Convergence criterion (GCONV=1E-8) satisfied.	0,76	2,33	0,042	Algorithm converged.	-0,039	0,122	1,27	Algorithm converged.	0,80	2,01	0,3192		0,79	Algorithm converged.	0,50	1,26
		I31RR	75	13,7	11	14,7	68	12,4	17	25,0	0,52	Convergence criterion (GCONV=1E-8) satisfied.	0,22	1,20	-0,103	Algorithm converged.	-0,234	0,027	0,59	Algorithm converged.	0,30	1,16	0,1263		1,70	Algorithm converged.	0,86	3,38
		Missing	13	2,4	3	23,1	14	2,6	2	14,3	1,80	Convergence criterion (GCONV=1E-8) satisfied.	0,25	12,99	0,008	Algorithm converged.	-0,205	0,381	1,62	Algorithm converged.	0,32	8,18	0,5623		0,62	Algorithm converged.	0,12	3,13
	FC Gamma Receptor IIIa	I58VV	46	8,4	17	37,0	42	7,7	7	16,7	2,03	Convergence criterion (GCONV=1E-8) satisfied.	1,07	8,03	0,203	Algorithm converged.	0,024	0,382	2,22	Algorithm converged.	1,02	4,81	0,0439	0,1491	0,45	Algorithm converged.	0,21	0,98
		I58VF	190	34,7	40	21,1	146	26,7	38	20,5	1,83	Convergence criterion (GCONV=1E-8) satisfied.	0,61	1,75	0,005	Algorithm converged.	-0,082	0,093	1,02	Algorithm converged.	0,67	1,56	0,9101		0,98	Algorithm converged.	0,64	1,49
		I58FF	149	27,2	26	17,4	158	28,9	28	17,7	0,98	Convergence criterion (GCONV=1E-8) satisfied.	0,55	1,77	-0,003	Algorithm converged.	-0,088	0,082	0,98	Algorithm converged.	0,61	1,60	0,9501		1,02	Algorithm converged.	0,63	1,65

		Missing	13	2,4	3	23,1	14	2,6	2	14,3	1,80		Convergence criterion (GCONV=1E-8) satisfied.	0,25	12,99	0,088		Algorithm converged.	-0,205	0,381	1,62		Algorithm converged.	0,32	3,18	0,5623		0,62		Algorithm converged.	0,12	3,13
	FC Gamma Receptor IIb/IIc	I32II	278	50,8	61	21,9	248	45,3	47	19,0	1,20		Convergence criterion (GCONV=1E-8) satisfied.	0,79	1,84	0,030		Algorithm converged.	-0,039	0,009	1,16		Algorithm converged.	0,82	1,63	0,3979	0,9674	0,86		Algorithm converged.	0,61	1,21
		I32IT	74	13,5	15	20,3	67	12,2	12	17,9	1,17		Convergence criterion (GCONV=1E-8) satisfied.	0,50	2,71	0,024		Algorithm converged.	-0,106	0,153	1,13		Algorithm converged.	0,57	2,24	0,7226		0,88		Algorithm converged.	0,45	1,75
		I32TT	5	0,9	1	20,0	65	11,5	1	12,5	1,75		Convergence criterion (GCONV=1E-8) satisfied.	0,08	36,29	0,075		Algorithm converged.	-0,344	0,494	1,60		Algorithm converged.	0,13	20,22	0,7165		0,63		Algorithm converged.	0,05	7,90
		Missing	41	7,5	9	22,0	37	6,8	7	18,9	1,21		Convergence criterion (GCONV=1E-8) satisfied.	0,40	3,64	0,030		Algorithm converged.	-0,149	0,209	1,16		Algorithm converged.	0,48	2,80	0,7412		0,86		Algorithm converged.	0,36	2,08
	Time from initial FL diagnosis to randomization	< 6 months	326	59,6	63	19,3	290	53,0	56	19,3	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,67	1,49	0,000		Algorithm converged.	-0,062	0,063	1,00		Algorithm converged.	0,72	1,38	0,9963	0,1477	1,00		Algorithm converged.	0,72	1,38
		6-12 months	26	4,8	8	30,8	19	3,5	4	21,1	1,67		Convergence criterion (GCONV=1E-8) satisfied.	0,42	8,64	0,097		Algorithm converged.	-0,158	0,352	1,46		Algorithm converged.	0,51	4,15	0,4763		0,68		Algorithm converged.	0,24	1,94
		> 12 months	45	8,2	14	31,1	51	9,3	7	13,7	2,84		Convergence criterion (GCONV=1E-8) satisfied.	1,03	7,85	0,174		Algorithm converged.	0,009	0,339	2,27		Algorithm converged.	1,00	5,12	0,0488		0,44		Algorithm converged.	0,20	1,00
		Missing		10,2	1	100,0																											
	Ann Arbor Stage 2	Stage I	9	1,6	3	33,3	4	0,7	1	25,0	1,50		Convergence criterion (GCONV=1E-8) satisfied.	0,11	21,31	0,083		Algorithm converged.	-0,441	0,608	1,33		Algorithm converged.	0,19	0,21	0,7705	0,6508	0,75		Algorithm converged.	0,11	5,18
		Stage II (w/o bulky disease)	7	1,3	2	28,6	7	1,3	4	57,1	0,30		Convergence criterion (GCONV=1E-8) satisfied.	0,03	2,76	-0,286		Algorithm converged.	-0,782	0,211	0,50		Algorithm converged.	0,13	1,90	0,3090		2,00		Algorithm converged.	0,53	7,60
		Stage II (with bulky disease)	21	3,8	4	19,0	16	2,9	4	25,0	0,71		Convergence criterion (GCONV=1E-8) satisfied.	0,15	3,39	-0,060		Algorithm converged.	-0,330	0,211	0,76		Algorithm converged.	0,22	2,59	0,6632		1,31		Algorithm converged.	0,30	4,46
		Stage III	135	24,7	31	23,0	132	24,1	23	17,4	1,41		Convergence criterion (GCONV=1E-8) satisfied.	0,77	2,58	0,055		Algorithm converged.	-0,041	0,151	1,32		Algorithm converged.	0,81	2,14	0,2628		0,76		Algorithm converged.	0,47	1,23
		Stage IV	224	41,0	45	20,1	198	36,2	35	17,7	1,17		Convergence criterion (GCONV=1E-8) satisfied.	0,72	1,91	0,024		Algorithm converged.	-0,051	0,009	1,14		Algorithm converged.	0,76	1,69	0,5289		0,88		Algorithm converged.	0,59	1,31
		Missing		20,4	1	50,0		30,5				*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.				*	WARNING: Negative of Hessian not positive definite.						*	WARNING: Negative of Hessian not positive definite.		

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is
uninterpretable. Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_base/qa/program/t_eff_resp2.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/t_eff_resp2_sg_PFGT6D_FACTGpop_FOLY_IT.xls
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6 (Anhang): Ergebnisse für FACT-LymS – Verbesserung der Gesundheitsbezogenen Lebensqualität um MID fünf - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients, Patients with Baseline and post Baseline FACT-Lymphoma Subscale result
ENDPOINT: FACT-LYM Subscale - Responder (MID=5), improvement
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Efficacy)

			G-chemo (N=549)				R-chemo (N=549)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo			
			Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk										Relative Risk			
Analysis Visit Window	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Follow Up Month 12	All	n/a	404	73,6	164	40,6	360	65,6	171	47,5	0,76	Convergence criterion (GCONV=1E-8) satisfied.	0,57	1,01	-0,069	Algorithm converged.	-0,139	0,001	0,85	Algorithm converged.	0,73	1,00	0,0548		1,17	Algorithm converged.	1,00	1,37
	Sex	Male	194	35,3	71	36,6	165	30,1	81	49,1	0,60	Convergence criterion (GCONV=1E-8) satisfied.	0,39	0,91	-0,125	Algorithm converged.	-0,227	-0,023	0,75	Algorithm converged.	0,59	0,95	0,0173	0,1253	1,34	Algorithm converged.	1,05	1,71
		Female	210	38,3	93	44,3	195	35,5	90	46,2	0,93	Convergence criterion (GCONV=1E-8) satisfied.	0,63	1,37	-0,019	Algorithm converged.	-0,116	0,078	0,96	Algorithm converged.	0,77	1,19	0,7057		1,04	Algorithm converged.	0,84	1,29
	Age	< 60 years	213	38,8	90	42,3	198	36,1	96	48,5	0,78	Convergence criterion (GCONV=1E-8) satisfied.	0,53	1,15	-0,062	Algorithm converged.	-0,158	0,034	0,87	Algorithm converged.	0,70	1,08	0,2050	0,8059	1,15	Algorithm converged.	0,93	1,42
		>= 60 years	191	34,8	74	38,7	162	29,5	75	46,3	0,73	Convergence criterion (GCONV=1E-8) satisfied.	0,48	1,12	-0,076	Algorithm converged.	-0,179	0,028	0,84	Algorithm converged.	0,66	1,07	0,1517		1,19	Algorithm converged.	0,94	1,52
	Race/ethnicity	White	110	56,5	130	41,9	278	50,6	127	45,7	0,86	Convergence criterion (GCONV=1E-8) satisfied.	0,62	1,19	-0,037	Algorithm converged.	-0,118	0,043	0,92	Algorithm converged.	0,76	1,10	0,3599	0,1102	1,09	Algorithm converged.	0,91	1,31
		Other	94	17,1	34	36,2	82	14,9	44	53,7	0,49	Convergence criterion (GCONV=1E-8) satisfied.	0,27	0,90	-0,175	Algorithm converged.	-0,320	-0,030	0,67	Algorithm converged.	0,48	0,94	0,0212		1,48	Algorithm converged.	1,06	2,07
	Geographic region	North America	55	10,0	19	34,5	52	9,5	34	65,4	0,28	Convergence criterion (GCONV=1E-8) satisfied.	0,13	0,62	-0,308	Algorithm converged.	-0,489	-0,128	0,53	Algorithm converged.	0,35	0,80	0,0025	0,0523	1,89	Algorithm converged.	1,25	2,86
		Western Europe	178	32,4	80	44,9	138	25,1	63	45,7	0,97	Convergence criterion (GCONV=1E-8) satisfied.	0,62	1,52	-0,007	Algorithm converged.	-0,118	0,104	0,98	Algorithm converged.	0,77	1,26	0,9001		1,02	Algorithm converged.	0,80	1,30
		Asia-Pacific	113	20,6	43	38,1	111	20,2	52	46,8	0,70	Convergence criterion (GCONV=1E-8) satisfied.	0,41	1,19	-0,088	Algorithm converged.	-0,217	0,041	0,81	Algorithm converged.	0,60	1,10	0,1852		1,23	Algorithm converged.	0,91	1,67
		Other	58	10,6	22	37,9	59	10,7	22	37,3	1,03	Convergence criterion (GCONV=1E-8) satisfied.	0,49	2,17	0,006	Algorithm converged.	-0,169	0,182	1,02	Algorithm converged.	0,64	1,62	0,0428		0,98	Algorithm converged.	0,62	1,57
	Baseline ECOG Performance Status score	0-1	396	72,1	157	39,6	351	63,9	166	47,3	0,73	Convergence criterion (GCONV=1E-8) satisfied.	0,55	0,98	-0,076	Algorithm converged.	-0,148	-0,005	0,84	Algorithm converged.	0,71	0,99	0,0353	0,1301	1,19	Algorithm converged.	1,01	1,41
		2	7	1,3	6	85,7	8	1,5	5	62,5	1,60	Convergence criterion (GCONV=1E-8) satisfied.	0,28	46,36	0,232	Algorithm converged.	-0,192	0,656	1,37	Algorithm converged.	0,74	2,54	0,3150		0,73	Algorithm converged.	0,39	1,35
		Missing	1	0,2	1	100,0	1	0,2			*	Complete separation of data points detected.			*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.					*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		
	Independence status (Katz ADL)	Independent (5-6)	319	58,1	133	41,7	281	51,2	135	48,0	0,77	Convergence criterion (GCONV=1E-8) satisfied.	0,56	1,07	-0,063	Algorithm converged.	-0,143	0,016	0,87	Algorithm converged.	0,73	1,04	0,1182		1,15	Algorithm converged.	0,96	1,38
		Some dependence (3-4)	1	0,2	1	100,0																						
		Very dependent (0-2)	3	0,5	1	33,3	6	1,1	4	66,7	0,25	Convergence criterion (GCONV=1E-8) satisfied.	0,01	4,73	-0,333	Algorithm converged.	-0,987	0,320	0,50	Algorithm converged.	0,09	2,73	0,4235		2,00	Algorithm converged.	0,37	10,92
		Outside valid range	35	6,4	14	40,0	32	5,8	12	37,5	1,11	Convergence criterion (GCONV=1E-8) satisfied.	0,42	2,97	0,025	Algorithm converged.	-0,208	0,258	1,07	Algorithm converged.	0,58	1,95	0,8341		0,94	Algorithm converged.	0,51	1,71
		Missing	46	8,4	15	32,6	41	7,5	20	48,8	0,51	Convergence criterion (GCONV=1E-8) satisfied.	0,21	1,21	-0,162	Algorithm converged.	-0,366	0,043	0,67	Algorithm converged.	0,40	1,13	0,1294		1,50	Algorithm converged.	0,89	2,52
	Independence status (Katz IADL)	Independent (5-6)	349	63,6	145	41,5	311	56,6	148	47,6	0,78	Convergence criterion (GCONV=1E-8) satisfied.	0,58	1,07	-0,060	Algorithm converged.	-0,136	0,015	0,87	Algorithm converged.	0,74	1,04	0,1187	0,8769	1,15	Algorithm converged.	0,97	1,36
		Some dependence (1-4)	3	0,5	1	33,3	4	0,7	2	50,0	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,02	11,09	-0,167	Algorithm converged.	-0,891	0,558	0,67	Algorithm converged.	0,10	4,35	0,6719		1,50	Algorithm converged.	0,23	9,80
		Outside valid range	13	2,4	5	38,5	5	0,9	3	60,0	0,42	Convergence criterion (GCONV=1E-8) satisfied.	0,05	3,43	-0,215	Algorithm converged.	-0,720	0,289	0,64	Algorithm converged.	0,24	1,73	0,3798		1,56	Algorithm converged.	0,58	4,21
		Missing	39	7,1	13	33,3	40	7,3	18	45,0	0,61	Convergence criterion (GCONV=1E-8) satisfied.	0,25	1,52	-0,117	Algorithm converged.	-0,330	0,097	0,74	Algorithm converged.	0,42	1,30	0,2942		1,35	Algorithm converged.	0,77	2,37
	Chemotherapy regimen	CHOP	142	25,9	57	40,1	143	26,0	59	41,3	0,95	Convergence criterion (GCONV=1E-8) satisfied.	0,60	1,53	-0,011	Algorithm converged.	-0,125	0,103	0,97	Algorithm converged.	0,74	1,29	0,8477	0,4419	1,03	Algorithm converged.	0,78	1,36
		CVP	39	7,1	14	35,9	26	4,7	10	38,5	0,90	Convergence criterion (GCONV=1E-8) satisfied.	0,32	2,50	-0,026	Algorithm converged.	-0,266	0,214	0,93	Algorithm converged.	0,49	1,77	0,8332		1,07	Algorithm converged.	0,56	2,04
		Bendamustine	223	40,6	93	41,7	191	34,8	102	53,4	0,62	Convergence criterion (GCONV=1E-8) satisfied.	0,42	0,92	-0,117	Algorithm converged.	-0,213	-0,021	0,78	Algorithm converged.	0,64	0,96	0,0175		1,28	Algorithm converged.	1,04	1,57
	Histologic grade	1	164	29,9	74	45,1	133	24,2	60	45,1	1,00	Convergence criterion (GCONV=1E-8) satisfied.	0,63	1,58	0,000	Algorithm converged.	-0,114	0,114	1,00	Algorithm converged.	0,78	1,29	0,9987		1,00	Algorithm converged.	0,78	1,29
		2	185	33,7	67	36,2	174	31,7	81	46,6	0,65	Convergence criterion (GCONV=1E-8) satisfied.	0,43	0,99	-0,103	Algorithm converged.	-0,205	-0,002	0,78	Algorithm converged.	0,61	1,00	0,0480		1,29	Algorithm converged.	1,00	1,65
		3	3	0,5	1	33,3	2	0,4	1	50,0	0,50	Convergence criterion (GCONV=1E-8) satisfied.	0,01	19,56	-0,167	Algorithm converged.	-1,041	0,708	0,67	Algorithm converged.	0,08	5,54	0,7074		1,50	Algorithm converged.	0,18	12,46
		3a	50	9,1	21	42,0	47	8,6	27	57,4	0,54	Convergence criterion (GCONV=1E-8) satisfied.	0,24	1,20	-0,154	Algorithm converged.	-0,351	0,042	0,73	Algorithm converged.	0,49	1,10	0,1327		1,37	Algorithm converged.	0,91	2,06
		Other					1	0,2	1	100,0																		
		Missing	2	0,4	1	50,0	3	0,5	1	33,3	2,00	Convergence criterion (GCONV=1E-8) satisfied.	0,05	78,25	0,167	Algorithm converged.	-0,708	1,041	1,50	Algorithm converged.	0,18	12,46	0,7874		0,67	Algorithm converged.	0,08	5,54
	FLIPI	Low (0-1)	96	17,5	33	34,4	84	15,3	32	38,1	0,85	Convergence criterion (GCONV=1E-8) satisfied.	0,46	1,57	-0,037	Algorithm converged.	-0,178	0,104	0,90	Algorithm converged.	0,61	1,33	0,6039	0,8343	1,11	Algorithm converged.	0,75	1,63
		Intermediate (2)	155	28,2	58	38,1	131	23,9	62	47,3	0,68	Convergence criterion (GCONV=1E-8) satisfied.	0,43	1,10	-0,093	Algorithm converged.	-0,207	0,022	0,80	Algorithm converged.	0,61	1,05	0,1140		1,24	Algorithm converged.	0,95	1,63
		High (>=3)	153	27,9	72	47,1	145	26,4	77	53,1	0,79	Convergence criterion (GCONV=1E-8) satisfied.	0,50	1,24	-0,060	Algorithm converged.	-0,174	0,053	0,89	Algorithm converged.	0,71	1,11	0,2973		1,13	Algorithm converged.	0,90	1,42
	FC Gamma Receptor IIa	131HH	129	23,5	49	38,0	118	21,5	61	51,7	0,57	Convergence criterion (GCONV=1E-8) satisfied.	0,34	0,95	-0,137	Algorithm converged.	-0,260	-0,014	0,73	Algorithm converged.	0,55	0,97	0,0317	0,3402	1,36	Algorithm converged.	1,03	1,80
		131HR	185	33,7	79	42,7	161	29,3	71	44,1	0,94	Convergence criterion (GCONV=1E-8) satisfied.	0,62	1,45	-0,014	Algorithm converged.	-0,119	0,091	0,97	Algorithm converged.	0,76	1,23	0,7936		1,03	Algorithm converged.	0,81	1,31
		131RR	77	14,0	31	40,3	67	12,2	31	46,3	0,78	Convergence criterion (GCONV=1E-8) satisfied.	0,40	1,52	-0,060	Algorithm converged.	-0,222	0,102	0,87	Algorithm converged.	0,60	1,27	0,4672		1,15	Algorithm converged.	0,79	1,67
		Missing	13	2,4	5	38,5	14	2,6	8	57,1	0,47	Convergence criterion (GCONV=1E-8) satisfied.	0,10	2,18	-0,187	Algorithm converged.	-0,557	0,184	0,67	Algorithm converged.	0,30	1,53	0,3462		1,49	Algorithm converged.	0,65	3,39
	FC Gamma Receptor IIIa	158VV	48	8,7	17	35,4	42	7,7	18	42,9	0,73	Convergence criterion (GCONV=1E-8) satisfied.	0,31	1,71	-0,074	Algorithm converged.	-0,276	0,127	0,83	Algorithm converged.	0,49	1,39	0,4702	0,6644	1,21	Algorithm converged.	0,72	2,03
		158VF	190	34,6	75	39,5	147	26,8	72	49,0	0,68	Convergence criterion (GCONV=1E-8) satisfied.	0,44	1,05	-0,095	Algorithm converged.	-0,202	0,012	0,81	Algorithm converged.	0,63	1,03	0,0707		1,24	Algorithm converged.	0,97	1,58
		158FF	153	27,9	67	43,8	157	28,6	73	46,5	0,90	Convergence criterion (GCONV=1E-8) satisfied.	0,57	1,40	-0,027	Algorithm converged.	-0,138	0,084	0,94	Algorithm converged.	0,74	1,20	0,6325		1,06	Algorithm converged.	0,83	1,36
		Missing	13	2,4	5	38,5	14	2,6	8	57,1	0,47	Convergence criterion (GCONV=1E-8) satisfied.	0,10	2,18	-0,187	Algorithm converged.	-0,557	0,184	0,67	Algorithm converged.	0,30	1,53	0,3462		1,49	Algorithm converged.	0,65	3,39
	FC Gamma Receptor IIb/IIc	232II	282	51,4	119	42,2	249	45,4	122	49,0	0,76	Convergence criterion (GCONV=1E-8) satisfied.	0,54	1,07	-0,068	Algorithm converged.	-0,153	0,017	0,86	Algorithm converged.	0,71	1,04	0,1162	0,7810	1,16	Algorithm converged.	0,96	1,40
		232IT	75	13,7	25	33,3	66	12,0	24	36,4	0,87	Convergence criterion (GCONV=1E-8) satisfied.	0,44	1,75	-0,030	Algorithm converged.	-0,188	0,127	0,92	Algorithm converged.	0,58	1,44	0,7859		1,09	Algorithm converged.	0,69	1,71
		232TT	5	0,9	3	60,0	8	1,5	7	87,5	0,21	Convergence criterion (GCONV=1E-8) satisfied.	0,01	3,37	-0,275	Algorithm converged.	-0,762	0,212	0,69	Algorithm converged.	0,32	1,47	0,3319		1,46	Algorithm converged.	0,68	3,12
		Missing	42	7,7	17	40,5	37	6,7	18	48,6	0,72	Convergence criterion (GCONV=1E-8) satisfied.	0,29	1,75	-0,082	Algorithm converged.	-0,301	0,137	0,83	Algorithm converged.	0,51	1,36	0,4656		1,20	Algorithm converged.	0,73	1,97

	Time from initial FL diagnosis to randomization	< 6 months	330	60,1	137	41,5	290	52,8	134	46,2	0,83		Convergence criterion (GCONV=1E-8) satisfied.	0,60	1,14	-0,047		Algorithm converged.	-0,125	0,031	0,90			Algorithm converged.	0,75	1,07	0,2394	0,4005	1,11			Algorithm converged.	0,93	1,33
		6-12 months	27	4,9	12	44,4	19	3,5	11	57,9	0,58		Convergence criterion (GCONV=1E-8) satisfied.	0,18	1,90	-0,135		Algorithm converged.	-0,425	0,156	0,77			Algorithm converged.	0,43	1,36	0,3633		1,30			Algorithm converged.	0,74	2,30
		> 12 months	46	8,4	15	32,6	51	9,3	26	51,0	0,47		Convergence criterion (GCONV=1E-8) satisfied.	0,20	1,06	-0,184		Algorithm converged.	-0,377	0,009	0,64			Algorithm converged.	0,39	1,05	0,0768		1,56			Algorithm converged.	0,95	2,56
		Missing		10,2																																
	Ann Arbor Stage 2	Stage I		9	1,6		5	55,6		4	0,7		3	75,0	0,42		Convergence criterion (GCONV=1E-8) satisfied.	0,03	5,71	-0,194		Algorithm converged.	-0,729	0,340	0,74			Algorithm converged.	0,33	1,67	0,4696		1,35			Algorithm converged.	0,60	3,04
		Stage II (w/o bulky disease)		7	1,3					7	1,3		2	28,6		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01			Algorithm converged.	0,00		NE	1,0000		>999.99			Algorithm converged.	0,00	NE
		Stage II (with bulky disease)	21	3,8		10	47,6	17	3,1		7	41,2	1,30		Convergence criterion (GCONV=1E-8) satisfied.	0,36	4,72	0,064		Algorithm converged.	-0,252	0,381	1,16			Algorithm converged.	0,56	2,39	0,6939		0,86			Algorithm converged.	0,42	1,78
		Stage III	138	25,1		55	39,9	131	23,9		66	50,4	0,65		Convergence criterion (GCONV=1E-8) satisfied.	0,40	1,06	-0,105		Algorithm converged.	-0,224	0,013	0,79			Algorithm converged.	0,61	1,03	0,0845		1,26			Algorithm converged.	0,97	1,65
		Stage IV	227	41,3		92	40,5	198	36,1		92	46,5	0,79		Convergence criterion (GCONV=1E-8) satisfied.	0,53	1,15	-0,059		Algorithm converged.	-0,154	0,035	0,87			Algorithm converged.	0,70	1,08	0,2175		1,15			Algorithm converged.	0,92	1,42
		Missing		20,4		21	00,0		30,5		1	33,3		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				*	WARNING: Negative of Hessian not positive definite.						*	WARNING: Negative of Hessian not positive definite.		

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_base/qa/program/t_eff_resp2.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/t_eff_resp2_sg_PLYSSI_FACTLpop_FOLY_IT.xls 10AUG2020 10:43

7 (Anhang): Ergebnisse für FACT-LymS - Verschlechterung der Gesundheitsbezogenen Lebensqualität um MID fünf - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients, Patients with Baseline and post Baseline FACT-Lymphoma Subscale result
ENDPOINT: FACT-LYM Subscale - Responder (MID=5), worsening
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Efficacy)

			G-chemo (N=549)				R-chemo (N=549)				G-Chemo vs. R-Chemo																R-Chemo vs. G-Chemo			
			Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk								Relative Risk			
Analysis Visit Window	Name	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
Follow Up Month 12	All	n/a	404	73,6	44	10,9	360	65,6	37	10,3	1,07	Convergence criterion (GCONV=1E-8) satisfied.	0,67	1,69	0,006	Algorithm converged.	-0,038	0,050	1,06	Algorithm converged.	0,70	1,60	0,7835		0,94	Algorithm converged.	0,62	1,43
	Sex	Male	194	35,3	20	10,3	165	30,1	16	9,7	1,07	Convergence criterion (GCONV=1E-8) satisfied.	0,54	2,14	0,006	Algorithm converged.	-0,056	0,068	1,06	Algorithm converged.	0,57	1,98	0,8474	0,9966	0,94	Algorithm converged.	0,50	1,76
		Female	210	38,3	24	11,4	195	35,5	21	10,8	1,07	Convergence criterion (GCONV=1E-8) satisfied.	0,57	1,99	0,007	Algorithm converged.	-0,055	0,068	1,06	Algorithm converged.	0,61	1,84	0,8330		0,94	Algorithm converged.	0,54	1,64
	Age	< 60 years	213	38,8	25	11,7	198	36,1	24	12,1	0,96	Convergence criterion (GCONV=1E-8) satisfied.	0,53	1,75	-0,004	Algorithm converged.	-0,067	0,059	0,97	Algorithm converged.	0,57	1,64	0,9044	0,5699	1,03	Algorithm converged.	0,61	1,75
		>= 60 years	191	34,8	19	9,9	162	29,5	13	8,0	1,27	Convergence criterion (GCONV=1E-8) satisfied.	0,60	2,65	0,019	Algorithm converged.	-0,040	0,079	1,24	Algorithm converged.	0,63	2,43	0,5320		0,81	Algorithm converged.	0,41	1,58
	Race/ethnicity	White	310	56,5	29	9,4	278	50,6	29	10,4	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,52	1,52	-0,011	Algorithm converged.	-0,059	0,038	0,90	Algorithm converged.	0,55	1,46	0,6621	0,2036	1,12	Algorithm converged.	0,68	1,82
		Other	94	17,1	15	16,0	82	14,9	8	9,8	1,76	Convergence criterion (GCONV=1E-8) satisfied.	0,70	4,38	0,062	Algorithm converged.	-0,036	0,160	1,64	Algorithm converged.	0,73	3,66	0,2311		0,61	Algorithm converged.	0,27	1,37
	Geographic region	North America	55	10,0	4	7,3	52	9,5	3	5,8	1,28	Convergence criterion (GCONV=1E-8) satisfied.	0,27	6,02	0,015	Algorithm converged.	-0,078	0,108	1,26	Algorithm converged.	0,30	5,36	0,7539	0,8643	0,79	Algorithm converged.	0,19	3,38
		Western Europe	178	32,4	18	10,1	138	25,1	15	10,9	0,92	Convergence criterion (GCONV=1E-8) satisfied.	0,45	1,90	-0,008	Algorithm converged.	-0,076	0,061	0,93	Algorithm converged.	0,49	1,78	0,8272		1,07	Algorithm converged.	0,56	2,06
		Asia-Pacific	113	20,6	15	13,3	111	20,2	11	9,9	1,39	Convergence criterion (GCONV=1E-8) satisfied.	0,61	3,18	0,034	Algorithm converged.	-0,050	0,117	1,34	Algorithm converged.	0,64	2,79	0,4342		0,75	Algorithm converged.	0,36	1,55
		Other	58	10,6	7	12,1	59	10,7	8	13,6	0,88	Convergence criterion (GCONV=1E-8) satisfied.	0,30	2,59	-0,015	Algorithm converged.	-0,136	0,106	0,89	Algorithm converged.	0,35	2,30	0,8097		1,12	Algorithm converged.	0,44	2,90
	Baseline ECOG Performance Status score	0-1	396	72,1	44	11,1	351	63,9	35	10,0	1,13	Convergence criterion (GCONV=1E-8) satisfied.	0,71	1,80	0,011	Algorithm converged.	-0,033	0,055	1,11	Algorithm converged.	0,73	1,70	0,6136	0,0851	0,90	Algorithm converged.	0,59	1,37
		2	7	1,3			8	1,5	2	25,0		* Quasi-complete separation of data points detected.				* ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01	Algorithm converged.	0,00	NE	0,9999		>999.99	Algorithm converged.	0,00	NE
		Missing	1	0,2			1	0,2																				
	Independence status (Katz ADL)	Independent (5-6)	319	58,1	35	11,0	281	51,2	27	9,6	1,16	Convergence criterion (GCONV=1E-8) satisfied.	0,68	1,97	0,014	Algorithm converged.	-0,035	0,062	1,14	Algorithm converged.	0,71	1,84	0,5846		0,88	Algorithm converged.	0,54	1,41
		Some dependence (3-4)	1	0,2																								
		Very dependent (0-2)	3	0,5	1	33,3	6	1,1				* Quasi-complete separation of data points detected.				* ERROR: Error in computing the link function, its derivatives, or the variance function.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
		Outside valid range	35	6,4	4	11,4	32	5,8	4	12,5	0,90	Convergence criterion (GCONV=1E-8) satisfied.	0,21	3,96	-0,011	Algorithm converged.	-0,166	0,145	0,91	Algorithm converged.	0,25	3,36	0,8926		1,09	Algorithm converged.	0,30	4,01
		Missing	46	8,4	4	8,7	41	7,5	6	14,6	0,56	Convergence criterion (GCONV=1E-8) satisfied.	0,15	2,13	-0,059	Algorithm converged.	-0,195	0,076	0,59	Algorithm converged.	0,18	1,96	0,3925		1,68	Algorithm converged.	0,51	5,55
	Independence status (Katz IADL)	Independent (5-8)	349	63,6	40	11,5	311	56,6	31	10,0	1,17	Convergence criterion (GCONV=1E-8) satisfied.	0,71	1,92	0,015	Algorithm converged.	-0,032	0,062	1,15	Algorithm converged.	0,74	1,79	0,5371		0,87	Algorithm converged.	0,56	1,35
		Some dependence (1-4)	3	0,5			4	0,7																				
		Outside valid range	13	2,4			5	0,9																				
		Missing	39	7,1	4	10,3	40	7,3	6	15,0	0,65	Convergence criterion (GCONV=1E-8) satisfied.	0,17	2,50	-0,047	Algorithm converged.	-0,193	0,099	0,68	Algorithm converged.	0,21	2,24	0,5298		1,46	Algorithm converged.	0,45	4,79
	Chemotherapy regimen	CHOP	142	25,9	16	11,3	143	26,0	22	15,4	0,70	Convergence criterion (GCONV=1E-8) satisfied.	0,35	1,39	-0,041	Algorithm converged.	-0,120	0,038	0,73	Algorithm converged.	0,40	1,34	0,3095	0,1617	1,37	Algorithm converged.	0,75	2,49
		CVP	39	7,1	4	10,3	26	4,7	3	11,5	0,88	Convergence criterion (GCONV=1E-8) satisfied.	0,18	4,28	-0,013	Algorithm converged.	-0,168	0,143	0,89	Algorithm converged.	0,22	3,65	0,8702		1,12	Algorithm converged.	0,27	4,62
		Bendamustine	223	40,6	24	10,8	191	34,8	12	6,3	1,80	Convergence criterion (GCONV=1E-8) satisfied.	0,87	3,70	0,045	Algorithm converged.	-0,008	0,098	1,71	Algorithm converged.	0,88	3,33	0,1129		0,58	Algorithm converged.	0,30	1,14
	Histologic grade	1	164	29,9	15	9,1	133	24,2	15	11,3	0,79	Convergence criterion (GCONV=1E-8) satisfied.	0,37	1,69	-0,021	Algorithm converged.	-0,091	0,048	0,81	Algorithm converged.	0,41	1,60	0,5448		1,23	Algorithm converged.	0,63	2,43
		2	185	33,7	21	11,4	174	31,7	18	10,3	1,11	Convergence criterion (GCONV=1E-8) satisfied.	0,57	2,16	0,010	Algorithm converged.	-0,054	0,074	1,10	Algorithm converged.	0,61	1,99	0,7595		0,91	Algorithm converged.	0,50	1,65
		3	3	0,5	1	33,3	2	0,4				* Quasi-complete separation of data points detected.				* WARNING: The relative Hessian convergence criterion of 1.0475907089 is greater than the limit of 0.0001. The convergence is questionable.			NE	Algorithm converged.	NE	NE	NE		NE	Algorithm converged.	NE	NE
		3a	50	9,1	6	12,0	47	8,6	4	8,5	1,47	Convergence criterion (GCONV=1E-8) satisfied.	0,39	5,56	0,035	Algorithm converged.	-0,085	0,155	1,41	Algorithm converged.	0,42	4,69	0,5749		0,71	Algorithm converged.	0,21	2,36
		Other					1	0,2																				
		Missing	2	0,4	1	50,0	3	0,5				* Quasi-complete separation of data points detected.				* ERROR: Error in computing the link function, its derivatives, or the variance function.				* WARNING: Negative of Hessian not positive definite.						* WARNING: Negative of Hessian not positive definite.		
	FLIPI	Low (0-1)	96	17,5	10	10,4	84	15,3	14	16,7	0,58	Convergence criterion (GCONV=1E-8) satisfied.	0,24	1,39	-0,063	Algorithm converged.	-0,163	0,038	0,63	Algorithm converged.	0,29	1,33	0,2235	0,2570	1,60	Algorithm converged.	0,75	3,41
		Intermediate (2)	155	28,2	20	12,9	131	23,9	12	9,2	1,47	Convergence criterion (GCONV=1E-8) satisfied.	0,69	3,13	0,037	Algorithm converged.	-0,035	0,110	1,41	Algorithm converged.	0,72	2,77	0,3211		0,71	Algorithm converged.	0,36	1,40
		High (>=3)	153	27,9	14	9,2	145	26,4	11	7,6	1,23	Convergence criterion (GCONV=1E-8) satisfied.	0,54	2,80	0,016	Algorithm converged.	-0,047	0,078	1,21	Algorithm converged.	0,57	2,57	0,6271		0,83	Algorithm converged.	0,39	1,77

	FC Gamma Receptor IIa	131HH	129	23,5	16	12,4	118	21,5	14	11,9	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,49	2,26	0,005		Algorithm converged.	-0,076	0,087	1,05		Algorithm converged.	0,53	2,05	0,8970	0,9037	0,96		Algorithm converged.	0,49	1,87
		131HR	185	33,7	20	10,8	161	29,3	15	9,3	1,18		Convergence criterion (GCONV=1E-8) satisfied.	0,58	2,39	0,015		Algorithm converged.	-0,048	0,078	1,16		Algorithm converged.	0,61	2,19	0,6463		0,86		Algorithm converged.	0,46	1,63
		131RR	77	14,0	8	10,4	67	12,2	5	7,5	1,44		Convergence criterion (GCONV=1E-8) satisfied.	0,45	4,63	0,029		Algorithm converged.	-0,063	0,122	1,39		Algorithm converged.	0,48	4,05	0,5438		0,72		Algorithm converged.	0,25	2,09
		Missing	13	2,4			14	2,6	3	21,4		*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
	FC Gamma Receptor IIIa	158VV	48	8,7	8	16,7	42	7,7	4	9,5	1,90		Convergence criterion (GCONV=1E-8) satisfied.	0,53	6,83	0,071		Algorithm converged.	-0,066	0,209	1,75		Algorithm converged.	0,57	5,40	0,3302	0,6528	0,57		Algorithm converged.	0,19	1,76
		158VF	190	34,6	20	10,5	147	26,8	13	8,8	1,21		Convergence criterion (GCONV=1E-8) satisfied.	0,58	2,53	0,017		Algorithm converged.	-0,047	0,080	1,19		Algorithm converged.	0,61	2,31	0,6073		0,84		Algorithm converged.	0,43	1,63
		158FF	153	27,9	16	10,5	157	28,6	17	10,8	0,96		Convergence criterion (GCONV=1E-8) satisfied.	0,47	1,98	-0,004		Algorithm converged.	-0,072	0,065	0,97		Algorithm converged.	0,51	1,84	0,9158		1,04		Algorithm converged.	0,54	1,97
		Missing	13	2,4			14	2,6	3	21,4		*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
	FC Gamma Receptor IIb/IIc	232II	282	51,4	30	10,6	249	45,4	23	9,2	1,17		Convergence criterion (GCONV=1E-8) satisfied.	0,66	2,07	0,014		Algorithm converged.	-0,037	0,065	1,15		Algorithm converged.	0,69	1,93	0,5914	0,8831	0,87		Algorithm converged.	0,52	1,45
		232IT	75	13,7	8	10,7	66	12,0	8	12,1	0,87		Convergence criterion (GCONV=1E-8) satisfied.	0,31	2,45	-0,015		Algorithm converged.	-0,120	0,091	0,88		Algorithm converged.	0,35	2,21	0,7859		1,14		Algorithm converged.	0,45	2,86
		232TT		50,9				51,5																									
		Missing	42	7,7	6	14,3	37	6,7	6	16,2	0,86		Convergence criterion (GCONV=1E-8) satisfied.	0,25	2,94	-0,019		Algorithm converged.	-0,178	0,140	0,88		Algorithm converged.	0,31	2,50	0,8115		1,14		Algorithm converged.	0,40	3,22
	Time from initial FL diagnosis to randomization	< 6 months	330	60,1	30	11,5	290	52,8	31	10,7	1,09		Convergence criterion (GCONV=1E-8) satisfied.	0,66	1,80	0,008		Algorithm converged.	-0,041	0,058	1,08		Algorithm converged.	0,69	1,68	0,7445	0,1240	0,93		Algorithm converged.	0,59	1,45
		6-12 months	27	4,9	3	11,1	19	3,5				*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
		> 12 months	46	8,4	3	6,5	51	9,3	6	11,8	0,52		Convergence criterion (GCONV=1E-8) satisfied.	0,12	2,23	-0,052		Algorithm converged.	-0,166	0,061	0,55		Algorithm converged.	0,15	2,09	0,3837		1,80		Algorithm converged.	0,48	6,80
		Missing		10,2																													
	Ann Arbor Stage 2	Stage I		91,6	1	11,1	4	80,7				*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE		Algorithm converged.	NE	NE	NE	0,9062	NE		Algorithm converged.	NE	NE
		Stage II (w/o bulky disease)		71,3	2	28,6		71,3	2	28,6	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,10	10,17	0,000		Algorithm converged.	-0,473	0,473	1,00		Algorithm converged.	0,19	5,24	1,0000		1,00		Algorithm converged.	0,19	5,24
		Stage II (with bulky disease)	21	3,8	1	4,8	17	3,1	1	5,9	0,80		Convergence criterion (GCONV=1E-8) satisfied.	0,05	13,81	-0,011		Algorithm converged.	-0,155	0,133	0,81		Algorithm converged.	0,05	12,01	0,8780		1,24		Algorithm converged.	0,08	18,33
		Stage III	138	25,1	14	10,1	131	23,9	14	10,7	0,94		Convergence criterion (GCONV=1E-8) satisfied.	0,43	2,06	-0,005		Algorithm converged.	-0,078	0,068	0,95		Algorithm converged.	0,47	1,91	0,8843		1,05		Algorithm converged.	0,52	2,12
		Stage IV	227	41,3	26	11,5	198	36,1	19	9,6	1,22		Convergence criterion (GCONV=1E-8) satisfied.	0,65	2,28	0,019		Algorithm converged.	-0,040	0,077	1,19		Algorithm converged.	0,68	2,09	0,5357		0,84		Algorithm converged.	0,48	1,47
		Missing		20,4				30,5	1	33,3		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01		Algorithm converged.	0,00	NE	1,0000		>999.99		Algorithm converged.	0,00	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_base/qa/program/t_eff_resp2.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/t_eff_resp2_sg_PLYS5D_FACTLpop_FOLY_IT.xls
10AUG2020 10:42

Anhang 4-G2: Weitere Analysen zu Gesundheitsbezogener Lebensqualität (FACT-Lym): MMRM-Analysen und Mittelwerte pro Visite

8 (Anhang): Ergebnisse für FACT-G MMRM - Hauptanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients, Patients with Baseline and post Baseline FACT-G Total result
ENDPOINT: FACT-G Total
MODEL: Stratified Analysis by Chemotherapy regimen, FLIPI
STUDY: BO21223
Analysis of MMRM for all Visits

		G-chemo (N=547)					R-chemo (N=547)					Difference between Treatments (G-Chemo - R-Chemo)					
		N			Statistics		N			Statistics							
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method[4]	
All	n/a	547	547	545	2,7	0,5	547	547	546	2,2	0,5	0,5	0,6	-0,7	1,7	Intent-to-Treat Patients, Follicular Lymphoma Patients, Patients with Baseline and post Baseline FACT-G Total result	adjusted

[1] Patients with a value at baseline and at least one post-baseline value
[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/t_eff_mmrm_all.sas
Output: root/clinical studies/RO5072759/CDPT7499/BO21223/data analysis/ACE CSRPrimary/qa/output/t eff mmrm all str PFGTOT FACTGpop FOLY IT.xls 08MAY2020 13:08

9 (Anhang): Ergebnisse für FACT-LymS MMRM - Hauptanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients, Patients with Baseline and post Baseline FACT-Lymphoma Subscale result
ENDPOINT: FACT-LYM Subscale
MODEL: Stratified Analysis by Chemotherapy regimen, FLIPI
STUDY: BO21223
Analysis of MMRM for all Visits

		G-chemo (N=549)					R-chemo (N=549)					Difference between Treatments (G-Chemo - R-Chemo)					
		N			Statistics		N			Statistics							
Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population/ Method[4]	
All	n/a	549	549	548	3,8	0,3	549	549	549	3,7	0,3	0,1	0,3	-0,6	0,8	Intent-to-Treat Patients, Follicular Lymphoma Patients, Patients with Baseline and post Baseline FACT-Lymphoma Subscale result	adjusted

[1] Patients with a value at baseline and at least one post-baseline value
[2] LSMeans of change from baseline from MMRM (including all available records from all visits) [3] Contrasts from MMRM
[4] Factors/Covariates: treatment, visit, treatment-by-visit interaction, baseline value. In addition, for the total population, adjusted for randomization stratification factors.
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/t_eff_mmrm_all.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/t_eff_mmrm_all_str_PLYMS_FACTLpop_FOLY_IT.xls
08MAY2020 13:10

10 (Anhang): Ergebnisse für FACT-G Mittelwerte pro Visite aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
ENDPOINT: FACT-G Total
MODEL: Unadjusted Analysis
STUDY: BO21223
Compliance/Mean

		G-chemo (N=601)						R-chemo (N=601)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study[1]	%	with value[1]	%	Mean[2]	SD (Mean)	in study[1]	%	with value[1]	%	Mean[2]	SD (Mean)
All													
Baseline	n/a	601	100,0	560	93,2	82,92	14,52	601	100,0	555	92,3	82,35	14,87
Cycle 3 Day 1	n/a	590	98,2	503	85,3	82,99	14,31	598	99,5	522	87,3	82,39	14,81
Induction Completion/Early Termination	n/a	588	97,8	491	83,5	84,86	14,36	589	98,0	503	85,4	83,86	15,82
Follow Up Month 2	n/a	582	96,8	404	69,4	86,40	14,12	587	97,7	369	62,9	86,16	15,09
Follow Up Month 12	n/a	567	94,3	416	73,4	86,82	14,01	559	93,0	385	68,9	86,77	15,39
Maintenance or Observation Completion/Early Termination	n/a	494	82,2	382	77,3	86,85	14,92	487	81,0	371	76,2	86,32	15,84

[1] in study: number of subjects in study at respective visit; % based on baseline
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
[2] mean: descriptive statistics - absolute values
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/t_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/t_pro_mean_PFGTOT_FOLY_IT.xls
24OCT2019 16:20

11 (Anhang): Ergebnisse für FACT-LymS Mittelwerte pro Visite aus RCT mit dem zu bewertenden Arzneimittel

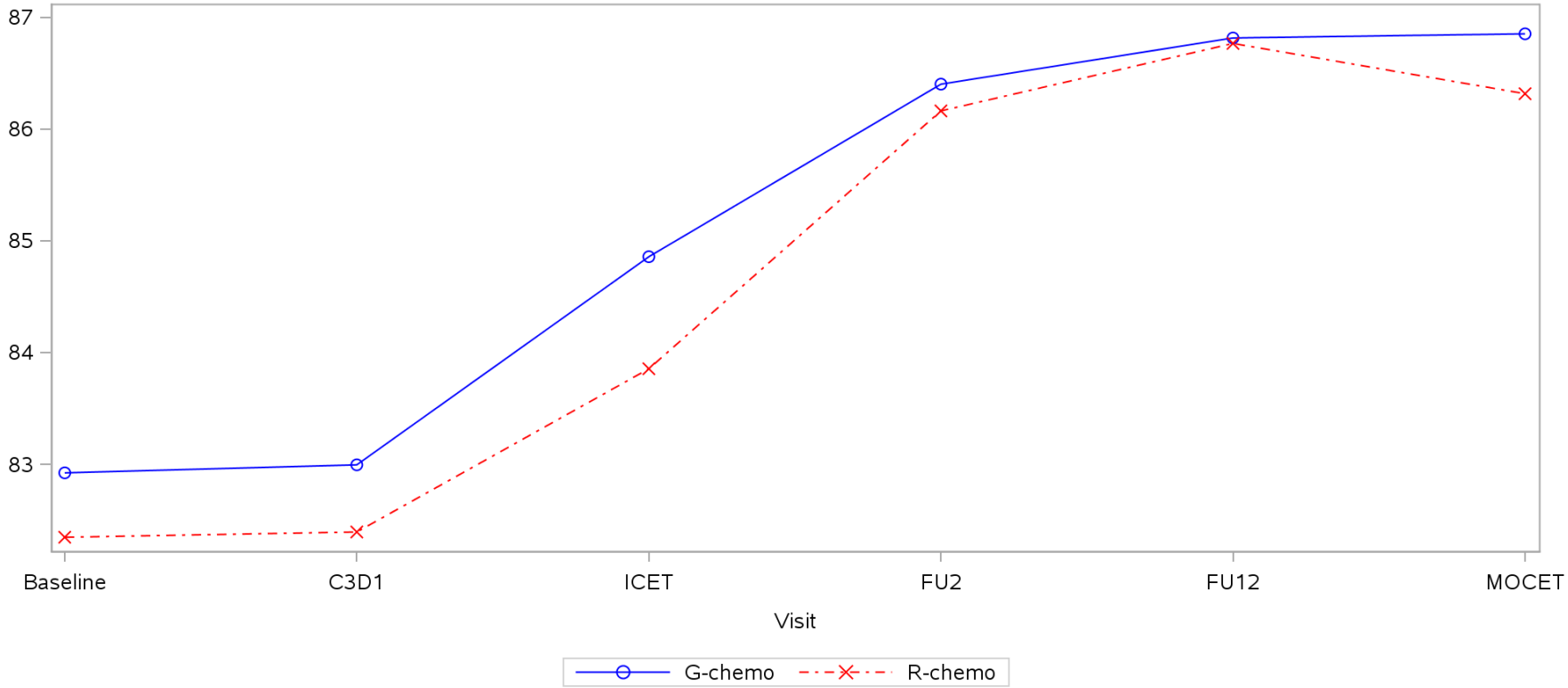
POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
ENDPOINT: FACT-LYM Subscale
MODEL: Unadjusted Analysis
STUDY: BO21223
Compliance/Mean

		G-chemo (N=601)						R-chemo (N=601)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study[1]	%	with value[1]	%	Mean[2]	SD (Mean)	in study[1]	%	with value[1]	%	Mean[2]	SD (Mean)
All													
Baseline	n/a	601	100,0	563	93,7	45,54	9,29	601	100,0	556	92,5	45,01	9,37
Cycle 3 Day 1	n/a	590	98,2	508	86,1	48,07	7,40	598	99,5	532	89,0	47,21	8,34
Induction Completion/Early Termination	n/a	588	97,8	496	84,4	48,69	7,96	589	98,0	500	84,9	48,17	9,12
Follow Up Month 2	n/a	582	96,8	406	69,8	49,89	7,59	587	97,7	375	63,9	49,79	8,25
Follow Up Month 12	n/a	567	94,3	423	74,6	50,35	7,27	559	93,0	385	68,9	50,49	8,20
Maintenance or Observation Completion/Early Termination	n/a	494	82,2	388	78,5	49,92	8,32	487	81,0	373	76,6	49,94	8,76

[1] in study: number of subjects in study at respective visit; % based on baseline
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
[2] mean: descriptive statistics - absolute values
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/t_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/t_pro_mean_PLYMS_FOLY_IT.xls
24OCT2019 16:20

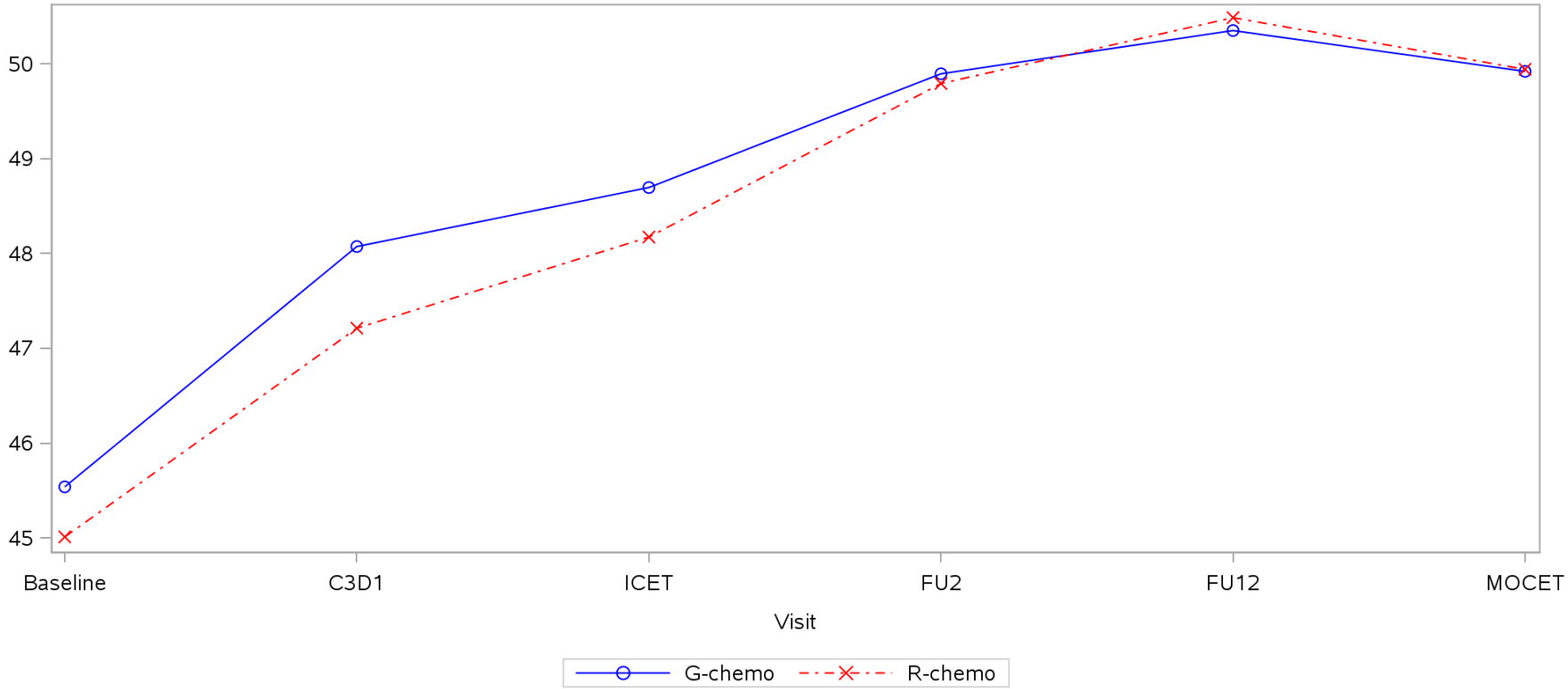
POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit
Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_PFGTOT_FOLY_IT.pdf
25OCT2019 12:41

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit
Laboratory Test: FACT-LYM Subscale



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

12 (Anhang): Ergebnisse für FACT-G Mittelwerte pro Visite - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients

ENDPOINT: **FACT-G Total**

MODEL: Unadjusted Analysis

STUDY: BO21223

Compliance/Mean

		G-chemo (N=601)						R-chemo (N=601)					
		Patients				Statisti		Patients				Statisti	
Name	Level	instudy[1]	%	withvalu	%	Mean[2]	SD (Mean)	instudy[1]	%	withvalu	%	Mean[2]	SD (Mean)
All													
Baseline	n/a	601	100	560	93,2	82,92	14,52	601	100	555	92,3	82,35	14,87
Cycle 3 Day 1	n/a	590	98,2	503	85,3	82,99	14,31	598	99,5	522	87,3	82,39	14,81
Induction Completion/Early Termination	n/a	588	97,8	491	83,5	84,86	14,36	589	98	503	85,4	83,86	15,82
Follow Up Month 2	n/a	582	96,8	404	69,4	86,4	14,12	587	97,7	369	62,9	86,16	15,09
Follow Up Month 12	n/a	567	94,3	416	73,4	86,82	14,01	559	93	385	68,9	86,77	15,39
Maintenance or Observation Completion/Early	n/a	494	82,2	382	77,3	86,85	14,92	487	81	371	76,2	86,32	15,84
Sex													
Baseline	Female	318	100	300	94,3	81,65	14,37	321	100	295	91,9	80,86	14,6
Cycle 3 Day 1	Female	311	97,8	264	84,9	81,44	15,12	320	99,7	275	85,9	80,75	14,82
Induction Completion/Early Termination	Female	310	97,5	262	84,5	83,45	14,67	315	98,1	272	86,3	82,35	16,19
Follow Up Month 2	Female	306	96,2	220	71,9	85,07	14,41		98,1	205	65,1	84,7	15,5
Follow Up Month 12	Female	300	94,3	217	72,3	85,68	15,11	299	93,1	208	69,6	85,91	15,59
Maintenance or Observation Completion/Early	Female	265	83,3	207	78,1	85,18	15,44	263	81,9	202	76,8	85,4	15,44
Baseline	Male	283	100	260	91,9	84,39	14,58	280	100	260	92,9	84,04	15,01
Cycle 3 Day 1	Male	279	98,6	239	85,7	84,71	13,18	278	99,3	247	88,8	84,22	14,62
Induction Completion/Early Termination	Male	278	98,2	229	82,4	86,46	13,84	274	97,9	231	84,3	85,63	15,22
Follow Up Month 2	Male	276	97,5	184	66,7	88	13,62	272	97,1	164	60,3	88	14,41
Follow Up Month 12	Male	267	94,3	199	74,5	88,06	12,62	260	92,9	177	68,1	87,77	15,13
Maintenance or Observation Completion/Early	Male	229	80,9	175	76,4	88,83	14,07	224	80	169	75,4	87,42	16,29
Age													
Baseline	< 60 years	298	100	284	95,3	83,41	14,06	323	100	302	93,5	83,24	13,77
Cycle 3 Day 1	< 60 years	292	98	255	87,3	83,77	13,73	322	99,7	285	88,5	82,75	14,77
Induction Completion/Early Termination	< 60 years	293	98,3	253	86,3	84,92	14,27	318	98,5	274	86,2	83,99	16,25
Follow Up Month 2	< 60 years	290	97,3	205	70,7	87,29	13,36	317	98,1	214	67,5	86,31	15,24
Follow Up Month 12	< 60 years	284	95,3	218	76,8	87,43	13,41	303	93,8	208	68,6	86,42	16,01
Maintenance or Observation Completion/Early	< 60 years	247	82,9	193	78,1	87,23	14,57	268	83	206	76,9	87,21	15,27
Baseline	>= 60 years	303	100	276	91,1	82,42	14,98	278	100	253	91	81,28	16,04
Cycle 3 Day 1	>= 60 years	298	98,3	248	83,2	82,2	14,88	276	99,3	237	85,9	81,96	14,88
Induction Completion/Early Termination	>= 60 years	295	97,4	238	80,7	84,79	14,48	271	97,5	229	84,5	83,7	15,33
Follow Up Month 2	>= 60 years	292	96,4	199	68,2	85,48	14,83	270	97,1	155	57,4	85,96	14,94
Follow Up Month 12	>= 60 years	283	93,4	198	70	86,14	14,65	256	92,1	177	69,1	87,17	14,65
Maintenance or Observation Completion/Early	>= 60 years	247	81,5	189	76,5	86,47	15,3	219	78,8	165	75,3	85,2	16,51
Race/ethnicity													
Baseline	Other	114	100	109	95,6	80,67	15,55	120	100	114	95	81,29	14,73

Cycle 3 Day 1	Other	111	97,4	106	95,5	79,74	13,94	120	100	112	93,3	76,19	14,65
Induction Completion/Early Termination	Other	111	97,4	106	95,5	80,34	14,76	118	98,3	107	90,7	79,85	15,88
Follow Up Month 2	Other	111	97,4	93	83,8	82,54	14,92	118	98,3	82	69,5	82,07	14,22
Follow Up Month 12	Other	108	94,7	96	88,9	83,14	13,68	115	95,8	87	75,7	83,79	13,88
Maintenance or Observation Completion/Early	Other	85	74,6	76	89,4	83,82	15,42	98	81,7	80	81,6	82,9	16,43
Baseline	White	487	100	451	92,6	83,47	14,22	481	100	441	91,7	82,62	14,91
Cycle 3 Day 1	White	479	98,4	397	82,9	83,86	14,3	478	99,4	410	85,8	84,09	14,41
Induction Completion/Early Termination	White	477	97,9	385	80,7	86,1	14,01	471	97,9	396	84,1	84,94	15,65
Follow Up Month 2	White	471	96,7	311	66	87,56	13,68	469	97,5	287	61,2	87,33	15,15
Follow Up Month 12	White	459	94,3	320	69,7	87,92	13,94	444	92,3	298	67,1	87,64	15,72
Maintenance or Observation Completion/Early	White	409	84	306	74,8	87,61	14,72	389	80,9	291	74,8	87,26	15,58
Geographic region													
Baseline	Asia-Pacific	152	100	146	96,1	81,15	16,14	155	100	155	100	83,87	14,14
Cycle 3 Day 1	Asia-Pacific	148	97,4	142	95,9	80,15	15,27	155	100	151	97,4	80,02	15,46
Induction Completion/Early Termination	Asia-Pacific	148	97,4	139	93,9	81,99	15,37	153	98,7	147	96,1	83,17	15,75
Follow Up Month 2	Asia-Pacific	147	96,7	118	80,3	83,72	15,32	153	98,7	108	70,6	84,64	14,58
Follow Up Month 12	Asia-Pacific	143	94,1	114	79,7	84,09	13,93	144	92,9	111	77,1	86,78	15
Maintenance or Observation Completion/Early	Asia-Pacific	118	77,6	103	87,3	85,03	14,96	122	78,7	102	83,6	85,48	16,67
Baseline	North America	75	100	72	96	86,67	13	77	100	75	97,4	83,97	13,53
Cycle 3 Day 1	North America	72	96	70	97,2	86,9	13,39	77	100	72	93,5	86,13	13,79
Induction Completion/Early Termination	North America	72	96	69	95,8	87,59	13,34	75	97,4	69	92	88,01	13,72
Follow Up Month 2	North America	71	94,7	46	64,8	90,61	12,1	75	97,4	40	53,3	92,87	13,02
Follow Up Month 12	North America	67	89,3	56	83,6	91,66	11,7	73	94,8	54	74	91,28	13,7
Maintenance or Observation Completion/Early	North America	63	84	57	90,5	90,4	14,46	66	85,7	56	84,8	88,06	16,32
Baseline	Other	80	100	77	96,3	83,85	13,09	83	100	76	91,6	79,74	15,23
Cycle 3 Day 1	Other	80	100	71	88,8	83,12	13,91	83	100	77	92,8	81,71	13,73
Induction Completion/Early Termination	Other	77	96,3	69	89,6	85,6	13,36	81	97,6	72	88,9	82,03	15,71
Follow Up Month 2	Other	76	95	61	80,3	86,62	14,17	81	97,6	69	85,2	82,81	15,13
Follow Up Month 12	Other	76	95	60	78,9	84,33	15,63	77	92,8	66	85,7	81,8	15,01
Maintenance or Observation Completion/Early	Other	65	81,3	49	75,4	86,77	14,9	68	81,9	56	82,4	83,27	14,01
Baseline	Western Europe	294	100	265	90,1	82,61	14,22	286	100	249	87,1	81,7	15,5
Cycle 3 Day 1	Western Europe	290	98,6	220	75,9	83,55	13,81	283	99	222	78,4	83,03	14,83
Induction Completion/Early Termination	Western Europe	291	99	214	73,5	85,6	14,1	280	97,9	215	76,8	83,6	16,41
Follow Up Month 2	Western Europe	288	98	179	62,2	87,01	13,52	278	97,2	152	54,7	87	15,43
Follow Up Month 12	Western Europe	281	95,6	186	66,2	87,83	13,73	265	92,7	154	58,1	87,31	15,92
Maintenance or Observation Completion/Early	Western Europe	248	84,4	173	69,8	86,8	14,98	231	80,8	157	68	87,33	15,7
Baseline ECOG Performance Status score													
Baseline	Missing	1	100	1	100	87,23	NE	2	100	2	100	81	25,46
Cycle 3 Day 1	Missing	1	100	1	100	92,42	NE	2	100	0	NE	NE	NE
Induction Completion/Early Termination	Missing	1	100			NE	NE	2	100			NE	NE
Follow Up Month 2	Missing	1	100	1	100	100,73	NE	2	100	0	NE	NE	NE
Follow Up Month 12	Missing	1	100	1	100	79	NE	2	100	1	50	100	NE
Maintenance or Observation Completion/Early	Missing	1	100	1	100	75,81	NE	1	50	1	100	98	NE
Baseline	0-1	585	100	546	93,3	83,12	14,42	576	100	532	92,4	82,76	14,8
Cycle 3 Day 1	0-1	577	98,6	492	85,3	83,15	14,25	574	99,7	505	88	82,36	14,87
Induction Completion/Early Termination	0-1	574	98,1	480	83,6	84,96	14,32	565	98,1	485	85,8	83,99	15,7
Follow Up Month 2	0-1	569	97,3	396	69,6	86,47	14,02	563	97,7	360	63,9	86,24	14,86

Follow Up Month 12	0-1	556	95	407	73,2	86,92	14,01	537	93,2	374	69,6	86,79	15,15
Maintenance or Observation Completion/Early	0-1	487	83,2	377	77,4	86,85	14,93	470	81,6	360	76,6	86,38	15,89
Baseline	2	15	100	13	86,7	74,33	16,92	23	100	21	91,3	71,94	12,37
Cycle 3 Day 1	2	12	80	10	83,3	74,36	15,89	22	95,7	17	77,3	83,26	13,39
Induction Completion/Early Termination	2	13	86,7	11	84,6	80,52	15,82	22	95,7	18	81,8	80,32	18,94
Follow Up Month 2	2	12	80	7	58,3	80,7	19,17	22	95,7	9	40,9	82,99	23,71
Follow Up Month 12	2	10	66,7	8	80	82,33	14,63	20	87	10	50	84,55	23,75
Maintenance or Observation Completion/Early	2	6	40	4	66,7	89,63	17,52	16	69,6	10	62,5	82,93	14,93
Independence status (Katz ADL)													
Baseline	Very dependent (0-2)	3	100	3	100	77,09	19,13	7	100	6	85,7	75,72	18,4
Cycle 3 Day 1	Very dependent (0-2)	3	100	2	66,7	78	2,83	7	100	6	85,7	84,08	18,89
Induction Completion/Early Termination	Very dependent (0-2)	3	100	3	100	88,77	2,54	7	100	7	100	87,44	17,22
Follow Up Month 2	Very dependent (0-2)	3	100	3	100	83,83	9,12	7	100	4	57,1	82,57	17,81
Follow Up Month 12	Very dependent (0-2)	3	100	2	66,7	84,51	14,13	7	100	6	85,7	85,32	21,09
Maintenance or Observation Completion/Early	Very dependent (0-2)	3	100	2	66,7	81,56	3,62	7	100	4	57,1	99,75	6,34
Baseline	Some dependence (3-4)	4	100	4	100	70,27	18,48	5	100	3	60	59,4	7,88
Cycle 3 Day 1	Some dependence (3-4)	4	100	4	100	73,99	14,25	4	80	2	50	89,31	11,75
Induction Completion/Early Termination	Some dependence (3-4)	4	100	4	100	84,39	17,14	3	60	1	33,3	76	NE
Follow Up Month 2	Some dependence (3-4)	4	100	3	75	93,36	11,02	3	60	1	33,3	84	NE
Follow Up Month 12	Some dependence (3-4)	3	75	1	33,3	66	NE	3	60	1	33,3	104	NE
Maintenance or Observation Completion/Early	Some dependence (3-4)	4	100	4	100	81,16	14,32	2	40	2	100	96,08	15,45
Baseline	Independent (5-6)	459	100	437	95,2	83,6	14,49	462	100	436	94,4	82,91	14,78
Cycle 3 Day 1	Independent (5-6)	453	98,7	389	85,9	84	14,14	462	100	406	87,9	82,13	14,93
Induction Completion/Early Termination	Independent (5-6)	451	98,3	387	85,8	85,75	13,96	455	98,5	397	87,3	83,77	15,8
Follow Up Month 2	Independent (5-6)	446	97,2	322	72,2	86,93	13,99	454	98,3	294	64,8	86,86	14,78
Follow Up Month 12	Independent (5-6)	435	94,8	329	75,6	87,09	14,01	429	92,9	299	69,7	87,03	15,64
Maintenance or Observation Completion/Early	Independent (5-6)	375	81,7	292	77,9	87,74	14,67	366	79,2	283	77,3	86,43	16,02
Baseline	Missing	83	100	66	79,5	82,57	13,49	80	100	66	82,5	80,68	15,57
Cycle 3 Day 1	Missing	80	96,4	64	80	81,91	13,85	79	98,8	65	82,3	83,02	14,73
Induction Completion/Early Termination	Missing	79	95,2	56	70,9	81,17	14,55	78	97,5	56	71,8	85,94	15,74
Follow Up Month 2	Missing	79	95,2	44	55,7	85,05	13,65	77	96,3	43	55,8	83,87	16,66
Follow Up Month 12	Missing	77	92,8	50	64,9	87,49	14,25	74	92,5	46	62,2	85	13,91
Maintenance or Observation Completion/Early	Missing	70	84,3	46	65,7	82,72	16,94	73	91,3	49	67,1	85,2	15,91
Baseline	Outside valid range	52	100	50	96,2	78,87	14,85	47	100	44	93,6	81,72	13,33
Cycle 3 Day 1	Outside valid range	50	96,2	44	88	76,71	15,23	46	97,9	43	93,5	83,41	13,83
Induction Completion/Early Termination	Outside valid range	51	98,1	41	80,4	81,26	16,99	46	97,9	42	91,3	81,49	16,2
Follow Up Month 2	Outside valid range	50	96,2	32	64	82,5	16,36	46	97,9	27	58,7	82,79	15,75
Follow Up Month 12	Outside valid range	49	94,2	34	69,4	83,91	13,71	46	97,9	33	71,7	86,63	14,42
Maintenance or Observation Completion/Early	Outside valid range	42	80,8	38	90,5	85,93	14,21	39	83	33	84,6	84,76	14,72
Independence status (Katz IADL)													
Baseline	Very dependent (0)	1	100	1	100	76	NE	1	100	1	100	66,46	NE
Cycle 3 Day 1	Very dependent (0)	1	100	1	100	79	NE	1	100	0	NE	NE	NE
Induction Completion/Early Termination	Very dependent (0)	1	100	1	100	100,73	NE	1	100	0	NE	NE	NE
Follow Up Month 2	Very dependent (0)	1	100			NE	NE	1	100			NE	NE
Follow Up Month 12	Very dependent (0)	1	100			NE	NE	1	100			NE	NE
Maintenance or Observation Completion/Early	Very dependent (0)	1	100	0	NE	NE	NE	1	100	1	100	101,77	NE

Baseline	Some dependence (1-4)	9	100	9	100	76,98	16,2	14	100	10	71,4	68,15	15,4
Cycle 3 Day 1	Some dependence (1-4)	9	100	9	100	79,26	12,47	14	100	9	64,3	71,12	18,67
Induction Completion/Early Termination	Some dependence (1-4)	8	88,9	8	100	86,98	11,78	13	92,9	10	76,9	71,66	11,7
Follow Up Month 2	Some dependence (1-4)	8	88,9	7	87,5	85,8	14,72	13	92,9	6	46,2	74,71	5,78
Follow Up Month 12	Some dependence (1-4)	7	77,8	3	42,9	83,33	19,12	13	92,9	6	46,2	76,79	14,09
Maintenance or Observation Completion/Early	Some dependence (1-4)	8	88,9	8	100	83,78	16,97	9	64,3	5	55,6	75,38	22,1
Baseline	Independent (5-8)	504	100	479	95	83,11	14,57	501	100	473	94,4	82,83	14,7
Cycle 3 Day 1	Independent (5-8)	496	98,4	428	86,3	83,09	14,4	499	99,6	444	89	82,4	14,83
Induction Completion/Early Termination	Independent (5-8)	496	98,4	424	85,5	85	14,36	492	98,2	433	88	84,02	15,88
Follow Up Month 2	Independent (5-8)	490	97,2	352	71,8	86,35	14,02	491	98	321	65,4	86,59	15,03
Follow Up Month 12	Independent (5-8)	477	94,6	358	75,1	86,74	13,88	468	93,4	330	70,5	87,29	15,52
Maintenance or Observation Completion/Early	Independent (5-8)	412	81,7	323	78,4	87,37	14,57	403	80,4	314	77,9	86,53	16,03
Baseline	Missing	71	100	56	78,9	80,84	13,63	74	100	61	82,4	80,73	15,72
Cycle 3 Day 1	Missing	68	95,8	52	76,5	80,71	14,38	73	98,6	59	80,8	83	14,19
Induction Completion/Early Termination	Missing	67	94,4	44	65,7	81,09	14,92	72	97,3	50	69,4	84,39	16,51
Follow Up Month 2	Missing	67	94,4	34	50,7	84,68	14,96	71	95,9	34	47,9	82,84	16,55
Follow Up Month 12	Missing	66	93	43	65,2	86,47	15	67	90,5	44	65,7	83,85	14,13
Maintenance or Observation Completion/Early	Missing	60	84,5	40	66,7	81,41	17,17	64	86,5	42	65,6	86,21	14,13
Baseline	Outside valid range	16	100	15	93,8	88,76	14,21	11	100	10	90,9	85	9,94
Cycle 3 Day 1	Outside valid range	16	100	13	81,3	91,73	9,78	11	100	10	90,9	88,48	10,12
Induction Completion/Early Termination	Outside valid range	16	100	14	87,5	89,97	12,2	11	100	10	90,9	86,26	8,12
Follow Up Month 2	Outside valid range	16	100	11	68,8	93,91	13,92	11	100	8	72,7	91,88	11,28
Follow Up Month 12	Outside valid range	16	100	12	75	91,13	14,24	10	90,9	5	50	89,58	15,7
Maintenance or Observation Completion/Early	Outside valid range	13	81,3	11	84,6	93,81	10,5	10	90,9	9	90	83,81	13,11
Chemotherapy regimen													
Baseline	Bendamustine	345	100	320	92,8	83,07	15,09	341	100	313	91,8	82,66	14,67
Cycle 3 Day 1	Bendamustine	338	98	279	82,5	83,52	15,12	340	99,7	293	86,2	83,59	14,8
Induction Completion/Early Termination	Bendamustine	337	97,7	280	83,1	86,18	14,9	335	98,2	289	86,3	84,54	15,74
Follow Up Month 2	Bendamustine	332	96,2	230	69,3	87,61	13,96	334	97,9	205	61,4	87,89	14,41
Follow Up Month 12	Bendamustine	321	93	225	70,1	87,1	14,48	312	91,5	207	66,3	88,11	15,36
Maintenance or Observation Completion/Early	Bendamustine	283	82	217	76,7	88,22	14,87	274	80,4	213	77,7	87,48	16
Baseline	CHOP	195	100	185	94,9	81,14	13,22	203	100	191	94,1	81,63	14,47
Cycle 3 Day 1	CHOP	192	98,5	175	91,1	81,04	12,79	203	100	184	90,6	79,58	14,25
Induction Completion/Early Termination	CHOP	191	97,9	166	86,9	82,43	13,08	201	99	174	86,6	81,94	15,97
Follow Up Month 2	CHOP	190	97,4	137	72,1	83,77	13,96	200	98,5	139	69,5	83,12	15,65
Follow Up Month 12	CHOP	187	95,9	145	77,5	84,92	12,84	194	95,6	150	77,3	84,11	15,15
Maintenance or Observation Completion/Early	CHOP	156	80	123	78,8	84,39	14,05	166	81,8	127	76,5	83,44	15,6
Baseline	CVP	61	100	55	90,2	88,05	14,2	57	100	51	89,5	83,1	17,52
Cycle 3 Day 1	CVP	60	98,4	49	81,7	86,96	13,9	55	96,5	45	81,8	86,09	15,58
Induction Completion/Early Termination	CVP	60	98,4	45	75	85,61	14,57	53	93	40	75,5	87,25	15,14
Follow Up Month 2	CVP	60	98,4	37	61,7	88,66	14,64	53	93	25	47,2	88,88	15,21
Follow Up Month 12	CVP	59	96,7	46	78	91,43	14,32	53	93	28	52,8	91,05	15,15
Maintenance or Observation Completion/Early	CVP	55	90,2	42	76,4	86,99	16,99	47	82,5	31	66	90,12	14,35
Histologic grade													
Baseline	Missing	4	100	4	100	90,35	17	4	100	4	100	85,82	14,47
Cycle 3 Day 1	Missing	4	100	2	50	75,94	23,96	4	100	2	50	86,62	0,87
Induction Completion/Early Termination	Missing	4	100	2	50	61,35	54,23	4	100	4	100	81,78	11,03

Follow Up Month 2	Missing	4	100	1	25	39	NE	4	100	0	NE	NE	NE
Follow Up Month 12	Missing	4	100	2	50	85,5	26,16	4	100	3	75	90,72	7,31
Maintenance or Observation Completion/Early	Missing	3	75	1	33,3	90,35	NE	4	100	2	50	80,48	19,12
Baseline	1	242	100	222	91,7	82,2	14,95	219	100	201	91,8	83	14,27
Cycle 3 Day 1	1	239	98,8	201	84,1	83,21	14,15	219	100	193	88,1	81,77	14,71
Induction Completion/Early Termination	1	240	99,2	203	84,6	84,56	14,43	213	97,3	182	85,4	83,76	16,24
Follow Up Month 2	1	237	97,9	172	72,6	85,47	13,87	212	96,8	140	66	85,31	15,6
Follow Up Month 12	1	231	95,5	167	72,3	87,69	13,47	201	91,8	141	70,1	85,08	16,72
Maintenance or Observation Completion/Early	1	198	81,8	145	73,2	86,61	15,18	179	81,7	132	73,7	86,54	16,73
Baseline	2	267	100	251	94	83,23	14,17	289	100	267	92,4	82,37	14,99
Cycle 3 Day 1	2	262	98,1	226	86,3	82,49	14,56	286	99	252	88,1	82,38	15
Induction Completion/Early Termination	2	260	97,4	218	83,8	84,61	13,95	283	97,9	240	84,8	84,16	15,96
Follow Up Month 2	2	257	96,3	170	66,1	86,39	14,46	282	97,6	182	64,5	86,83	15,16
Follow Up Month 12	2	252	94,4	191	75,8	86,07	14,23	270	93,4	187	69,3	88,13	14,45
Maintenance or Observation Completion/Early	2	219	82	174	79,5	87,06	14,98	237	82	190	80,2	86,74	15,38
Baseline	3	4	100	4	100	91,25	13,94	3	100	3	100	86,79	18,32
Cycle 3 Day 1	3	4	100	4	100	92,97	11,99	3	100	3	100	88,31	19,78
Induction Completion/Early Termination	3	4	100	4	100	100,75	4,72	3	100	3	100	80,79	26,16
Follow Up Month 2	3	4	100	4	100	101,5	3,32	3	100	2	66,7	100,81	4,51
Follow Up Month 12	3	4	100	3	75	91,33	18,5	2	66,7	2	100	101,33	3,78
Maintenance or Observation Completion/Early	3	4	100	4	100	95,62	9,71	2	66,7	2	100	104,4	2,26
Baseline	3a	82	100	78	95,1	83,24	14,44	85	100	79	92,9	80,46	15,95
Cycle 3 Day 1	3a	79	96,3	69	87,3	83,97	13,82	85	100	71	83,5	83,76	14,7
Induction Completion/Early Termination	3a	78	95,1	62	79,5	86,46	13,67	85	100	73	85,9	83,25	14,52
Follow Up Month 2	3a	78	95,1	57	73,1	89,02	12,22	85	100	45	52,9	85,46	13,27
Follow Up Month 12	3a	74	90,2	52	70,3	86,61	14,81	81	95,3	51	63	85,62	15,18
Maintenance or Observation Completion/Early	3a	68	82,9	57	83,8	86,29	14,73	64	75,3	44	68,8	83,28	15,23
Baseline	Other	2	100	1	50	77,88	NE	1	100	1	100	64,38	NE
Cycle 3 Day 1	Other	2	100	1	50	60,75	NE	1	100	1	100	83	NE
Induction Completion/Early Termination	Other	2	100	2	100	83,6	5,14	1	100	1	100	88,56	NE
Follow Up Month 2	Other	2	100			NE	NE	1	100			NE	NE
Follow Up Month 12	Other	2	100	1	50	84,24	NE	1	100	1	100	87,23	NE
Maintenance or Observation Completion/Early	Other	2	100	1	50	79,92	NE	1	100	1	100	85,15	NE
FLIPI													
Baseline	High (>=3)	249	100	230	92,4	80,54	14,58	253	100	234	92,5	79,9	14,58
Cycle 3 Day 1	High (>=3)	247	99,2	208	84,2	81,68	14,59	252	99,6	216	85,7	82,36	13,78
Induction Completion/Early Termination	High (>=3)	244	98	203	83,2	84,38	14,45	248	98	210	84,7	83,81	15,18
Follow Up Month 2	High (>=3)	240	96,4	174	72,5	86,13	13,5	247	97,6	156	63,2	85,9	14,85
Follow Up Month 12	High (>=3)	233	93,6	160	68,7	86,47	14,69	237	93,7	155	65,4	86,87	14,25
Maintenance or Observation Completion/Early	High (>=3)	206	82,7	154	74,8	85,94	14,72	201	79,4	150	74,6	85,48	14,46
Baseline	Intermediate (2)	224	100	208	92,9	85,22	13,67	223	100	205	91,9	84,52	15,87
Cycle 3 Day 1	Intermediate (2)	216	96,4	187	86,6	83,76	14,14	223	100	200	89,7	83,12	15,82
Induction Completion/Early Termination	Intermediate (2)	217	96,9	183	84,3	85	14,19	221	99,1	190	86	84,45	16,03
Follow Up Month 2	Intermediate (2)	215	96	144	67	86,84	14,41	220	98,7	134	60,9	87,04	14,55
Follow Up Month 12	Intermediate (2)	211	94,2	157	74,4	86,97	13,65	206	92,4	143	69,4	87,22	15,18
Maintenance or Observation Completion/Early	Intermediate (2)	185	82,6	148	80	86,89	15,42	183	82,1	142	77,6	87,28	17,13

Baseline	Low (0-1)	128	100	122	95,3	83,5	15,2	125	100	116	92,8	83,44	12,87
Cycle 3 Day 1	Low (0-1)	127	99,2	108	85	84,21	13,99	123	98,4	106	86,2	81,08	14,92
Induction Completion/Early Termination	Low (0-1)	127	99,2	105	82,7	85,55	14,57	120	96	103	85,8	82,85	16,82
Follow Up Month 2	Low (0-1)	127	99,2	86	67,7	86,22	14,97	120	96	79	65,8	85,21	16,53
Follow Up Month 12	Low (0-1)	123	96,1	99	80,5	87,14	13,57	116	92,8	87	75	85,86	17,67
Maintenance or Observation Completion/Early	Low (0-1)	103	80,5	80	77,7	88,55	14,41	103	82,4	79	76,7	86,16	16,05
FC Gamma Receptor IIa													
Baseline	Missing	28	100	21	75	80,58	13,58	30	100	25	83,3	85,1	14,04
Cycle 3 Day 1	Missing	23	82,1	19	82,6	79,7	14,05	28	93,3	20	71,4	83,81	14,18
Induction Completion/Early Termination	Missing	24	85,7	19	79,2	80,47	12,85	27	90	14	51,9	90,9	13,89
Follow Up Month 2	Missing	22	78,6	14	63,6	86,8	11,7	27	90	15	55,6	89,84	13,02
Follow Up Month 12	Missing	21	75	13	61,9	83,98	13,32	25	83,3	14	56	88,27	14,11
Maintenance or Observation Completion/Early	Missing	19	67,9	14	73,7	89,95	12,61	19	63,3	11	57,9	87,41	15,73
Baseline	131HH	182	100	177	97,3	84,1	14,99	184	100	172	93,5	81,09	14,27
Cycle 3 Day 1	131HH	178	97,8	160	89,9	83,41	14,25	184	100	170	92,4	80,16	14,98
Induction Completion/Early Termination	131HH	178	97,8	156	87,6	85,53	15,15	183	99,5	166	90,7	82,58	15,35
Follow Up Month 2	131HH	177	97,3	130	73,4	87,05	14,62	183	99,5	121	66,1	84,41	15,27
Follow Up Month 12	131HH	173	95,1	133	76,9	86,66	14,81	178	96,7	128	71,9	84,57	15,42
Maintenance or Observation Completion/Early	131HH	152	83,5	120	78,9	86,81	15,82	159	86,4	123	77,4	85,69	14,31
Baseline	131HR	277	100	258	93,1	81,98	14,45	270	100	250	92,6	81,73	15,65
Cycle 3 Day 1	131HR	276	99,6	233	84,4	82,66	14,37	270	100	234	86,7	82,55	15,07
Induction Completion/Early Termination	131HR	274	98,9	228	83,2	84,16	14,4	266	98,5	230	86,5	83,77	15,65
Follow Up Month 2	131HR	271	97,8	186	68,6	85,54	14,63	265	98,1	164	61,9	86,19	14,89
Follow Up Month 12	131HR	263	94,9	192	73	86,61	14,22	250	92,6	172	68,8	87,75	14,94
Maintenance or Observation Completion/Early	131HR	230	83	179	77,8	86,37	15,3	218	80,7	167	76,6	86,46	16,72
Baseline	131RR	114	100	104	91,2	83,74	14,01	117	100	108	92,3	85,13	13,85
Cycle 3 Day 1	131RR	113	99,1	91	80,5	83,81	14,43	116	99,1	98	84,5	85,6	13,53
Induction Completion/Early Termination	131RR	112	98,2	88	78,6	86,43	12,95	113	96,6	93	82,3	85,28	17,15
Follow Up Month 2	131RR	112	98,2	74	66,1	87,34	12,35	112	95,7	69	61,6	88,38	15,53
Follow Up Month 12	131RR	110	96,5	78	70,9	88,06	12,24	106	90,6	71	67	88,05	16,48
Maintenance or Observation Completion/Early	131RR	93	81,6	69	74,2	87,56	12,79	91	77,8	70	76,9	86,91	16,56
FC Gamma Receptor IIIa													
Baseline	Missing	28	100	21	75	80,58	13,58	30	100	25	83,3	85,1	14,04
Cycle 3 Day 1	Missing	23	82,1	19	82,6	79,7	14,05	28	93,3	20	71,4	83,81	14,18
Induction Completion/Early Termination	Missing	24	85,7	19	79,2	80,47	12,85	27	90	14	51,9	90,9	13,89
Follow Up Month 2	Missing	22	78,6	14	63,6	86,8	11,7	27	90	15	55,6	89,84	13,02
Follow Up Month 12	Missing	21	75	13	61,9	83,98	13,32	25	83,3	14	56	88,27	14,11
Maintenance or Observation Completion/Early	Missing	19	67,9	14	73,7	89,95	12,61	19	63,3	11	57,9	87,41	15,73
Baseline	158FF	223	100	207	92,8	82,85	14,09	256	100	237	92,6	83,68	14,69
Cycle 3 Day 1	158FF	221	99,1	188	85,1	82,62	13,81	256	100	221	86,3	83,62	14,53
Induction Completion/Early Termination	158FF	218	97,8	183	83,9	84,62	14,28	253	98,8	221	87,4	85,43	15,7
Follow Up Month 2	158FF	217	97,3	148	68,2	86,65	13,81	252	98,4	171	67,9	86,9	15,59
Follow Up Month 12	158FF	211	94,6	156	73,9	87,56	14,35	241	94,1	168	69,7	87,29	16,35
Maintenance or Observation Completion/Early	158FF	173	77,6	131	75,7	87,07	14,64	205	80,1	163	79,5	87,03	16,34
Baseline	158VF	283	100	266	94	82,82	15,41	238	100	223	93,7	81,42	14,88
Cycle 3 Day 1	158VF	281	99,3	239	85,1	83,03	15,06	237	99,6	210	88,6	81,66	14,76
Induction Completion/Early Termination	158VF	281	99,3	231	82,2	85,42	14,59	233	97,9	201	86,3	82,71	15,12

Follow Up Month 2	158VF	279	98,6	193	69,2	86,63	14,29	232	97,5	141	60,8	84,55	14,78
Follow Up Month 12	158VF	272	96,1	200	73,5	86,71	13,44	220	92,4	155	70,5	86,82	14,25
Maintenance or Observation Completion/Early	158VF	245	86,6	191	78	86,98	14,93	195	81,9	146	74,9	85,77	15,63
Baseline	158VV	67	100	66	98,5	84,29	12,39	77	100	70	90,9	79,82	15,39
Cycle 3 Day 1	158VV	65	97	57	87,7	85,2	12,76	77	100	71	92,2	80,34	15,88
Induction Completion/Early Termination	158VV	65	97	58	89,2	84,78	14,18	76	98,7	67	88,2	80,63	17,85
Follow Up Month 2	158VV	64	95,5	49	76,6	84,64	15,24	76	98,7	42	55,3	87,3	14,65
Follow Up Month 12	158VV	63	94	47	74,6	85,59	15,62	73	94,8	48	65,8	84,33	15,99
Maintenance or Observation Completion/Early	158VV	57	85,1	46	80,7	84,77	16,47	68	88,3	51	75	85,39	15,19
FC Gamma Receptor IIb/IIc													
Baseline	Missing	71	100	60	84,5	82,54	14,82	69	100	63	91,3	85,5	13,88
Cycle 3 Day 1	Missing	64	90,1	54	84,4	82,43	12,35	67	97,1	54	80,6	82,29	14,25
Induction Completion/Early Termination	Missing	65	91,5	54	83,1	82,5	11,97	65	94,2	48	73,8	85,35	16,63
Follow Up Month 2	Missing	63	88,7	39	61,9	85,79	12,37	65	94,2	33	50,8	89,51	14,62
Follow Up Month 12	Missing	61	85,9	43	70,5	85,98	11,76	61	88,4	37	60,7	88,62	16,25
Maintenance or Observation Completion/Early	Missing	53	74,6	41	77,4	85,89	12,89	48	69,6	36	75	85,51	19,3
Baseline	232II	417	100	391	93,8	83	14,45	406	100	376	92,6	82,33	14,28
Cycle 3 Day 1	232II	415	99,5	356	85,8	83,33	14,47	406	100	362	89,2	83,2	14,36
Induction Completion/Early Termination	232II	413	99	339	82,1	85,14	14,79	402	99	352	87,6	84,14	15,51
Follow Up Month 2	232II	410	98,3	287	70	86,42	14,27	400	98,5	262	65,5	86,16	14,81
Follow Up Month 12	232II	397	95,2	291	73,3	86,85	14,42	380	93,6	263	69,2	87,3	14,64
Maintenance or Observation Completion/Early	232II	343	82,3	268	78,1	87,32	15,17	335	82,5	253	75,5	86,73	15,18
Baseline	232IT	104	100	100	96,2	83,26	14,98	116	100	106	91,4	81	16,9
Cycle 3 Day 1	232IT	102	98,1	85	83,3	81,87	14,89	115	99,1	97	84,3	80,06	16,15
Induction Completion/Early Termination	232IT	101	97,1	90	89,1	85,01	13,97	112	96,6	96	85,7	82,33	16,6
Follow Up Month 2	232IT	101	97,1	73	72,3	86,44	14,24	112	96,6	67	59,8	84,31	16,71
Follow Up Month 12	232IT	101	97,1	77	76,2	87,05	13,7	108	93,1	77	71,3	84,43	17,5
Maintenance or Observation Completion/Early	232IT	90	86,5	69	76,7	85,5	15,28	95	81,9	73	76,8	86,15	16,19
Baseline	232TT	9	100	9	100	78,26	11,03	10	100	10	100	77,44	18,41
Cycle 3 Day 1	232TT	9	100	8	88,9	83,64	15,07	10	100	9	90	75,86	18,9
Induction Completion/Early Termination	232TT	9	100	8	88,9	87,03	15,62	10	100	7	70	80,1	16,31
Follow Up Month 2	232TT	8	88,9	5	62,5	89,53	20,02	10	100	7	70	88,18	10,91
Follow Up Month 12	232TT	8	88,9	5	62,5	88,25	16,17	10	100	8	80	83,39	13,61
Maintenance or Observation Completion/Early	232TT	8	88,9	4	50	88,59	14,27	9	90	9	100	79,35	17,44
Time from initial FL diagnosis to													
Baseline	Missing	3	100	2	66,7	80,83	12,97	0	NE	0	NE	NE	NE
Cycle 3 Day 1	Missing	3	100	3	100	82,92	16,39	0	NE	0	NE	NE	NE
Induction Completion/Early Termination	Missing	3	100	2	66,7	92,05	4,93	0	NE	0	NE	NE	NE
Follow Up Month 2	Missing	3	100	1	33,3	88,56	NE	0	NE	0	NE	NE	NE
Follow Up Month 12	Missing	2	66,7	2	100	85,15	10,28	0	NE	0	NE	NE	NE
Maintenance or Observation Completion/Early	Missing	2	66,7	2	100	89,46	14,9	0	NE	0	NE	NE	NE
Baseline	6-12 months	35	100	33	94,3	86,51	13,33	32	100	29	90,6	80,99	15,22
Cycle 3 Day 1	6-12 months	35	100	31	88,6	84,48	12,35	32	100	27	84,4	79,09	14,6
Induction Completion/Early Termination	6-12 months	35	100	31	88,6	87,67	12,77	31	96,9	28	90,3	84,29	12,73
Follow Up Month 2	6-12 months	35	100	25	71,4	88,07	10,65	31	96,9	24	77,4	82,51	13,36
Follow Up Month 12	6-12 months	35	100	26	74,3	88,93	12	30	93,8	21	70	88,8	10,84
Maintenance or Observation Completion/Early	6-12 months	29	82,9	18	62,1	91,81	11,3	28	87,5	23	82,1	87,15	14,03

Baseline	< 6 months	490	100	458	93,5	82,3	14,65	474	100	441	93	82,31	14,83
Cycle 3 Day 1	< 6 months	481	98,2	413	85,9	82,49	14,56	471	99,4	410	87	82,28	15,19
Induction Completion/Early Termination	< 6 months	479	97,8	398	83,1	84,01	14,52	464	97,9	398	85,8	83,72	16,32
Follow Up Month 2	< 6 months	475	96,9	336	70,7	86,33	14,25	462	97,5	286	61,9	86,2	15,42
Follow Up Month 12	< 6 months	464	94,7	341	73,5	86,53	14,28	441	93	307	69,6	86,26	15,85
Maintenance or Observation Completion/Early	< 6 months	404	82,4	316	78,2	86,57	14,95	385	81,2	295	76,6	85,87	16,1
Baseline	> 12 months	73	100	67	91,8	85,47	13,93	95	100	85	89,5	83,01	15,09
Cycle 3 Day 1	> 12 months	71	97,3	56	78,9	85,93	13,25	95	100	85	89,5	84,01	12,84
Induction Completion/Early Termination	> 12 months	71	97,3	60	84,5	88,81	13,52	94	98,9	77	81,9	84,37	14,33
Follow Up Month 2	> 12 months	69	94,5	42	60,9	85,95	15,24	94	98,9	59	62,8	87,47	14,08
Follow Up Month 12	> 12 months	66	90,4	47	71,2	87,84	13,39	88	92,6	57	64,8	88,77	14,22
Maintenance or Observation Completion/Early	> 12 months	59	80,8	46	78	86,78	16,06	74	77,9	53	71,6	88,45	15,2
Ann Arbor Stage 2													
Baseline	Missing	3	100	3	100	80,35	30,38	4	100	4	100	85,98	16,85
Cycle 3 Day 1	Missing	3	100	2	66,7	89,94	4,16	4	100	4	100	82,36	14,75
Induction Completion/Early Termination	Missing	3	100	3	100	98,46	5,94	4	100	4	100	83,73	11,36
Follow Up Month 2	Missing	3	100	1	33,3	94	NE	4	100	2	50	72,52	24,72
Follow Up Month 12	Missing	3	100	2	66,7	89,6	4,81	4	100	3	75	91,29	11,61
Maintenance or Observation Completion/Early	Missing	3	100	2	66,7	81,22	27,18	4	100	3	75	101,28	4,58
Baseline	Stage I	10	100	10	100	86,2	12,24	8	100	6	75	76,12	20,12
Cycle 3 Day 1	Stage I	10	100	8	80	85,79	11,17	8	100	7	87,5	83,48	7,45
Induction Completion/Early Termination	Stage I	10	100	9	90	86,53	11,87	8	100	5	62,5	88	10,98
Follow Up Month 2	Stage I	10	100	7	70	84,06	14,47	8	100	7	87,5	91,1	8,92
Follow Up Month 12	Stage I	10	100	9	90	91,79	12,74	8	100	5	62,5	88,25	10,4
Maintenance or Observation Completion/Early	Stage I	8	80	6	75	93,3	8,87	7	87,5	4	57,1	88,77	13,37
Baseline	Stage II (w/o bulky disease)	14	100	12	85,7	84,21	16,74	14	100	12	85,7	84,11	14,08
Cycle 3 Day 1	Stage II (w/o bulky disease)	14	100	8	57,1	83,53	16,43	14	100	12	85,7	84,76	10,04
Induction Completion/Early Termination	Stage II (w/o bulky disease)	14	100	9	64,3	81,3	25,88	14	100	11	78,6	80,63	13,47
Follow Up Month 2	Stage II (w/o bulky disease)	14	100	6	42,9	88,66	24,95	14	100	4	28,6	80,47	10,47
Follow Up Month 12	Stage II (w/o bulky disease)	13	92,9	7	53,8	85,34	14,36	14	100	7	50	85,2	19,51
Maintenance or Observation Completion/Early	Stage II (w/o bulky disease)	11	78,6	5	45,5	96,63	7,2	12	85,7	10	83,3	80,18	15,39
Baseline	Stage II (with bulky	27	100	25	92,6	83,7	14,67	30	100	29	96,7	79,86	12,94
Cycle 3 Day 1	Stage II (with bulky	27	100	24	88,9	83,89	13,81	30	100	24	80	78,16	16,17
Induction Completion/Early Termination	Stage II (with bulky	27	100	22	81,5	86,59	11,78	29	96,7	23	79,3	82,34	18,53
Follow Up Month 2	Stage II (with bulky	27	100	21	77,8	86,87	11,71	29	96,7	18	62,1	81,36	18,75
Follow Up Month 12	Stage II (with bulky	27	100	23	85,2	88,22	11,36	26	86,7	17	65,4	81,49	18,05
Maintenance or Observation Completion/Early	Stage II (with bulky	20	74,1	16	80	92,43	11,87	22	73,3	17	77,3	83,3	19,84
Baseline	Stage III	208	100	194	93,3	83,33	13,75	209	100	195	93,3	83,8	13,3
Cycle 3 Day 1	Stage III	204	98,1	173	84,8	82,49	14,28	208	99,5	185	88,9	81,95	14,6
Induction Completion/Early Termination	Stage III	202	97,1	169	83,7	84,36	14,31	206	98,6	174	84,5	83,88	16,39
Follow Up Month 2	Stage III	199	95,7	137	68,8	85,65	14,07	206	98,6	134	65	86,66	13,57
Follow Up Month 12	Stage III	194	93,3	142	73,2	86,12	14,13	191	91,4	141	73,8	87,63	15,42
Maintenance or Observation Completion/Early	Stage III	170	81,7	130	76,5	85,37	15,82	162	77,5	126	77,8	87,01	16,15
Baseline	Stage IV	339	100	316	93,2	82,48	14,86	336	100	309	92	81,67	15,85
Cycle 3 Day 1	Stage IV	332	97,9	288	86,7	83,08	14,5	334	99,4	290	86,8	82,9	15,15
Induction Completion/Early Termination	Stage IV	332	97,9	279	84	84,94	14,23	328	97,6	286	87,2	84,01	15,53
Follow Up Month 2	Stage IV	329	97,1	232	70,5	86,78	14,12	326	97	204	62,6	86,34	15,82

Follow Up Month 12	Stage IV	320	94,4	233	72,8	86,93	14,32	316	94	212	67,1	86,57	15,2
Maintenance or Observation Completion/Early	Stage IV	282	83,2	223	79,1	86,98	14,63	280	83,3	211	75,4	86,18	15,43

[1] in study: number of subjects in study at respective visit; % based on baseline
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit
[2] mean: descriptive statistics - absolute
values Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/t_pro_mean.sas
Output:
root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/t_pro_mean_sg_PFGTOT_FO
LY_IT.xls 24OCT2019 16:23

13 (Anhang): Ergebnisse für FACT-LymS Mittelwerte pro Visite - Subgruppenanalysen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
ENDPOINT: FACT-LYM Subscale
MODEL: Unadjusted Analysis STUDY:
BO21223
Compliance/Mean

		G-chemo (N=601)						R-chemo (N=601)					
		Patients				Statistics		Patients				Statistics	
Name	Level	in study[1]	%	with valu	%	Mean[2]	SD (Mean)	in study[1]	%	with valu	%	Mean[2]	SD (Mean)
All													
Baseline	n/a	601	100	563	93,7	45,54	9,29	601	100	556	92,5	45,01	9,37
Cycle 3 Day 1	n/a	590	98,2	508	86,1	48,07	7,4	598	99,5	532	89	47,21	8,34
Induction Completion/Early Termination	n/a	588	97,8	496	84,4	48,69	7,96	589	98	500	84,9	48,17	9,12
Follow Up Month 2	n/a	582	96,8	406	69,8	49,89	7,59	587	97,7	375	63,9	49,79	8,25
Follow Up Month 12	n/a	567	94,3	423	74,6	50,35	7,27	559	93	385	68,9	50,49	8,2
Maintenance or Observation Completion/Early Termina	n/a	494	82,2	388	78,5	49,92	8,32	487	81	373	76,6	49,94	8,76
Sex													
Baseline	Female	318	100	301	94,7	44,45	9,23	321	100	297	92,5	43,62	9,46
Cycle 3 Day 1	Female	311	97,8	266	85,5	47,09	7,62	320	99,7	283	88,4	45,88	8,46
Induction Completion/Early Termination	Female	310	97,5	263	84,8	47,33	8,37	315	98,1	269	85,4	46,83	9,37
Follow Up Month 2	Female	306	96,2	222	72,5	48,66	8,03	315	98,1	210	66,7	48,57	8,38
Follow Up Month 12	Female	300	94,3	217	72,3	49,67	7,87	299	93,1	210	70,2	49,68	8,37
Maintenance or Observation Completion/Early Termina	Female	265	83,3	211	79,6	48,86	8,97	263	81,9	203	77,2	49,11	8,24
Baseline	Male	283	100	262	92,6	46,79	9,22	280	100	259	92,5	46,61	9,03
Cycle 3 Day 1	Male	279	98,6	242	86,7	49,15	7,02	278	99,3	249	89,6	48,72	7,95
Induction Completion/Early Termination	Male	278	98,2	233	83,8	50,24	7,18	274	97,9	231	84,3	49,73	8,59
Follow Up Month 2	Male	276	97,5	184	66,7	51,38	6,74	272	97,1	165	60,7	51,35	7,84
Follow Up Month 12	Male	267	94,3	206	77,2	51,07	6,52	260	92,9	175	67,3	51,45	7,9
Maintenance or Observation Completion/Early Termina	Male	229	80,9	177	77,3	51,18	7,3	224	80	170	75,9	50,94	9,27
Age													
Baseline	< 60 years	298	100	283	95	45,26	9,46	323	100	300	92,9	44,95	9,18
Cycle 3 Day 1	< 60 years	292	98	258	88,4	48,25	7,54	322	99,7	289	89,8	47,22	8,65
Induction Completion/Early Termination	< 60 years	293	98,3	255	87	48,3	8,15	318	98,5	274	86,2	47,87	9,95
Follow Up Month 2	< 60 years	290	97,3	206	71	49,71	7,74	317	98,1	217	68,5	49,78	8,71
Follow Up Month 12	< 60 years	284	95,3	222	78,2	50,33	7,13	303	93,8	208	68,6	49,82	9,1
Maintenance or Observation Completion/Early Termina	< 60 years	247	82,9	195	78,9	49,87	8,48	268	83	206	76,9	49,77	9,17
Baseline	>= 60 years	303	100	280	92,4	45,82	9,12	278	100	256	92,1	45,08	9,61
Cycle 3 Day 1	>= 60 years	298	98,3	250	83,9	47,89	7,27	276	99,3	243	88	47,2	7,98
Induction Completion/Early Termination	>= 60 years	295	97,4	241	81,7	49,11	7,75	271	97,5	226	83,4	48,54	8,01
Follow Up Month 2	>= 60 years	292	96,4	200	68,5	50,08	7,44	270	97,1	158	58,5	49,81	7,61
Follow Up Month 12	>= 60 years	283	93,4	201	71	50,37	7,44	256	92,1	177	69,1	51,26	6,93
Maintenance or Observation Completion/Early Termina	>= 60 years	247	81,5	193	78,1	49,97	8,18	219	78,8	167	76,3	50,16	8,26
Race/ethnicity													
Baseline	Other	114	100	109	95,6	45,38	9,6	120	100	114	95	45,14	9,3
Cycle 3 Day 1	Other	111	97,4	107	96,4	47,25	7,67	120	100	111	92,5	45,89	8,49

Induction Completion/Early Termination	Other	111	97,4	106	95,5	47,34	8,81	118	98,3	107	90,7	48,19	9,57
Follow Up Month 2	Other	111	97,4	93	83,8	48,6	8,71	118	98,3	83	70,3	49,92	7,55
Follow Up Month 12	Other	108	94,7	96	88,9	49,35	7,98	115	95,8	87	75,7	50,53	6,46
Maintenance or Observation Completion/Early Termina	Other	85	74,6	76	89,4	49,93	9,04	98	81,7	80	81,6	50,57	7,57
Baseline	White	487	100	454	93,2	45,58	9,23	481	100	442	91,9	44,98	9,4
Cycle 3 Day 1	White	479	98,4	401	83,7	48,29	7,33	478	99,4	421	88,1	47,56	8,28
Induction Completion/Early Termination	White	477	97,9	390	81,8	49,06	7,68	471	97,9	393	83,4	48,17	9,01
Follow Up Month 2	White	471	96,7	313	66,5	50,28	7,19	469	97,5	292	62,3	49,76	8,45
Follow Up Month 12	White	459	94,3	327	71,2	50,64	7,04	444	92,3	298	67,1	50,47	8,65
Maintenance or Observation Completion/Early Termina	White	409	84	312	76,3	49,92	8,15	389	80,9	293	75,3	49,77	9,07
Geographic region													
Baseline	Asia-Pacific	152	100	146	96,1	44,44	9,74	155	100	155	100	46,22	8,55
Cycle 3 Day 1	Asia-Pacific	148	97,4	143	96,6	47,03	7,57	155	100	151	97,4	46,66	8,53
Induction Completion/Early Termination	Asia-Pacific	148	97,4	140	94,6	47,61	8,35	153	98,7	148	96,7	49,02	8,47
Follow Up Month 2	Asia-Pacific	147	96,7	118	80,3	49,03	7,8	153	98,7	109	71,2	49,82	7,96
Follow Up Month 12	Asia-Pacific	143	94,1	116	81,1	49,27	7,33	144	92,9	111	77,1	51,04	7,23
Maintenance or Observation Completion/Early Termina	Asia-Pacific	118	77,6	103	87,3	49,92	8,22	122	78,7	103	84,4	51,42	7,84
Baseline	North America	75	100	72	96	46,5	9,33	77	100	75	97,4	42,67	9,52
Cycle 3 Day 1	North America	72	96	70	97,2	48,57	7,54	77	100	74	96,1	46,74	7,5
Induction Completion/Early Termination	North America	72	96	70	97,2	49,07	7,76	75	97,4	67	89,3	47,36	9,92
Follow Up Month 2	North America	71	94,7	46	64,8	51,15	6,88	75	97,4	41	54,7	50,16	8,08
Follow Up Month 12	North America	67	89,3	56	83,6	51,76	7,1	73	94,8	54	74	50,45	8,15
Maintenance or Observation Completion/Early Termina	North America	63	84	57	90,5	51,08	7,24	66	85,7	56	84,8	48,08	10,37
Baseline	Other	80	100	77	96,3	46,58	7,9	83	100	75	90,4	45,76	8,72
Cycle 3 Day 1	Other	80	100	71	88,8	48,28	7,93	83	100	77	92,8	47,8	7,76
Induction Completion/Early Termination	Other	77	96,3	69	89,6	49,41	7,71	81	97,6	73	90,1	48,11	8,92
Follow Up Month 2	Other	76	95	62	81,6	50,82	7,18	81	97,6	69	85,2	50,19	8,34
Follow Up Month 12	Other	76	95	60	78,9	49,03	8,39	77	92,8	66	85,7	49,68	7,92
Maintenance or Observation Completion/Early Termina	Other	65	81,3	50	76,9	50,08	8,8	68	81,9	56	82,4	50,18	7,4
Baseline	Western Europe	294	100	268	91,2	45,58	9,39	286	100	251	87,8	44,74	9,89
Cycle 3 Day 1	Western Europe	290	98,6	224	77,2	48,52	7,06	283	99	230	81,3	47,53	8,67
Induction Completion/Early Termination	Western Europe	291	99	217	74,6	49,05	7,83	280	97,9	212	75,7	47,86	9,39
Follow Up Month 2	Western Europe	288	98	180	62,5	49,82	7,73	278	97,2	156	56,1	49,5	8,53
Follow Up Month 12	Western Europe	281	95,6	191	68	51	6,8	265	92,7	154	58,1	50,45	8,99
Maintenance or Observation Completion/Early Termina	Western Europe	248	84,4	178	71,8	49,5	8,59	231	80,8	158	68,4	49,55	9,08
Baseline ECOG Performance Status score													
Baseline	Missing	1	100	1	100	39	NE	2	100	2	100	46,5	10,61
Cycle 3 Day 1	Missing	1	100	1	100	48	NE	2	100	0	NE	NE	NE
Induction Completion/Early Termination	Missing	1	100			NE	NE	2	100			NE	NE
Follow Up Month 2	Missing	1	100	1	100	55	NE	2	100	0	NE	NE	NE
Follow Up Month 12	Missing	1	100	1	100	47	NE	2	100	1	50	57	NE
Maintenance or Observation Completion/Early Termina	Missing	1	100	1	100	42	NE	1	50	1	100	53	NE
Baseline	0-1	585	100	549	93,8	45,77	9,07	576	100	533	92,5	45,25	9,36
Cycle 3 Day 1	0-1	577	98,6	497	86,1	48,12	7,41	574	99,7	513	89,4	47,18	8,4
Induction Completion/Early Termination	0-1	574	98,1	485	84,5	48,8	7,89	565	98,1	482	85,3	48,19	9,15
Follow Up Month 2	0-1	569	97,3	398	69,9	49,97	7,54	563	97,7	365	64,8	49,77	8,26
Follow Up Month 12	0-1	556	95	414	74,5	50,38	7,3	537	93,2	374	69,6	50,53	8,11
Maintenance or Observation Completion/Early Termina	0-1	487	83,2	383	78,6	49,92	8,35	470	81,6	362	77	49,94	8,8

Baseline	2	15	100	13	86,7	36,15	13,71	23	100	21	91,3	38,71	7,56
Cycle 3 Day 1	2	12	80	10	83,3	45,5	7,34	22	95,7	19	86,4	48,08	6,7
Induction Completion/Early Termination	2	13	86,7	11	84,6	43,89	10	22	95,7	18	81,8	47,83	8,73
Follow Up Month 2	2	12	80	7	58,3	44,57	9,54	22	95,7	10	45,5	50,6	8,59
Follow Up Month 12	2	10	66,7	8	80	49,38	6,57	20	87	10	50	48,3	11,45
Maintenance or Observation Completion/Early Termina	2	6	40	4	66,7	51,75	4,79	16	69,6	10	62,5	49,73	8,25
Independence status (Katz ADL)													
Baseline	Very dependent (0-2)	3	100	3	100	41	18,19	7	100	7	100	43,29	11,66
Cycle 3 Day 1	Very dependent (0-2)	3	100	2	66,7	46,5	10,61	7	100	7	100	45,43	12,19
Induction Completion/Early Termination	Very dependent (0-2)	3	100	3	100	48,33	3,79	7	100	7	100	48,14	11,78
Follow Up Month 2	Very dependent (0-2)	3	100	3	100	47,67	1,15	7	100	4	57,1	44,75	12,31
Follow Up Month 12	Very dependent (0-2)	3	100	3	100	46,67	2,08	7	100	6	85,7	48,67	12,42
Maintenance or Observation Completion/Early Termina	Very dependent (0-2)	3	100	2	66,7	47,5	2,12	7	100	4	57,1	56,5	1,91
Baseline	Some dependence (3-4)	4	100	4	100	31,75	16,56	5	100	3	60	33,33	15,5
Cycle 3 Day 1	Some dependence (3-4)	4	100	4	100	45,5	8,23	4	80	2	50	52	2,83
Induction Completion/Early Termination	Some dependence (3-4)	4	100	4	100	46,25	10,87	3	60	1	33,3	57	NE
Follow Up Month 2	Some dependence (3-4)	4	100	3	75	51,33	5,13	3	60	1	33,3	53	NE
Follow Up Month 12	Some dependence (3-4)	3	75	1	33,3	42	NE	3	60	1	33,3	56	NE
Maintenance or Observation Completion/Early Termina	Some dependence (3-4)	4	100	4	100	47	6,73	2	40	2	100	54	2,83
Baseline	Independent (5-6)	459	100	438	95,4	45,9	9,07	462	100	438	94,8	45,1	9,41
Cycle 3 Day 1	Independent (5-6)	453	98,7	392	86,5	48,39	7,29	462	100	413	89,4	46,92	8,52
Induction Completion/Early Termination	Independent (5-6)	451	98,3	391	86,7	48,94	7,75	455	98,5	395	86,8	48,14	9,31
Follow Up Month 2	Independent (5-6)	446	97,2	322	72,2	50,12	7,37	454	98,3	299	65,9	49,98	8,21
Follow Up Month 12	Independent (5-6)	435	94,8	332	76,3	50,67	7,05	429	92,9	297	69,2	50,4	8,34
Maintenance or Observation Completion/Early Termina	Independent (5-6)	375	81,7	296	78,9	50,45	7,88	366	79,2	286	78,1	49,95	8,61
Baseline	Missing	83	100	68	81,9	46,61	7,77	80	100	64	80	45,58	8,85
Cycle 3 Day 1	Missing	80	96,4	64	80	48,06	6,81	79	98,8	66	83,5	48,83	7,23
Induction Completion/Early Termination	Missing	79	95,2	57	72,2	47,89	8,13	78	97,5	57	73,1	49,6	7,54
Follow Up Month 2	Missing	79	95,2	46	58,2	49,57	7,47	77	96,3	44	57,1	50,5	7,08
Follow Up Month 12	Missing	77	92,8	51	66,2	49,86	7,99	74	92,5	48	64,9	51,21	6,95
Maintenance or Observation Completion/Early Termina	Missing	70	84,3	47	67,1	48,26	10,36	73	91,3	48	65,8	50,73	8,11
Baseline	Outside valid range	52	100	50	96,2	42,29	10,67	47	100	44	93,6	44,41	8,85
Cycle 3 Day 1	Outside valid range	50	96,2	46	92	45,68	8,71	46	97,9	44	95,7	47,57	7,58
Induction Completion/Early Termination	Outside valid range	51	98,1	41	80,4	47,73	9,63	46	97,9	40	87	46,24	8,86
Follow Up Month 2	Outside valid range	50	96,2	32	64	48,16	10,14	46	97,9	27	58,7	47,19	9,7
Follow Up Month 12	Outside valid range	49	94,2	36	73,5	48,6	8,28	46	97,9	33	71,7	50,33	8,06
Maintenance or Observation Completion/Early Termina	Outside valid range	42	80,8	39	92,9	48,28	8,94	39	83	33	84,6	47,64	11,09
Independence status (Katz IADL)													
Baseline	Very dependent (0)	1	100	1	100	42	NE	1	100	1	100	31	NE
Cycle 3 Day 1	Very dependent (0)	1	100	1	100	46	NE	1	100	0	NE	NE	NE
Induction Completion/Early Termination	Very dependent (0)	1	100	1	100	47	NE	1	100	0	NE	NE	NE
Follow Up Month 2	Very dependent (0)	1	100			NE	NE	1	100			NE	NE
Follow Up Month 12	Very dependent (0)	1	100			NE	NE	1	100			NE	NE
Maintenance or Observation Completion/Early Termina	Very dependent (0)	1	100	0	NE	NE	NE	1	100	1	100	55	NE
Baseline	Some dependence (1-4)	9	100	9	100	43,89	7,15	14	100	10	71,4	35,71	10,13
Cycle 3 Day 1	Some dependence (1-4)	9	100	9	100	50,67	5,61	14	100	10	71,4	37,94	11,49
Induction Completion/Early Termination	Some dependence (1-4)	8	88,9	8	100	51,75	5,9	13	92,9	10	76,9	43,6	11,1

Follow Up Month 2	Some dependence (1-4)	8	88,9	7	87,5	51,06	5,07	13	92,9	6	46,2	46,17	8,8
Follow Up Month 12	Some dependence (1-4)	7	77,8	3	42,9	46,33	7,57	13	92,9	6	46,2	47,17	10,44
Maintenance or Observation Completion/Early Termina	Some dependence (1-4)	8	88,9	8	100	49,91	6,46	9	64,3	5	55,6	52	4,85
Baseline	Independent (5-8)	504	100	481	95,4	45,47	9,45	501	100	476	95	45,09	9,29
Cycle 3 Day 1	Independent (5-8)	496	98,4	432	87,1	48,02	7,51	499	99,6	454	91	47,11	8,31
Induction Completion/Early Termination	Independent (5-8)	496	98,4	426	85,9	48,66	7,97	492	98,2	430	87,4	48,1	9,24
Follow Up Month 2	Independent (5-8)	490	97,2	352	71,8	49,92	7,7	491	98	326	66,4	49,74	8,41
Follow Up Month 12	Independent (5-8)	477	94,6	362	75,9	50,41	7,19	468	93,4	328	70,1	50,5	8,35
Maintenance or Observation Completion/Early Termina	Independent (5-8)	412	81,7	328	79,6	50,12	8,14	403	80,4	317	78,7	49,67	9,11
Baseline	Missing	71	100	57	80,3	45,78	8,1	74	100	59	79,7	46,2	9,22
Cycle 3 Day 1	Missing	68	95,8	52	76,5	47,23	7,45	73	98,6	58	79,5	49,39	7,37
Induction Completion/Early Termination	Missing	67	94,4	45	67,2	47,78	8,36	72	97,3	51	70,8	50,22	7,57
Follow Up Month 2	Missing	67	94,4	36	53,7	48,83	7,12	71	95,9	35	49,3	50,77	7,35
Follow Up Month 12	Missing	66	93	44	66,7	49,09	8,26	67	90,5	46	68,7	50,8	7,15
Maintenance or Observation Completion/Early Termina	Missing	60	84,5	41	68,3	47,85	10,41	64	86,5	41	64,1	52,22	5,86
Baseline	Outside valid range	16	100	15	93,8	47,94	10,3	11	100	10	90,9	45	9,23
Cycle 3 Day 1	Outside valid range	16	100	14	87,5	51,39	3,57	11	100	10	90,9	48,65	4,4
Induction Completion/Early Termination	Outside valid range	16	100	16	100	50,75	7,58	11	100	9	81,8	45,08	7,19
Follow Up Month 2	Outside valid range	16	100	11	68,8	51,84	6,94	11	100	8	72,7	50,5	4,96
Follow Up Month 12	Outside valid range	16	100	14	87,5	53,5	5,18	10	90,9	5	50	50,77	4,56
Maintenance or Observation Completion/Early Termina	Outside valid range	13	81,3	11	84,6	51,73	5,42	10	90,9	9	90	47,22	8,12
Chemotherapy regimen													
Baseline	Bendamustine	345	100	323	93,6	44,52	9,99	341	100	314	92,1	44,05	9,62
Cycle 3 Day 1	Bendamustine	338	98	282	83,4	47,55	7,88	340	99,7	297	87,4	46,82	8,55
Induction Completion/Early Termination	Bendamustine	337	97,7	284	84,3	48,01	8,41	335	98,2	288	86	47,45	9,3
Follow Up Month 2	Bendamustine	332	96,2	231	69,6	49,55	7,85	334	97,9	209	62,6	49,56	8,46
Follow Up Month 12	Bendamustine	321	93	233	72,6	49,99	7,76	312	91,5	207	66,3	50,49	8,29
Maintenance or Observation Completion/Early Termina	Bendamustine	283	82	222	78,4	49,38	8,79	274	80,4	214	78,1	49,26	9,24
Baseline	CHOP	195	100	186	95,4	46,64	7,51	203	100	189	93,1	46,64	8,3
Cycle 3 Day 1	CHOP	192	98,5	175	91,1	48,55	6,4	203	100	188	92,6	47,43	7,59
Induction Completion/Early Termination	CHOP	191	97,9	166	86,9	49,82	6,92	201	99	174	86,6	49,13	8,47
Follow Up Month 2	CHOP	190	97,4	138	72,6	50,54	6,83	200	98,5	141	70,5	49,82	7,84
Follow Up Month 12	CHOP	187	95,9	145	77,5	50,68	6,67	194	95,6	151	77,8	50,51	7,28
Maintenance or Observation Completion/Early Termina	CHOP	156	80	123	78,8	51,08	6,69	166	81,8	127	76,5	51,23	7,15
Baseline	CVP	61	100	54	88,5	47,85	9,82	57	100	53	93	44,88	10,8
Cycle 3 Day 1	CVP	60	98,4	51	85	49,32	7,77	55	96,5	47	85,5	48,76	9,72
Induction Completion/Early Termination	CVP	60	98,4	46	76,7	48,85	8,3	53	93	38	71,7	49,28	10,3
Follow Up Month 2	CVP	60	98,4	37	61,7	49,66	8,61	53	93	25	47,2	51,56	8,9
Follow Up Month 12	CVP	59	96,7	45	76,3	51,13	6,54	53	93	27	50,9	50,37	11,88
Maintenance or Observation Completion/Early Termina	CVP	55	90,2	43	78,2	49,39	9,76	47	82,5	32	68,1	49,41	10,85
Histologic grade													
Baseline	Missing	4	100	4	100	48,75	6,34	4	100	4	100	47	9,13
Cycle 3 Day 1	Missing	4	100	2	50	43	2,83	4	100	3	75	49	4,58
Induction Completion/Early Termination	Missing	4	100	2	50	39	21,21	4	100	4	100	50,75	4,79
Follow Up Month 2	Missing	4	100	1	25	33	NE	4	100	0	NE	NE	NE
Follow Up Month 12	Missing	4	100	2	50	50	9,9	4	100	3	75	52,33	2,08
Maintenance or Observation Completion/Early Termina	Missing	3	75	1	33,3	54	NE	4	100	2	50	50,5	10,61

Baseline	1	242	100	226	93,4	45,28	9,15	219	100	203	92,7	45,18	9,7
Cycle 3 Day 1	1	239	98,8	203	84,9	47,98	7,5	219	100	197	90	46,79	8,26
Induction Completion/Early Termination	1	240	99,2	204	85	48,34	7,99	213	97,3	182	85,4	47,79	9,81
Follow Up Month 2	1	237	97,9	174	73,4	49,52	7,81	212	96,8	143	67,5	49,22	8,83
Follow Up Month 12	1	231	95,5	170	73,6	50,96	6,34	201	91,8	142	70,6	49,9	9,1
Maintenance or Observation Completion/Early Termina	1	198	81,8	147	74,2	49,97	8,38	179	81,7	132	73,7	50,4	9,17
Baseline	2	267	100	250	93,6	45,67	9,02	289	100	266	92	44,79	9,39
Cycle 3 Day 1	2	262	98,1	229	87,4	48,23	7,24	286	99	258	90,2	47,32	8,44
Induction Completion/Early Termination	2	260	97,4	222	85,4	48,94	7,43	283	97,9	238	84,1	48,22	8,74
Follow Up Month 2	2	257	96,3	170	66,1	50,14	7	282	97,6	184	65,2	50,18	7,71
Follow Up Month 12	2	252	94,4	195	77,4	50,06	7,57	270	93,4	187	69,3	50,89	7,56
Maintenance or Observation Completion/Early Termina	2	219	82	177	80,8	50,1	8,18	237	82	192	81	49,68	8,79
Baseline	3	4	100	4	100	50,75	7,93	3	100	3	100	45,1	10,39
Cycle 3 Day 1	3	4	100	4	100	52,5	4,51	3	100	3	100	43	7,21
Induction Completion/Early Termination	3	4	100	4	100	55,5	1,29	3	100	3	100	44	11,36
Follow Up Month 2	3	4	100	4	100	56,25	0,96	3	100	2	66,7	55,5	3,54
Follow Up Month 12	3	4	100	3	75	52,33	7,37	2	66,7	2	100	55	1,41
Maintenance or Observation Completion/Early Termina	3	4	100	4	100	54	4,24	2	66,7	2	100	57,5	0,71
Baseline	3a	82	100	78	95,1	45,38	10,76	85	100	79	92,9	45,38	8,61
Cycle 3 Day 1	3a	79	96,3	69	87,3	47,94	7,72	85	100	70	82,4	48,2	8,41
Induction Completion/Early Termination	3a	78	95,1	62	79,5	48,8	9,35	85	100	72	84,7	48,99	8,85
Follow Up Month 2	3a	78	95,1	57	73,1	50,15	8,46	85	100	46	54,1	49,76	8,66
Follow Up Month 12	3a	74	90,2	52	70,3	49,27	8,94	81	95,3	50	61,7	50,42	8,26
Maintenance or Observation Completion/Early Termina	3a	68	82,9	58	85,3	48,83	8,93	64	75,3	44	68,8	49,46	7,63
Baseline	Other	2	100	1	50	50	NE	1	100	1	100	34	NE
Cycle 3 Day 1	Other	2	100	1	50	33,21	NE	1	100	1	100	42	NE
Induction Completion/Early Termination	Other	2	100	2	100	50,5	0,71	1	100	1	100	49,29	NE
Follow Up Month 2	Other	2	100			NE	NE	1	100			NE	NE
Follow Up Month 12	Other	2	100	1	50	53	NE	1	100	1	100	47	NE
Maintenance or Observation Completion/Early Termina	Other	2	100	1	50	53	NE	1	100	1	100	45	NE
FLIPI													
Baseline	High (>=3)	249	100	233	93,6	44,4	9,49	253	100	235	92,9	43,81	8,61
Cycle 3 Day 1	High (>=3)	247	99,2	211	85,4	47,32	7,71	252	99,6	221	87,7	47,29	7,35
Induction Completion/Early Termination	High (>=3)	244	98	204	83,6	48,9	7,5	248	98	209	84,3	48,26	8,27
Follow Up Month 2	High (>=3)	240	96,4	174	72,5	50,15	7	247	97,6	160	64,8	50,16	7,07
Follow Up Month 12	High (>=3)	233	93,6	163	70	50,52	7,53	237	93,7	155	65,4	51,13	6,58
Maintenance or Observation Completion/Early Termina	High (>=3)	206	82,7	157	76,2	49,71	8,13	201	79,4	150	74,6	49,98	7,29
Baseline	Intermediate (2)	224	100	209	93,3	46,18	9,21	223	100	205	91,9	45,75	10,37
Cycle 3 Day 1	Intermediate (2)	216	96,4	188	87	48,2	7,37	223	100	202	90,6	47,36	8,72
Induction Completion/Early Termination	Intermediate (2)	217	96,9	187	86,2	48,33	8,21	221	99,1	188	85,1	48,47	9,49
Follow Up Month 2	Intermediate (2)	215	96	145	67,4	49,66	8,05	220	98,7	135	61,4	49,82	8,64
Follow Up Month 12	Intermediate (2)	211	94,2	160	75,8	49,67	7,37	206	92,4	143	69,4	50,27	8,7
Maintenance or Observation Completion/Early Termina	Intermediate (2)	185	82,6	149	80,5	49,48	8,61	183	82,1	144	78,7	49,76	9,92
Baseline	Low (0-1)	128	100	121	94,5	46,62	8,89	125	100	116	92,8	46,12	8,8
Cycle 3 Day 1	Low (0-1)	127	99,2	109	85,8	49,32	6,71	123	98,4	109	88,6	46,77	9,49
Induction Completion/Early Termination	Low (0-1)	127	99,2	105	82,7	48,94	8,42	120	96	103	85,8	47,46	10,09
Follow Up Month 2	Low (0-1)	127	99,2	87	68,5	49,78	8	120	96	80	66,7	48,99	9,7
Follow Up Month 12	Low (0-1)	123	96,1	100	81,3	51,16	6,64	116	92,8	87	75	49,68	9,8

Maintenance or Observation Completion/Early Termina	Low (0-1)	103	80,5	82	79,6	51,1	8,12	103	82,4	79	76,7	50,2	9,17
FC Gamma Receptor IIa													
Baseline	Missing	28	100	21	75	43,24	11,24	30	100	25	83,3	45,87	8,1
Cycle 3 Day 1	Missing	23	82,1	19	82,6	47	6,64	28	93,3	21	75	48,67	6,65
Induction Completion/Early Termination	Missing	24	85,7	19	79,2	46,58	6,89	27	90	14	51,9	53	6,76
Follow Up Month 2	Missing	22	78,6	14	63,6	50,79	7,33	27	90	17	63	51,68	5,69
Follow Up Month 12	Missing	21	75	13	61,9	51	5,54	25	83,3	14	56	50,13	8,43
Maintenance or Observation Completion/Early Termina	Missing	19	67,9	14	73,7	51,43	5,27	19	63,3	12	63,2	52,27	7,07
Baseline	131HH	182	100	177	97,3	46,16	9,46	184	100	173	94	44,12	9,29
Cycle 3 Day 1	131HH	178	97,8	161	90,4	48,37	7,76	184	100	174	94,6	46,77	8,38
Induction Completion/Early Termination	131HH	178	97,8	157	88,2	49,45	7,36	183	99,5	165	90,2	47,63	9,49
Follow Up Month 2	131HH	177	97,3	132	74,6	50,13	7,57	183	99,5	124	67,8	49,56	8,3
Follow Up Month 12	131HH	173	95,1	134	77,5	50,6	7,45	178	96,7	128	71,9	50,27	8,39
Maintenance or Observation Completion/Early Termina	131HH	152	83,5	123	80,9	50,72	8,57	159	86,4	124	78	50,22	7,2
Baseline	131HR	277	100	259	93,5	44,99	9,28	270	100	248	91,9	44,89	9,81
Cycle 3 Day 1	131HR	276	99,6	237	85,9	48,01	7,27	270	100	238	88,1	47,08	8,27
Induction Completion/Early Termination	131HR	274	98,9	232	84,7	47,98	8,58	266	98,5	227	85,3	47,77	9,04
Follow Up Month 2	131HR	271	97,8	187	69	49,59	8,03	265	98,1	165	62,3	49,29	8,4
Follow Up Month 12	131HR	263	94,9	197	74,9	49,91	7,41	250	92,6	173	69,2	50,59	7,9
Maintenance or Observation Completion/Early Termina	131HR	230	83	182	79,1	49,2	8,79	218	80,7	166	76,1	50,02	8,87
Baseline	131RR	114	100	106	93	46,29	8,56	117	100	110	94	46,49	8,65
Cycle 3 Day 1	131RR	113	99,1	91	80,5	47,93	7,36	116	99,1	99	85,3	47,99	8,77
Induction Completion/Early Termination	131RR	112	98,2	88	78,6	49,7	7,31	113	96,6	94	83,2	49,38	8,77
Follow Up Month 2	131RR	112	98,2	73	65,2	50,06	6,54	112	95,7	69	61,6	50,94	8,33
Follow Up Month 12	131RR	110	96,5	79	71,8	50,91	6,9	106	90,6	70	66	50,69	8,68
Maintenance or Observation Completion/Early Termina	131RR	93	81,6	69	74,2	50,07	6,95	91	77,8	71	78	48,87	11,02
FC Gamma Receptor IIIa													
Baseline	Missing	28	100	21	75	43,24	11,24	30	100	25	83,3	45,87	8,1
Cycle 3 Day 1	Missing	23	82,1	19	82,6	47	6,64	28	93,3	21	75	48,67	6,65
Induction Completion/Early Termination	Missing	24	85,7	19	79,2	46,58	6,89	27	90	14	51,9	53	6,76
Follow Up Month 2	Missing	22	78,6	14	63,6	50,79	7,33	27	90	17	63	51,68	5,69
Follow Up Month 12	Missing	21	75	13	61,9	51	5,54	25	83,3	14	56	50,13	8,43
Maintenance or Observation Completion/Early Termina	Missing	19	67,9	14	73,7	51,43	5,27	19	63,3	12	63,2	52,27	7,07
Baseline	158FF	223	100	211	94,6	45,52	9,03	256	100	237	92,6	45,77	9,2
Cycle 3 Day 1	158FF	221	99,1	191	86,4	48,15	7,03	256	100	226	88,3	47,96	8,16
Induction Completion/Early Termination	158FF	218	97,8	184	84,4	48,18	8,69	253	98,8	219	86,6	49,46	8,3
Follow Up Month 2	158FF	217	97,3	150	69,1	49,19	7,94	252	98,4	172	68,3	50,28	8,41
Follow Up Month 12	158FF	211	94,6	158	74,9	50,29	7,43	241	94,1	168	69,7	50,89	8,57
Maintenance or Observation Completion/Early Termina	158FF	173	77,6	133	76,9	49,63	8,7	205	80,1	163	79,5	50,58	9,14
Baseline	158VF	283	100	264	93,3	45,92	9,21	238	100	225	94,5	44,27	9,6
Cycle 3 Day 1	158VF	281	99,3	240	85,4	47,94	7,79	237	99,6	213	89,9	46,61	8,48
Induction Completion/Early Termination	158VF	281	99,3	236	84	49,39	7,48	233	97,9	200	85,8	47,52	8,74
Follow Up Month 2	158VF	279	98,6	193	69,2	50,63	7,2	232	97,5	143	61,6	48,9	8,47
Follow Up Month 12	158VF	272	96,1	204	75	50,84	6,93	220	92,4	155	70,5	50,64	7,54
Maintenance or Observation Completion/Early Termina	158VF	245	86,6	193	78,8	50,09	8,23	195	81,9	147	75,4	49,45	8,87
Baseline	158VV	67	100	67	100	44,81	9,82	77	100	69	89,6	44,5	9,62
Cycle 3 Day 1	158VV	65	97	58	89,2	48,74	7,28	77	100	72	93,5	46,22	8,81

Induction Completion/Early Termination	158VV	65	97	57	87,7	48,21	7,64	76	98,7	67	88,2	44,92	11,85
Follow Up Month 2	158VV	64	95,5	49	76,6	48,87	7,95	76	98,7	43	56,6	50,06	7,63
Follow Up Month 12	158VV	63	94	48	76,2	48,3	8,38	73	94,8	48	65,8	48,69	8,84
Maintenance or Observation Completion/Early Termina	158VV	57	85,1	48	84,2	49,6	8,48	68	88,3	51	75	48,75	7,44
FC Gamma Receptor IIb/IIc													
Baseline	Missing	71	100	60	84,5	44,94	10,87	69	100	63	91,3	46,51	8,54
Cycle 3 Day 1	Missing	64	90,1	55	85,9	47,85	6,51	67	97,1	55	82,1	48,77	8,07
Induction Completion/Early Termination	Missing	65	91,5	54	83,1	47,98	6,37	65	94,2	48	73,8	50,24	9,84
Follow Up Month 2	Missing	63	88,7	39	61,9	50,28	6,66	65	94,2	35	53,8	51,96	7,02
Follow Up Month 12	Missing	61	85,9	44	72,1	50,7	6,35	61	88,4	37	60,7	51	8,39
Maintenance or Observation Completion/Early Termina	Missing	53	74,6	43	81,1	50,63	6,26	48	69,6	37	77,1	51,44	9,83
Baseline	232II	417	100	394	94,5	45,48	8,97	406	100	378	93,1	45,12	8,97
Cycle 3 Day 1	232II	415	99,5	358	86,3	48,09	7,54	406	100	368	90,6	47,09	8,26
Induction Completion/Early Termination	232II	413	99	342	82,8	48,89	8,14	402	99	350	87,1	48,17	9,07
Follow Up Month 2	232II	410	98,3	288	70,2	49,81	7,62	400	98,5	263	65,8	49,86	8,35
Follow Up Month 12	232II	397	95,2	295	74,3	50,49	7,2	380	93,6	264	69,5	50,86	7,77
Maintenance or Observation Completion/Early Termina	232II	343	82,3	271	79	49,69	8,8	335	82,5	253	75,5	49,83	8,6
Baseline	232IT	104	100	100	96,2	46,5	9,67	116	100	105	90,5	44,61	10,24
Cycle 3 Day 1	232IT	102	98,1	87	85,3	48,13	7,61	115	99,1	100	87	47,19	8,47
Induction Completion/Early Termination	232IT	101	97,1	91	90,1	48,48	8,09	112	96,6	94	83,9	47,35	8,67
Follow Up Month 2	232IT	101	97,1	74	73,3	49,92	7,96	112	96,6	70	62,5	48,37	8,41
Follow Up Month 12	232IT	101	97,1	79	78,2	49,74	8,06	108	93,1	76	70,4	49,27	9,3
Maintenance or Observation Completion/Early Termina	232IT	90	86,5	70	77,8	50,35	7,69	95	81,9	74	77,9	49,83	8,48
Baseline	232TT	9	100	9	100	41,22	6,7	10	100	10	100	35,5	14,58
Cycle 3 Day 1	232TT	9	100	8	88,9	48,38	5,9	10	100	9	90	43	11,03
Induction Completion/Early Termination	232TT	9	100	9	100	47,67	8,93	10	100	8	80	45,75	11,8
Follow Up Month 2	232TT	8	88,9	5	62,5	51,2	9,36	10	100	7	70	50,71	7,78
Follow Up Month 12	232TT	8	88,9	5	62,5	48,8	7,66	10	100	8	80	47,38	9,84
Maintenance or Observation Completion/Early Termina	232TT	8	88,9	4	50	50,25	5,5	9	90	9	100	47,92	11,54
Time from initial FL diagnosis to randomization													
Baseline	Missing	3	100	2	66,7	43	7,07	0	NE	0	NE	NE	NE
Cycle 3 Day 1	Missing	3	100	3	100	47,33	7,64	0	NE	0	NE	NE	NE
Induction Completion/Early Termination	Missing	3	100	2	66,7	54	8,49	0	NE	0	NE	NE	NE
Follow Up Month 2	Missing	3	100	1	33,3	48	NE	0	NE	0	NE	NE	NE
Follow Up Month 12	Missing	2	66,7	2	100	54	8,49	0	NE	0	NE	NE	NE
Maintenance or Observation Completion/Early Termina	Missing	2	66,7	2	100	50	11,31	0	NE	0	NE	NE	NE
Baseline	6-12 months	35	100	33	94,3	47,42	7,72	32	100	29	90,6	41,71	11,68
Cycle 3 Day 1	6-12 months	35	100	31	88,6	48,32	6	32	100	28	87,5	45,04	10,18
Induction Completion/Early Termination	6-12 months	35	100	31	88,6	50,03	6,77	31	96,9	28	90,3	47,42	9,98
Follow Up Month 2	6-12 months	35	100	25	71,4	51,39	5,63	31	96,9	24	77,4	46,88	9,87
Follow Up Month 12	6-12 months	35	100	28	80	51,75	5,05	30	93,8	21	70	50,14	8,58
Maintenance or Observation Completion/Early Termina	6-12 months	29	82,9	19	65,5	52,68	4,42	28	87,5	23	82,1	50,74	7,76
Baseline	< 6 months	490	100	460	93,9	45,31	9,41	474	100	442	93,2	44,96	9,54
Cycle 3 Day 1	< 6 months	481	98,2	416	86,5	47,83	7,56	471	99,4	419	89	47,18	8,56
Induction Completion/Early Termination	< 6 months	479	97,8	403	84,1	48,44	8,05	464	97,9	395	85,1	47,98	9,46
Follow Up Month 2	< 6 months	475	96,9	337	70,9	49,87	7,71	462	97,5	290	62,8	49,82	8,39
Follow Up Month 12	< 6 months	464	94,7	346	74,6	50,08	7,54	441	93	307	69,6	50,25	8,51
Maintenance or Observation Completion/Early Termina	< 6 months	404	82,4	320	79,2	49,77	8,37	385	81,2	296	76,9	49,89	8,85

Baseline	> 12 months	73	100	68	93,2	46,25	9,28	95	100	85	89,5	46,41	7,18
Cycle 3 Day 1	> 12 months	71	97,3	58	81,7	49,71	6,91	95	100	85	89,5	48,09	6,26
Induction Completion/Early Termination	> 12 months	71	97,3	60	84,5	49,52	7,88	94	98,9	77	81,9	49,45	6,75
Follow Up Month 2	> 12 months	69	94,5	43	62,3	49,29	7,75	94	98,9	61	64,9	50,8	6,61
Follow Up Month 12	> 12 months	66	90,4	47	71,2	51,37	6,26	88	92,6	57	64,8	51,86	6,03
Maintenance or Observation Completion/Early Termina	> 12 months	59	80,8	47	79,7	49,84	9,09	74	77,9	54	73	49,85	8,85
Ann Arbor Stage 2													
Baseline	Missing	3	100	3	100	33	20,42	4	100	4	100	49,13	9,47
Cycle 3 Day 1	Missing	3	100	2	66,7	45	0	4	100	4	100	48,5	7,23
Induction Completion/Early Termination	Missing	3	100	3	100	57	2,65	4	100	4	100	46,75	8,85
Follow Up Month 2	Missing	3	100	1	33,3	52	NE	4	100	2	50	37	12,73
Follow Up Month 12	Missing	3	100	2	66,7	55,5	4,95	4	100	3	75	49	8
Maintenance or Observation Completion/Early Termina	Missing	3	100	2	66,7	43	21,21	4	100	3	75	54	2,65
Baseline	Stage I	10	100	10	100	47,1	6,81	8	100	6	75	42,17	12,37
Cycle 3 Day 1	Stage I	10	100	8	80	50,63	3,96	8	100	7	87,5	48,96	5,67
Induction Completion/Early Termination	Stage I	10	100	9	90	49,89	4,4	8	100	5	62,5	49,6	4,34
Follow Up Month 2	Stage I	10	100	7	70	49,14	6,82	8	100	7	87,5	52,29	3,77
Follow Up Month 12	Stage I	10	100	9	90	52,67	3,61	8	100	5	62,5	53,53	5,48
Maintenance or Observation Completion/Early Termina	Stage I	8	80	6	75	52,5	4,59	7	87,5	4	57,1	50,5	8,58
Baseline	Stage II (w/o bulky disease)	14	100	12	85,7	47,58	9,3	14	100	12	85,7	47,42	6,17
Cycle 3 Day 1	Stage II (w/o bulky disease)	14	100	8	57,1	49	6,35	14	100	12	85,7	48,42	6,61
Induction Completion/Early Termination	Stage II (w/o bulky disease)	14	100	9	64,3	46,7	12,2	14	100	11	78,6	47,77	9,45
Follow Up Month 2	Stage II (w/o bulky disease)	14	100	6	42,9	52,33	9,54	14	100	4	28,6	44,7	10,95
Follow Up Month 12	Stage II (w/o bulky disease)	13	92,9	7	53,8	49,29	4,96	14	100	7	50	51,57	6,68
Maintenance or Observation Completion/Early Termina	Stage II (w/o bulky disease)	11	78,6	7	63,6	51,14	7,13	12	85,7	10	83,3	46,8	8,35
Baseline	Stage II (with bulky disease	27	100	25	92,6	47,44	8,08	30	100	30	100	45,59	9,29
Cycle 3 Day 1	Stage II (with bulky disease	27	100	24	88,9	49,88	4,71	30	100	24	80	47,61	8,96
Induction Completion/Early Termination	Stage II (with bulky disease	27	100	22	81,5	51,5	6,11	29	96,7	23	79,3	46,65	9,67
Follow Up Month 2	Stage II (with bulky disease	27	100	20	74,1	52,2	5,02	29	96,7	18	62,1	48,39	9,11
Follow Up Month 12	Stage II (with bulky disease	27	100	23	85,2	53,1	4,48	26	86,7	17	65,4	50,65	8,71
Maintenance or Observation Completion/Early Termina	Stage II (with bulky disease	20	74,1	16	80	53,56	6,1	22	73,3	17	77,3	49,87	8,43
Baseline	Stage III	208	100	195	93,8	45,66	9,21	209	100	193	92,3	45,22	8,76
Cycle 3 Day 1	Stage III	204	98,1	176	86,3	47,68	7,92	208	99,5	187	89,9	47,18	7,79
Induction Completion/Early Termination	Stage III	202	97,1	171	84,7	48,66	8,19	206	98,6	175	85	47,92	9,75
Follow Up Month 2	Stage III	199	95,7	136	68,3	49,31	8,53	206	98,6	138	67	49,58	7,81
Follow Up Month 12	Stage III	194	93,3	144	74,2	50,23	7,73	191	91,4	140	73,3	50,42	8,42
Maintenance or Observation Completion/Early Termina	Stage III	170	81,7	132	77,6	49,12	8,79	162	77,5	127	78,4	50,08	8,73
Baseline	Stage IV	339	100	318	93,8	45,3	9,33	336	100	311	92,6	44,74	9,81
Cycle 3 Day 1	Stage IV	332	97,9	290	87,3	48,09	7,38	334	99,4	298	89,2	47,09	8,78
Induction Completion/Early Termination	Stage IV	332	97,9	282	84,9	48,44	7,86	328	97,6	282	86	48,46	8,78
Follow Up Month 2	Stage IV	329	97,1	236	71,7	49,99	7,17	326	97	206	63,2	50,2	8,42
Follow Up Month 12	Stage IV	320	94,4	238	74,4	50,06	7,34	316	94	213	67,4	50,43	8,17
Maintenance or Observation Completion/Early Termina	Stage IV	282	83,2	225	79,8	50,09	8,13	280	83,3	212	75,7	49,94	8,93

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

cut-off: 31JAN2016

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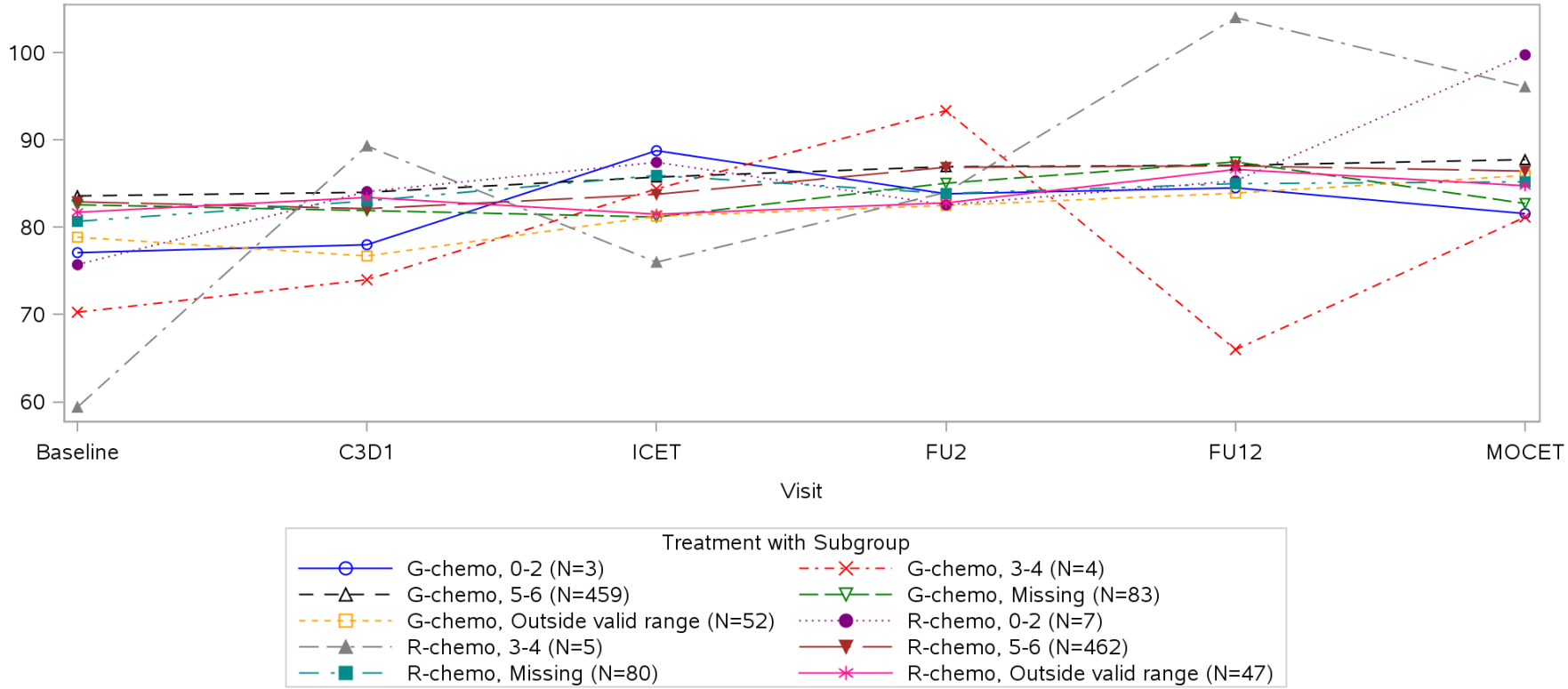
POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Independence status (Katz ADL) (N=1202) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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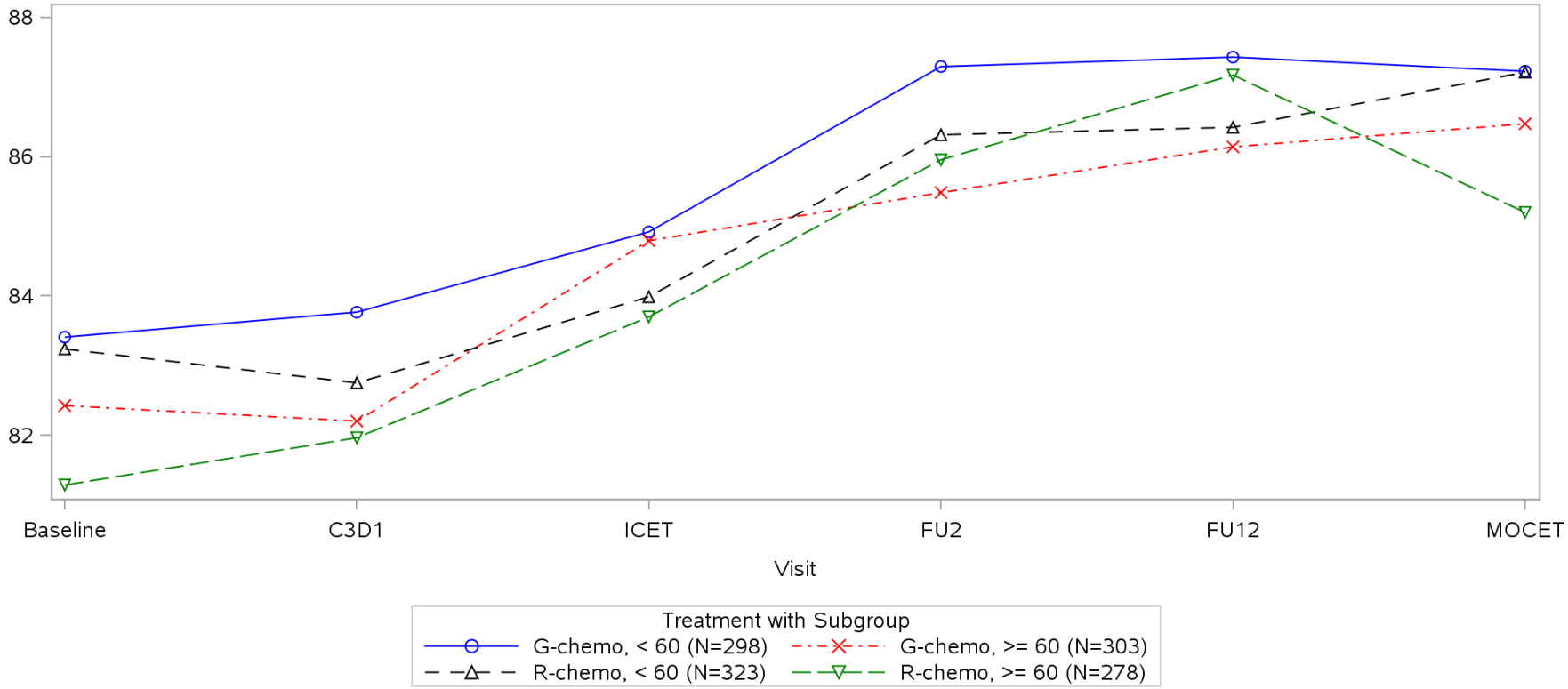
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Age (N=1202) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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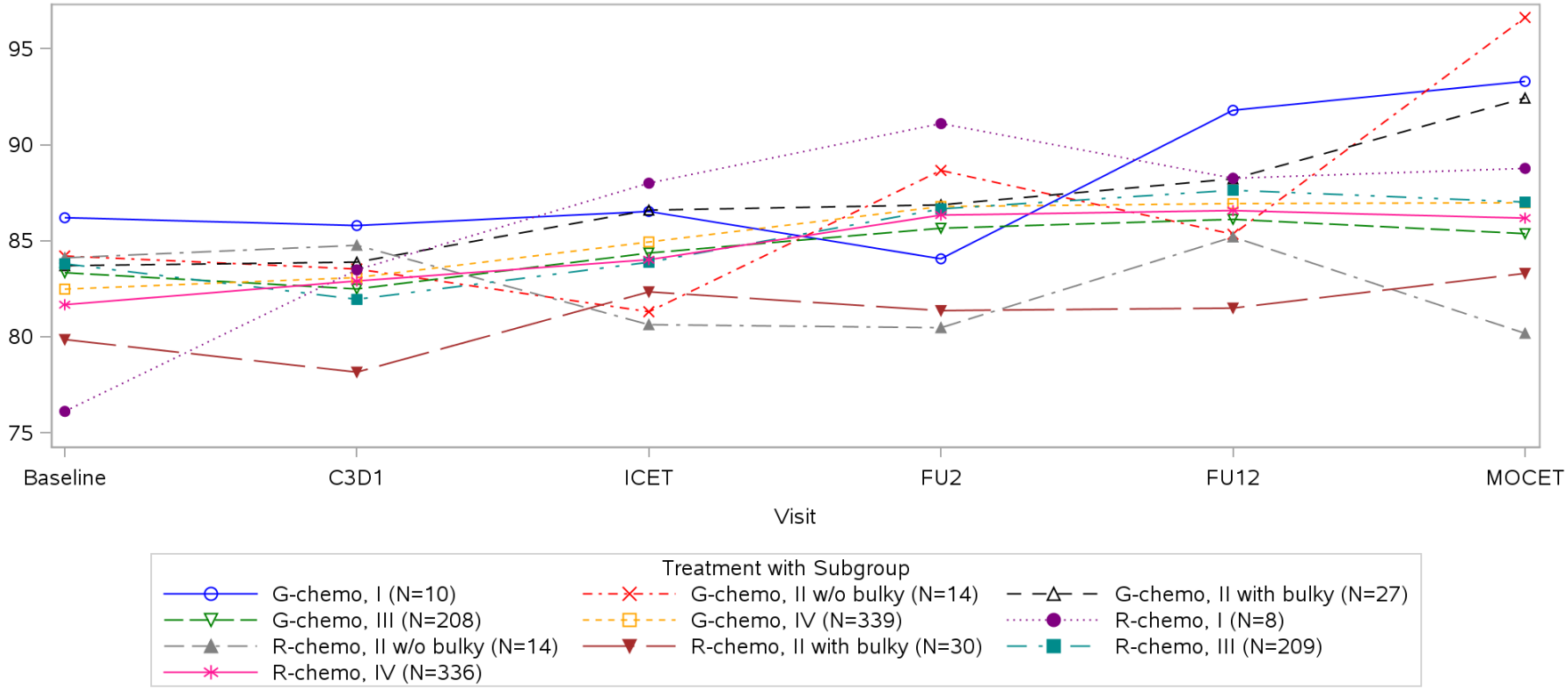
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Ann Arbor Stage 2 (N=1195) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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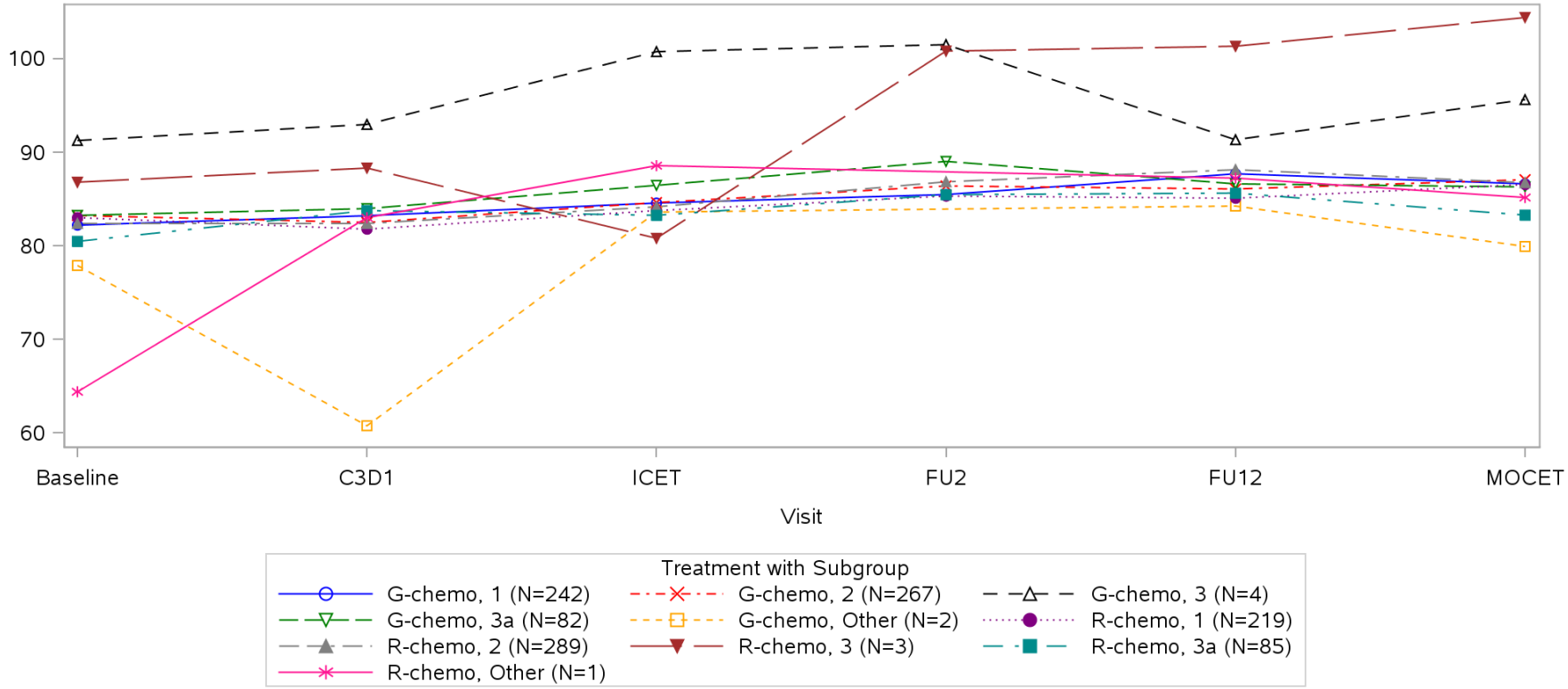
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Histologic grade (N=1194) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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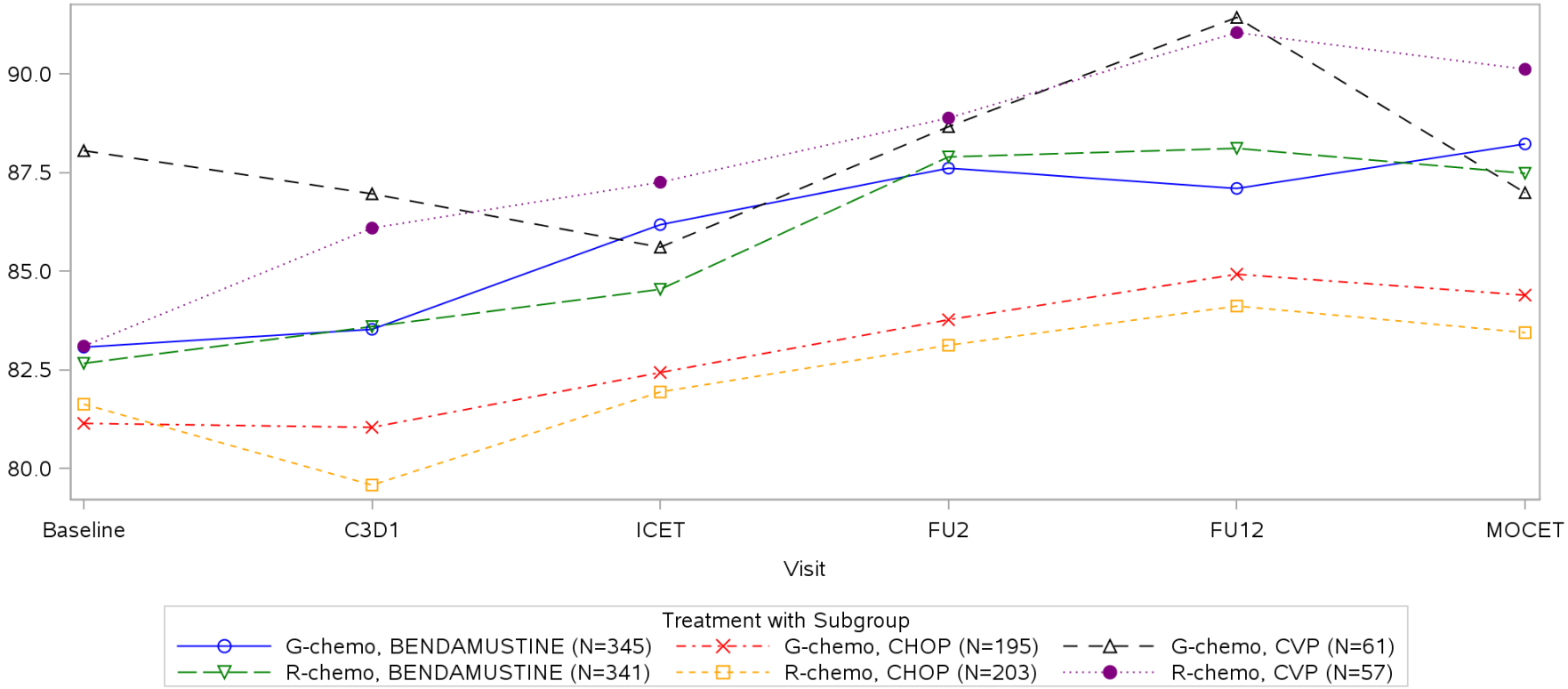
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Chemotherapy regimen (N=1202) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
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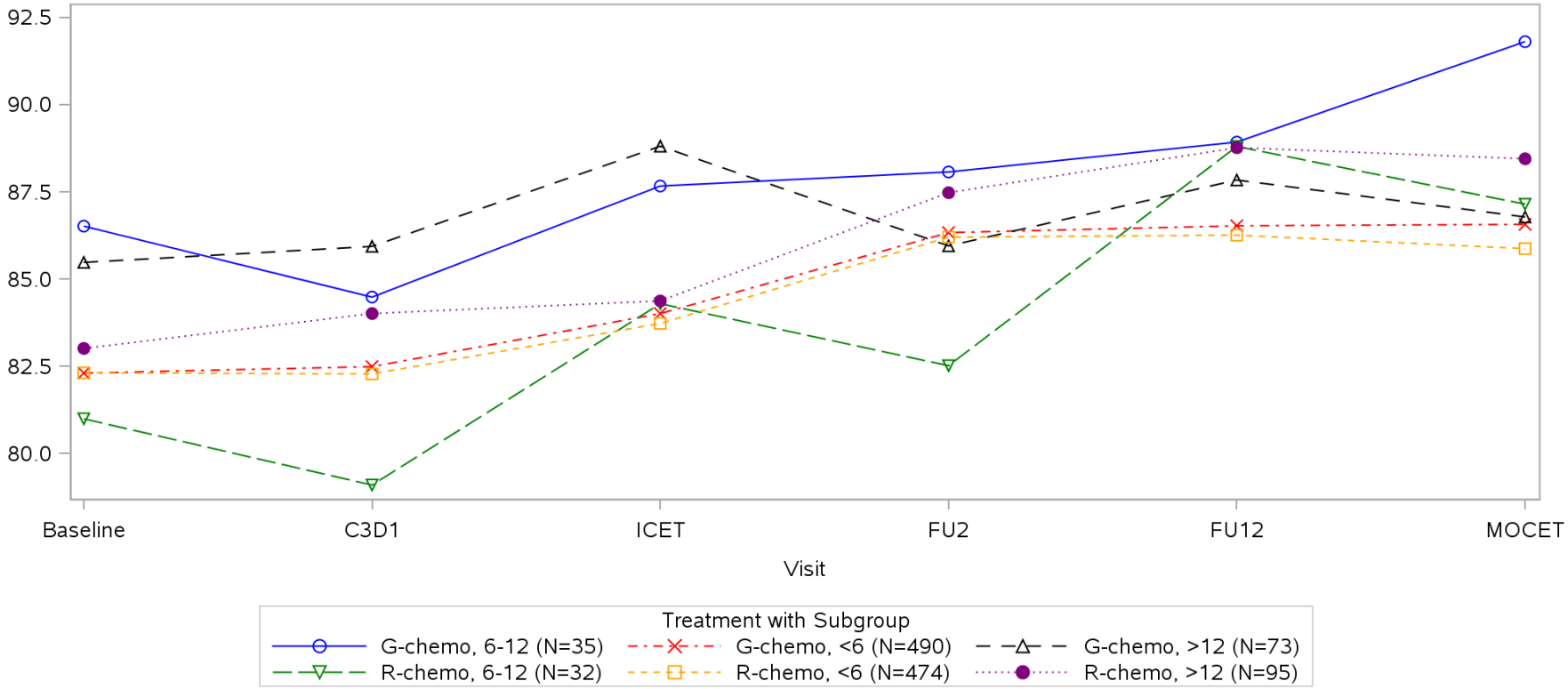
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Time from initial NHL diagnosis to randomization (N=1199) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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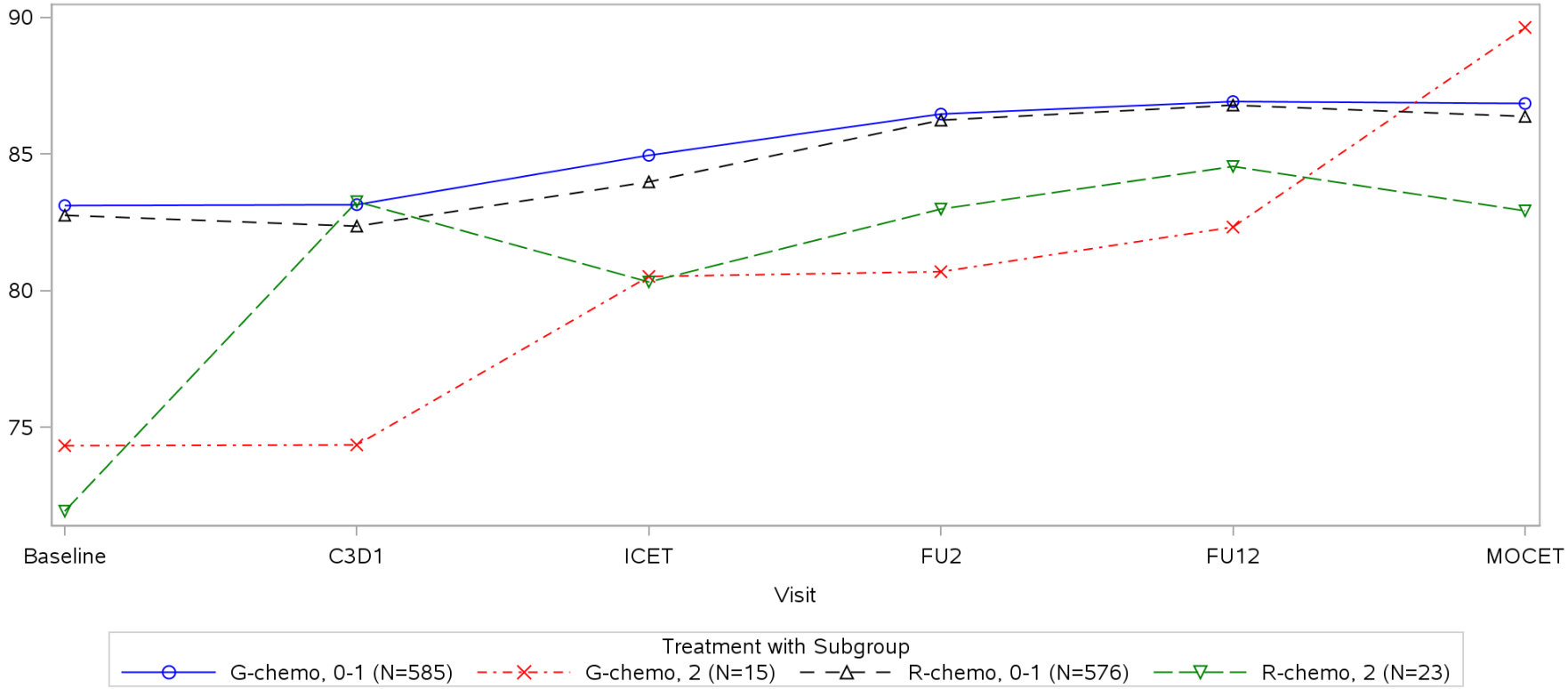
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Baseline ECOG Performance Status score (N=1199) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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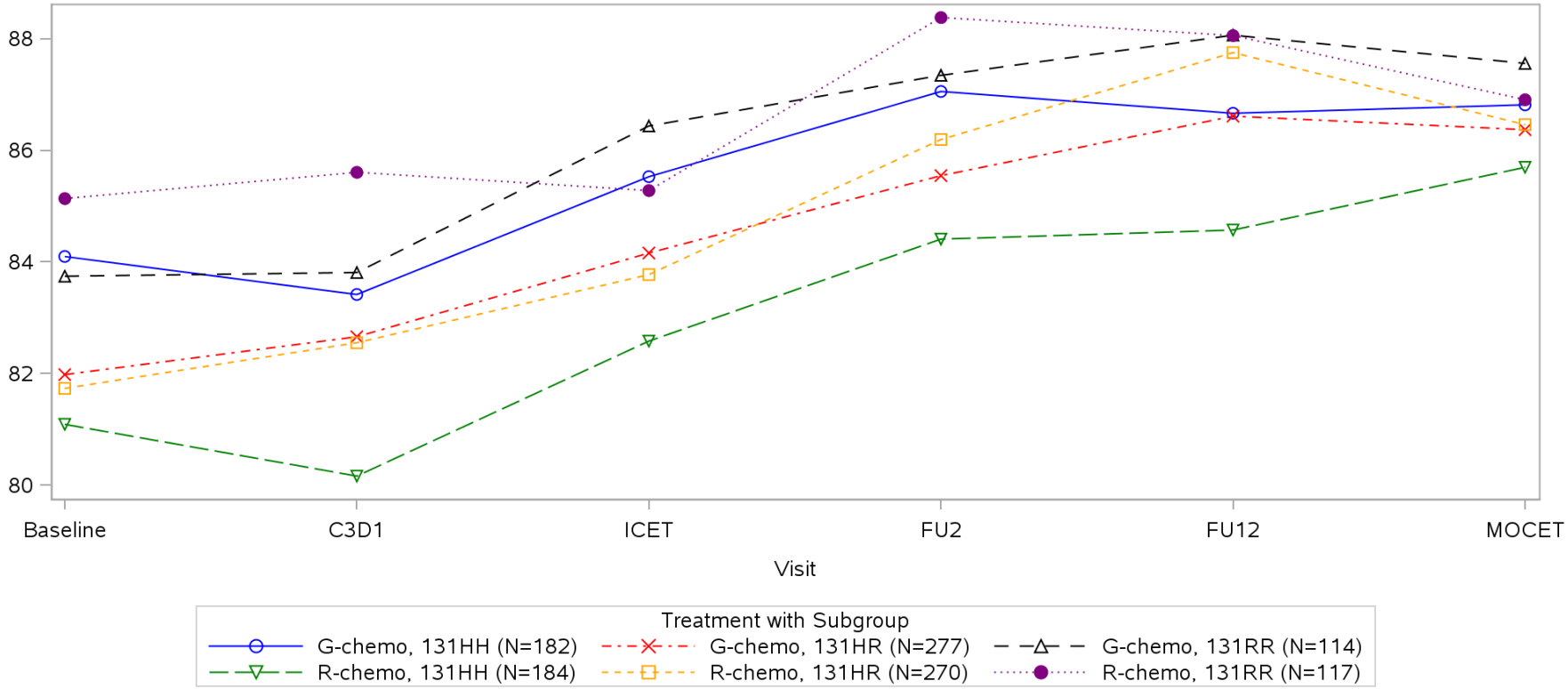
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Fc gamma receptor IIa (N=1144) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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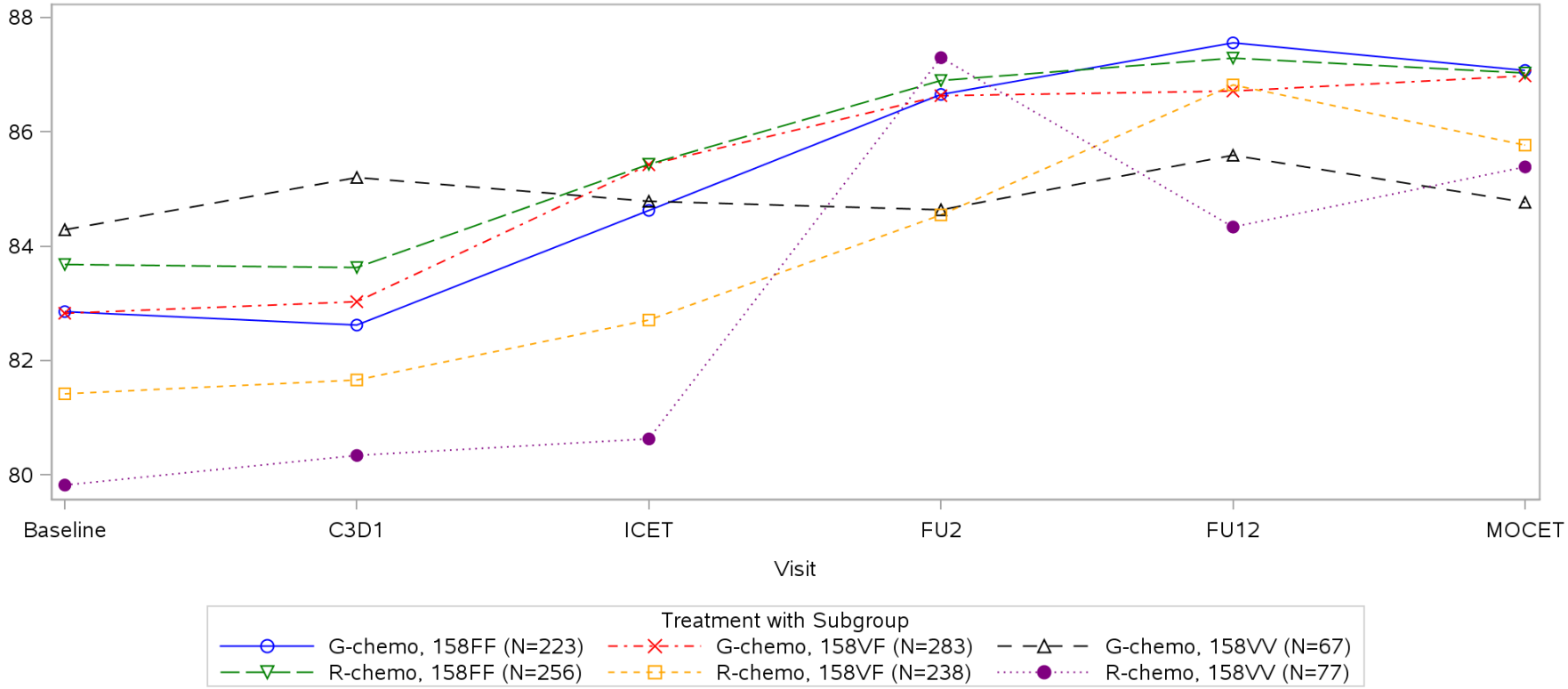
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Fc gamma receptor IIIa (N=1144) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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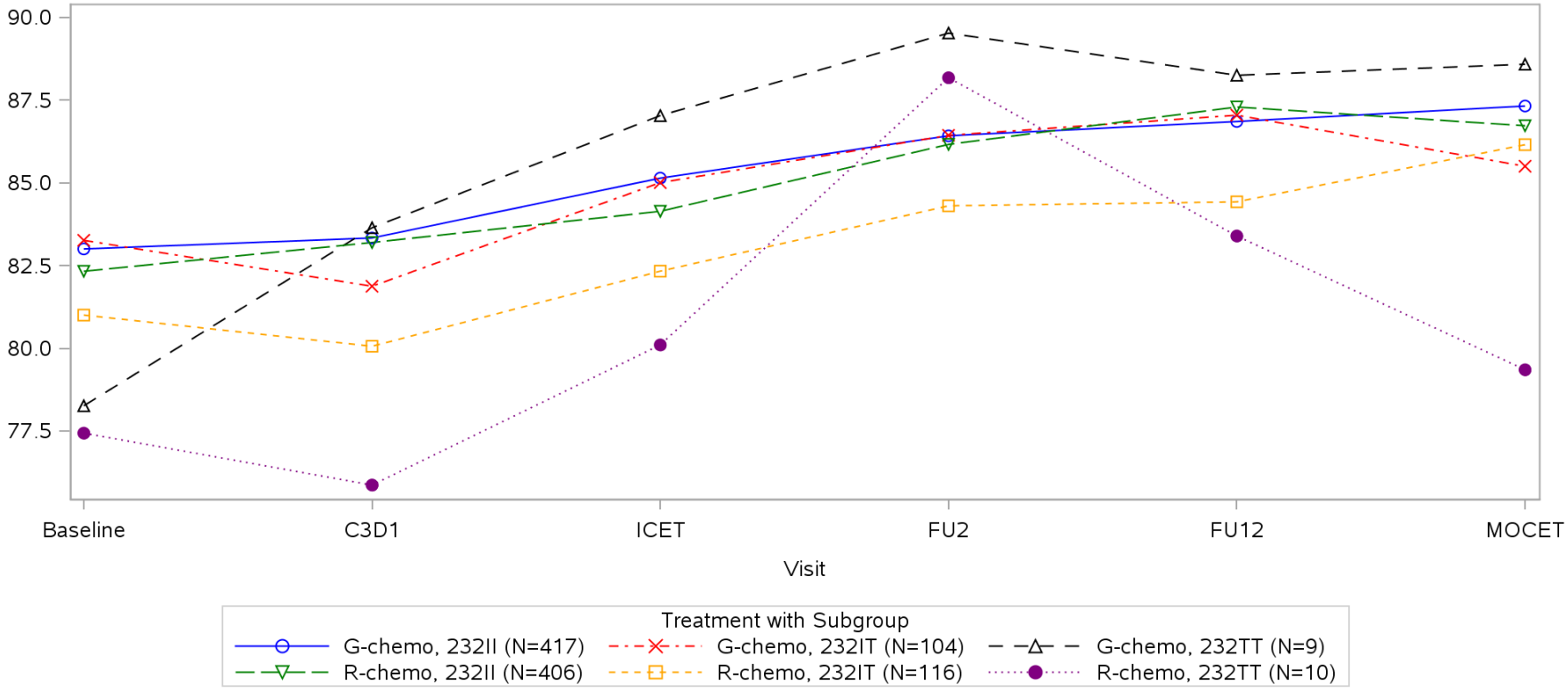
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Fc gamma receptor IIb/IIc (N=1062) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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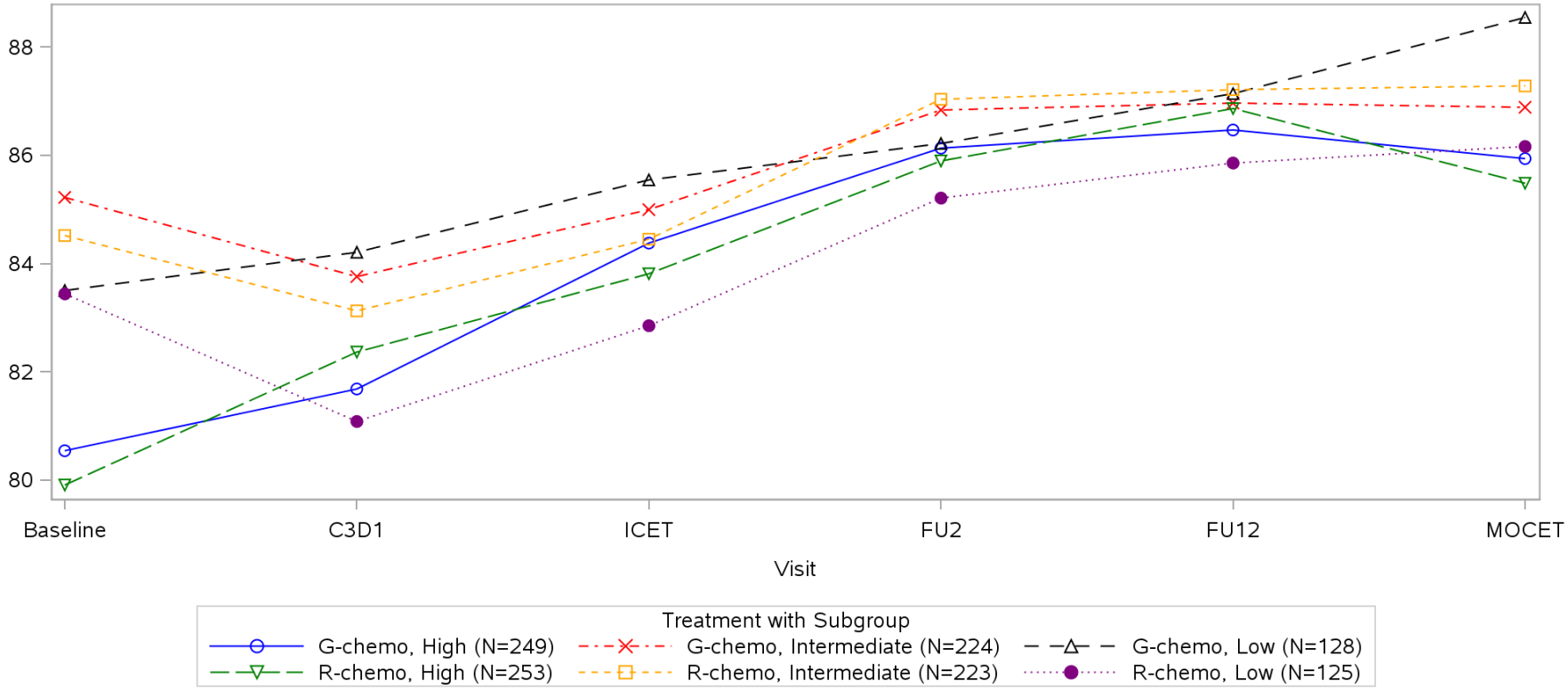
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

FLIPI (N=1202) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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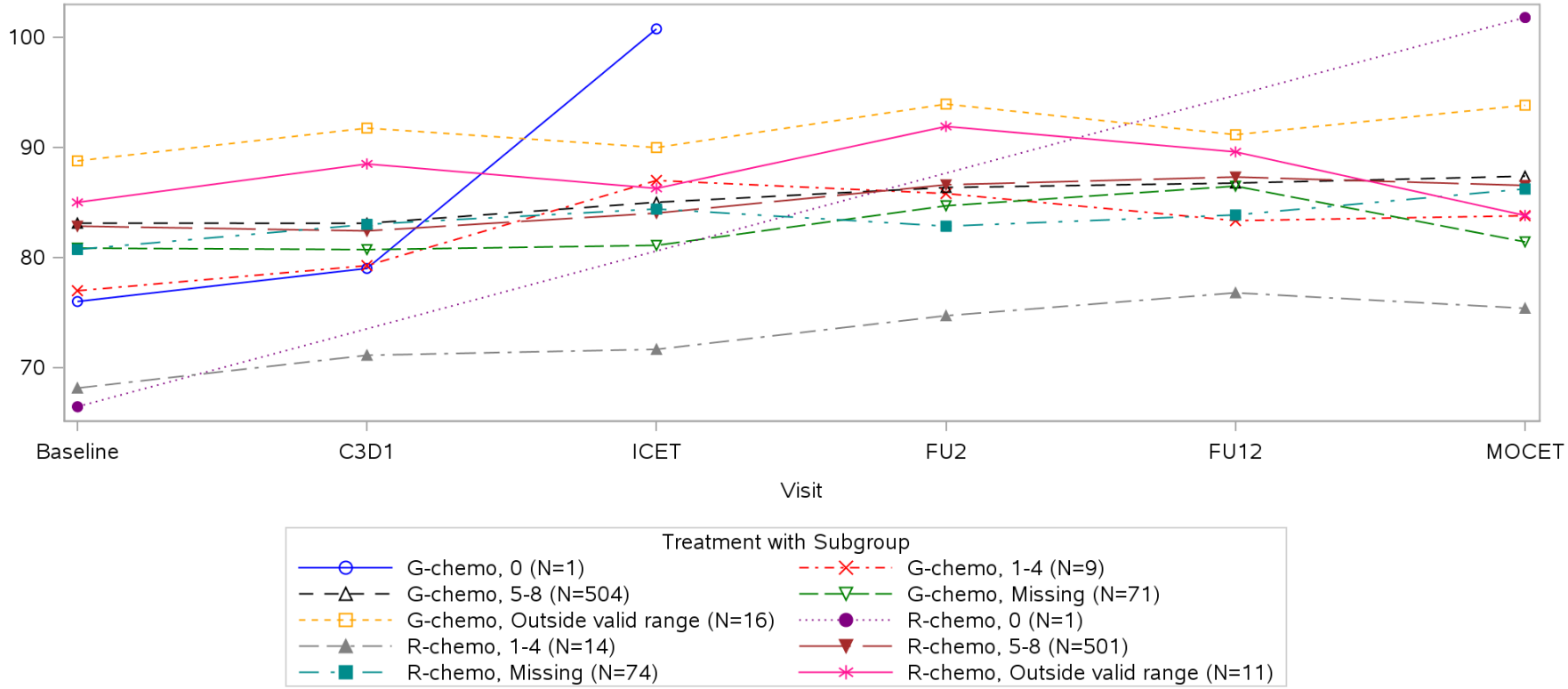
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Independence status (Katz IADL) (N=1202) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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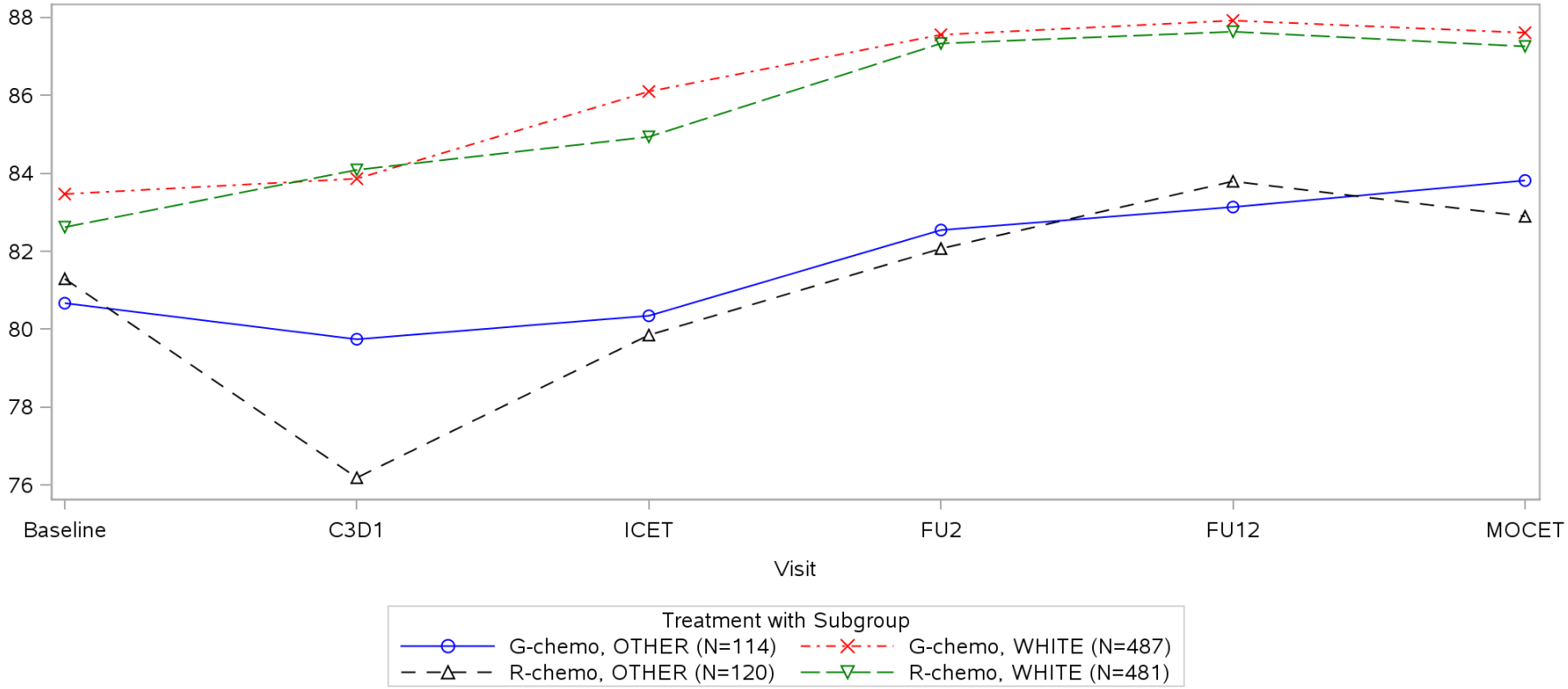
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Race/ethnicity (N=1202) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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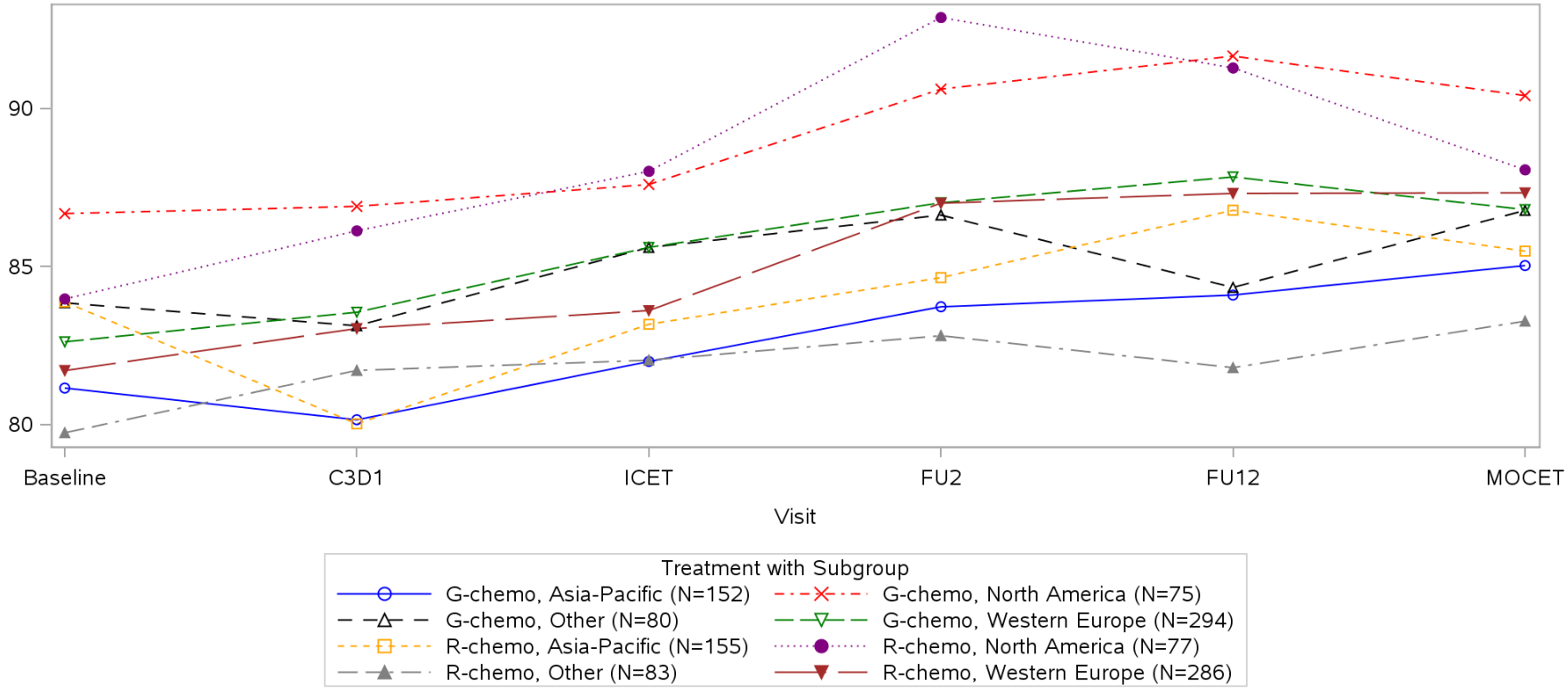
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Geographic region (N=1202) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
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Clinical cut-off: 31JAN2016

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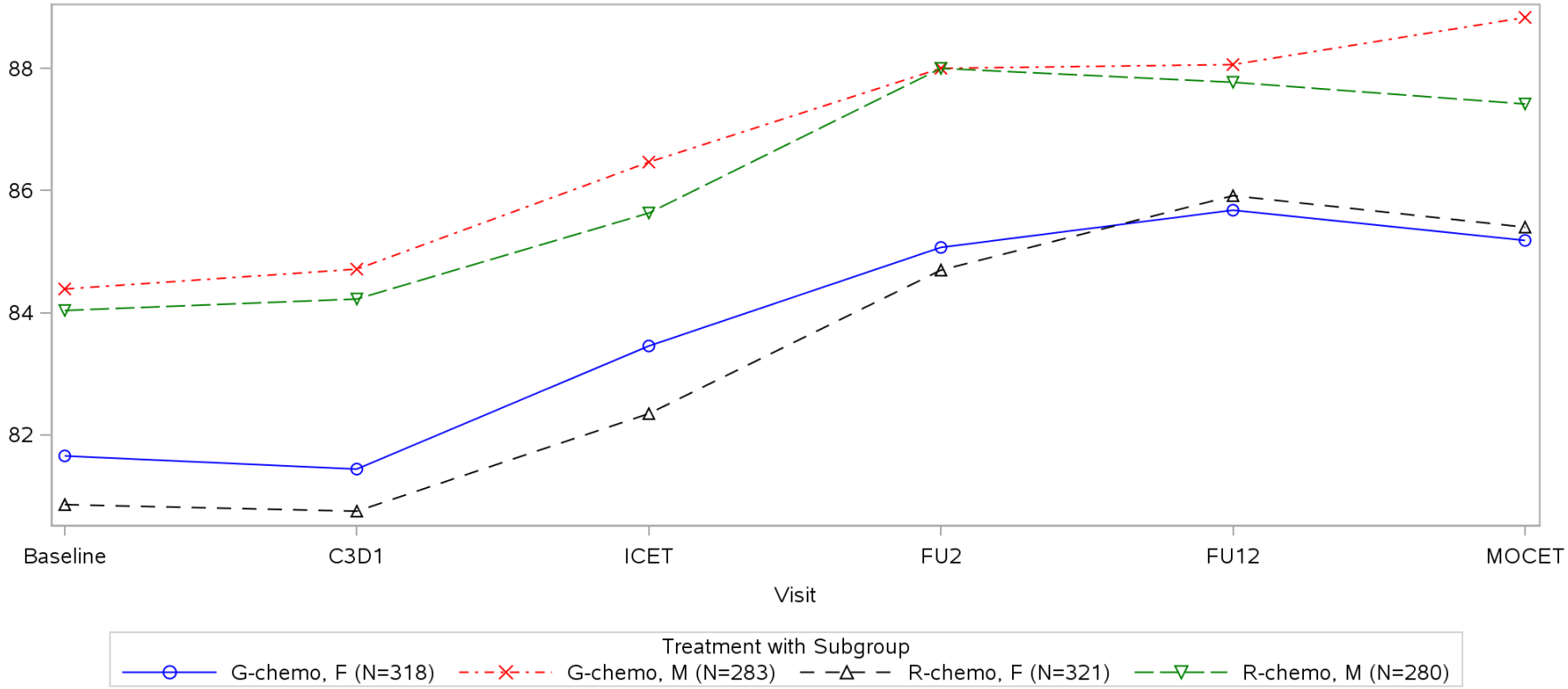
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Sex (N=1202) Laboratory Test: FACT-G Total



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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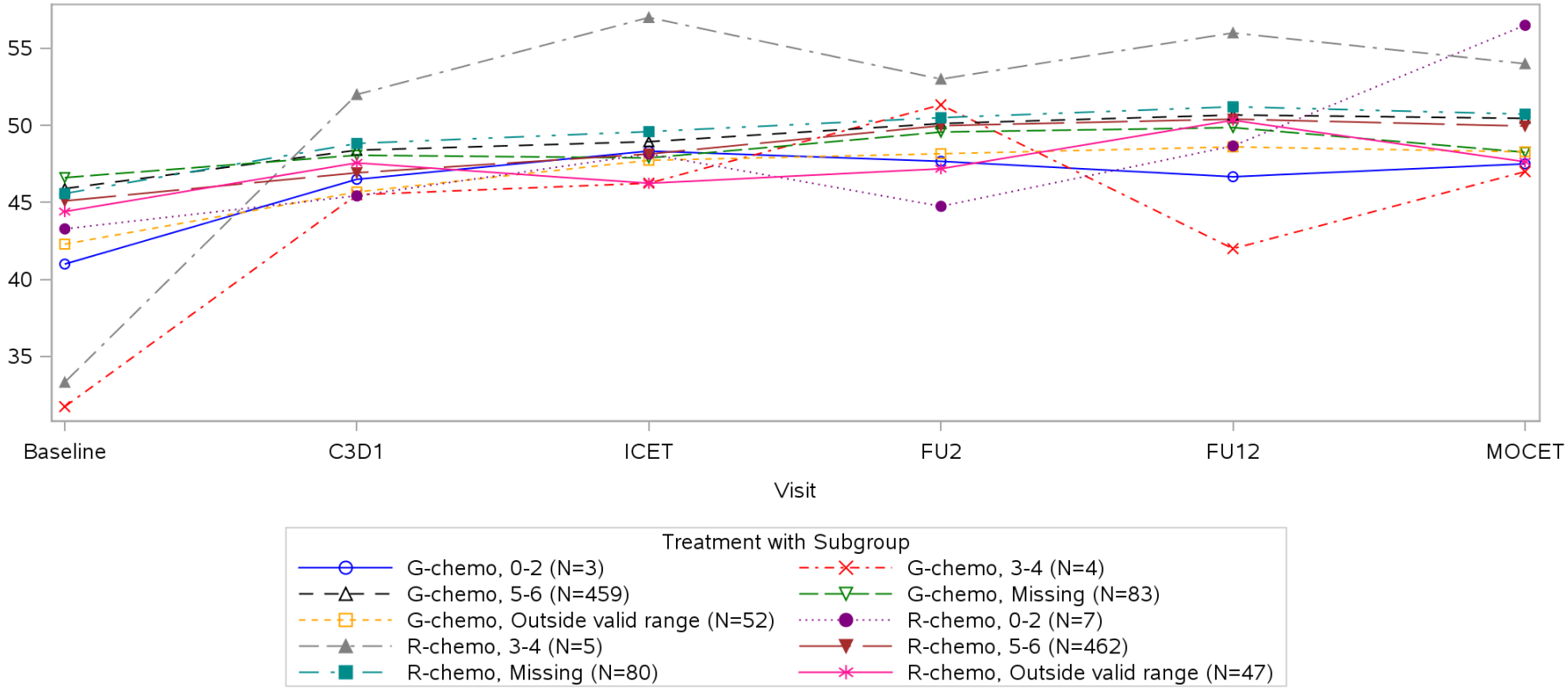
25OCT2019 12:42

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Independence status (Katz ADL) (N=1202) Laboratory Test: FACT-LYM Subscale



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Clinical cut-off: 31JAN2016

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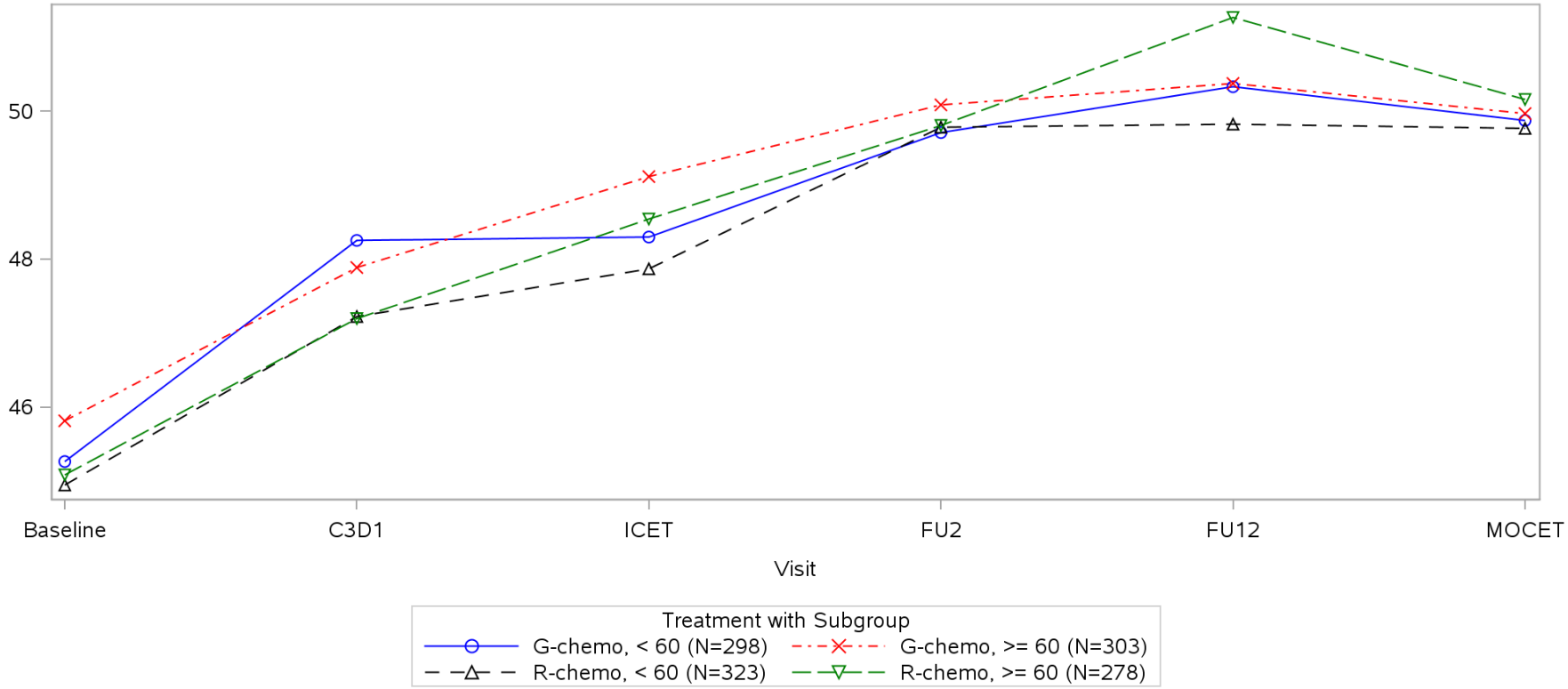
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Age (N=1202) Laboratory Test: FACT-LYM Subscale



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MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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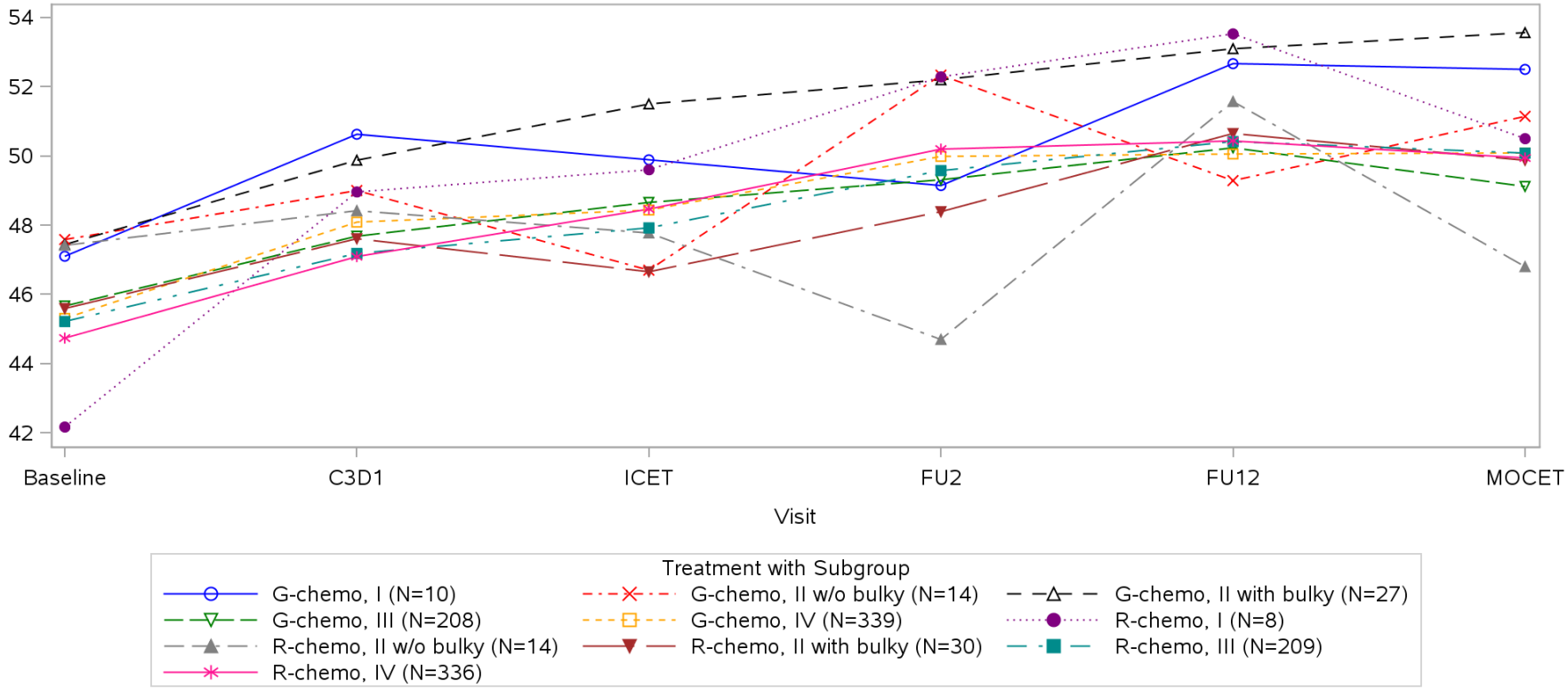
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Ann Arbor Stage 2 (N=1195) Laboratory Test: FACT-LYM Subscale



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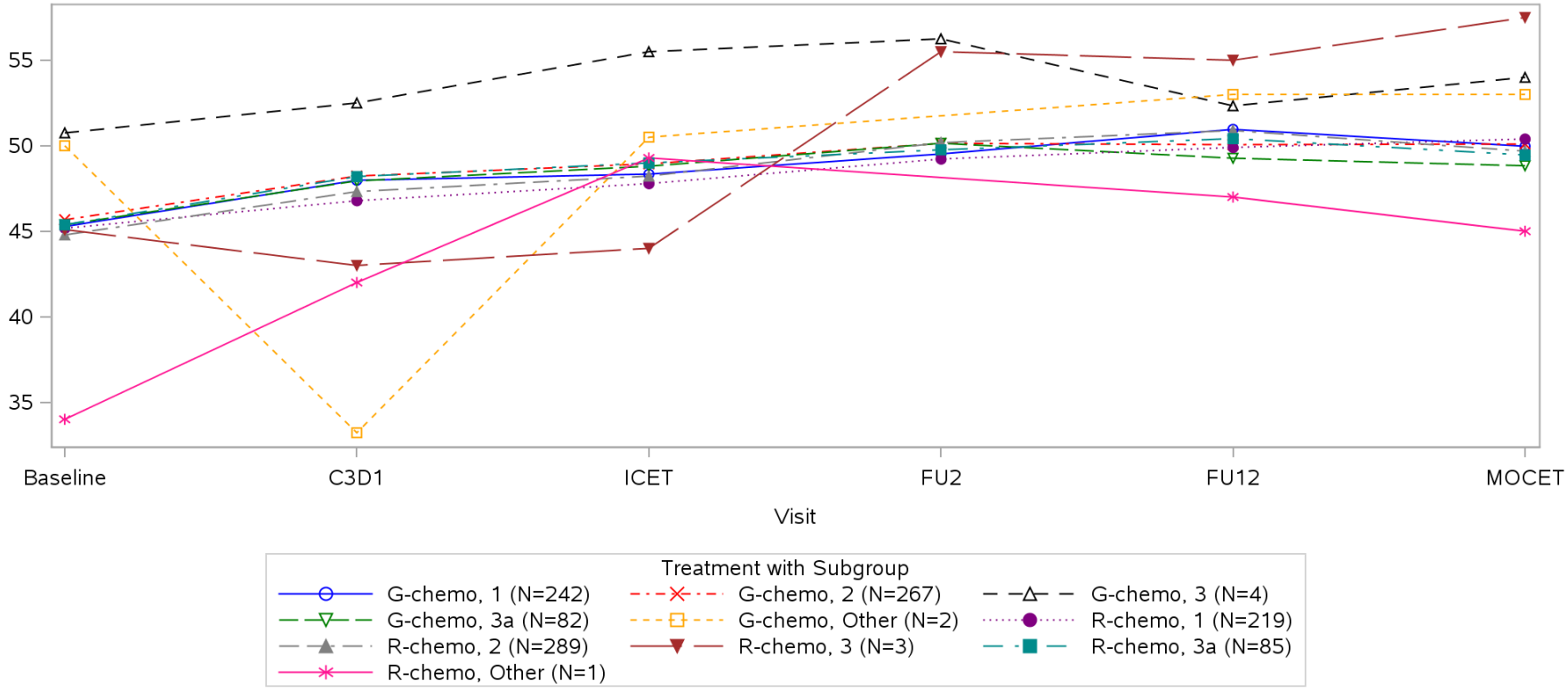
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Histologic grade (N=1194) Laboratory Test: FACT-LYM Subscale



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

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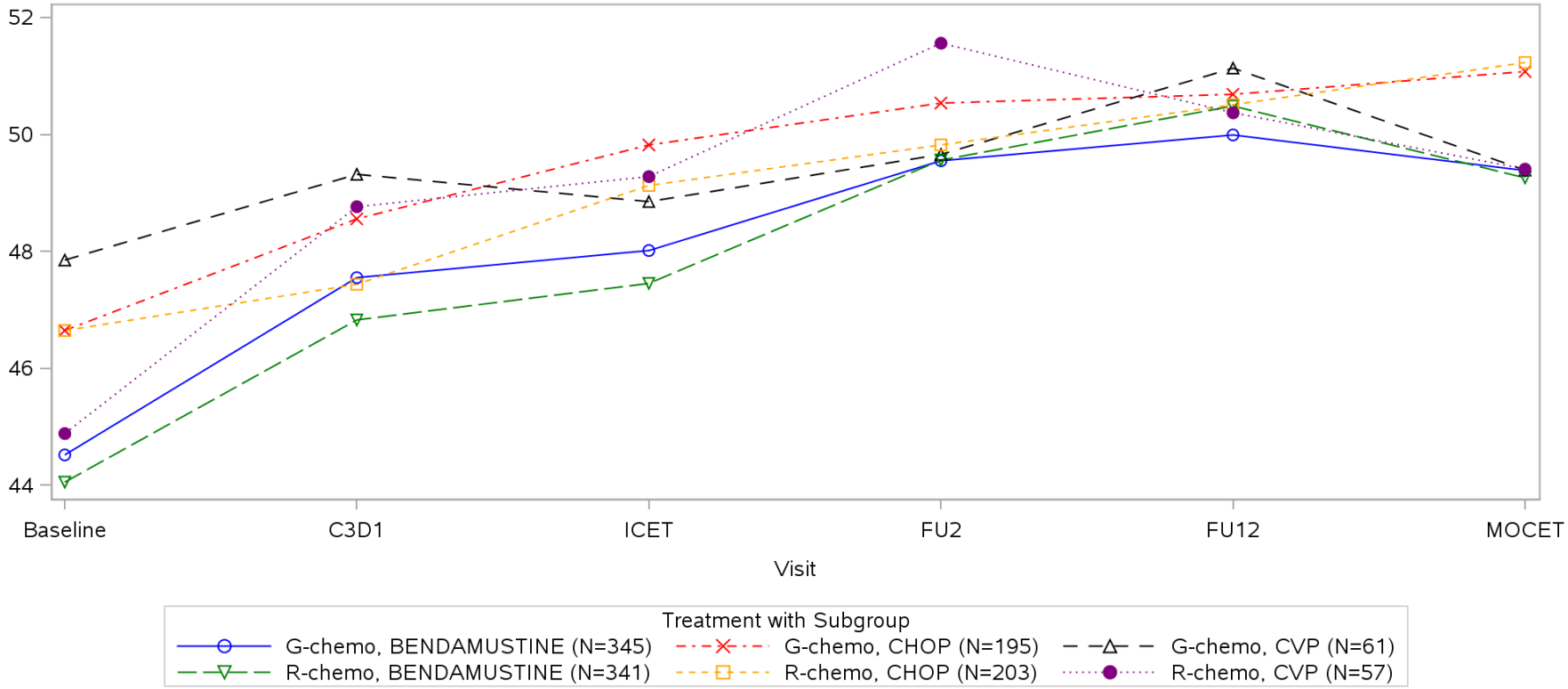
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Chemotherapy regimen (N=1202) Laboratory Test: FACT-LYM Subscale

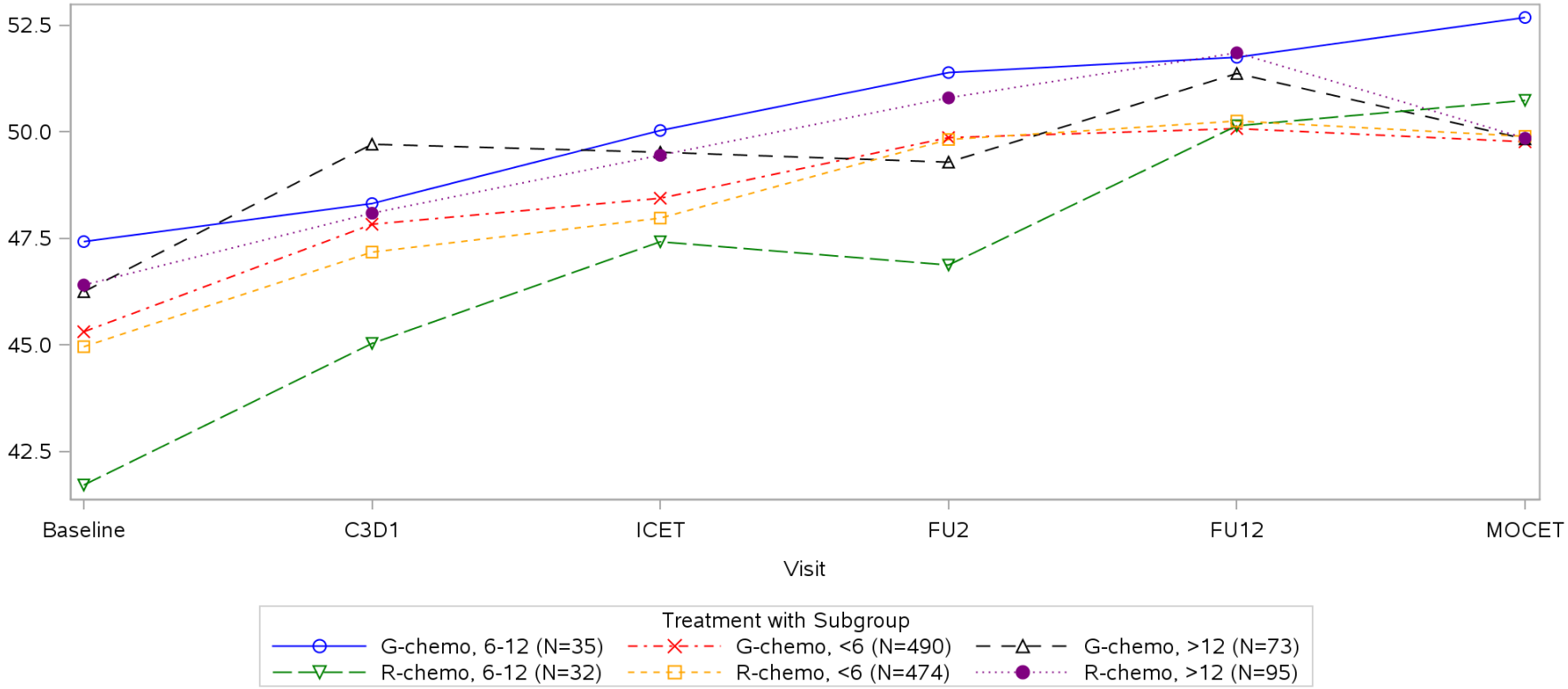


C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Time from initial NHL diagnosis to randomization (N=1199) Laboratory Test: FACT-LYM Subscale

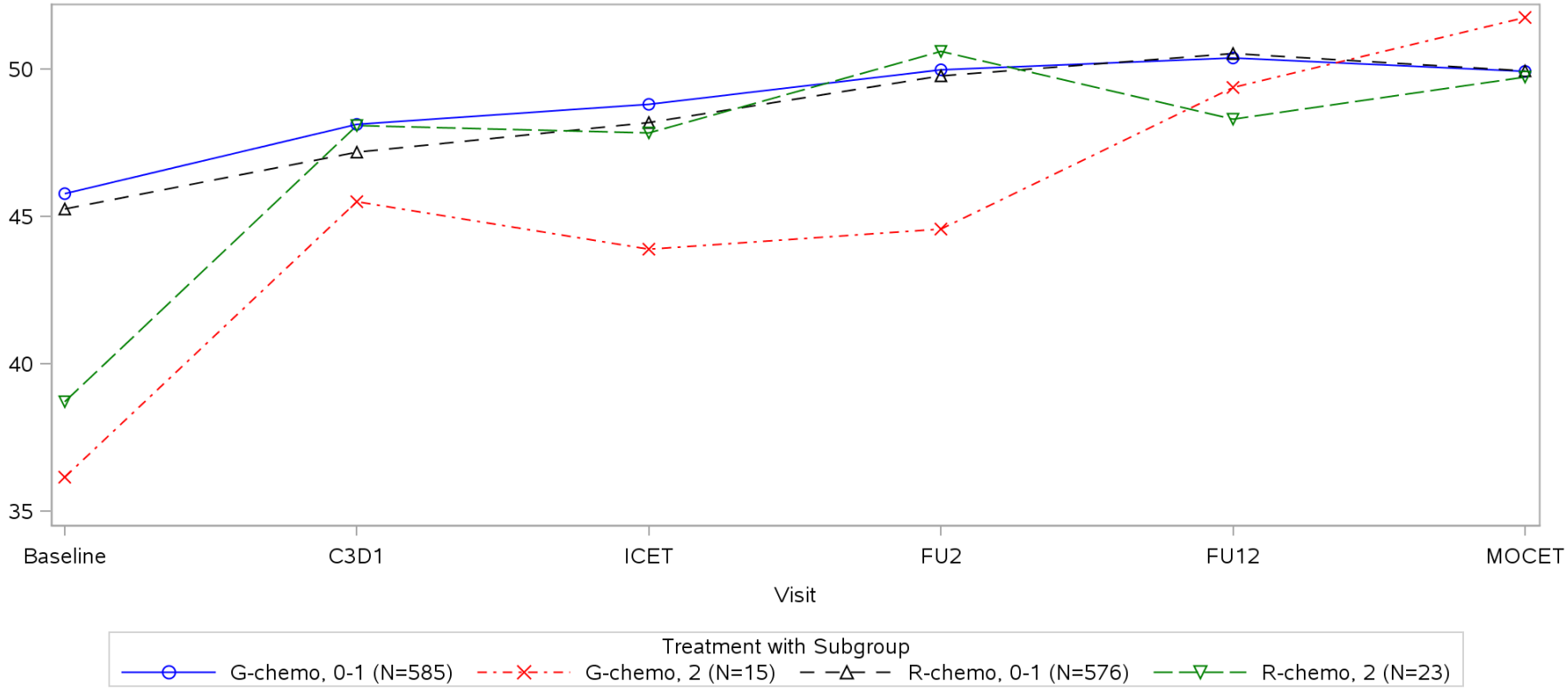


C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Baseline ECOG Performance Status score (N=1199) Laboratory Test: FACT-LYM Subscale

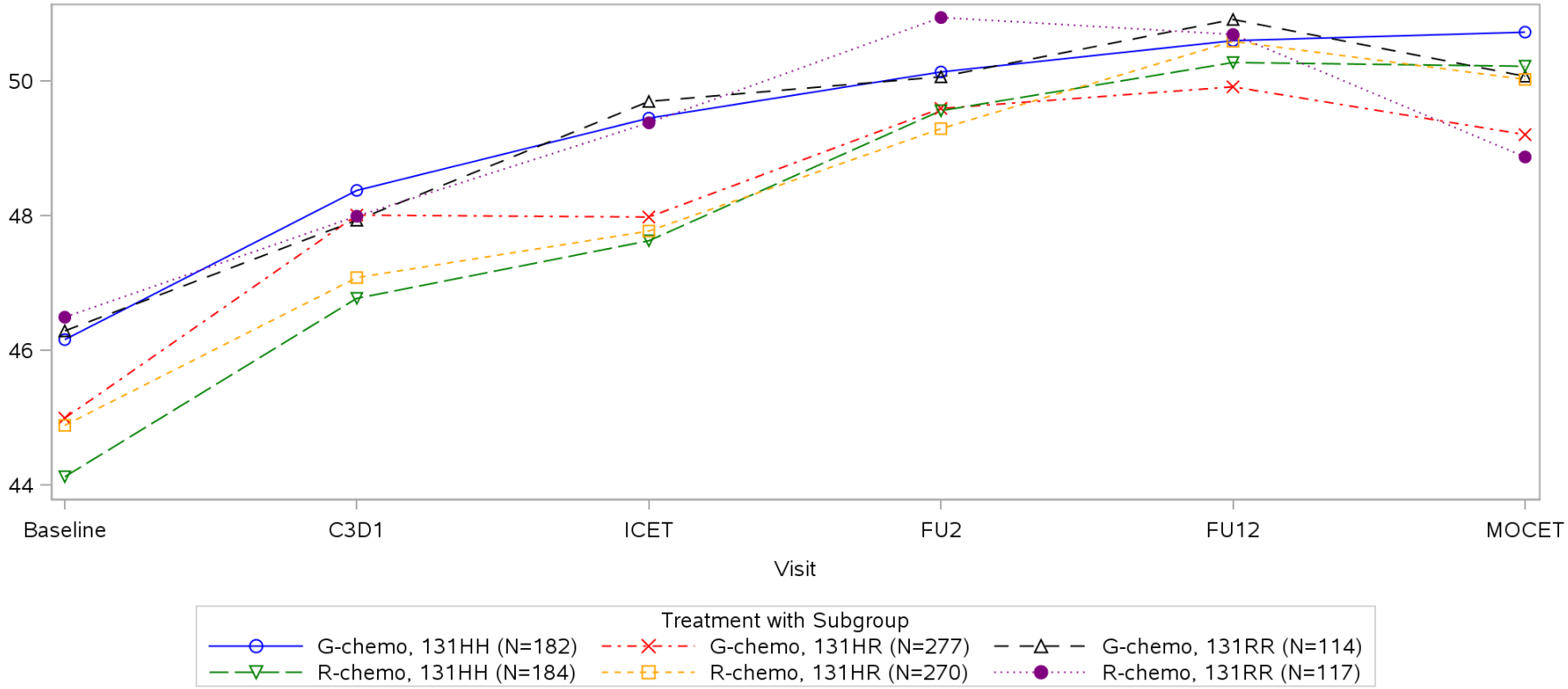


C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Fc gamma receptor IIa (N=1144) Laboratory Test: FACT-LYM Subscale

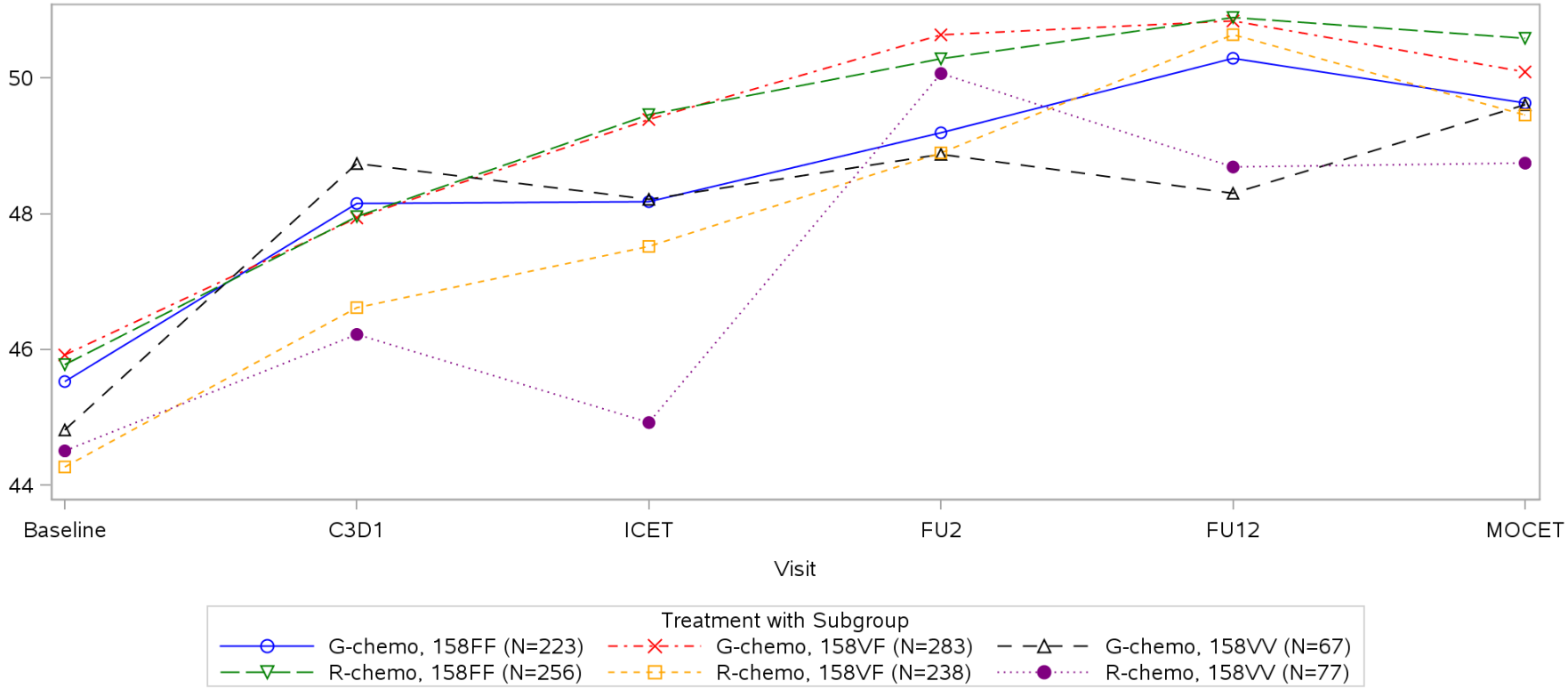


C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Fc gamma receptor IIIa (N=1144) Laboratory Test: FACT-LYM Subscale

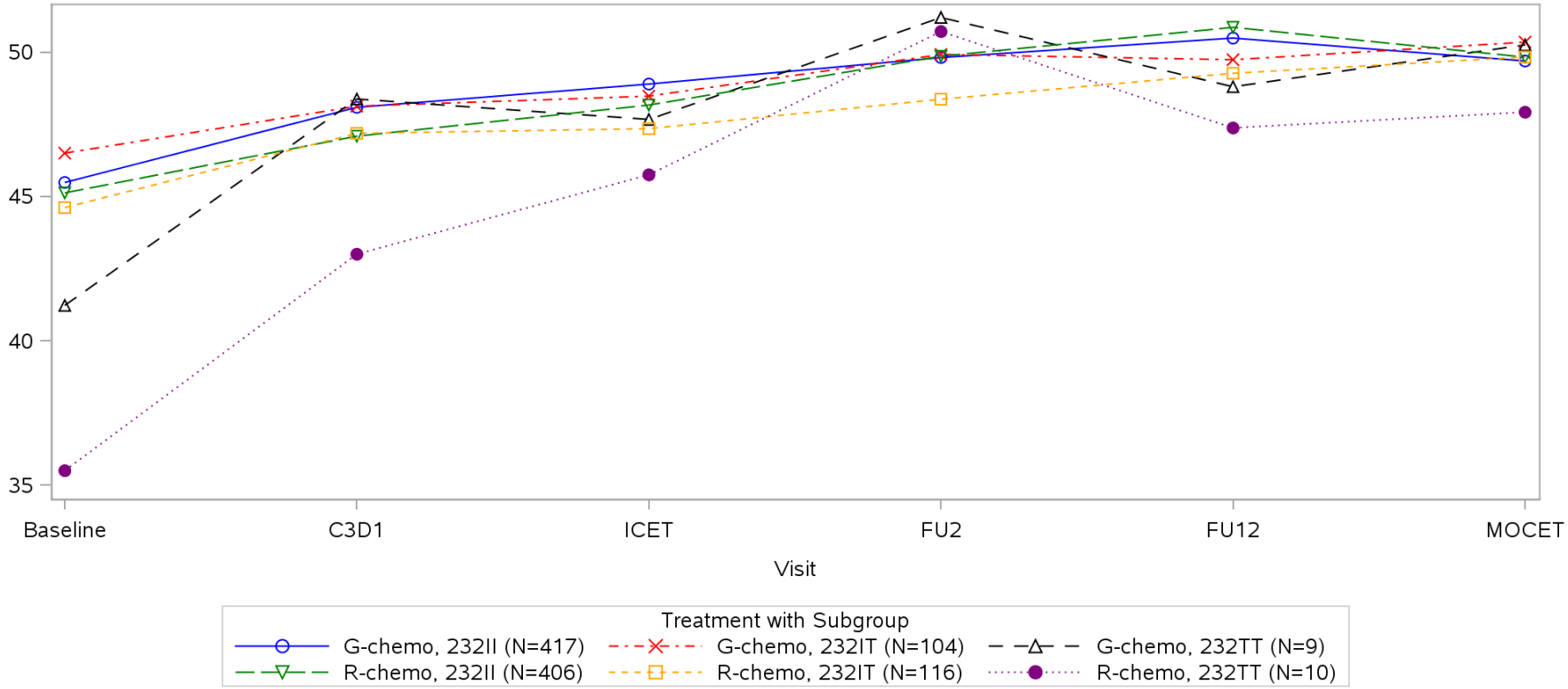


C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Fc gamma receptor IIb/IIc (N=1062) Laboratory Test: FACT-LYM Subscale

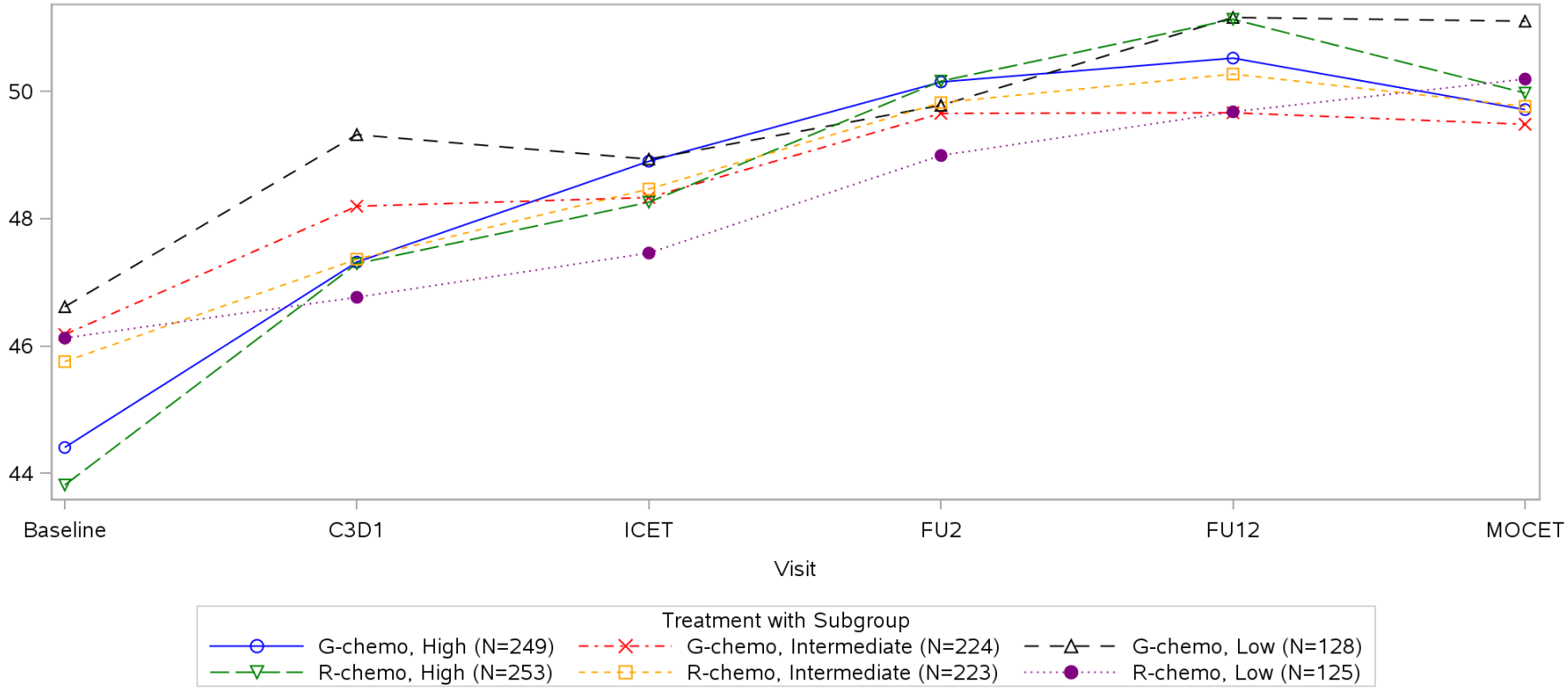


C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

FLIPI (N=1202) Laboratory Test: FACT-LYM Subscale

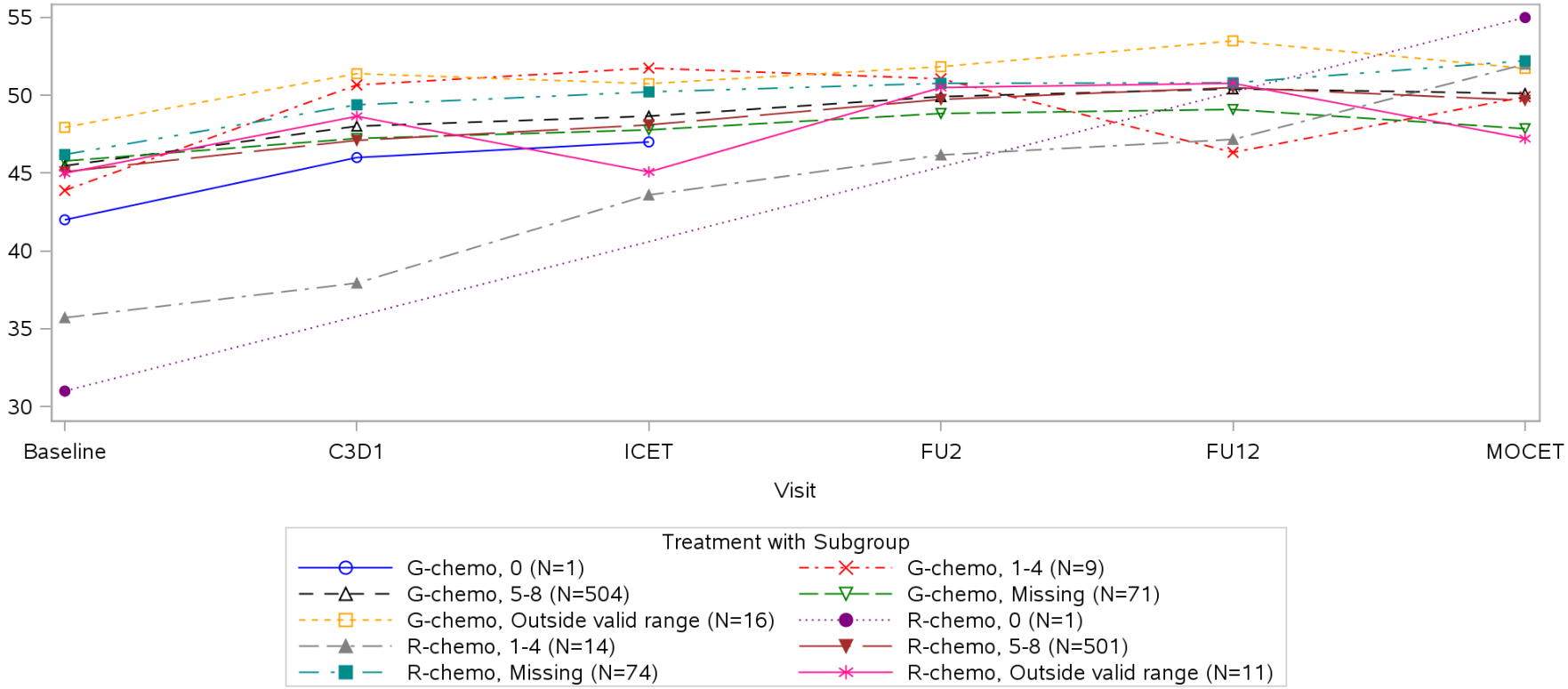


C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Independence status (Katz IADL) (N=1202) Laboratory Test: FACT-LYM Subscale

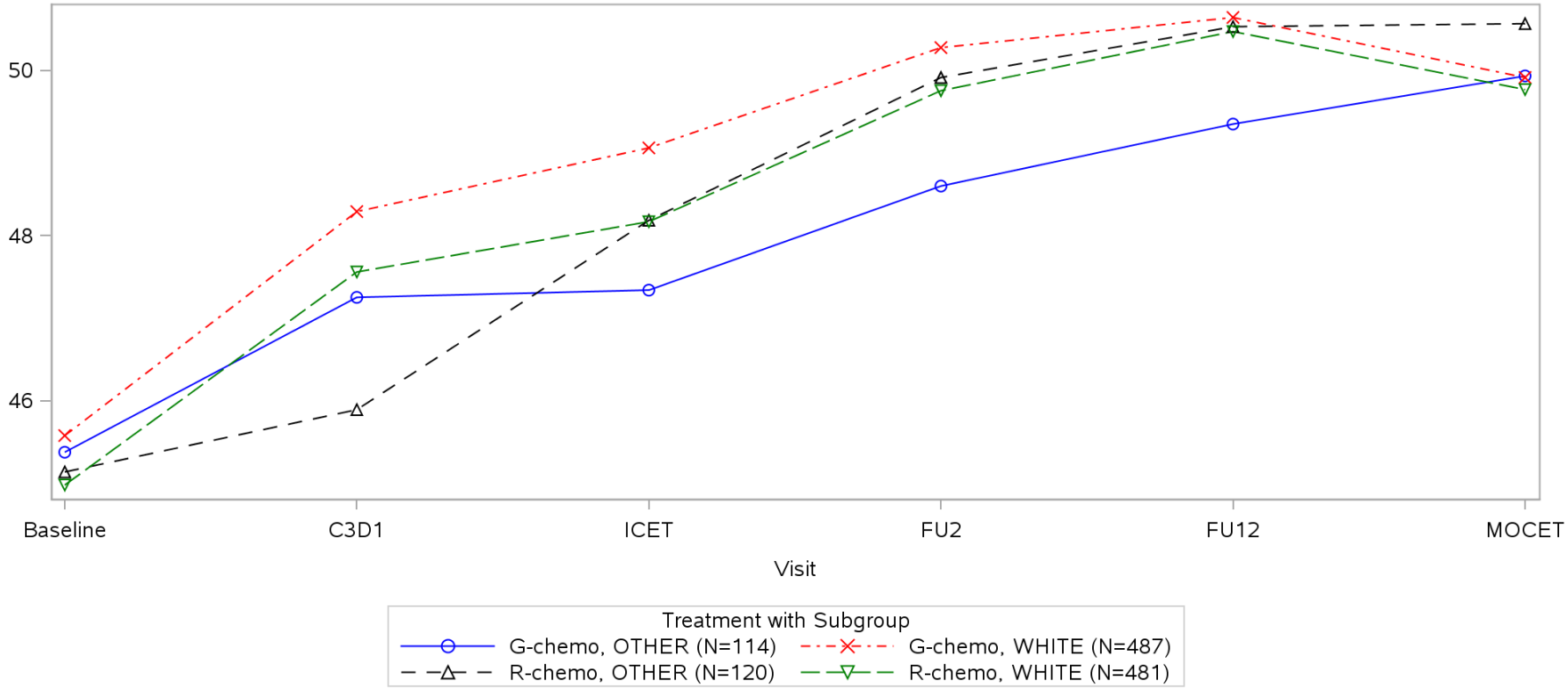


C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Race/ethnicity (N=1202) Laboratory Test: FACT-LYM Subscale

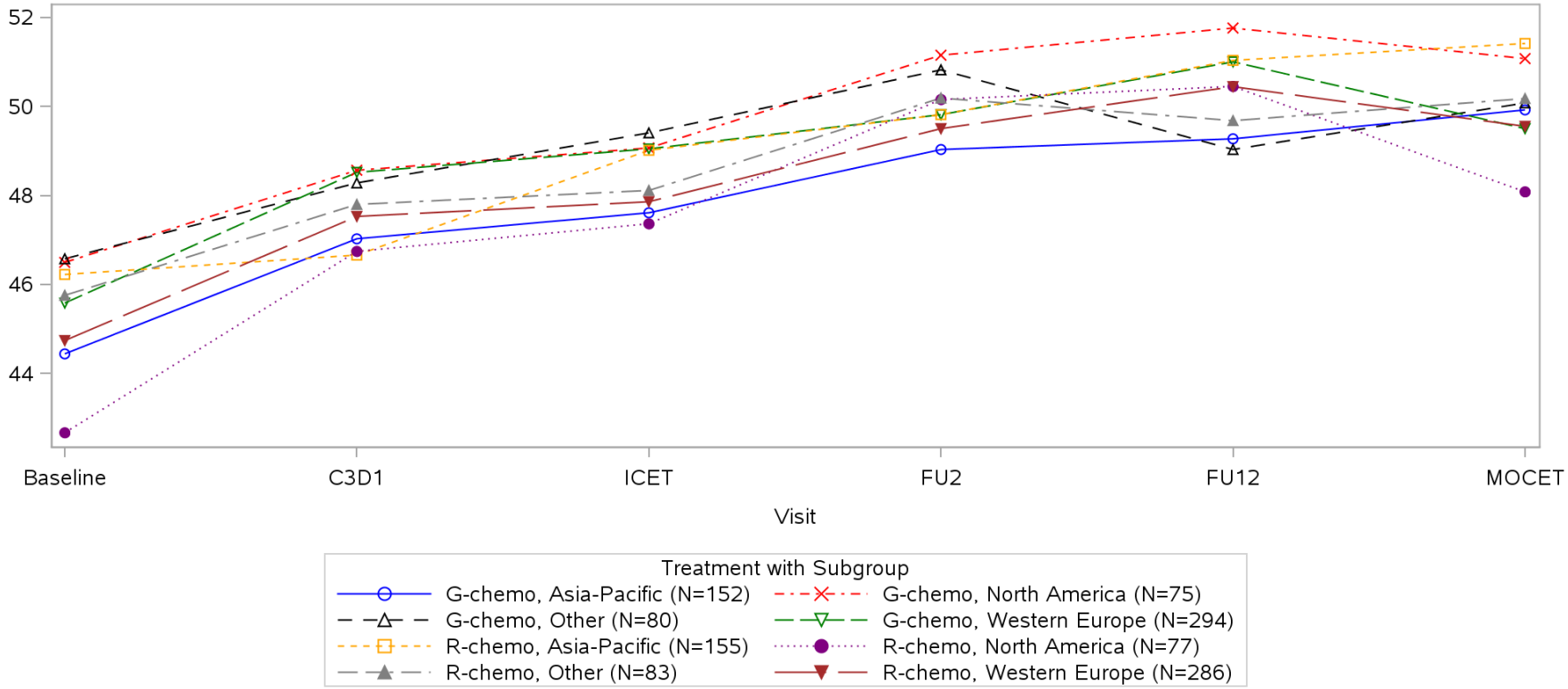


C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Geographic region (N=1202) Laboratory Test: FACT-LYM Subscale

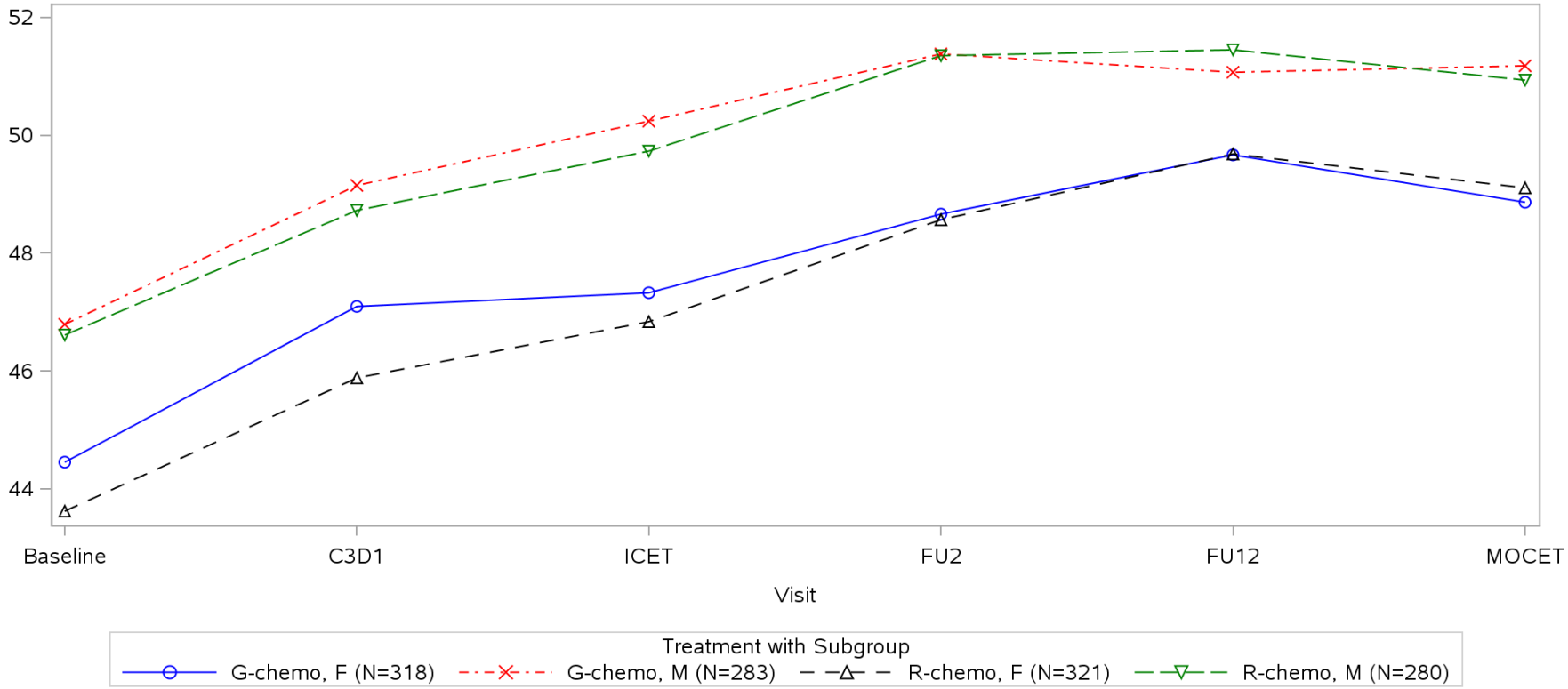


C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

POPULATION: Intent-to-Treat Patients, Follicular Lymphoma Patients
STUDY: BO21223
Cutoff Date: 31JAN2016
Line Plot of Mean by Visit

Sex (N=1202) Laboratory Test: FACT-LYM Subscale



C3D1 = Cycle 3 Day 1, ICET = Induction Completion/Early Termination,
FU2 = Follow Up Month 2, FU12 = Follow Up Month 12,
MOCET = Maintenance or Observation Completion/Early Termination
Clinical cut-off: 31JAN2016

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/program/g_pro_mean.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_CSRPrimary/qa/output/g_pro_mean_sg_PLYMS_FOLY_IT.pdf
25OCT2019 12:40

Anhang 4-G3: Generelle Verträglichkeit

14 (Anhang): Ergebnisse für Patienten mit UE aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Any AEs, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk								Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	594	99,8	597	100,0	592	99,2	5,02		Convergence criterion (GCONV=1E-8) satisfied.	0,58	43,07	0,007		Algorithm converged.	-0,001	0,015	1,01		Algorithm converged.	1,00	1,01	0,1025		0,99		Algorithm converged.	0,99	1,00
Sex	Male	281	47,2	281	100,0	278	46,6	275	98,9		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				NE		*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		
	Female	314	52,8	313	99,7	319	53,4	317	99,4	1,97		Convergence criterion (GCONV=1E-8) satisfied.	0,18	21,89	0,003		Algorithm converged.	-0,008	0,014	1,00		Algorithm converged.	0,99	1,01	0,5710		1,00		Algorithm converged.	0,99	1,01
Age	< 60 years	298	50,1	298	100,0	320	53,6	316	98,8		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				NE		*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		
	>= 60 years	297	49,9	296	99,7	277	46,4	276	99,6	1,07		Convergence criterion (GCONV=1E-8) satisfied.	0,07	17,23	0,000		Algorithm converged.	-0,009	0,010	1,00		Algorithm converged.	0,99	1,01	0,9606		1,00		Algorithm converged.	0,99	1,01
Geographic region	North America	73	12,3	73	100,0	77	12,9	77	100,0																	NE						
	Western Europe	293	49,2	293	100,0	282	47,2	281	99,6		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				*	WARNING: The relative Hessian convergence criterion of 114172541474 is greater than the limit of 0.0001. The convergence is questionable.						*	WARNING: The relative Hessian convergence criterion of 114172541474 is greater than the limit of 0.0001. The convergence is questionable.		
	Asia-Pacific	150	25,2	150	100,0	155	26,0	155	100,0																							
	Other	79	13,3	78	98,7	83	13,9	79	95,2	3,95		Convergence criterion (GCONV=1E-8) satisfied.	0,43	36,13	0,036		Algorithm converged.	-0,017	0,088	1,04		Algorithm converged.	0,98	1,10	0,1872		0,96		Algorithm converged.	0,91	1,02
Actual Chemotherapy regimen	CHOP	194	32,6	193	99,5	203	34,0	202	99,5	0,96		Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,38	0,000		Algorithm converged.	-0,014	0,014	1,00		Algorithm converged.	0,99	1,01	0,9744	NE	1,00		Algorithm converged.	0,99	1,01
	CVP	60	10,1	60	100,0	56	9,4	55	98,2		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.						*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.		
	Bendamustine	338	56,8	338	100,0	338	56,6	335	99,1		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.				*	WARNING: Negative of Hessian not positive definite.						*	WARNING: Negative of Hessian not positive definite.		
	No Chemo	3	0,5	3	100,0																											
FLIPI	Low (0-1)	128	21,5	127	99,2	121	20,3	120	99,2	1,06		Convergence criterion (GCONV=1E-8) satisfied.	0,07	17,11	0,000		Algorithm converged.	-0,022	0,023	1,00		Algorithm converged.	0,98	1,02	0,9682	NE	1,00		Algorithm converged.	0,98	1,02
	Intermediate (2)	221	37,1	221	100,0	222	37,2	222	100,0																							
	High (>=3)	246	41,3	246	100,0	254	42,5	250	98,4		*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 11.12710472 is greater than the limit of 0.0001. The convergence is questionable.				*	WARNING: Negative of Hessian not positive definite.						*	WARNING: Negative of Hessian not positive definite.		

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AAE_FOLY_SE_03MAR2017_21223.xls 01OCT2019
14:02

15 (Anhang): Ergebnisse für Patienten mit SUE aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Any SAEs, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
		Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	282	47,4	597	100,0	248	41,5	1,27		Convergence criterion (GCONV=1E-8) satisfied.	1,01	1,59	0,059		Algorithm converged.	0,002	0,115	1,14		Algorithm converged.	1,00	1,30	0,0425		0,88		Algorithm converged.	0,77	1,00
Sex	Male	281	47,2	131	46,6	278	46,6	112	40,3	1,29		Convergence criterion (GCONV=1E-8) satisfied.	0,93	1,81	0,063		Algorithm converged.	-0,019	0,145	1,16		Algorithm converged.	0,96	1,40	0,1323	0,8449	0,86		Algorithm converged.	0,71	1,05
	Female	314	52,8	151	48,1	319	53,4	136	42,6	1,25		Convergence criterion (GCONV=1E-8) satisfied.	0,91	1,71	0,055		Algorithm converged.	-0,023	0,132	1,13		Algorithm converged.	0,95	1,34	0,1687		0,89		Algorithm converged.	0,75	1,05
Age	< 60 years	298	50,1	116	38,9	320	53,6	111	34,7	1,20		Convergence criterion (GCONV=1E-8) satisfied.	0,86	1,66	0,042		Algorithm converged.	-0,034	0,118	1,12		Algorithm converged.	0,91	1,38	0,2749	0,9578	0,89		Algorithm converged.	0,72	1,10
	>= 60 years	297	49,9	166	55,9	277	46,4	137	49,5	1,29		Convergence criterion (GCONV=1E-8) satisfied.	0,93	1,80	0,064		Algorithm converged.	-0,017	0,146	1,13		Algorithm converged.	0,97	1,32	0,1248		0,88		Algorithm converged.	0,76	1,03
Geographic region	North America	73	12,3	32	43,8	77	12,9	28	36,4	1,37		Convergence criterion (GCONV=1E-8) satisfied.	0,71	2,63	0,075		Algorithm converged.	-0,082	0,231	1,21		Algorithm converged.	0,81	1,79	0,3518	0,9247	0,83		Algorithm converged.	0,56	1,23
	Western Europe	293	49,2	149	50,9	282	47,2	127	45,0	1,26		Convergence criterion (GCONV=1E-8) satisfied.	0,91	1,75	0,058		Algorithm converged.	-0,023	0,140	1,13		Algorithm converged.	0,95	1,34	0,1642		0,89		Algorithm converged.	0,75	1,05
	Asia-Pacific	150	25,2	72	48,0	155	26,0	63	40,6	1,35		Convergence criterion (GCONV=1E-8) satisfied.	0,86	2,12	0,074		Algorithm converged.	-0,038	0,185	1,18		Algorithm converged.	0,92	1,52	0,1973		0,85		Algorithm converged.	0,66	1,09
	Other	79	13,3	29	36,7	83	13,9	30	36,1	1,02		Convergence criterion (GCONV=1E-8) satisfied.	0,54	1,94	0,006		Algorithm converged.	-0,143	0,154	1,02		Algorithm converged.	0,68	1,53	0,9405		0,98		Algorithm converged.	0,66	1,48
Actual Chemotherapy regimen	CHOP	194	32,6	77	39,7	203	34,0	67	33,0	1,34		Convergence criterion (GCONV=1E-8) satisfied.	0,89	2,01	0,067		Algorithm converged.	-0,028	0,161	1,20		Algorithm converged.	0,93	1,56	0,1672		0,83		Algorithm converged.	0,64	1,08
	CVP	60	10,1	25	41,7	56	9,4	20	35,7	1,29		Convergence criterion (GCONV=1E-8) satisfied.	0,61	2,72	0,060		Algorithm converged.	-0,117	0,236	1,17		Algorithm converged.	0,74	1,85	0,5128		0,86		Algorithm converged.	0,54	1,36
	Bendamustine	338	56,8	177	52,4	338	56,6	161	47,6	1,21		Convergence criterion (GCONV=1E-8) satisfied.	0,89	1,63	0,047		Algorithm converged.	-0,028	0,123	1,10		Algorithm converged.	0,95	1,28	0,2191		0,91		Algorithm converged.	0,78	1,06
	No Chemo	3	0,5	3	100,0																										
FLIPI	Low (0-1)	128	21,5	59	46,1	121	20,3	43	35,5	1,55		Convergence criterion (GCONV=1E-8) satisfied.	0,93	2,58	0,106		Algorithm converged.	-0,016	0,227	1,30		Algorithm converged.	0,96	1,76	0,0940	0,6390	0,77		Algorithm converged.	0,57	1,05
	Intermediate (2)	221	37,1	100	45,2	222	37,2	89	40,1	1,24		Convergence criterion (GCONV=1E-8) satisfied.	0,85	1,80	0,052		Algorithm converged.	-0,040	0,144	1,13		Algorithm converged.	0,91	1,40	0,2732		0,89		Algorithm converged.	0,71	1,10
	High (>=3)	246	41,3	123	50,0	254	42,5	116	45,7	1,19		Convergence criterion (GCONV=1E-8) satisfied.	0,84	1,69	0,043		Algorithm converged.	-0,044	0,131	1,09		Algorithm converged.	0,91	1,32	0,3327		0,91		Algorithm converged.	0,76	1,10

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_ASAE_FOLY_SE_03MAR2017_21223.xls 01OCT2019
13:35

16 (Anhang): Ergebnisse für Patienten mit Behandlungsabbruch wegen UE aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs leading to treatment discontinuation, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
		Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	96	16,1	597	100,0	87	14,6	1,13		Convergence criterion (GCONV=1E-8) satisfied.	0,82	1,55	0,016		Algorithm converged.	-0,025	0,057	1,11		Algorithm converged.	0,85	1,45	0,4549		0,90		Algorithm converged.	0,69	1,18
Sex	Male	281	47,2	38	13,5	278	46,6	31	11,2	1,25		Convergence criterion (GCONV=1E-8) satisfied.	0,75	2,07	0,024		Algorithm converged.	-0,031	0,078	1,21		Algorithm converged.	0,78	1,89	0,3950	0,6158	0,82		Algorithm converged.	0,53	1,29
	Female	314	52,8	58	18,5	319	53,4	56	17,6	1,06		Convergence criterion (GCONV=1E-8) satisfied.	0,71	1,60	0,009		Algorithm converged.	-0,051	0,069	1,05		Algorithm converged.	0,75	1,47	0,7642		0,95		Algorithm converged.	0,68	1,33
Age	< 60 years	298	50,1	35	11,7	320	53,6	38	11,9	0,99		Convergence criterion (GCONV=1E-8) satisfied.	0,61	1,61	-0,001		Algorithm converged.	-0,052	0,050	0,99		Algorithm converged.	0,64	1,52	0,9601	0,5661	1,01		Algorithm converged.	0,66	1,56
	>= 60 years	297	49,9	61	20,5	277	46,4	49	17,7	1,20		Convergence criterion (GCONV=1E-8) satisfied.	0,79	1,83	0,028		Algorithm converged.	-0,036	0,093	1,16		Algorithm converged.	0,83	1,63	0,3872		0,86		Algorithm converged.	0,61	1,21
Geographic region	North America	73	12,3	8	11,0	77	12,9	9	11,7	0,93		Convergence criterion (GCONV=1E-8) satisfied.	0,34	2,56	-0,007		Algorithm converged.	-0,109	0,094	0,94		Algorithm converged.	0,38	2,30	0,8880	0,9702	1,07		Algorithm converged.	0,43	2,62
	Western Europe	293	49,2	45	15,4	282	47,2	40	14,2	1,10		Convergence criterion (GCONV=1E-8) satisfied.	0,69	1,74	0,012		Algorithm converged.	-0,046	0,070	1,08		Algorithm converged.	0,73	1,60	0,6919		0,92		Algorithm converged.	0,62	1,37
	Asia-Pacific	150	25,2	30	20,0	155	26,0	26	16,8	1,24		Convergence criterion (GCONV=1E-8) satisfied.	0,69	2,22	0,032		Algorithm converged.	-0,055	0,119	1,19		Algorithm converged.	0,74	1,92	0,4678		0,84		Algorithm converged.	0,52	1,35
	Other	79	13,3	13	16,5	83	13,9	12	14,5	1,17		Convergence criterion (GCONV=1E-8) satisfied.	0,50	2,74	0,020		Algorithm converged.	-0,091	0,131	1,14		Algorithm converged.	0,55	2,34	0,7252		0,88		Algorithm converged.	0,43	1,81
Actual Chemotherapy regimen	CHOP	194	32,6	30	15,5	203	34,0	29	14,3	1,10		Convergence criterion (GCONV=1E-8) satisfied.	0,63	1,91	0,012		Algorithm converged.	-0,058	0,082	1,08		Algorithm converged.	0,68	1,73	0,7415		0,92		Algorithm converged.	0,58	1,48
	CVP	60	10,1	11	18,3	56	9,4	9	16,1	1,17		Convergence criterion (GCONV=1E-8) satisfied.	0,45	3,09	0,023		Algorithm converged.	-0,115	0,160	1,14		Algorithm converged.	0,51	2,54	0,7476		0,88		Algorithm converged.	0,39	1,96
	Bendamustine	338	56,8	52	15,4	338	56,6	49	14,5	1,07		Convergence criterion (GCONV=1E-8) satisfied.	0,70	1,64	0,009		Algorithm converged.	-0,045	0,063	1,06		Algorithm converged.	0,74	1,52	0,7462		0,94		Algorithm converged.	0,66	1,35
	No Chemo	30	5,0	30	100,0																										
FLIPI	Low (0-1)	128	21,5	10	7,8	121	20,3	14	11,6	0,65		Convergence criterion (GCONV=1E-8) satisfied.	0,28	1,52	-0,038		Algorithm converged.	-0,111	0,036	0,68		Algorithm converged.	0,31	1,46	0,3191	0,2834	1,48		Algorithm converged.	0,68	3,21
	Intermediate (2)	221	37,1	37	16,7	222	37,2	35	15,8	1,07		Convergence criterion (GCONV=1E-8) satisfied.	0,65	1,78	0,010		Algorithm converged.	-0,059	0,078	1,06		Algorithm converged.	0,70	1,62	0,7807		0,94		Algorithm converged.	0,62	1,44
	High (>=3)	246	41,3	49	19,9	254	42,5	38	15,0	1,41		Convergence criterion (GCONV=1E-8) satisfied.	0,89	2,25	0,050		Algorithm converged.	-0,017	0,116	1,33		Algorithm converged.	0,91	1,96	0,1458		0,75		Algorithm converged.	0,51	1,10

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AELDIS_FOLY_SE_03MAR2017_21223.xls 01OCT2019
13:38

17 (Anhang): Ergebnisse für Patienten mit nicht schweren UE (Grad 1 und Grad 2) aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade 1-2, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																			R-Chemo vs. G-Chemo				
		Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk								Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	129	21,7	597	100,0	169	28,3	0,70		Convergence criterion (GCONV=1E-8) satisfied.	0,54	0,91	-0,066		Algorithm converged.	-0,115	-0,017	0,77		Algorithm converged.	0,63	0,93	0,0086		1,31		Algorithm converged.	1,07	1,59
Sex	Male	281	47,2	64	22,8	278	46,6	84	30,2	0,68		Convergence criterion (GCONV=1E-8) satisfied.	0,47	0,99	-0,074		Algorithm converged.	-0,147	-0,001	0,75		Algorithm converged.	0,57	1,00	0,0477	0,8817	1,33		Algorithm converged.	1,00	1,75
	Female	314	52,8	65	20,7	319	53,4	85	26,6	0,72		Convergence criterion (GCONV=1E-8) satisfied.	0,50	1,04	-0,059		Algorithm converged.	-0,125	0,007	0,78		Algorithm converged.	0,59	1,03	0,0802		1,29		Algorithm converged.	0,97	1,71
Age	< 60 years	298	50,1	76	25,5	320	53,6	103	32,2	0,72		Convergence criterion (GCONV=1E-8) satisfied.	0,51	1,02	-0,067		Algorithm converged.	-0,138	0,004	0,79		Algorithm converged.	0,62	1,02	0,0690	0,7870	1,26		Algorithm converged.	0,98	1,62
	>= 60 years	297	49,9	53	17,8	277	46,4	66	23,8	0,69		Convergence criterion (GCONV=1E-8) satisfied.	0,46	1,04	-0,060		Algorithm converged.	-0,126	0,007	0,75		Algorithm converged.	0,54	1,03	0,0788		1,34		Algorithm converged.	0,97	1,84
Geographic region	North America	73	12,3	21	28,8	77	12,9	30	39,0	0,63		Convergence criterion (GCONV=1E-8) satisfied.	0,32	1,25	-0,102		Algorithm converged.	-0,252	0,049	0,74		Algorithm converged.	0,47	1,17	0,1929	0,8970	1,35		Algorithm converged.	0,86	2,14
	Western Europe	293	49,2	73	24,9	282	47,2	93	33,0	0,67		Convergence criterion (GCONV=1E-8) satisfied.	0,47	0,97	-0,081		Algorithm converged.	-0,155	-0,007	0,76		Algorithm converged.	0,58	0,98	0,0340		1,32		Algorithm converged.	1,02	1,72
	Asia-Pacific	150	25,2	18	12,0	155	26,0	20	12,9	0,92		Convergence criterion (GCONV=1E-8) satisfied.	0,47	1,82	-0,009		Algorithm converged.	-0,083	0,065	0,93		Algorithm converged.	0,51	1,69	0,8113		1,08		Algorithm converged.	0,59	1,95
	Other	79	13,3	17	21,5	83	13,9	26	31,3	0,60		Convergence criterion (GCONV=1E-8) satisfied.	0,30	1,22	-0,098		Algorithm converged.	-0,233	0,037	0,69		Algorithm converged.	0,41	1,16	0,1634		1,46		Algorithm converged.	0,86	2,47
Actual Chemotherapy regimen	CHOP	194	32,6	17	8,8	203	34,0	44	21,7	0,35		Convergence criterion (GCONV=1E-8) satisfied.	0,19	0,63	-0,129		Algorithm converged.	-0,198	-0,060	0,40		Algorithm converged.	0,24	0,68	0,0007	0,0210	2,47		Algorithm converged.	1,46	4,18
	CVP	60	10,1	17	28,3	56	9,4	24	42,9	0,53		Convergence criterion (GCONV=1E-8) satisfied.	0,24	1,14	-0,145		Algorithm converged.	-0,318	0,027	0,66		Algorithm converged.	0,40	1,09	0,1071		1,51		Algorithm converged.	0,91	2,50
	Bendamustine	338	56,8	95	28,1	338	56,6	101	29,9	0,92		Convergence criterion (GCONV=1E-8) satisfied.	0,66	1,28	-0,018		Algorithm converged.	-0,086	0,051	0,94		Algorithm converged.	0,74	1,19	0,6112		1,06		Algorithm converged.	0,84	1,35
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	30	23,4	121	20,3	43	35,5	0,56		Convergence criterion (GCONV=1E-8) satisfied.	0,32	0,97	-0,121		Algorithm converged.	-0,234	-0,008	0,66		Algorithm converged.	0,44	0,98	0,0386	0,6982	1,52		Algorithm converged.	1,02	2,25
	Intermediate (2)	221	37,1	50	22,6	222	37,2	64	28,8	0,72		Convergence criterion (GCONV=1E-8) satisfied.	0,47	1,11	-0,062		Algorithm converged.	-0,143	0,019	0,78		Algorithm converged.	0,57	1,08	0,1373		1,27		Algorithm converged.	0,93	1,75
	High (>=3)	246	41,3	49	19,9	254	42,5	62	24,4	0,77		Convergence criterion (GCONV=1E-8) satisfied.	0,50	1,18	-0,045		Algorithm converged.	-0,118	0,028	0,82		Algorithm converged.	0,59	1,14	0,2288		1,23		Algorithm converged.	0,88	1,71

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEG12_FOLY_SE_03MAR2017_21223.xls
01OCT2019 14:11

18 (Anhang): Ergebnisse für Patienten mit schweren UE (Grad ≥ 3) aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade >= 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo			
		Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference				Relative Risk								Relative Risk			
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	465	78,2	597	100,0	423	70,9	1,47		Convergence criterion (GCONV=1E-8) satisfied.	1,13	1,91	0,073		Algorithm converged.	0,024	0,122	1,10		Algorithm converged.	1,03	1,18	0,0040		0,91		Algorithm converged.	0,85	0,97
Sex	Male	281	47,2	217	77,2	278	46,6	191	68,7	1,54		Convergence criterion (GCONV=1E-8) satisfied.	1,06	2,25	0,085		Algorithm converged.	0,012	0,159	1,12		Algorithm converged.	1,02	1,24	0,0242	0,6160	0,89		Algorithm converged.	0,80	0,98
	Female	314	52,8	248	79,0	319	53,4	232	72,7	1,41		Convergence criterion (GCONV=1E-8) satisfied.	0,98	2,03	0,063		Algorithm converged.	-0,004	0,129	1,09		Algorithm converged.	0,99	1,19	0,0667		0,92		Algorithm converged.	0,84	1,01
Age	< 60 years	298	50,1	222	74,5	320	53,6	213	66,6	1,47		Convergence criterion (GCONV=1E-8) satisfied.	1,04	2,08	0,079		Algorithm converged.	0,008	0,151	1,12		Algorithm converged.	1,01	1,24	0,0308	0,5927	0,89		Algorithm converged.	0,81	0,99
	>= 60 years	297	49,9	243	81,8	277	46,4	210	75,8	1,44		Convergence criterion (GCONV=1E-8) satisfied.	0,96	2,15	0,060		Algorithm converged.	-0,007	0,127	1,08		Algorithm converged.	0,99	1,18	0,0803		0,93		Algorithm converged.	0,85	1,01
Geographic region	North America	73	12,3	52	71,2	77	12,9	47	61,0	1,58		Convergence criterion (GCONV=1E-8) satisfied.	0,80	3,13	0,102		Algorithm converged.	-0,049	0,252	1,17		Algorithm converged.	0,93	1,47	0,1890	0,2044	0,86		Algorithm converged.	0,68	1,08
	Western Europe	293	49,2	220	75,1	282	47,2	188	66,7	1,51		Convergence criterion (GCONV=1E-8) satisfied.	1,05	2,17	0,084		Algorithm converged.	0,010	0,158	1,13		Algorithm converged.	1,01	1,25	0,0274		0,89		Algorithm converged.	0,80	0,99
	Asia-Pacific	150	25,2	132	88,0	155	26,0	135	87,1	1,09		Convergence criterion (GCONV=1E-8) satisfied.	0,55	2,15	0,009		Algorithm converged.	-0,065	0,083	1,01		Algorithm converged.	0,93	1,10	0,8112		0,99		Algorithm converged.	0,91	1,08
	Other	79	13,3	61	77,2	83	13,9	53	63,9	1,92		Convergence criterion (GCONV=1E-8) satisfied.	0,96	3,83	0,134		Algorithm converged.	-0,005	0,272	1,21		Algorithm converged.	0,99	1,48	0,0644		0,83		Algorithm converged.	0,68	1,01
Actual Chemotherapy regimen	CHOP	194	32,6	176	90,7	203	34,0	158	77,8	2,78		Convergence criterion (GCONV=1E-8) satisfied.	1,55	5,01	0,129		Algorithm converged.	0,059	0,199	1,17		Algorithm converged.	1,07	1,27	0,0005		0,86		Algorithm converged.	0,79	0,94
	CVP	60	10,1	43	71,7	56	9,4	31	55,4	2,04		Convergence criterion (GCONV=1E-8) satisfied.	0,94	4,41	0,163		Algorithm converged.	-0,010	0,336	1,29		Algorithm converged.	0,97	1,72	0,0747		0,77		Algorithm converged.	0,58	1,03
	Bendamustine	338	56,8	243	71,9	338	56,6	234	69,2	1,14		Convergence criterion (GCONV=1E-8) satisfied.	0,82	1,58	0,027		Algorithm converged.	-0,042	0,095	1,04		Algorithm converged.	0,94	1,14	0,4478		0,96		Algorithm converged.	0,87	1,06
	No Chemo	3	0,5	3	100,0																										
FLIPI	Low (0-1)	128	21,5	97	75,8	121	20,3	77	63,6	1,79		Convergence criterion (GCONV=1E-8) satisfied.	1,03	3,09	0,121		Algorithm converged.	0,008	0,235	1,19		Algorithm converged.	1,01	1,41	0,0398	0,5918	0,84		Algorithm converged.	0,71	0,99
	Intermediate (2)	221	37,1	171	77,4	222	37,2	158	71,2	1,39		Convergence criterion (GCONV=1E-8) satisfied.	0,90	2,13	0,062		Algorithm converged.	-0,019	0,143	1,09		Algorithm converged.	0,97	1,21	0,1363		0,92		Algorithm converged.	0,82	1,03
	High (>=3)	246	41,3	197	80,1	254	42,5	188	74,0	1,41		Convergence criterion (GCONV=1E-8) satisfied.	0,93	2,15	0,061		Algorithm converged.	-0,013	0,134	1,08		Algorithm converged.	0,98	1,19	0,1074		0,92		Algorithm converged.	0,84	1,02

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEG345_FOLY_SE_03MAR2017_21223.xls 01OCT2019
14:33

19 (Anhang): Ergebnisse für Patienten mit UE Grad 1 aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade 1, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk								Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	101	17	597	100,0	22	3,7	0,45		Convergence criterion (GCONV=1E-8) satisfied.	0,21	0,95	-0,020		Algorithm converged.	-0,038	-0,002	0,46		Algorithm converged.	0,22	0,95	0,0373		2,19		Algorithm converged.	1,05	4,59
Sex	Male	281	47,2	72	25	278	46,6	11	4,0	0,62		Convergence criterion (GCONV=1E-8) satisfied.	0,24	1,62	-0,015		Algorithm converged.	-0,044	0,015	0,63		Algorithm converged.	0,25	1,60	0,3310	0,2949	1,59		Algorithm converged.	0,62	4,04
	Female	314	52,8	31	10	319	53,4	11	3,4	0,27		Convergence criterion (GCONV=1E-8) satisfied.	0,07	0,98	-0,025		Algorithm converged.	-0,048	-0,002	0,28		Algorithm converged.	0,08	0,98	0,0471		3,61		Algorithm converged.	1,02	12,81
Age	< 60 years	298	50,1	82	27	320	53,6	11	3,4	0,77		Convergence criterion (GCONV=1E-8) satisfied.	0,31	1,95	-0,008		Algorithm converged.	-0,035	0,020	0,78		Algorithm converged.	0,32	1,92	0,5890	0,0648	1,28		Algorithm converged.	0,52	3,14
	>= 60 years	297	49,9	20	7	277	46,4	11	4,0	0,16		Convergence criterion (GCONV=1E-8) satisfied.	0,04	0,75	-0,033		Algorithm converged.	-0,058	-0,008	0,17		Algorithm converged.	0,04	0,76	0,0202		5,90		Algorithm converged.	1,32	26,37
Geographic region	North America	73	12,3	11	4	77	12,9	4	5,2	0,25		Convergence criterion (GCONV=1E-8) satisfied.	0,03	2,32	-0,038		Algorithm converged.	-0,095	0,018	0,26		Algorithm converged.	0,03	2,30	0,2281	0,2267	3,79		Algorithm converged.	0,43	33,14
	Western Europe	293	49,2	62	20	282	47,2	7	2,5	0,82		Convergence criterion (GCONV=1E-8) satisfied.	0,27	2,47	-0,004		Algorithm converged.	-0,029	0,020	0,82		Algorithm converged.	0,28	2,42	0,7265		1,21		Algorithm converged.	0,41	3,56
	Asia-Pacific	150	25,2			155	26,0	4	2,6		*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 7.8082680236 is greater than the limit of 0.0001. The convergence is questionable.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
	Other	79	13,3	33	8	83	13,9	7	8,4	0,43		Convergence criterion (GCONV=1E-8) satisfied.	0,11	1,72	-0,046		Algorithm converged.	-0,120	0,027	0,45		Algorithm converged.	0,12	1,68	0,2350		2,22		Algorithm converged.	0,60	8,29
Actual Chemotherapy regimen	CHOP	194	32,6	21	0	203	34,0	6	3,0	0,34		Convergence criterion (GCONV=1E-8) satisfied.	0,07	1,72	-0,019		Algorithm converged.	-0,047	0,008	0,35		Algorithm converged.	0,07	1,71	0,1937	0,8778	2,87		Algorithm converged.	0,59	14,03
	CVP	60	10,1	23	3	56	9,4	2	3,6	0,93		Convergence criterion (GCONV=1E-8) satisfied.	0,13	6,84	-0,002		Algorithm converged.	-0,069	0,064	0,93		Algorithm converged.	0,14	6,40	0,9440		1,07		Algorithm converged.	0,16	7,35
	Bendamustine	338	56,8	61	8	338	56,6	14	4,1	0,42		Convergence criterion (GCONV=1E-8) satisfied.	0,16	1,10	-0,024		Algorithm converged.	-0,049	0,002	0,43		Algorithm converged.	0,17	1,10	0,0787		2,33		Algorithm converged.	0,91	6,00
	No Chemo		30,5																													
FLIPI	Low (0-1)	128	21,5	32	3	121	20,3	6	5,0	0,46		Convergence criterion (GCONV=1E-8) satisfied.	0,11	1,88	-0,026		Algorithm converged.	-0,073	0,021	0,47		Algorithm converged.	0,12	1,85	0,2814	0,6369	2,12		Algorithm converged.	0,54	8,27
	Intermediate (2)	221	37,1	52	3	222	37,2	8	3,6	0,62		Convergence criterion (GCONV=1E-8) satisfied.	0,20	1,92	-0,013		Algorithm converged.	-0,045	0,018	0,63		Algorithm converged.	0,21	1,89	0,4076		1,59		Algorithm converged.	0,53	4,79
	High (>=3)	246	41,3	20	8	254	42,5	8	3,1	0,25		Convergence criterion (GCONV=1E-8) satisfied.	0,05	1,20	-0,023		Algorithm converged.	-0,048	0,001	0,26		Algorithm converged.	0,06	1,20	0,0847		3,87		Algorithm converged.	0,83	18,06

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEG1_FOLY_SE_03MAR2017_21223.xls 01OCT2019
14:06

20 (Anhang): Ergebnisse für Patienten mit UE Grad 2 aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade 2, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
		Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	119	20,0	597	100,0	147	24,6	0,77		Convergence criterion (GCONV=1E-8) satisfied.	0,58	1,01	-0,046		Algorithm converged.	-0,093	0,001	0,81		Algorithm converged.	0,66	1,01	0,0561		1,23		Algorithm converged.	0,99	1,52
Sex	Male	281	47,2	57	20,3	278	46,6	73	26,3	0,71		Convergence criterion (GCONV=1E-8) satisfied.	0,48	1,06	-0,060		Algorithm converged.	-0,130	0,010	0,77		Algorithm converged.	0,57	1,05	0,0963	0,6559	1,29		Algorithm converged.	0,96	1,75
	Female	314	52,8	62	19,7	319	53,4	74	23,2	0,81		Convergence criterion (GCONV=1E-8) satisfied.	0,56	1,19	-0,035		Algorithm converged.	-0,098	0,029	0,85		Algorithm converged.	0,63	1,15	0,2914		1,17		Algorithm converged.	0,87	1,58
Age	< 60 years	298	50,1	68	22,8	320	53,6	92	28,8	0,73		Convergence criterion (GCONV=1E-8) satisfied.	0,51	1,05	-0,059		Algorithm converged.	-0,128	0,009	0,79		Algorithm converged.	0,61	1,04	0,0945	0,7008	1,26		Algorithm converged.	0,96	1,65
	>= 60 years	297	49,9	51	17,2	277	46,4	55	19,9	0,84		Convergence criterion (GCONV=1E-8) satisfied.	0,55	1,28	-0,027		Algorithm converged.	-0,090	0,037	0,86		Algorithm converged.	0,61	1,22	0,4081		1,16		Algorithm converged.	0,82	1,63
Geographic region	North America	73	12,3	20	27,4	77	12,9	26	33,8	0,74		Convergence criterion (GCONV=1E-8) satisfied.	0,37	1,49	-0,064		Algorithm converged.	-0,211	0,083	0,81		Algorithm converged.	0,50	1,32	0,4004	0,6682	1,23		Algorithm converged.	0,76	2,01
	Western Europe	293	49,2	67	22,9	282	47,2	86	30,5	0,68		Convergence criterion (GCONV=1E-8) satisfied.	0,47	0,98	-0,076		Algorithm converged.	-0,148	-0,004	0,75		Algorithm converged.	0,57	0,99	0,0397		1,33		Algorithm converged.	1,01	1,75
	Asia-Pacific	150	25,2	18	12,0	155	26,0	16	10,3	1,18		Convergence criterion (GCONV=1E-8) satisfied.	0,58	2,42	0,017		Algorithm converged.	-0,054	0,087	1,16		Algorithm converged.	0,62	2,19	0,6421		0,86		Algorithm converged.	0,46	1,62
	Other	79	13,3	14	17,7	83	13,9	19	22,9	0,73		Convergence criterion (GCONV=1E-8) satisfied.	0,34	1,57	-0,052		Algorithm converged.	-0,175	0,072	0,77		Algorithm converged.	0,42	1,44	0,4167		1,29		Algorithm converged.	0,70	2,40
Actual Chemotherapy regimen	CHOP	194	32,6	15	7,7	203	34,0	38	18,7	0,36		Convergence criterion (GCONV=1E-8) satisfied.	0,19	0,69	-0,110		Algorithm converged.	-0,175	-0,044	0,41		Algorithm converged.	0,23	0,73	0,0021	0,0168	2,42		Algorithm converged.	1,38	4,26
	CVP	60	10,1	15	25,0	56	9,4	22	39,3	0,52		Convergence criterion (GCONV=1E-8) satisfied.	0,23	1,14	-0,143		Algorithm converged.	-0,311	0,026	0,64		Algorithm converged.	0,37	1,10	0,1047		1,57		Algorithm converged.	0,91	2,71
	Bendamustine	338	56,8	89	26,3	338	56,6	87	25,7	1,03		Convergence criterion (GCONV=1E-8) satisfied.	0,73	1,45	0,006		Algorithm converged.	-0,060	0,072	1,02		Algorithm converged.	0,79	1,32	0,8609		0,98		Algorithm converged.	0,76	1,26
	No Chemo		39,5																												
FLIPI	Low (0-1)	128	21,5	27	21,1	121	20,3	37	30,6	0,61		Convergence criterion (GCONV=1E-8) satisfied.	0,34	1,08	-0,095		Algorithm converged.	-0,203	0,013	0,69		Algorithm converged.	0,45	1,06	0,0901	0,6435	1,45		Algorithm converged.	0,94	2,23
	Intermediate (2)	221	37,1	45	20,4	222	37,2	56	25,2	0,76		Convergence criterion (GCONV=1E-8) satisfied.	0,49	1,18	-0,049		Algorithm converged.	-0,127	0,029	0,81		Algorithm converged.	0,57	1,14	0,2242		1,24		Algorithm converged.	0,88	1,75
	High (>=3)	246	41,3	47	19,1	254	42,5	54	21,3	0,87		Convergence criterion (GCONV=1E-8) satisfied.	0,56	1,35	-0,022		Algorithm converged.	-0,092	0,049	0,90		Algorithm converged.	0,63	1,27	0,5491		1,11		Algorithm converged.	0,78	1,58

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEG2_FOLY_SE_03MAR2017_21223.xls 01OCT2019 14:16

21 (Anhang): Ergebnisse für Patienten mit UE Grad 3 aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	218	36,6	597	100,0	224	37,5	0,96		Convergence criterion (GCONV=1E-8) satisfied.	0,76	1,22	-0,009		Algorithm converged.	-0,064	0,046	0,98		Algorithm converged.	0,84	1,13	0,7525		1,02		Algorithm converged.	0,88	1,19
Sex	Male	281	47,2	109	38,8	278	46,6	105	37,8	1,04		Convergence criterion (GCONV=1E-8) satisfied.	0,74	1,47	0,010		Algorithm converged.	-0,070	0,091	1,03		Algorithm converged.	0,83	1,27	0,8041	0,5135	0,97		Algorithm converged.	0,79	1,20
	Female	314	52,8	109	34,7	319	53,4	119	37,3	0,89		Convergence criterion (GCONV=1E-8) satisfied.	0,65	1,24	-0,026		Algorithm converged.	-0,101	0,049	0,93		Algorithm converged.	0,76	1,15	0,4975		1,07		Algorithm converged.	0,87	1,32
Age	< 60 years	298	50,1	103	34,6	320	53,6	122	38,1	0,86		Convergence criterion (GCONV=1E-8) satisfied.	0,62	1,19	-0,036		Algorithm converged.	-0,111	0,040	0,91		Algorithm converged.	0,74	1,12	0,3589	0,3268	1,10		Algorithm converged.	0,89	1,36
	>= 60 years	297	49,9	115	38,7	277	46,4	102	36,8	1,08		Convergence criterion (GCONV=1E-8) satisfied.	0,77	1,52	0,019		Algorithm converged.	-0,060	0,098	1,05		Algorithm converged.	0,85	1,30	0,6397		0,95		Algorithm converged.	0,77	1,17
Geographic region	North America	73	12,3	27	37,0	77	12,9	35	45,5	0,70		Convergence criterion (GCONV=1E-8) satisfied.	0,37	1,35	-0,085		Algorithm converged.	-0,242	0,072	0,81		Algorithm converged.	0,55	1,20	0,2960	0,1254	1,23		Algorithm converged.	0,83	1,81
	Western Europe	293	49,2	120	41,0	282	47,2	115	40,8	1,01		Convergence criterion (GCONV=1E-8) satisfied.	0,72	1,40	0,002		Algorithm converged.	-0,079	0,082	1,00		Algorithm converged.	0,82	1,22	0,9659		1,00		Algorithm converged.	0,82	1,21
	Asia-Pacific	150	25,2	38	25,3	155	26,0	50	32,3	0,71		Convergence criterion (GCONV=1E-8) satisfied.	0,43	1,17	-0,069		Algorithm converged.	-0,171	0,032	0,79		Algorithm converged.	0,55	1,12	0,1848		1,27		Algorithm converged.	0,89	1,82
	Other	79	13,3	33	41,8	83	13,9	24	28,9	1,76		Convergence criterion (GCONV=1E-8) satisfied.	0,92	3,38	0,129		Algorithm converged.	-0,018	0,275	1,44		Algorithm converged.	0,94	2,21	0,0906		0,69		Algorithm converged.	0,45	1,06
Actual Chemotherapy regimen	CHOP	194	32,6	47	24,2	203	34,0	57	28,1	0,82		Convergence criterion (GCONV=1E-8) satisfied.	0,52	1,28	-0,039		Algorithm converged.	-0,125	0,048	0,86		Algorithm converged.	0,62	1,20	0,3841		1,16		Algorithm converged.	0,83	1,62
	CVP	60	10,1	22	36,7	56	9,4	20	35,7	1,04		Convergence criterion (GCONV=1E-8) satisfied.	0,49	2,22	0,010		Algorithm converged.	-0,165	0,185	1,03		Algorithm converged.	0,63	1,67	0,9151		0,97		Algorithm converged.	0,60	1,58
	Bendamustine	338	56,8	149	44,1	338	56,6	147	43,5	1,02		Convergence criterion (GCONV=1E-8) satisfied.	0,76	1,39	0,006		Algorithm converged.	-0,069	0,081	1,01		Algorithm converged.	0,85	1,20	0,8768		0,99		Algorithm converged.	0,83	1,17
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	45	35,2	121	20,3	47	38,8	0,85		Convergence criterion (GCONV=1E-8) satisfied.	0,51	1,43	-0,037		Algorithm converged.	-0,157	0,083	0,91		Algorithm converged.	0,65	1,25	0,5470	0,8385	1,10		Algorithm converged.	0,80	1,53
	Intermediate (2)	221	37,1	84	38,0	222	37,2	87	39,2	0,95		Convergence criterion (GCONV=1E-8) satisfied.	0,65	1,39	-0,012		Algorithm converged.	-0,102	0,079	0,97		Algorithm converged.	0,77	1,23	0,7987		1,03		Algorithm converged.	0,82	1,30
	High (>=3)	246	41,3	89	36,2	254	42,5	90	35,4	1,03		Convergence criterion (GCONV=1E-8) satisfied.	0,72	1,49	0,007		Algorithm converged.	-0,077	0,092	1,02		Algorithm converged.	0,81	1,29	0,8619		0,98		Algorithm converged.	0,77	1,24

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEG3_FOLY_SE_03MAR2017_21223.xls
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22 (Anhang): Ergebnisse für Patienten mit UE Grad 4 aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade 4, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk								Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	223	37,5	597	100,0	178	29,8	1,41		Convergence criterion (GCONV=1E-8) satisfied.	1,11	1,80	0,077		Algorithm converged.	0,023	0,130	1,26		Algorithm converged.	1,07	1,48	0,0054		0,80		Algorithm converged.	0,68	0,93
Sex	Male	281	47,2	93	33,1	278	46,6	73	26,3	1,39		Convergence criterion (GCONV=1E-8) satisfied.	0,96	2,00	0,068		Algorithm converged.	-0,007	0,144	1,26		Algorithm converged.	0,97	1,63	0,0785	0,9903	0,79		Algorithm converged.	0,61	1,03
	Female	314	52,8	130	41,4	319	53,4	105	32,9	1,44		Convergence criterion (GCONV=1E-8) satisfied.	1,04	1,99	0,085		Algorithm converged.	0,010	0,160	1,26		Algorithm converged.	1,03	1,54	0,0280		0,80		Algorithm converged.	0,65	0,98
Age	< 60 years	298	50,1	116	38,9	320	53,6	86	26,9	1,73		Convergence criterion (GCONV=1E-8) satisfied.	1,23	2,44	0,121		Algorithm converged.	0,047	0,194	1,45		Algorithm converged.	1,15	1,82	0,0016	0,0783	0,69		Algorithm converged.	0,55	0,87
	>= 60 years	297	49,9	107	36,0	277	46,4	92	33,2	1,13		Convergence criterion (GCONV=1E-8) satisfied.	0,80	1,60	0,028		Algorithm converged.	-0,050	0,106	1,08		Algorithm converged.	0,87	1,36	0,4797		0,92		Algorithm converged.	0,74	1,16
Geographic region	North America	73	12,3	20	27,4	77	12,9	10	13,0	2,53		Convergence criterion (GCONV=1E-8) satisfied.	1,09	5,86	0,144		Algorithm converged.	0,017	0,271	2,11		Algorithm converged.	1,06	4,20	0,0335	0,2746	0,47		Algorithm converged.	0,24	0,94
	Western Europe	293	49,2	89	30,4	282	47,2	63	22,3	1,52		Convergence criterion (GCONV=1E-8) satisfied.	1,04	2,21	0,080		Algorithm converged.	0,009	0,152	1,36		Algorithm converged.	1,03	1,80	0,0304		0,74		Algorithm converged.	0,56	0,97
	Asia-Pacific	150	25,2	89	59,3	155	26,0	81	52,3	1,33		Convergence criterion (GCONV=1E-8) satisfied.	0,85	2,10	0,071		Algorithm converged.	-0,040	0,182	1,14		Algorithm converged.	0,93	1,39	0,2145		0,88		Algorithm converged.	0,72	1,08
	Other	79	13,3	25	31,6	83	13,9	24	28,9	1,14		Convergence criterion (GCONV=1E-8) satisfied.	0,58	2,23	0,027		Algorithm converged.	-0,114	0,169	1,09		Algorithm converged.	0,69	1,75	0,7054		0,91		Algorithm converged.	0,57	1,46
Actual Chemotherapy regimen	CHOP	194	32,6	126	64,9	203	34,0	97	47,8	2,02		Convergence criterion (GCONV=1E-8) satisfied.	1,35	3,03	0,172		Algorithm converged.	0,076	0,268	1,36		Algorithm converged.	1,14	1,62	0,0007		0,74		Algorithm converged.	0,62	0,88
	CVP	60	10,1	20	33,3	56	9,4	10	17,9	2,30		Convergence criterion (GCONV=1E-8) satisfied.	0,96	5,49	0,155		Algorithm converged.	-0,001	0,311	1,87		Algorithm converged.	0,96	3,63	0,0662		0,54		Algorithm converged.	0,28	1,04
	Bendamustine	338	56,8	74	21,9	338	56,6	71	21,0	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,73	1,52	0,009		Algorithm converged.	-0,053	0,071	1,04		Algorithm converged.	0,78	1,39	0,7787		0,96		Algorithm converged.	0,72	1,28
	No Chemo	3	0,5	3	100,0																											
FLIPI	Low (0-1)	128	21,5	47	36,7	121	20,3	28	23,1	1,93		Convergence criterion (GCONV=1E-8) satisfied.	1,11	3,36	0,136		Algorithm converged.	0,023	0,248	1,59		Algorithm converged.	1,07	2,36	0,0225	0,4072	0,63		Algorithm converged.	0,42	0,94
	Intermediate (2)	221	37,1	79	35,7	222	37,2	64	28,8	1,37		Convergence criterion (GCONV=1E-8) satisfied.	0,92	2,05	0,069		Algorithm converged.	-0,018	0,156	1,24		Algorithm converged.	0,94	1,63	0,1211		0,81		Algorithm converged.	0,61	1,06
	High (>=3)	246	41,3	97	39,4	254	42,5	86	33,9	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,88	1,83	0,056		Algorithm converged.	-0,029	0,140	1,16		Algorithm converged.	0,92	1,47	0,1968		0,86		Algorithm converged.	0,68	1,08

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEG4_FOLY_SE_03MAR2017_21223.xls 01OCT2019 14:37

23 (Anhang): Ergebnisse für Patienten mit UE Grad 5 aus RCT mit dem zu bewertenden Arzneimittel - Subgruppenanalysen

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade 5 (AEs leading to death), Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		Patients with		Patients		Patients with		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	24	4,0	597	100,0	21	3,5	1,15		Convergence criterion (GCONV=1E-8) satisfied.	0,63	2,09	0,005		Algorithm converged.	-0,016	0,027	1,15		Algorithm converged.	0,65	2,04	0,6405		0,87		Algorithm converged.	0,49	1,55
Sex	Male	281	47,2	15	5,3	278	46,6	13	4,7	1,15		Convergence criterion (GCONV=1E-8) satisfied.	0,54	2,46	0,007		Algorithm converged.	-0,030	0,043	1,14		Algorithm converged.	0,55	2,35	0,7201	0,9984	0,88		Algorithm converged.	0,42	1,81
	Female	314	52,8	9	2,9	319	53,4	8	2,5	1,15		Convergence criterion (GCONV=1E-8) satisfied.	0,44	3,01	0,004		Algorithm converged.	-0,022	0,029	1,14		Algorithm converged.	0,45	2,92	0,7805		0,87		Algorithm converged.	0,34	2,24
Age	< 60 years	298	50,1	3	1,0	320	53,6	5	1,6	0,64		Convergence criterion (GCONV=1E-8) satisfied.	0,15	2,70	-0,006		Algorithm converged.	-0,023	0,012	0,64		Algorithm converged.	0,16	2,67	0,5448	0,4119	1,55		Algorithm converged.	0,37	6,44
	>= 60 years	297	49,9	21	7,1	277	46,4	16	5,8	1,24		Convergence criterion (GCONV=1E-8) satisfied.	0,63	2,43	0,013		Algorithm converged.	-0,027	0,053	1,22		Algorithm converged.	0,65	2,30	0,5289		0,82		Algorithm converged.	0,44	1,53
Geographic region	North America	73	12,3	5	6,8	77	12,9	2	2,6	2,76		Convergence criterion (GCONV=1E-8) satisfied.	0,52	14,68	0,043		Algorithm converged.	-0,025	0,110	2,64		Algorithm converged.	0,53	13,17	0,2373	0,5850	0,38		Algorithm converged.	0,08	1,89
	Western Europe	293	49,2	11	3,8	282	47,2	10	3,5	1,06		Convergence criterion (GCONV=1E-8) satisfied.	0,44	2,54	0,002		Algorithm converged.	-0,029	0,033	1,06		Algorithm converged.	0,46	2,45	0,8942		0,94		Algorithm converged.	0,41	2,19
	Asia-Pacific	150	25,2	5	3,3	155	26,0	4	2,6	1,30		Convergence criterion (GCONV=1E-8) satisfied.	0,34	4,94	0,008		Algorithm converged.	-0,031	0,046	1,29		Algorithm converged.	0,35	4,72	0,6986		0,77		Algorithm converged.	0,21	2,83
	Other	79	13,3	3	3,8	83	13,9	5	6,0	0,62		Convergence criterion (GCONV=1E-8) satisfied.	0,14	2,67	-0,022		Algorithm converged.	-0,089	0,044	0,63		Algorithm converged.	0,16	2,55	0,5176		1,59		Algorithm converged.	0,39	6,42
Actual Chemotherapy regimen	CHOP	194	32,6	3	1,5	203	34,0	4	2,0	0,78		Convergence criterion (GCONV=1E-8) satisfied.	0,17	3,54	-0,004		Algorithm converged.	-0,030	0,022	0,78		Algorithm converged.	0,18	3,46	0,7489	0,9400	1,27		Algorithm converged.	0,29	5,62
	CVP	60	10,1	1	1,7	56	9,4	1	1,8	0,93		Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,27	-0,001		Algorithm converged.	-0,049	0,046	0,93		Algorithm converged.	0,06	14,57	0,9608		1,07		Algorithm converged.	0,07	16,72
	Bendamustine	338	56,8	20	5,9	338	56,6	16	4,7	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,64	2,49	0,012		Algorithm converged.	-0,022	0,046	1,25		Algorithm converged.	0,66	2,37	0,4943		0,80		Algorithm converged.	0,42	1,52
	No Chemo	30,5																														
FLIPI	Low (0-1)	128	21,5	5	3,9	121	20,3	2	1,7	2,42		Convergence criterion (GCONV=1E-8) satisfied.	0,46	12,71	0,023		Algorithm converged.	-0,018	0,063	2,36		Algorithm converged.	0,47	11,95	0,2984	0,5892	0,42		Algorithm converged.	0,08	2,14
	Intermediate (2)	221	37,1	8	3,6	222	37,2	7	3,2	1,15		Convergence criterion (GCONV=1E-8) satisfied.	0,41	3,24	0,005		Algorithm converged.	-0,029	0,038	1,15		Algorithm converged.	0,42	3,11	0,7861		0,87		Algorithm converged.	0,32	2,36
	High (>=3)	246	41,3	11	4,5	254	42,5	12	4,7	0,94		Convergence criterion (GCONV=1E-8) satisfied.	0,41	2,18	-0,003		Algorithm converged.	-0,039	0,034	0,95		Algorithm converged.	0,43	2,10	0,8927		1,06		Algorithm converged.	0,48	2,35

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEG5_FOLY_SE_03MAR2017_21223.xls 01OCT2019
14:41

Anhang 4-G4: Spezifische Verträglichkeit: Unerwünschte Ereignisse von besonderem Interesse (AESI)

Für die AESI Hepatitis B (HBV) Reaktivierung, verlängerte Neutropenie und spät einsetzende Neutropenie liegen weder Informationen zum Zeitpunkt des Ereignisses vor, noch dazu, ob es sich jeweils um ein schweres oder schwerwiegendes Ereignis handelt. Für diese AESI werden daher keine Tabellen nach SUE und UE Grad ≥ 3 dargestellt.

24 (Anhang): Ergebnisse für Akute Thrombozytopenie nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Acute Thrombocytopenia, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	7	1,2	597	100,0				*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Sex	Male	281	47,2	4	1,4	278	46,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	Female	314	52,8	3	1,0	319	53,4				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Age	< 60 years	298	50,1	5	1,7	320	53,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	>= 60 years	297	49,9	2	0,7	277	46,4				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Geographic region	North America	73	12,3			77	12,9								NE		NE	NE	NE												
	Western Europe	293	49,2	3	1,0	282	47,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Asia-Pacific	150	25,2	2	1,3	155	26,0				*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Other	79	13,3	2	2,5	83	13,9				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Actual Chemotherapy regimen	CHOP	194	32,6	3	1,5	203	34,0				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CVP	60	10,1			56	9,4								NE		NE	NE	NE												
	Bendamustine	338	56,8	4	1,2	338	56,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	No Chemo	3	0,5												NE		NE	NE	NE												
FLIPI	Low (0-1)	128	21,5	1	0,8	121	20,3				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Intermediate (2)	221	37,1	3	1,4	222	37,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	High (>=3)	246	41,3	3	1,2	254	42,5				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIATHROM_FOLY_SE_03MAR2017_21223.xls
01OCT2019 13:42

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Acute Thrombocytopenia Serious, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	20	3,3	597	100,0				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Sex	Male	281	47,2			278	46,6								NE		NE	NE	NE							NE					
	Female	314	52,8	20	6,6	319	53,4				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Age	< 60 years	298	50,1	10	3,3	320	53,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	>= 60 years	297	49,9	10	3,3	277	46,4				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Geographic region	North America	73	12,3			77	12,9								NE		NE	NE	NE												
	Western Europe	293	49,2	20	6,7	282	47,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Asia-Pacific	150	25,2			155	26,0								NE		NE	NE	NE												
	Other	79	13,3			83	13,9								NE		NE	NE	NE												
Actual Chemotherapy regimen	CHOP	194	32,6			203	34,0								NE		NE	NE	NE												
	CVP	60	10,1			56	9,4								NE		NE	NE	NE												
	Bendamustine	338	56,8	20	6,6	338	56,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	No Chemo	30	5,5												NE		NE	NE	NE												
FLIPI	Low (0-1)	128	21,5			121	20,3								NE		NE	NE	NE												
	Intermediate (2)	221	37,1			222	37,2								NE		NE	NE	NE												
	High (>=3)	246	41,3	20	8,8	254	42,5				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIATHROMS_FOLY_SE_03MAR2017_21223.xls
01OCT2019 14:05

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Acute Thrombocytopenia Grade >= 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																			R-Chemo vs. G-Chemo				
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk								Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	4	0,7	597	100,0				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Sex	Male	281	47,2	1	0,4	278	46,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	Female	314	52,8	3	1,0	319	53,4				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Age	< 60 years	298	50,1	3	1,0	320	53,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	>= 60 years	297	49,9	1	0,3	277	46,4				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Geographic region	North America	73	12,3			77	12,9																									
	Western Europe	293	49,2	2	0,7	282	47,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Asia-Pacific	150	25,2	1	0,7	155	26,0				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Other	79	13,3	1	1,3	83	13,9				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 14.002558038 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Actual Chemotherapy regimen	CHOP	194	32,6	1	0,5	203	34,0				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CVP	60	10,1			56	9,4																									
	Bendamustine	338	56,8	3	0,9	338	56,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	No Chemo		30,5																													
FLIPI	Low (0-1)	128	21,5	1	0,8	121	20,3				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	Intermediate (2)	221	37,1	1	0,5	222	37,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	High (>=3)	246	41,3	2	0,8	254	42,5				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIATHROM3_FOLY_SE_03MAR2017_21223.xls
01OCT2019 13:38

25 (Anhang): Ergebnisse für Gastrointestinale Perforation nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: GI Perforation, Complete Study Duration
MODEL: Unstratified Analysis STUDY:
BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																			R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference						Relative Risk								Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	6	1,0	597	100,0	3	0,5	2,02		Convergence criterion (GCONV=1E-8) satisfied.	0,50	8,10	0,005		Algorithm converged.	-0,005	0,015	2,01		Algorithm converged.	0,50	7,99	0,3230		0,50		Algorithm converged.	0,13	1,98
Sex	Male	281	47,2	4	1,4	278	46,6	2	0,7	1,99		Convergence criterion (GCONV=1E-8) satisfied.	0,36	10,97	0,007		Algorithm converged.	-0,010	0,024	1,98		Algorithm converged.	0,37	10,72	0,4285	0,9858	0,51		Algorithm converged.	0,09	2,74
	Female	314	52,8	2	0,6	319	53,4	1	0,3	2,04		Convergence criterion (GCONV=1E-8) satisfied.	0,18	22,59	0,003		Algorithm converged.	-0,007	0,014	2,03		Algorithm converged.	0,19	22,29	0,5619		0,49		Algorithm converged.	0,04	5,40
Age	< 60 years	298	50,1	5	1,7	320	53,6	2	0,6	2,71		Convergence criterion (GCONV=1E-8) satisfied.	0,52	14,09	0,011		Algorithm converged.	-0,006	0,027	2,68		Algorithm converged.	0,52	13,73	0,2357	0,5211	0,37		Algorithm converged.	0,07	1,91
	>= 60 years	297	49,9	1	0,3	277	46,4	1	0,4	0,93		Convergence criterion (GCONV=1E-8) satisfied.	0,06	14,98	0,000		Algorithm converged.	-0,010	0,009	0,93		Algorithm converged.	0,06	14,84	0,9606		1,07		Algorithm converged.	0,07	17,06
Geographic region	North America	73	12,3	2	2,7	77	12,9	1	1,3	2,14		Convergence criterion (GCONV=1E-8) satisfied.	0,19	24,13	0,014		Algorithm converged.	-0,031	0,060	2,11		Algorithm converged.	0,20	22,77	0,5386	0,5361	0,47		Algorithm converged.	0,04	5,12
	Western Europe	293	49,2	1	0,3	282	47,2	1	0,4	0,96		Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,46	0,000		Algorithm converged.	-0,010	0,009	0,96		Algorithm converged.	0,06	15,31	0,9784		1,04		Algorithm converged.	0,07	16,53
	Asia-Pacific	150	25,2	1	0,7	155	26,0	1	0,6	1,03		Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,67	0,000		Algorithm converged.	-0,018	0,018	1,03		Algorithm converged.	0,07	16,37	0,9814		0,97		Algorithm converged.	0,06	15,33
	Other	79	13,3	2	2,5	83	13,9				*	Quasi-complete separation of data points detected.				*	relative Hessian convergence criterion of 8.581786602 is greater than the limit of 0.0001. The convergence is			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Actual Chemotherapy regimen	CHOP	194	32,6	2	1,0	203	34,0	1	0,5	2,10		Convergence criterion (GCONV=1E-8) satisfied.	0,19	23,39	0,005		Algorithm converged.	-0,012	0,023	2,09		Algorithm converged.	0,19	22,89	0,5452		0,48		Algorithm converged.	0,04	5,23
	CVP	60	10,1			56	9,4																									
	Bendamustine	338	56,8	4	1,2	338	56,6	2	0,6	2,01		Convergence criterion (GCONV=1E-8) satisfied.	0,37	11,06	0,006		Algorithm converged.	-0,008	0,020	2,00		Algorithm converged.	0,37	10,85	0,4217		0,50		Algorithm converged.	0,09	2,71
	No Chemo		3		0,5																											
FLIPI	Low (0-1)	128	21,5	3	2,3	121	20,3	1	0,8	2,88		Convergence criterion (GCONV=1E-8) satisfied.	0,30	28,07	0,015		Algorithm converged.	-0,016	0,046	2,84		Algorithm converged.	0,30	26,89	0,3638	0,4966	0,35		Algorithm converged.	0,04	3,34
	Intermediate (2)	221	37,1	2	0,9	222	37,2	2	0,9	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,14	7,20	0,000		Algorithm converged.	-0,018	0,018	1,00		Algorithm converged.	0,14	7,07	0,9964		1,00		Algorithm converged.	0,14	7,00
	High (>=3)	246	41,3	1	0,4	254	42,5				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIGIP_FOLY_SE_03MAR2017_21223.xls 01OCT2019
13:50

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: GI Perforation Serious, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	30	5,5	597	100,0				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Sex	Male	281	47,2	20	7,7	278	46,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	Female	314	52,8	10	3,3	319	53,4				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 47.274674752 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Age	< 60 years	298	50,1	20	7,7	320	53,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	>= 60 years	297	49,9	10	3,3	277	46,4				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Geographic region	North America	73	12,3	11	1,4	77	12,9				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 13.31502636 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Western Europe	293	49,2	10	3,3	282	47,2				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 42.225277012 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Asia-Pacific	150	25,2			155	26,0																								
	Other	79	13,3	11	1,3	83	13,9				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 14.002558038 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Actual Chemotherapy regimen	CHOP	194	32,6	21	1,0	203	34,0				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CVP	60	10,1			56	9,4																								
	Bendamustine	338	56,8	10	3,3	338	56,6				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 49.548746195 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	No Chemo		30,5																												

FLIPI	Low (0-1)	128	21,5	1	0,8	121	20,3				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Intermediate (2)	221	37,1	1	0,5	222	37,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	High (>=3)	246	41,3	1	0,4	254	42,5				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIGIPS_FOLY_SE_03MAR2017_21223.xls
01OCT2019 14:06

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: GI Perforation Grade >= 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	40	0,7	597	100,0				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Sex	Male	281	47,2	31	1,1	278	46,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	Female	314	52,8	10	0,3	319	53,4				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 47.274674752 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Age	< 60 years	298	50,1	31	1,0	320	53,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	>= 60 years	297	49,9	10	0,3	277	46,4				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Geographic region	North America	73	12,3	22	2,7	77	12,9				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 8.1361078858 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Western Europe	293	49,2	10	0,3	282	47,2				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 42.225277012 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Asia-Pacific	150	25,2			155	26,0																								
	Other	79	13,3	11	1,3	83	13,9				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 14.002558038 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Actual Chemotherapy regimen	CHOP	194	32,6	21	1,0	203	34,0				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CVP	60	10,1			56	9,4																								
	Bendamustine	338	56,8	20	0,6	338	56,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	No Chemo	3	0,5																												
FLIPI	Low (0-1)	128	21,5	21	1,6	121	20,3				*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE		Algorithm converged.	NE	NE	NE	1,0000	NE		Algorithm converged.	NE	NE
	Intermediate (2)	221	37,1	10	0,5	222	37,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	High (>=3)	246	41,3	10	0,4	254	42,5				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIGIP3_FOLY_SE_03MAR2017_21223.xls
01OCT2019 13:42

26 (Anhang): Ergebnisse für Infektionen nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Infections, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	481	80,8	597	100,0	440	73,7	1,51		Convergence criterion (GCONV=1E-8) satisfied.	1,15	1,98	0,071		Algorithm converged.	0,024	0,119	1,10		Algorithm converged.	1,03	1,17	0,0034		0,91		Algorithm converged.	0,86	0,97
Sex	Male	281	47,2	223	79,4	278	46,6	190	68,3	1,78		Convergence criterion (GCONV=1E-8) satisfied.	1,21	2,61	0,110		Algorithm converged.	0,038	0,182	1,16		Algorithm converged.	1,05	1,28	0,0033	0,1116	0,86		Algorithm converged.	0,78	0,95
	Female	314	52,8	258	82,2	319	53,4	250	78,4	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,86	1,88	0,038		Algorithm converged.	-0,024	0,100	1,05		Algorithm converged.	0,97	1,13	0,2306		0,95		Algorithm converged.	0,88	1,03
Age	< 60 years	298	50,1	240	80,5	320	53,6	230	71,9	1,62		Convergence criterion (GCONV=1E-8) satisfied.	1,11	2,36	0,087		Algorithm converged.	0,020	0,153	1,12		Algorithm converged.	1,03	1,22	0,0116	0,4674	0,89		Algorithm converged.	0,82	0,97
	>= 60 years	297	49,9	241	81,1	277	46,4	210	75,8	1,37		Convergence criterion (GCONV=1E-8) satisfied.	0,92	2,05	0,053		Algorithm converged.	-0,014	0,121	1,07		Algorithm converged.	0,98	1,17	0,1222		0,93		Algorithm converged.	0,86	1,02
Geographic region	North America	73	12,3	67	91,8	77	12,9	59	76,6	3,41		Convergence criterion (GCONV=1E-8) satisfied.	1,27	9,15	0,152		Algorithm converged.	0,038	0,265	1,20		Algorithm converged.	1,04	1,38	0,0122	0,1003	0,83		Algorithm converged.	0,72	0,96
	Western Europe	293	49,2	235	80,2	282	47,2	220	78,0	1,14		Convergence criterion (GCONV=1E-8) satisfied.	0,76	1,71	0,022		Algorithm converged.	-0,045	0,088	1,03		Algorithm converged.	0,95	1,12	0,5187		0,97		Algorithm converged.	0,89	1,06
	Asia-Pacific	150	25,2	112	74,7	155	26,0	105	67,7	1,40		Convergence criterion (GCONV=1E-8) satisfied.	0,85	2,31	0,069		Algorithm converged.	-0,032	0,171	1,10		Algorithm converged.	0,96	1,27	0,1827		0,91		Algorithm converged.	0,79	1,05
	Other	79	13,3	67	84,8	83	13,9	56	67,5	2,69		Convergence criterion (GCONV=1E-8) satisfied.	1,25	5,80	0,173		Algorithm converged.	0,045	0,302	1,26		Algorithm converged.	1,05	1,50	0,0109		0,80		Algorithm converged.	0,67	0,95
Actual Chemotherapy regimen	CHOP	194	32,6	148	76,3	203	34,0	138	68,0	1,52		Convergence criterion (GCONV=1E-8) satisfied.	0,97	2,36	0,083		Algorithm converged.	-0,005	0,171	1,12		Algorithm converged.	0,99	1,27	0,0656	0,3277	0,89		Algorithm converged.	0,79	1,01
	CVP	60	10,1	45	75,0	56	9,4	38	67,9	1,42		Convergence criterion (GCONV=1E-8) satisfied.	0,63	3,19	0,071		Algorithm converged.	-0,093	0,236	1,11		Algorithm converged.	0,88	1,39	0,3979		0,90		Algorithm converged.	0,72	1,14
	Bendamustine	338	56,8	287	84,9	338	56,6	264	78,1	1,58		Convergence criterion (GCONV=1E-8) satisfied.	1,06	2,34	0,068		Algorithm converged.	0,010	0,126	1,09		Algorithm converged.	1,01	1,17	0,0233		0,92		Algorithm converged.	0,86	0,99
	No Chemo	3	0,5	1	33,3																											
FLIPI	Low (0-1)	128	21,5	104	81,3	121	20,3	82	67,8	2,06		Convergence criterion (GCONV=1E-8) satisfied.	1,15	3,70	0,135		Algorithm converged.	0,028	0,242	1,20		Algorithm converged.	1,03	1,39	0,0166	0,4006	0,83		Algorithm converged.	0,72	0,97
	Intermediate (2)	221	37,1	174	78,7	222	37,2	164	73,9	1,31		Convergence criterion (GCONV=1E-8) satisfied.	0,84	2,03	0,049		Algorithm converged.	-0,030	0,128	1,07		Algorithm converged.	0,96	1,18	0,2299		0,94		Algorithm converged.	0,85	1,04
	High (>=3)	246	41,3	203	82,5	254	42,5	194	76,4	1,46		Convergence criterion (GCONV=1E-8) satisfied.	0,94	2,26	0,061		Algorithm converged.	-0,009	0,132	1,08		Algorithm converged.	0,99	1,18	0,0898		0,93		Algorithm converged.	0,85	1,01

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIINFEC_FOLY_SE_03MAR2017_21223.xls
01OCT2019 13:55

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Any SAEs, Complete Study Duration, INFECTIONS AND INFESTATIONS
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																			R-Chemo vs. G-Chemo				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk								Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	114	19,2	597	100,0	95	15,9	1,25		Convergence criterion (GCONV=1E-8) satisfied.	0,93	1,69	0,032		Algorithm converged.	-0,011	0,076	1,20		Algorithm converged.	0,94	1,54	0,1414		0,83		Algorithm converged.	0,65	1,06
Sex	Male	281	47,2	52	18,5	278	46,6	42	15,1	1,28		Convergence criterion (GCONV=1E-8) satisfied.	0,82	1,99	0,034		Algorithm converged.	-0,028	0,096	1,22		Algorithm converged.	0,84	1,78	0,2843	0,9054	0,82		Algorithm converged.	0,56	1,18
	Female	314	52,8	62	19,7	319	53,4	53	16,6	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,82	1,85	0,031		Algorithm converged.	-0,029	0,091	1,19		Algorithm converged.	0,85	1,66	0,3080		0,84		Algorithm converged.	0,60	1,17
Age	< 60 years	298	50,1	48	16,1	320	53,6	47	14,7	1,12		Convergence criterion (GCONV=1E-8) satisfied.	0,72	1,73	0,014		Algorithm converged.	-0,043	0,071	1,10		Algorithm converged.	0,76	1,59	0,6249	0,5379	0,91		Algorithm converged.	0,63	1,32
	>= 60 years	297	49,9	66	22,2	277	46,4	48	17,3	1,36		Convergence criterion (GCONV=1E-8) satisfied.	0,90	2,06	0,049		Algorithm converged.	-0,016	0,114	1,28		Algorithm converged.	0,92	1,79	0,1442		0,78		Algorithm converged.	0,56	1,09
Geographic region	North America	73	12,3	12	16,4	77	12,9	9	11,7	1,49		Convergence criterion (GCONV=1E-8) satisfied.	0,59	3,77	0,048		Algorithm converged.	-0,064	0,159	1,41		Algorithm converged.	0,63	3,14	0,4051	0,2909	0,71		Algorithm converged.	0,32	1,59
	Western Europe	293	49,2	56	19,1	282	47,2	51	18,1	1,07		Convergence criterion (GCONV=1E-8) satisfied.	0,70	1,63	0,010		Algorithm converged.	-0,053	0,074	1,06		Algorithm converged.	0,75	1,49	0,7517		0,95		Algorithm converged.	0,67	1,33
	Asia-Pacific	150	25,2	36	24,0	155	26,0	22	14,2	1,91		Convergence criterion (GCONV=1E-8) satisfied.	1,06	3,43	0,098		Algorithm converged.	0,010	0,186	1,69		Algorithm converged.	1,05	2,73	0,0322		0,59		Algorithm converged.	0,37	0,96
	Other	79	13,3	10	12,7	83	13,9	13	15,7	0,78		Convergence criterion (GCONV=1E-8) satisfied.	0,32	1,90	-0,030		Algorithm converged.	-0,137	0,077	0,81		Algorithm converged.	0,38	1,74	0,5852		1,24		Algorithm converged.	0,58	2,66
Actual Chemotherapy regimen	CHOP	194	32,6	28	14,4	203	34,0	21	10,3	1,46		Convergence criterion (GCONV=1E-8) satisfied.	0,80	2,67	0,041		Algorithm converged.	-0,024	0,106	1,40		Algorithm converged.	0,82	2,37	0,2185	0,6522	0,72		Algorithm converged.	0,42	1,22
	CVP	60	10,1	5	8,3	56	9,4	7	12,5	0,64		Convergence criterion (GCONV=1E-8) satisfied.	0,19	2,14	-0,042		Algorithm converged.	-0,153	0,070	0,67		Algorithm converged.	0,22	1,98	0,4653		1,50		Algorithm converged.	0,51	4,45
	Bendamustine	338	56,8	81	24,0	338	56,6	67	19,8	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,88	1,84	0,041		Algorithm converged.	-0,021	0,104	1,21		Algorithm converged.	0,91	1,61	0,1941		0,83		Algorithm converged.	0,62	1,10
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	28	21,9	121	20,3	19	15,7	1,50		Convergence criterion (GCONV=1E-8) satisfied.	0,79	2,86	0,062		Algorithm converged.	-0,035	0,158	1,39		Algorithm converged.	0,82	2,36	0,2175	0,6650	0,72		Algorithm converged.	0,42	1,22
	Intermediate (2)	221	37,1	35	15,8	222	37,2	34	15,3	1,04		Convergence criterion (GCONV=1E-8) satisfied.	0,62	1,74	0,005		Algorithm converged.	-0,062	0,073	1,03		Algorithm converged.	0,67	1,60	0,8796		0,97		Algorithm converged.	0,63	1,49
	High (>=3)	246	41,3	51	20,7	254	42,5	42	16,5	1,32		Convergence criterion (GCONV=1E-8) satisfied.	0,84	2,08	0,042		Algorithm converged.	-0,026	0,110	1,25		Algorithm converged.	0,87	1,81	0,2295		0,80		Algorithm converged.	0,55	1,15

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIINFEC_FOLY_SE_03MAR2017_21223.xls
01OCT2019 13:55

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade >= 3, Complete Study Duration, INFECTIONS AND INFESTATIONS
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																			R-Chemo vs. G-Chemo				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk									Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	127	21,3	597	100,0	107	17,9	1,24		Convergence criterion (GCONV=1E-8) satisfied.	0,93	1,66	0,034		Algorithm converged.	-0,011	0,079	1,19		Algorithm converged.	0,95	1,50	0,1379		0,84		Algorithm converged.	0,67	1,06
Sex	Male	281	47,2	57	20,3	278	46,6	46	16,5	1,28		Convergence criterion (GCONV=1E-8) satisfied.	0,84	1,97	0,037		Algorithm converged.	-0,027	0,102	1,23		Algorithm converged.	0,86	1,74	0,2558	0,8325	0,82		Algorithm converged.	0,57	1,16
	Female	314	52,8	70	22,3	319	53,4	61	19,1	1,21		Convergence criterion (GCONV=1E-8) satisfied.	0,83	1,78	0,032		Algorithm converged.	-0,031	0,095	1,17		Algorithm converged.	0,86	1,58	0,3256		0,86		Algorithm converged.	0,63	1,16
Age	< 60 years	298	50,1	60	20,1	320	53,6	53	16,6	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,84	1,91	0,036		Algorithm converged.	-0,025	0,097	1,22		Algorithm converged.	0,87	1,70	0,2519	0,8343	0,82		Algorithm converged.	0,59	1,15
	>= 60 years	297	49,9	67	22,6	277	46,4	54	19,5	1,20		Convergence criterion (GCONV=1E-8) satisfied.	0,80	1,80	0,031		Algorithm converged.	-0,036	0,097	1,16		Algorithm converged.	0,84	1,59	0,3695		0,86		Algorithm converged.	0,63	1,19
Geographic region	North America	73	12,3	17	23,3	77	12,9	11	14,3	1,82		Convergence criterion (GCONV=1E-8) satisfied.	0,79	4,21	0,090		Algorithm converged.	-0,035	0,215	1,63		Algorithm converged.	0,82	3,24	0,1636	0,5517	0,61		Algorithm converged.	0,31	1,22
	Western Europe	293	49,2	61	20,8	282	47,2	52	18,4	1,16		Convergence criterion (GCONV=1E-8) satisfied.	0,77	1,76	0,024		Algorithm converged.	-0,041	0,089	1,13		Algorithm converged.	0,81	1,57	0,4735		0,89		Algorithm converged.	0,64	1,23
	Asia-Pacific	150	25,2	38	25,3	155	26,0	30	19,4	1,41		Convergence criterion (GCONV=1E-8) satisfied.	0,82	2,43	0,060		Algorithm converged.	-0,034	0,153	1,31		Algorithm converged.	0,86	2,00	0,2121		0,76		Algorithm converged.	0,50	1,17
	Other	79	13,3	11	13,9	83	13,9	14	16,9	0,80		Convergence criterion (GCONV=1E-8) satisfied.	0,34	1,88	-0,029		Algorithm converged.	-0,140	0,082	0,83		Algorithm converged.	0,40	1,71	0,6052		1,21		Algorithm converged.	0,59	2,51
Actual Chemotherapy regimen	CHOP	194	32,6	26	13,4	203	34,0	27	13,3	1,01		Convergence criterion (GCONV=1E-8) satisfied.	0,57	1,80	0,001		Algorithm converged.	-0,066	0,068	1,01		Algorithm converged.	0,61	1,66	0,9763	0,7426	0,99		Algorithm converged.	0,60	1,64
	CVP	60	10,1	8	13,3	56	9,4	8	14,3	0,92		Convergence criterion (GCONV=1E-8) satisfied.	0,32	2,65	-0,010		Algorithm converged.	-0,135	0,116	0,93		Algorithm converged.	0,38	2,32	0,8818		1,07		Algorithm converged.	0,43	2,66
	Bendamustine	338	56,8	93	27,5	338	56,6	72	21,3	1,40		Convergence criterion (GCONV=1E-8) satisfied.	0,99	2,00	0,062		Algorithm converged.	-0,002	0,127	1,29		Algorithm converged.	0,99	1,69	0,0614		0,77		Algorithm converged.	0,59	1,01
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	35	27,3	121	20,3	21	17,4	1,79		Convergence criterion (GCONV=1E-8) satisfied.	0,97	3,30	0,100		Algorithm converged.	-0,003	0,202	1,58		Algorithm converged.	0,97	2,55	0,0637	0,4065	0,63		Algorithm converged.	0,39	1,03
	Intermediate (2)	221	37,1	40	18,1	222	37,2	38	17,1	1,07		Convergence criterion (GCONV=1E-8) satisfied.	0,66	1,75	0,010		Algorithm converged.	-0,061	0,081	1,06		Algorithm converged.	0,71	1,58	0,7861		0,95		Algorithm converged.	0,63	1,42
	High (>=3)	246	41,3	52	21,1	254	42,5	48	18,9	1,15		Convergence criterion (GCONV=1E-8) satisfied.	0,74	1,78	0,022		Algorithm converged.	-0,048	0,093	1,12		Algorithm converged.	0,79	1,59	0,5315		0,89		Algorithm converged.	0,63	1,27

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae_soc.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_soc_sg_SOC24_COMPL_AEG345_FOLY_SE_03MAR2017_21223.xls
10OCT2019 13:19

27 (Anhang): Ergebnisse für Infusionsbedingte Reaktionen (IRR) nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Infusion Related AEs, Complete Study Duration MODEL:
Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																			R-Chemo vs. G-Chemo				
		Patients		with Event		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk								Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	420	70,6	597	100,0	361	60,5	1,57		Convergence criterion (GCONV=1E-8) satisfied.	1,23	2,00	0,101		Algorithm converged.	0,048	0,155	1,17		Algorithm converged.	1,07	1,27	0,0003		0,86		Algorithm converged.	0,79	0,93
Sex	Male	281	47,2	185	65,8	278	46,6	152	54,7	1,60		Convergence criterion (GCONV=1E-8) satisfied.	1,14	2,25	0,112		Algorithm converged.	0,031	0,192	1,20		Algorithm converged.	1,05	1,38	0,0075	0,5438	0,83		Algorithm converged.	0,72	0,95
	Female	314	52,8	235	74,8	319	53,4	209	65,5	1,57		Convergence criterion (GCONV=1E-8) satisfied.	1,11	2,21	0,093		Algorithm converged.	0,022	0,164	1,14		Algorithm converged.	1,03	1,27	0,0107		0,88		Algorithm converged.	0,79	0,97
Age	< 60 years	298	50,1	216	72,5	320	53,6	198	61,9	1,62		Convergence criterion (GCONV=1E-8) satisfied.	1,16	2,28	0,106		Algorithm converged.	0,033	0,180	1,17		Algorithm converged.	1,05	1,31	0,0051	0,9665	0,85		Algorithm converged.	0,76	0,95
	>= 60 years	297	49,9	204	68,7	277	46,4	163	58,8	1,53		Convergence criterion (GCONV=1E-8) satisfied.	1,09	2,16	0,098		Algorithm converged.	0,020	0,177	1,17		Algorithm converged.	1,03	1,32	0,0152		0,86		Algorithm converged.	0,76	0,97
Geographic region	North America	73	12,3	54	74,0	77	12,9	58	75,3	0,93		Convergence criterion (GCONV=1E-8) satisfied.	0,45	1,94	-0,014		Algorithm converged.	-0,153	0,126	0,98		Algorithm converged.	0,81	1,18	0,8492	0,1990	1,02		Algorithm converged.	0,84	1,23
	Western Europe	293	49,2	215	73,4	282	47,2	173	61,3	1,74		Convergence criterion (GCONV=1E-8) satisfied.	1,22	2,47	0,120		Algorithm converged.	0,044	0,196	1,20		Algorithm converged.	1,07	1,34	0,0024		0,84		Algorithm converged.	0,74	0,94
	Asia-Pacific	150	25,2	109	72,7	155	26,0	99	63,9	1,50		Convergence criterion (GCONV=1E-8) satisfied.	0,92	2,45	0,088		Algorithm converged.	-0,016	0,192	1,14		Algorithm converged.	0,98	1,33	0,1001		0,88		Algorithm converged.	0,75	1,03
	Other	79	13,3	42	53,2	83	13,9	31	37,3	1,90		Convergence criterion (GCONV=1E-8) satisfied.	1,02	3,56	0,158		Algorithm converged.	0,007	0,310	1,42		Algorithm converged.	1,01	2,01	0,0462		0,70		Algorithm converged.	0,50	0,99
Actual Chemotherapy regimen	CHOP	194	32,6	130	67,0	203	34,0	119	58,6	1,43		Convergence criterion (GCONV=1E-8) satisfied.	0,95	2,16	0,084		Algorithm converged.	-0,011	0,179	1,14		Algorithm converged.	0,98	1,33	0,0846		0,87		Algorithm converged.	0,75	1,02
	CVP	60	10,1	46	76,7	56	9,4	32	57,1	2,46		Convergence criterion (GCONV=1E-8) satisfied.	1,11	5,48	0,195		Algorithm converged.	0,027	0,363	1,34		Algorithm converged.	1,03	1,75	0,0305		0,75		Algorithm converged.	0,57	0,97
	Bendamustine	338	56,8	241	71,3	338	56,6	210	62,1	1,51		Convergence criterion (GCONV=1E-8) satisfied.	1,10	2,09	0,092		Algorithm converged.	0,021	0,162	1,15		Algorithm converged.	1,03	1,28	0,0119		0,87		Algorithm converged.	0,78	0,97
	No Chemo	3	0,5	3	100,0																											
FLIPI	Low (0-1)	128	21,5	82	64,1	121	20,3	63	52,1	1,64		Convergence criterion (GCONV=1E-8) satisfied.	0,99	2,73	0,120		Algorithm converged.	-0,002	0,242	1,23		Algorithm converged.	0,99	1,52	0,0583	0,4718	0,81		Algorithm converged.	0,66	1,01
	Intermediate (2)	221	37,1	156	70,6	222	37,2	143	64,4	1,33		Convergence criterion (GCONV=1E-8) satisfied.	0,89	1,98	0,062		Algorithm converged.	-0,025	0,149	1,10		Algorithm converged.	0,96	1,25	0,1664		0,91		Algorithm converged.	0,80	1,04
	High (>=3)	246	41,3	182	74,0	254	42,5	155	61,0	1,82		Convergence criterion (GCONV=1E-8) satisfied.	1,24	2,66	0,130		Algorithm converged.	0,048	0,211	1,21		Algorithm converged.	1,07	1,37	0,0022		0,82		Algorithm converged.	0,73	0,93

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIIRR_FOLY_SE_03MAR2017_21223.xls 01OCT2019 14:00

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Infusion Related AEs Serious, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223

Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk								Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	34	5,7	597	100,0	14	2,3	2,52		Convergence criterion (GCONV=1E-8) satisfied.	1,34	4,75	0,034		Algorithm converged.	0,011	0,056	2,44		Algorithm converged.	1,32	4,49	0,0043		0,41		Algorithm converged.	0,22	0,76
Sex	Male	281	47,2	15	5,3	278	46,6	5	1,8	3,08		Convergence criterion (GCONV=1E-8) satisfied.	1,10	8,59	0,035		Algorithm converged.	0,005	0,066	2,97		Algorithm converged.	1,09	8,06	0,0327	0,6124	0,34		Algorithm converged.	0,12	0,91
	Female	314	52,8	19	6,1	319	53,4	9	2,8	2,22		Convergence criterion (GCONV=1E-8) satisfied.	0,99	4,98	0,032		Algorithm converged.	0,000	0,064	2,14		Algorithm converged.	0,99	4,67	0,0545		0,47		Algorithm converged.	0,21	1,01
Age	< 60 years	298	50,1	17	5,7	320	53,6	10	3,1	1,88		Convergence criterion (GCONV=1E-8) satisfied.	0,84	4,16	0,026		Algorithm converged.	-0,007	0,058	1,83		Algorithm converged.	0,85	3,92	0,1231	0,2370	0,55		Algorithm converged.	0,25	1,18
	>= 60 years	297	49,9	17	5,7	277	46,4	4	1,4	4,14		Convergence criterion (GCONV=1E-8) satisfied.	1,38	12,47	0,043		Algorithm converged.	0,013	0,073	3,96		Algorithm converged.	1,35	11,64	0,0122		0,25		Algorithm converged.	0,09	0,74
Geographic region	North America	73	12,3			77	12,9																			0,3850						
	Western Europe	293	49,2	22	7,5	282	47,2	12	4,3	1,83		Convergence criterion (GCONV=1E-8) satisfied.	0,89	3,76	0,033		Algorithm converged.	-0,006	0,071	1,76		Algorithm converged.	0,89	3,50	0,1037		0,57		Algorithm converged.	0,29	1,12
	Asia-Pacific	150	25,2	11	7,3	155	26,0	2	1,3	6,05		Convergence criterion (GCONV=1E-8) satisfied.	1,32	27,79	0,060		Algorithm converged.	0,015	0,106	5,68		Algorithm converged.	1,28	25,21	0,0223		0,18		Algorithm converged.	0,04	0,78
	Other	79	13,3	3	1,3	83	13,9				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 14.002557988 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Actual Chemotherapy regimen	CHOP	194	32,6	8	4,1	203	34,0	3	1,5	2,87		Convergence criterion (GCONV=1E-8) satisfied.	0,75	10,97	0,026		Algorithm converged.	-0,006	0,059	2,79		Algorithm converged.	0,75	10,36	0,1253		0,36		Algorithm converged.	0,10	1,33
	CVP	60	10,1	3	5,0	56	9,4	1	1,8	2,89		Convergence criterion (GCONV=1E-8) satisfied.	0,29	28,67	0,032		Algorithm converged.	-0,033	0,097	2,80		Algorithm converged.	0,30	26,14	0,3663		0,36		Algorithm converged.	0,04	3,33
	Bendamustine	338	56,8	20	5,9	338	56,6	10	3,0	2,06		Convergence criterion (GCONV=1E-8) satisfied.	0,95	4,48	0,030		Algorithm converged.	-0,001	0,061	2,00		Algorithm converged.	0,95	4,21	0,0678		0,50		Algorithm converged.	0,24	1,05
	No Chemo	3	0,5	3	####																											
FLIPI	Low (0-1)	128	21,5	6	4,7	121	20,3	4	3,3	1,44		Convergence criterion (GCONV=1E-8) satisfied.	0,40	5,23	0,014		Algorithm converged.	-0,035	0,062	1,42		Algorithm converged.	0,41	4,90	0,5811	0,6083	0,71		Algorithm converged.	0,20	2,44
	Intermediate (2)	221	37,1	13	5,9	222	37,2	4	1,8	3,41		Convergence criterion (GCONV=1E-8) satisfied.	1,09	10,61	0,041		Algorithm converged.	0,005	0,076	3,26		Algorithm converged.	1,08	9,86	0,0359		0,31		Algorithm converged.	0,10	0,92
	High (>=3)	246	41,3	15	6,1	254	42,5	6	2,4	2,68		Convergence criterion (GCONV=1E-8) satisfied.	1,02	7,03	0,037		Algorithm converged.	0,002	0,073	2,58		Algorithm converged.	1,02	6,54	0,0457		0,39		Algorithm converged.	0,15	0,98

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIIRRS_FOLY_SE_03MAR2017_21223.xls 01OCT2019 14:14

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Infusion Related AEs Grade >= 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with Event		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	73	12,3	597	100,0	44	7,4	1,76		Convergence criterion (GCONV=1E-8) satisfied.	1,19	2,60	0,049		Algorithm converged.	0,015	0,083	1,66		Algorithm converged.	1,17	2,38	0,0051		0,60		Algorithm converged.	0,42	0,86
Sex	Male	281	47,2	29	10,3	278	46,6	16	5,8	1,88		Convergence criterion (GCONV=1E-8) satisfied.	1,00	3,55	0,046		Algorithm converged.	0,001	0,091	1,79		Algorithm converged.	1,00	3,23	0,0514	0,7574	0,56		Algorithm converged.	0,31	1,00
	Female	314	52,8	44	14,0	319	53,4	28	8,8	1,69		Convergence criterion (GCONV=1E-8) satisfied.	1,03	2,80	0,052		Algorithm converged.	0,003	0,102	1,60		Algorithm converged.	1,02	2,50	0,0405		0,63		Algorithm converged.	0,40	0,98
Age	< 60 years	298	50,1	37	12,4	320	53,6	27	8,4	1,54		Convergence criterion (GCONV=1E-8) satisfied.	0,91	2,60	0,040		Algorithm converged.	-0,008	0,088	1,47		Algorithm converged.	0,92	2,36	0,1074	0,4248	0,68		Algorithm converged.	0,42	1,09
	>= 60 years	297	49,9	36	12,1	277	46,4	17	6,1	2,11		Convergence criterion (GCONV=1E-8) satisfied.	1,16	3,85	0,060		Algorithm converged.	0,013	0,106	1,98		Algorithm converged.	1,14	3,43	0,0159		0,51		Algorithm converged.	0,29	0,88
Geographic region	North America	73	12,3	4	5,5	77	12,9	1	1,3	4,41		Convergence criterion (GCONV=1E-8) satisfied.	0,48	40,38	0,042		Algorithm converged.	-0,016	0,100	4,22		Algorithm converged.	0,48	36,87	0,1930	0,2355	0,24		Algorithm converged.	0,03	2,07
	Western Europe	293	49,2	35	11,9	282	47,2	27	9,6	1,28		Convergence criterion (GCONV=1E-8) satisfied.	0,75	2,18	0,024		Algorithm converged.	-0,027	0,074	1,25		Algorithm converged.	0,78	2,01	0,3609		0,80		Algorithm converged.	0,50	1,29
	Asia-Pacific	150	25,2	24	16,0	155	26,0	9	5,8	3,09		Convergence criterion (GCONV=1E-8) satisfied.	1,39	6,89	0,102		Algorithm converged.	0,033	0,171	2,76		Algorithm converged.	1,32	5,73	0,0067		0,36		Algorithm converged.	0,17	0,75
	Other	79	13,3	10	12,7	83	13,9	7	8,4	1,57		Convergence criterion (GCONV=1E-8) satisfied.	0,57	4,36	0,042		Algorithm converged.	-0,052	0,137	1,50		Algorithm converged.	0,60	3,75	0,3846		0,67		Algorithm converged.	0,27	1,66
Actual Chemotherapy regimen	CHOP	194	32,6	33	17,0	203	34,0	17	8,4	2,24		Convergence criterion (GCONV=1E-8) satisfied.	1,20	4,18	0,086		Algorithm converged.	0,021	0,152	2,03		Algorithm converged.	1,17	3,52	0,0117		0,49		Algorithm converged.	0,28	0,85
	CVP	60	10,1	6	10,0	56	9,4	4	7,1	1,44		Convergence criterion (GCONV=1E-8) satisfied.	0,39	5,41	0,029		Algorithm converged.	-0,073	0,130	1,40		Algorithm converged.	0,42	4,70	0,5862		0,71		Algorithm converged.	0,21	2,40
	Bendamustine	338	56,8	31	9,2	338	56,6	23	6,8	1,38		Convergence criterion (GCONV=1E-8) satisfied.	0,79	2,43	0,024		Algorithm converged.	-0,017	0,065	1,35		Algorithm converged.	0,80	2,26	0,2586		0,74		Algorithm converged.	0,44	1,25
	No Chemo	3	0,5	3	100,0																											
FLIPI	Low (0-1)	128	21,5	10	7,8	121	20,3	7	5,8	1,38		Convergence criterion (GCONV=1E-8) satisfied.	0,51	3,75	0,020		Algorithm converged.	-0,042	0,083	1,35		Algorithm converged.	0,53	3,43	0,5281	0,7863	0,74		Algorithm converged.	0,29	1,88
	Intermediate (2)	221	37,1	23	10,4	222	37,2	15	6,8	1,60		Convergence criterion (GCONV=1E-8) satisfied.	0,81	3,16	0,037		Algorithm converged.	-0,016	0,089	1,54		Algorithm converged.	0,83	2,87	0,1743		0,65		Algorithm converged.	0,35	1,21
	High (>=3)	246	41,3	40	16,3	254	42,5	22	8,7	2,05		Convergence criterion (GCONV=1E-8) satisfied.	1,18	3,56	0,076		Algorithm converged.	0,018	0,134	1,88		Algorithm converged.	1,15	3,06	0,0117		0,53		Algorithm converged.	0,33	0,87

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is
uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output:
root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIIRR3_FOLY_SE_03MAR2017_21223.xls
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28 (Anhang): Ergebnisse für Neutropenie nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Neutropenia, Complete Study Duration,
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	315	52,9	597	100,0	281	47,1	1,26		Convergence criterion (GCONV=1E-8) satisfied.	1,01	1,59	0,059		Algorithm converged.	0,002	0,115	1,12		Algorithm converged.	1,00	1,26	0,0431		0,89		Algorithm converged.	0,79	1,00
Sex	Male	281	47,2	140	49,8	278	46,6	119	42,8	1,33		Convergence criterion (GCONV=1E-8) satisfied.	0,95	1,85	0,070		Algorithm converged.	-0,012	0,153	1,16		Algorithm converged.	0,97	1,39	0,0975	0,6185	0,86		Algorithm converged.	0,72	1,03
	Female	314	52,8	175	55,7	319	53,4	162	50,8	1,22		Convergence criterion (GCONV=1E-8) satisfied.	0,89	1,67	0,049		Algorithm converged.	-0,028	0,127	1,10		Algorithm converged.	0,95	1,27	0,2127		0,91		Algorithm converged.	0,79	1,05
Age	< 60 years	298	50,1	152	51,0	320	53,6	148	46,3	1,21		Convergence criterion (GCONV=1E-8) satisfied.	0,88	1,66	0,048		Algorithm converged.	-0,031	0,126	1,10		Algorithm converged.	0,94	1,30	0,2371	0,7582	0,91		Algorithm converged.	0,77	1,07
	>= 60 years	297	49,9	163	54,9	277	46,4	133	48,0	1,32		Convergence criterion (GCONV=1E-8) satisfied.	0,95	1,83	0,069		Algorithm converged.	-0,013	0,150	1,14		Algorithm converged.	0,97	1,34	0,1018		0,87		Algorithm converged.	0,75	1,03
Geographic region	North America	73	12,3	28	38,4	77	12,9	21	27,3	1,66		Convergence criterion (GCONV=1E-8) satisfied.	0,83	3,30	0,111		Algorithm converged.	-0,039	0,260	1,41		Algorithm converged.	0,88	2,24	0,1519	0,4636	0,71		Algorithm converged.	0,45	1,13
	Western Europe	293	49,2	137	46,8	282	47,2	115	40,8	1,28		Convergence criterion (GCONV=1E-8) satisfied.	0,92	1,77	0,060		Algorithm converged.	-0,021	0,141	1,15		Algorithm converged.	0,95	1,38	0,1502		0,87		Algorithm converged.	0,72	1,05
	Asia-Pacific	150	25,2	108	72,0	155	26,0	98	63,2	1,50		Convergence criterion (GCONV=1E-8) satisfied.	0,92	2,43	0,088		Algorithm converged.	-0,017	0,192	1,14		Algorithm converged.	0,97	1,33	0,1028		0,88		Algorithm converged.	0,75	1,03
	Other	79	13,3	42	53,2	83	13,9	47	56,6	0,87		Convergence criterion (GCONV=1E-8) satisfied.	0,47	1,62	-0,035		Algorithm converged.	-0,188	0,119	0,94		Algorithm converged.	0,71	1,24	0,6586		1,07		Algorithm converged.	0,81	1,41
Actual Chemotherapy regimen	CHOP	194	32,6	154	79,4	203	34,0	138	68,0	1,81		Convergence criterion (GCONV=1E-8) satisfied.	1,15	2,86	0,114		Algorithm converged.	0,028	0,200	1,17		Algorithm converged.	1,04	1,31	0,0104		0,86		Algorithm converged.	0,76	0,96
	CVP	60	10,1	34	56,7	56	9,4	16	28,6	3,27		Convergence criterion (GCONV=1E-8) satisfied.	1,51	7,08	0,281		Algorithm converged.	0,109	0,453	1,98		Algorithm converged.	1,24	3,17	0,0043		0,50		Algorithm converged.	0,32	0,81
	Bendamustine	338	56,8	127	37,6	338	56,6	127	37,6	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,73	1,37	0,000		Algorithm converged.	-0,073	0,073	1,00		Algorithm converged.	0,82	1,21	1,0000		1,00		Algorithm converged.	0,82	1,21
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	62	48,4	121	20,3	49	40,5	1,38		Convergence criterion (GCONV=1E-8) satisfied.	0,84	2,28	0,079		Algorithm converged.	-0,044	0,202	1,20		Algorithm converged.	0,90	1,58	0,2106	0,2647	0,84		Algorithm converged.	0,63	1,11
	Intermediate (2)	221	37,1	108	48,9	222	37,2	109	49,1	0,99		Convergence criterion (GCONV=1E-8) satisfied.	0,68	1,44	-0,002		Algorithm converged.	-0,095	0,091	1,00		Algorithm converged.	0,82	1,20	0,9613		1,00		Algorithm converged.	0,83	1,22
	High (>=3)	246	41,3	145	58,9	254	42,5	123	48,4	1,53		Convergence criterion (GCONV=1E-8) satisfied.	1,07	2,18	0,105		Algorithm converged.	0,018	0,192	1,22		Algorithm converged.	1,03	1,43	0,0190		0,82		Algorithm converged.	0,70	0,97

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is
uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output:
root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPINEU_FOLY_SE_03MAR2017_21223.xls
01OCT2019 14:10

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Any SAEs, Complete Study Duration, BLOOD AND LYMPHATIC SYSTEM DISORDERS
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

				G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
				Patients		with Event		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
MedDRA System Class	MedDRA Preferred Term		Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (Likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM	NEUTROPENIA	All	n/a	595	100,0	23	3,9	597	100,0	27	4,5	0,85		Convergence criterion (GCONV=1E-8) satisfied.	0,48	1,50	-0,007		Algorithm converged.	-0,029	0,016	0,85		Algorithm converged.	0,50	1,47	0,5720		1,17		Algorithm converged.	0,68	2,02
	NEUTROPENIA	Sex	Male	281	47,2	8	2,8	278	46,6	11	4,0	0,71		Convergence criterion (GCONV=1E-8) satisfied.	0,28	1,80	-0,011		Algorithm converged.	-0,041	0,019	0,72		Algorithm converged.	0,29	1,76	0,4712	0,6254	1,39		Algorithm converged.	0,57	3,40
			Female	314	52,8	15	4,8	319	53,4	16	5,0	0,95		Convergence criterion (GCONV=1E-8) satisfied.	0,46	1,96	-0,002		Algorithm converged.	-0,036	0,031	0,95		Algorithm converged.	0,48	1,89	0,8894		1,05		Algorithm converged.	0,53	2,09
	NEUTROPENIA	Age	< 60 years	298	50,1	12	4,0	320	53,6	13	4,1	0,99		Convergence criterion (GCONV=1E-8) satisfied.	0,44	2,21	0,000		Algorithm converged.	-0,031	0,031	0,99		Algorithm converged.	0,46	2,14	0,9821	0,5867	1,01		Algorithm converged.	0,47	2,18
			>= 60 years	297	49,9	11	3,7	277	46,4	14	5,1	0,72		Convergence criterion (GCONV=1E-8) satisfied.	0,32	1,62	-0,014		Algorithm converged.	-0,047	0,020	0,73		Algorithm converged.	0,34	1,59	0,4303		1,36		Algorithm converged.	0,63	2,95
	NEUTROPENIA	Geographic region	North America	73	12,3			77	12,9																								
			Western Europe	293	49,2	19	6,5	282	47,2	21	7,4	0,86		Convergence criterion (GCONV=1E-8) satisfied.	0,45	1,64	-0,010		Algorithm converged.	-0,051	0,032	0,87		Algorithm converged.	0,48	1,58	0,6506		1,15		Algorithm converged.	0,63	2,09
			Asia-Pacific	150	25,2	3	2,0	155	26,0	3	1,9	1,03		Convergence criterion (GCONV=1E-8) satisfied.	0,21	5,21	0,001		Algorithm converged.	-0,031	0,032	1,03		Algorithm converged.	0,21	5,04	0,9676		0,97		Algorithm converged.	0,20	4,72
			Other	79	13,3	1	1,3	83	13,9	3	3,6	0,34		Convergence criterion (GCONV=1E-8) satisfied.	0,03	3,36	-0,023		Algorithm converged.	-0,071	0,024	0,35		Algorithm converged.	0,04	3,30	0,3590		2,86		Algorithm converged.	0,30	26,88
	NEUTROPENIA	Actual Chemotherapy regimen	CHOP	194	32,6	8	4,1	203	34,0	8	3,9	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,39	2,85	0,002		Algorithm converged.	-0,037	0,041	1,05		Algorithm converged.	0,40	2,73	0,9262	0,2528	0,96		Algorithm converged.	0,37	2,50
			CVP	60	10,1	7	11,7	56	9,4	3	5,4	2,33		Convergence criterion (GCONV=1E-8) satisfied.	0,57	9,51	0,063		Algorithm converged.	-0,037	0,163	2,18		Algorithm converged.	0,59	8,01	0,2415		0,46		Algorithm converged.	0,12	1,69
			Bendamustine	338	56,8	8	2,4	338	56,6	16	4,7	0,49		Convergence criterion (GCONV=1E-8) satisfied.	0,21	1,16	-0,024		Algorithm converged.	-0,052	0,004	0,50		Algorithm converged.	0,22	1,15	0,1038		2,00		Algorithm converged.	0,87	4,61
			No Chemo	3	0,5																												
	NEUTROPENIA	FLIPI	Low (0-1)	128	21,5	5	3,9	121	20,3	5	4,1	0,94		Convergence criterion (GCONV=1E-8) satisfied.	0,27	3,34	-0,002		Algorithm converged.	-0,051	0,047	0,95		Algorithm converged.	0,28	3,18	0,9277	0,9554	1,06		Algorithm converged.	0,31	3,56
			Intermediate (2)	221	37,1	6	2,7	222	37,2	8	3,6	0,75		Convergence criterion (GCONV=1E-8) satisfied.	0,25	2,19	-0,009		Algorithm converged.	-0,041	0,024	0,75		Algorithm converged.	0,27	2,14	0,5943		1,33		Algorithm converged.	0,47	3,76
			High (>=3)	246	41,3	12	4,9	254	42,5	14	5,5	0,88		Convergence criterion (GCONV=1E-8) satisfied.	0,40	1,94	-0,006		Algorithm converged.	-0,045	0,033	0,89		Algorithm converged.	0,42	1,88	0,7498		1,13		Algorithm converged.	0,53	2,39

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae_soc.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_soc_sg_SOC01_COMPL_ASAE_FOLY_SE_03MAR2017_21223.xls 10OCT2019 18:14

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade >= 3, Complete Study Duration, BLOOD AND LYMPHATIC SYSTEM DISORDERS
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

				G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo			
				Patients		with Event		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk						Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term		Level	n	%	n	%	n	%	n	Odds			Convergence Reason	95% r CL	95% r CL	e Risk		Convergence Reason	95% Lower CL	95% Upper CL	Rela tive Risk		Convergence Reason	95% Lowe	95% Upper CL	Intera ction Test p- value (Wald)	p- value ihood ratio)	ive Risk		Convergence Reason	95% CL	95% CL
BLOOD AND LYMPHATIC SYSTEM		All	n/a	595	100,0	277	46,6	597	100,0	238	39,9	1,31		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	0,011	0,123	1,17		Algorithm converged.	1,02	1,33	0,0202		0,86		Algorithm converged.	0,75	0,98
	NEUTROPENIA	Sex	Male	281	47,2	125	44,5	278	46,6	103	37,1	1,36		Convergence criterion (GCONV=1E-8) satisfied.	0,97	1,91	0,074		Algorithm converged.	-0,007	0,156	1,20		Algorithm converged.	0,98	1,47	0,0751	0,7196	0,83		Algorithm converged.	0,68	1,02
			Female	314	52,8	152	48,4	319	53,4	135	42,3	1,28			0,93	1,75	0,061		Algorithm converged.	-0,017	0,138	1,14		Algorithm converged.	0,96	1,36	0,1248		0,87		Algorithm converged.	0,74	1,04
	NEUTROPENIA	Age	< 60 years	298	50,1	133	44,6	320	53,6	124	38,8	1,27		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	-0,019	0,136	1,15		Algorithm converged.	0,96	1,39	0,1386	0,8656	0,87		Algorithm converged.	0,72	1,05
			>= 60	297	49,9	144	48,5	277	46,4	114	41,2	1,35		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	-0,008	0,154	1,18		Algorithm converged.	0,98	1,41	0,0796		0,85		Algorithm converged.	0,71	1,02
	NEUTROPENIA	Geographic region	North America	73	12,3	25	34,2	77	12,9	19	24,7	1,59		Convergence criterion (GCONV=1E-8) satisfied.					Algorithm converged.	-0,050	0,241	1,39		Algorithm converged.	0,84	2,30	0,2018	0,3560	0,72		Algorithm converged.	0,44	1,19
			Western Europe	293	49,2	121	41,3	282	47,2	89	31,6	1,53		Convergence criterion (GCONV=1E-8) satisfied.	1,08	2,15	0,097		Algorithm converged.	0,019	0,176	1,31		Algorithm converged.	1,05	1,63	0,0163		0,76		Algorithm converged.	0,61	0,95
			Asia-Pacific	150	25,2	95	63,3	155	26,0	93	60,0	1,15			0,73	1,83	0,033		Algorithm converged.	-0,076	0,142	1,06		Algorithm converged.	0,88	1,26	0,5495		0,95		Algorithm converged.	0,79	1,13
			Other	79	13,3	36	45,6	83	13,9	37	44,6	1,04		Convergence criterion (GCONV=1E-8) satisfied.	0,56	1,93	0,010		Algorithm converged.	-0,143	0,163	1,02		Algorithm converged.	0,73	1,44	0,8991		0,98		Algorithm converged.	0,70	1,37
	NEUTROPENIA	Actual Chemotherapy regimen	CHOP	194	32,6	141	72,7	203	34,0	117	57,6	1,96		Convergence criterion (GCONV=1E-8) satisfied.	1,28	2,98	0,150		Algorithm converged.	0,058	0,243	1,26		Algorithm converged.	1,09	1,46	0,0019		0,79		Algorithm converged.	0,69	0,92
			CVP	60	10,1	30	50,0	56	9,4	13	23,2	3,31		satisfied.	1,49	7,37	0,268		Algorithm converged.	0,100	0,436	2,15		Algorithm converged.	1,26	3,69	0,0053		0,46		Algorithm converged.	0,27	0,80
			Bendamustine	338	56,8	106	31,4	338	56,6	108	32,0	0,97		Convergence criterion (GCONV=1E-8) satisfied.	0,70	1,35	-0,006		Algorithm converged.	-0,076	0,064	0,98		Algorithm converged.	0,79	1,22	0,8687		1,02		Algorithm converged.	0,82	1,27
NEUTROPENIA		**FLIPI**	**Low (0-1)**	**128**	**21,5**	**57**	**44,5**	**121**	**20,3**	**41**	**33,9**	**1,57**		**Convergence criterion (GCONV=1E-8) satisfied.**	**0,94**	**2,62**	**0,106**		**Algorithm converged.**	**-0,014**	**0,227**	**1,31**		**Algorithm converged.**	**0,96**	**1,80**	**0,0893**	**0,1202**	**0,76**		**Algorithm converged.**	**0,56**	**1,04**
			Intermediate (2)	**221**	**37,1**	**90**	**40,7**	**222**	**37,2**	**93**	**41,9**	**0,95**		**Convergence criterion (GCONV=1E-8) satisfied.**	**0,65**	**1,39**	**-0,012**		**Algorithm converged.**	**-0,103**	**0,080**	**0,97**		**Algorithm converged.**	**0,78**	**1,21**	**0,8029**		**1,03**		**Algorithm converged.**	**0,82**	**1,28**
			High (>=3)	**246**	**41,3**	**130**	**52,8**	**254**	**42,5**	**104**	**40,9**	**1,62**		**Convergence criterion (GCONV=1E-8) satisfied.**	**1,13**	**2,30**	**0,119**		**Algorithm converged.**	**0,032**	**0,206**	**1,29**		**Algorithm converged.**	**1,07**	**1,56**	**0,0082**		**0,77**		**Algorithm converged.**	**0,64**	**0,94**

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017
Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae_soc.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_soc_sg_SOC01_COMPL_AEG345_FOLY_SE_03MAR2017_21223.xls
01OCT2019 14:59

29 (Anhang): Ergebnisse für Progressive multifokale Leukenzephalopathie nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Progressive multifocal leukoencephalopathy, Complete Study Duration MODEL:
Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPRMLE_FOLY_SE_03MAR2017_21223.xls
01OCT2019 13:11

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Progressive multifocal leukoencephalopathy1 Serious, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPRMLES_FOLY_SE_03MAR2017_21223.xls
01OCT2019 13:04

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Progressive multifocal leukoencephalopathy1 Grade >= 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

Null Report: No results could be derived for this output.

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPRMLE3_FOLY_SE_03MAR2017_21223.xls
01OCT2019 14:02

30 (Anhang): Ergebnisse für Thrombozytopenie nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Thrombocytopenia, Complete Study Duration MODEL:
Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	74	12,4	597	100,0	48	8,0	1,62		Convergence criterion (GCONV=1E-8) satisfied.	1,11	2,38	0,044		Algorithm converged.	0,010	0,078	1,55		Algorithm converged.	1,10	2,18	0,0132		0,65		Algorithm converged.	0,46	0,91
Sex	Male	281	47,2	33	11,7	278	46,6	22	7,9	1,55		Convergence criterion (GCONV=1E-8) satisfied.	0,88	2,73	0,038		Algorithm converged.	-0,011	0,088	1,48		Algorithm converged.	0,89	2,48	0,1318	0,8287	0,67		Algorithm converged.	0,40	1,13
	Female	314	52,8	41	13,1	319	53,4	26	8,2	1,69		Convergence criterion (GCONV=1E-8) satisfied.	1,01	2,84	0,049		Algorithm converged.	0,001	0,097	1,60		Algorithm converged.	1,01	2,55	0,0475		0,62		Algorithm converged.	0,39	0,99
Age	< 60 years	298	50,1	32	10,7	320	53,6	20	6,3	1,80		Convergence criterion (GCONV=1E-8) satisfied.	1,01	3,23	0,045		Algorithm converged.	0,001	0,089	1,72		Algorithm converged.	1,01	2,94	0,0478	0,5642	0,58		Algorithm converged.	0,34	0,99
	>= 60 years	297	49,9	42	14,1	277	46,4	28	10,1	1,46		Convergence criterion (GCONV=1E-8) satisfied.	0,88	2,44	0,040		Algorithm converged.	-0,013	0,094	1,40		Algorithm converged.	0,89	2,19	0,1430		0,71		Algorithm converged.	0,46	1,12
Geographic region	North America	73	12,3	11	15,1	77	12,9	7	9,1	1,77		Convergence criterion (GCONV=1E-8) satisfied.	0,65	4,86	0,060		Algorithm converged.	-0,044	0,164	1,66		Algorithm converged.	0,68	4,04	0,2668	0,9873	0,60		Algorithm converged.	0,25	1,47
	Western Europe	293	49,2	30	10,2	282	47,2	19	6,7	1,58		Convergence criterion (GCONV=1E-8) satisfied.	0,87	2,88	0,035		Algorithm converged.	-0,010	0,080	1,52		Algorithm converged.	0,88	2,64	0,1365		0,66		Algorithm converged.	0,38	1,14
	Asia-Pacific	150	25,2	21	14,0	155	26,0	13	8,4	1,78		Convergence criterion (GCONV=1E-8) satisfied.	0,86	3,70	0,056		Algorithm converged.	-0,014	0,127	1,67		Algorithm converged.	0,87	3,21	0,1248		0,60		Algorithm converged.	0,31	1,15
	Other	79	13,3	12	15,2	83	13,9	9	10,8	1,47		Convergence criterion (GCONV=1E-8) satisfied.	0,58	3,71	0,043		Algorithm converged.	-0,060	0,147	1,40		Algorithm converged.	0,62	3,14	0,4133		0,71		Algorithm converged.	0,32	1,60
Actual Chemotherapy regimen	CHOP	194	32,6	30	15,5	203	34,0	16	7,9	2,14		Convergence criterion (GCONV=1E-8) satisfied.	1,13	4,06	0,076		Algorithm converged.	0,013	0,139	1,96		Algorithm converged.	1,11	3,48	0,0214		0,51		Algorithm converged.	0,29	0,90
	CVP	60	10,1	2	3,3	56	9,4				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Bendamustine	338	56,8	42	12,4	338	56,6	32	9,5	1,36		Convergence criterion (GCONV=1E-8) satisfied.	0,83	2,21	0,030		Algorithm converged.	-0,017	0,077	1,31		Algorithm converged.	0,85	2,03	0,2199		0,76		Algorithm converged.	0,49	1,18
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	10	7,8	121	20,3	1	0,8	10,16		Convergence criterion (GCONV=1E-8) satisfied.	1,28	80,60	0,070		Algorithm converged.	0,021	0,119	9,45		Algorithm converged.	1,23	72,74	0,0310	0,0703	0,11		Algorithm converged.	0,01	0,81
	Intermediate (2)	221	37,1	23	10,4	222	37,2	16	7,2	1,50		Convergence criterion (GCONV=1E-8) satisfied.	0,77	2,91	0,032		Algorithm converged.	-0,021	0,085	1,44		Algorithm converged.	0,78	2,66	0,2380		0,69		Algorithm converged.	0,38	1,27
	High (>=3)	246	41,3	41	16,7	254	42,5	31	12,2	1,44		Convergence criterion (GCONV=1E-8) satisfied.	0,87	2,38	0,045		Algorithm converged.	-0,017	0,106	1,37		Algorithm converged.	0,89	2,10	0,1577		0,73		Algorithm converged.	0,48	1,13

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off:
03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPITHROM_FOLY_SE_03MAR2017_21223.xls 01OCT2019 13:06

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Thrombocytopenia Serious, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk								Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	40	6,7	597	100,0	10	1,2	4,03		Convergence criterion (GCONV=1E-8) satisfied.	0,45	36,20	0,005		Algorithm converged.	-0,002	0,012	4,01		Algorithm converged.	0,45	####	0,2133		0,25		Algorithm converged.	0,03	2,22
Sex	Male	281	47,2			278	46,6																			1,0000						
	Female	314	52,8	41	1,3	319	53,4	10	3,3	4,10		Convergence criterion (GCONV=1E-8) satisfied.	0,46	36,92	0,010		Algorithm converged.	-0,004	0,023	4,06		Algorithm converged.	0,46	####	0,2087		0,25		Algorithm converged.	0,03	2,19
Age	< 60 years	298	50,1	20	6,7	320	53,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	0,2535	NE		Algorithm converged.	NE	NE
	>= 60 years	297	49,9	20	6,7	277	46,4	10	3,4	1,87		Convergence criterion (GCONV=1E-8) satisfied.	0,17	20,75	0,003		Algorithm converged.	-0,009	0,015	1,87		Algorithm converged.	0,17	####	0,6099		0,54		Algorithm converged.	0,05	5,88
Geographic region	North America	73	12,3	11	1,4	77	12,9	11	1,3	1,06		Convergence criterion (GCONV=1E-8) satisfied.	0,06	17,19	0,001		Algorithm converged.	-0,036	0,037	1,05		Algorithm converged.	0,07	####	0,9697		0,95		Algorithm converged.	0,06	14,88
	Western Europe	293	49,2	31	1,0	282	47,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Asia-Pacific	150	25,2			155	26,0																									
	Other	79	13,3			83	13,9																									
Actual Chemotherapy regimen	CHOP	194	32,6	10	5,5	203	34,0				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CVP	60	10,1			56	9,4																									
	Bendamustine	338	56,8	30	8,9	338	56,6	10	3,3	3,02		Convergence criterion (GCONV=1E-8) satisfied.	0,31	29,15	0,006		Algorithm converged.	-0,006	0,017	3,00		Algorithm converged.	0,31	####	0,3403		0,33		Algorithm converged.	0,03	3,19
	No Chemo	30	5,5																													
FLIPI	Low (0-1)	128	21,5			121	20,3																									
	Intermediate (2)	221	37,1	10	5,5	222	37,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	High (>=3)	246	41,3	31	1,2	254	42,5	10	3,4	3,12		Convergence criterion (GCONV=1E-8) satisfied.	0,32	30,22	0,008		Algorithm converged.	-0,007	0,024	3,10		Algorithm converged.	0,32	####	0,3261		0,32		Algorithm converged.	0,03	3,08

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPITHROMS_FOLY_SE_03MAR2017_21223.xls 01OCT2019 12:53

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Thrombocytopenia Grade >= 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	36	6,1	597	100,0	17	2,8	2,20		Convergence criterion (GCONV=1E-8) satisfied.	1,22	3,96	0,032		Algorithm converged.	0,009	0,055	2,12		Algorithm converged.	1,21	3,74	0,0090		0,47		Algorithm converged.	0,27	0,83
Sex	Male	281	47,2	14	5,0	278	46,6	5	1,8	2,86		Convergence criterion (GCONV=1E-8) satisfied.	1,02	8,06	0,032		Algorithm converged.	0,002	0,062	2,77		Algorithm converged.	1,01	7,59	0,0475	0,5183	0,36		Algorithm converged.	0,13	0,99
	Female	314	52,8	22	7,0	319	53,4	12	3,8	1,93		Convergence criterion (GCONV=1E-8) satisfied.	0,94	3,97	0,032		Algorithm converged.	-0,003	0,068	1,86		Algorithm converged.	0,94	3,70	0,0755		0,54		Algorithm converged.	0,27	1,07
Age	< 60 years	298	50,1	15	5,0	320	53,6	4	1,3	4,19		Convergence criterion (GCONV=1E-8) satisfied.	1,37	12,76	0,038		Algorithm converged.	0,010	0,065	4,03		Algorithm converged.	1,35	12,00	0,0124	0,1178	0,25		Algorithm converged.	0,08	0,74
	>= 60 years	297	49,9	21	7,1	277	46,4	13	4,7	1,54		Convergence criterion (GCONV=1E-8) satisfied.	0,76	3,15	0,024		Algorithm converged.	-0,015	0,062	1,51		Algorithm converged.	0,77	2,95	0,2320		0,66		Algorithm converged.	0,34	1,30
Geographic region	North America	73	12,3	5	6,8	77	12,9	5	6,5	1,06		Convergence criterion (GCONV=1E-8) satisfied.	0,29	3,82	0,004		Algorithm converged.	-0,076	0,083	1,05		Algorithm converged.	0,32	3,49	0,9304	0,1307	0,95		Algorithm converged.	0,29	3,14
	Western Europe	293	49,2	16	5,5	282	47,2	3	1,1	5,37		Convergence criterion (GCONV=1E-8) satisfied.	1,55	18,64	0,044		Algorithm converged.	0,015	0,073	5,13		Algorithm converged.	1,51	17,43	0,0087		0,19		Algorithm converged.	0,06	0,66
	Asia-Pacific	150	25,2	9	6,0	155	26,0	3	1,9	3,23		Convergence criterion (GCONV=1E-8) satisfied.	0,86	12,18	0,041		Algorithm converged.	-0,003	0,084	3,10		Algorithm converged.	0,86	11,23	0,0849		0,32		Algorithm converged.	0,09	1,17
	Other	79	13,3	6	7,6	83	13,9	6	7,2	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,33	3,42	0,004		Algorithm converged.	-0,077	0,084	1,05		Algorithm converged.	0,35	3,12	0,9292		0,95		Algorithm converged.	0,32	2,83
Actual Chemotherapy regimen	CHOP	194	32,6	15	7,7	203	34,0	5	2,5	3,32		Convergence criterion (GCONV=1E-8) satisfied.	1,18	9,31	0,053		Algorithm converged.	0,009	0,096	3,14		Algorithm converged.	1,16	8,47	0,0239		0,32		Algorithm converged.	0,12	0,86
	CVP	60	10,1	1	1,7	56	9,4				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Bendamustine	338	56,8	20	5,9	338	56,6	12	3,6	1,71		Convergence criterion (GCONV=1E-8) satisfied.	0,82	3,55	0,024		Algorithm converged.	-0,008	0,056	1,67		Algorithm converged.	0,83	3,35	0,1524		0,60		Algorithm converged.	0,30	1,21
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	4	3,1	121	20,3				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	0,2128	NE		Algorithm converged.	NE	NE
	Intermediate (2)	221	37,1	9	4,1	222	37,2	5	2,3	1,84		Convergence criterion (GCONV=1E-8) satisfied.	0,61	5,59	0,018		Algorithm converged.	-0,014	0,051	1,81		Algorithm converged.	0,62	5,31	0,2812		0,55		Algorithm converged.	0,19	1,62
	High (>=3)	246	41,3	23	9,3	254	42,5	12	4,7	2,08		Convergence criterion (GCONV=1E-8) satisfied.	1,01	4,28	0,046		Algorithm converged.	0,001	0,091	1,98		Algorithm converged.	1,01	3,89	0,0477		0,51		Algorithm converged.	0,26	0,99

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off:
03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPITHROM3_FOLY_SE_03MAR2017_21223.xls 01OCT2019 13:55

31 (Anhang): Ergebnisse für Tumorlyse-Syndrom (TLS) nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Tumor Lysis Syndrome, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	6	1,0	597	100,0	3	0,5	2,02		Convergence criterion (GCONV=1E-8) satisfied.	0,50	8,10	0,005		Algorithm converged.	-0,005	0,015	2,01		Algorithm converged.	0,50	7,99	0,3230		0,50		Algorithm converged.	0,13	1,98
Sex	Male	281	47,2	6	2,1	278	46,6	2	0,7	3,01		Convergence criterion (GCONV=1E-8) satisfied.	0,60	15,04	0,014		Algorithm converged.	-0,005	0,034	2,97		Algorithm converged.	0,60	14,58	0,1804	0,1190	0,34		Algorithm converged.	0,07	1,66
	Female	314	52,8			319	53,4	1	0,3		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
Age	< 60 years	298	50,1	1	0,3	320	53,6	2	0,6	0,54		Convergence criterion (GCONV=1E-8) satisfied.	0,05	5,93	-0,003		Algorithm converged.	-0,014	0,008	0,54		Algorithm converged.	0,05	5,89	0,6108	0,1604	1,86		Algorithm converged.	0,17	20,43
	>= 60 years	297	49,9	5	1,7	277	46,4	1	0,4	4,73		Convergence criterion (GCONV=1E-8) satisfied.	0,55	40,71	0,013		Algorithm converged.	-0,003	0,029	4,66		Algorithm converged.	0,55	39,67	0,1586		0,21		Algorithm converged.	0,03	1,82
Geographic region	North America	73	12,3			77	12,9	1	1,3		*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 12.463665708 is greater than the limit of 0.0001. The convergence is questionable.			<0.01		Algorithm converged.	0,00	NE	1,0000		>999.99		Algorithm converged.	0,00	NE
	Western Europe	293	49,2	6	2,0	282	47,2	2	0,7	2,93		Convergence criterion (GCONV=1E-8) satisfied.	0,59	14,62	0,013		Algorithm converged.	-0,006	0,032	2,89		Algorithm converged.	0,59	14,19	0,1917		0,35		Algorithm converged.	0,07	1,70
	Asia-Pacific	150	25,2			155	26,0																								
	Other	79	13,3			83	13,9																								
Actual Chemotherapy regimen	CHOP	194	32,6	3	1,5	203	34,0	1	0,5	3,17		Convergence criterion (GCONV=1E-8) satisfied.	0,33	30,76	0,011		Algorithm converged.	-0,009	0,030	3,14		Algorithm converged.	0,33	29,92	0,3200		0,32		Algorithm converged.	0,03	3,04
	CVP	60	10,1			56	9,4	1	1,8		*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 11.232968456 is greater than the limit of 0.0001. The convergence is questionable.			<0.01		Algorithm converged.	0,00	NE	1,0000		>999.99		Algorithm converged.	0,00	NE
	Bendamustine	338	56,8	3	0,9	338	56,6	1	0,3	3,02		Convergence criterion (GCONV=1E-8) satisfied.	0,31	29,15	0,006		Algorithm converged.	-0,006	0,017	3,00		Algorithm converged.	0,31	28,70	0,3403		0,33		Algorithm converged.	0,03	3,19
	No Chemo	3	0,5																												
FLIPI	Low (0-1)	128	21,5			121	20,3																			0,2121					
	Intermediate (2)	221	37,1	3	1,4	222	37,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	High (>=3)	246	41,3	3	1,2	254	42,5	3	1,2	1,03		Convergence criterion (GCONV=1E-8) satisfied.	0,21	5,17	0,000		Algorithm converged.	-0,019	0,019	1,03		Algorithm converged.	0,21	5,07	0,9685		0,97		Algorithm converged.	0,20	4,75

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPITLS_FOLY_SE_03MAR2017_21223.xls 01OCT2019
13:08

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Tumor Lysis Syndrome Serious, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	3	0,5	597	100,0	1	0,2	3,02		Convergence criterion (GCONV=1E-8) satisfied.	0,31	29,11	0,003		Algorithm converged.	-0,003	0,010	3,01		Algorithm converged.	0,31	####	0,3393		0,33		Algorithm converged.	0,03	3,18
Sex	Male	281	47,2	3	1,1	278	46,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE	0,0346	NE		Algorithm converged.	NE	NE
	Female	314	52,8			319	53,4	1	0,3		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
Age	< 60 years	298	50,1			320	53,6	1	0,3		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01		Algorithm converged.	0,00	NE	0,9999	0,0382	>999.99		Algorithm converged.	0,00	NE
	>= 60 years	297	49,9	3	1,0	277	46,4				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
Geographic region	North America	73	12,3			77	12,9																								
	Western Europe	293	49,2	3	1,0	282	47,2	1	0,4	2,91		Convergence criterion (GCONV=1E-8) satisfied.	0,30	28,11	0,007		Algorithm converged.	-0,007	0,020	2,89		Algorithm converged.	0,30	####	0,3572		0,35		Algorithm converged.	0,04	3,31
	Asia-Pacific	150	25,2			155	26,0																								
	Other	79	13,3			83	13,9																								
Actual Chemotherapy regimen	CHOP	194	32,6	1	0,5	203	34,0	1	0,5	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,07	16,85	0,000		Algorithm converged.	-0,014	0,014	1,05		Algorithm converged.	0,07	####	0,9744		0,96		Algorithm converged.	0,06	15,17
	CVP	60	10,1			56	9,4																								
	Bendamustine	338	56,8	2	0,6	338	56,6				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	No Chemo	3	0,5																												
FLIPI	Low (0-1)	128	21,5			121	20,3																								
	Intermediate (2)	221	37,1	2	0,9	222	37,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	High (>=3)	246	41,3	1	0,4	254	42,5	1	0,4	1,03		Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,60	0,000		Algorithm converged.	-0,011	0,011	1,03		Algorithm converged.	0,06	####	0,9819		0,97		Algorithm converged.	0,06	15,40

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off:
03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPITLSS_FOLY_SE_03MAR2017_21223.xls 02OCT2019 11:27

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Tumor Lysis Syndrome Grade >= 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	6	1,0	597	100,0	3	0,5	2,02		Convergence criterion (GCONV=1E-8) satisfied.	0,50	8,10	0,005		Algorithm converged.	-0,005	0,015	2,01		Algorithm converged.	0,50	7,99	0,3230		0,50		Algorithm converged.	0,13	1,98
Sex	Male	281	47,2	6	2,1	278	46,6	2	0,7	3,01		Convergence criterion (GCONV=1E-8) satisfied.	0,60	15,04	0,014		Algorithm converged.	-0,005	0,034	2,97		Algorithm converged.	0,60	14,58	0,1804	0,1190	0,34		Algorithm converged.	0,07	1,66
	Female	314	52,8			319	53,4	1	0,3		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
Age	< 60 years	298	50,1	1	0,3	320	53,6	2	0,6	0,54		Convergence criterion (GCONV=1E-8) satisfied.	0,05	5,93	-0,003		Algorithm converged.	-0,014	0,008	0,54		Algorithm converged.	0,05	5,89	0,6108	0,1604	1,86		Algorithm converged.	0,17	20,43
	>= 60 years	297	49,9	5	1,7	277	46,4	1	0,4	4,73		Convergence criterion (GCONV=1E-8) satisfied.	0,55	40,71	0,013		Algorithm converged.	-0,003	0,029	4,66		Algorithm converged.	0,55	39,67	0,1586		0,21		Algorithm converged.	0,03	1,82
Geographic region	North America	73	12,3			77	12,9	1	1,3		*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 12.463665708 is greater than the limit of 0.0001. The convergence is questionable.			<0.01		Algorithm converged.	0,00	NE	1,0000		>999.99		Algorithm converged.	0,00	NE
	Western Europe	293	49,2	6	2,0	282	47,2	2	0,7	2,93		Convergence criterion (GCONV=1E-8) satisfied.	0,59	14,62	0,013		Algorithm converged.	-0,006	0,032	2,89		Algorithm converged.	0,59	14,19	0,1917		0,35		Algorithm converged.	0,07	1,70
	Asia-Pacific	150	25,2			155	26,0																								
	Other	79	13,3			83	13,9																								
Actual Chemotherapy regimen	CHOP	194	32,6	3	1,5	203	34,0	1	0,5	3,17		Convergence criterion (GCONV=1E-8) satisfied.	0,33	30,76	0,011		Algorithm converged.	-0,009	0,030	3,14		Algorithm converged.	0,33	29,92	0,3200		0,32		Algorithm converged.	0,03	3,04
	CVP	60	10,1			56	9,4	1	1,8		*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 11.232968456 is greater than the limit of 0.0001. The convergence is questionable.			<0.01		Algorithm converged.	0,00	NE	1,0000		>999.99		Algorithm converged.	0,00	NE
	Bendamustine	338	56,8	3	0,9	338	56,6	1	0,3	3,02		Convergence criterion (GCONV=1E-8) satisfied.	0,31	29,15	0,006		Algorithm converged.	-0,006	0,017	3,00		Algorithm converged.	0,31	28,70	0,3403		0,33		Algorithm converged.	0,03	3,19
	No Chemo	3	0,5																												
FLIPI	Low (0-1)	128	21,5			121	20,3																			0,2121					
	Intermediate (2)	221	37,1	3	1,4	222	37,2				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	High (>=3)	246	41,3	3	1,2	254	42,5	3	1,2	1,03		Convergence criterion (GCONV=1E-8) satisfied.	0,21	5,17	0,000		Algorithm converged.	-0,019	0,019	1,03		Algorithm converged.	0,21	5,07	0,9685		0,97		Algorithm converged.	0,20	4,75

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPITLS3_FOLY_SE_03MAR2017_21223.xls 01OCT2019
14:00

32 (Anhang): Ergebnisse für Kardiale Ereignisse nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Cardiac Events, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	86	14,5	597	100,0	62	10,4	1,46		Convergence criterion (GCONV=1E-8) satisfied.	1,03	2,07	0,041		Algorithm converged.	0,003	0,078	1,39		Algorithm converged.	1,02	1,89	0,0343		0,72		Algorithm converged.	0,53	0,98
Sex	Male	281	47,2	46	16,4	278	46,6	28	10,1	1,75		Convergence criterion (GCONV=1E-8) satisfied.	1,06	2,89	0,063		Algorithm converged.	0,007	0,119	1,63		Algorithm converged.	1,05	2,52	0,0303	0,3260	0,62		Algorithm converged.	0,40	0,95
	Female	314	52,8	40	12,7	319	53,4	34	10,7	1,22		Convergence criterion (GCONV=1E-8) satisfied.	0,75	1,99	0,021		Algorithm converged.	-0,029	0,071	1,20		Algorithm converged.	0,78	1,84	0,4161		0,84		Algorithm converged.	0,54	1,29
Age	< 60 years	298	50,1	32	10,7	320	53,6	25	7,8	1,42		Convergence criterion (GCONV=1E-8) satisfied.	0,82	2,46	0,029		Algorithm converged.	-0,017	0,075	1,37		Algorithm converged.	0,83	2,26	0,2113	0,9758	0,73		Algorithm converged.	0,44	1,20
	>= 60 years	297	49,9	54	18,2	277	46,4	37	13,4	1,44		Convergence criterion (GCONV=1E-8) satisfied.	0,91	2,27	0,048		Algorithm converged.	-0,011	0,108	1,36		Algorithm converged.	0,93	2,00	0,1164		0,73		Algorithm converged.	0,50	1,08
Geographic region	North America	73	12,3	8	11,0	77	12,9	12	15,6	0,67		Convergence criterion (GCONV=1E-8) satisfied.	0,26	1,74	-0,046		Algorithm converged.	-0,154	0,062	0,70		Algorithm converged.	0,30	1,62	0,4087	0,1566	1,42		Algorithm converged.	0,62	3,28
	Western Europe	293	49,2	47	16,0	282	47,2	34	12,1	1,39		Convergence criterion (GCONV=1E-8) satisfied.	0,87	2,24	0,040		Algorithm converged.	-0,017	0,097	1,33		Algorithm converged.	0,88	2,00	0,1721		0,75		Algorithm converged.	0,50	1,13
	Asia-Pacific	150	25,2	25	16,7	155	26,0	11	7,1	2,62		Convergence criterion (GCONV=1E-8) satisfied.	1,24	5,53	0,096		Algorithm converged.	0,024	0,168	2,35		Algorithm converged.	1,20	4,60	0,0129		0,43		Algorithm converged.	0,22	0,83
	Other	79	13,3	6	7,6	83	13,9	5	6,0	1,28		Convergence criterion (GCONV=1E-8) satisfied.	0,38	4,38	0,016		Algorithm converged.	-0,062	0,093	1,26		Algorithm converged.	0,40	3,97	0,6919		0,79		Algorithm converged.	0,25	2,50
Actual Chemotherapy regimen	CHOP	194	32,6	33	17,0	203	34,0	15	7,4	2,57		Convergence criterion (GCONV=1E-8) satisfied.	1,35	4,90	0,096		Algorithm converged.	0,032	0,160	2,30		Algorithm converged.	1,29	4,10	0,0047	0,0853	0,43		Algorithm converged.	0,24	0,77
	CVP	60	10,1	10	16,7	56	9,4	5	8,9	2,04		Convergence criterion (GCONV=1E-8) satisfied.	0,65	6,39	0,077		Algorithm converged.	-0,043	0,198	1,87		Algorithm converged.	0,68	5,12	0,2258		0,54		Algorithm converged.	0,20	1,47
	Bendamustine	338	56,8	42	12,4	338	56,6	42	12,4	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,63	1,58	0,000		Algorithm converged.	-0,050	0,050	1,00		Algorithm converged.	0,67	1,49	1,0000		1,00		Algorithm converged.	0,67	1,49
	No Chemo	3	0,5	1	33,3																										
FLIPI	Low (0-1)	128	21,5	12	9,4	121	20,3	7	5,8	1,68		Convergence criterion (GCONV=1E-8) satisfied.	0,64	4,43	0,036		Algorithm converged.	-0,030	0,101	1,62		Algorithm converged.	0,66	3,98	0,2923	0,6238	0,62		Algorithm converged.	0,25	1,52
	Intermediate (2)	221	37,1	37	16,7	222	37,2	23	10,4	1,74		Convergence criterion (GCONV=1E-8) satisfied.	1,00	3,04	0,064		Algorithm converged.	0,000	0,127	1,62		Algorithm converged.	0,99	2,63	0,0529		0,62		Algorithm converged.	0,38	1,01
	High (>=3)	246	41,3	37	15,0	254	42,5	32	12,6	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,74	2,04	0,024		Algorithm converged.	-0,036	0,085	1,19		Algorithm converged.	0,77	1,85	0,4294		0,84		Algorithm converged.	0,54	1,30

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPICARD_FOLY_SE_03MAR2017_21223.xls 01OCT2019 13:45

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Any SAEs, Complete Study Duration, CARDIAC DISORDERS
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	26	4,4	597	100,0	12	2,0	2,23		Convergence criterion (GCONV=1E-8) satisfied.	1,11	4,46	0,024		Algorithm converged.	0,004	0,044	2,17		Algorithm converged.	1,11	4,27	0,0240		0,46		Algorithm converged.	0,23	0,90
Sex	Male	281	47,2	16	5,7	278	46,6	6	2,2	2,74		Convergence criterion (GCONV=1E-8) satisfied.	1,05	7,10	0,035		Algorithm converged.	0,003	0,067	2,64		Algorithm converged.	1,05	6,64	0,0395	0,5230	0,38		Algorithm converged.	0,15	0,95
	Female	314	52,8	10	3,2	319	53,4	6	1,9	1,72		Convergence criterion (GCONV=1E-8) satisfied.	0,62	4,78	0,013		Algorithm converged.	-0,011	0,038	1,69		Algorithm converged.	0,62	4,60	0,3020		0,59		Algorithm converged.	0,22	1,61
Age	< 60 years	298	50,1	10	3,4	320	53,6	4	1,3	2,74		Convergence criterion (GCONV=1E-8) satisfied.	0,85	8,84	0,021		Algorithm converged.	-0,003	0,045	2,68		Algorithm converged.	0,85	8,47	0,0920	0,6122	0,37		Algorithm converged.	0,12	1,17
	>= 60 years	297	49,9	16	5,4	277	46,4	8	2,9	1,91		Convergence criterion (GCONV=1E-8) satisfied.	0,81	4,55	0,025		Algorithm converged.	-0,007	0,057	1,87		Algorithm converged.	0,81	4,29	0,1423		0,54		Algorithm converged.	0,23	1,23
Geographic region	North America	73	12,3	3	4,1	77	12,9	3	3,9	1,06		Convergence criterion (GCONV=1E-8) satisfied.	0,21	5,41	0,002		Algorithm converged.	-0,061	0,065	1,05		Algorithm converged.	0,22	5,06	0,9468	0,2652	0,95		Algorithm converged.	0,20	4,55
	Western Europe	293	49,2	12	4,1	282	47,2	7	2,5	1,68		Convergence criterion (GCONV=1E-8) satisfied.	0,65	4,32	0,016		Algorithm converged.	-0,013	0,045	1,65		Algorithm converged.	0,66	4,13	0,2849		0,61		Algorithm converged.	0,24	1,52
	Asia-Pacific	150	25,2	9	6,0	155	26,0	1	0,6	9,83		Convergence criterion (GCONV=1E-8) satisfied.	1,23	78,50	0,054		Algorithm converged.	0,014	0,094	9,30		Algorithm converged.	1,19	72,51	0,0333		0,11		Algorithm converged.	0,01	0,84
	Other	79	13,3	2	2,5	83	13,9	1	1,2	2,13		Convergence criterion (GCONV=1E-8) satisfied.	0,19	23,96	0,013		Algorithm converged.	-0,029	0,055	2,10		Algorithm converged.	0,19	22,72	0,5410		0,48		Algorithm converged.	0,04	5,15
Actual Chemotherapy regimen	CHOP	194	32,6	9	4,6	203	34,0	2	1,0	4,89		Convergence criterion (GCONV=1E-8) satisfied.	1,04	22,92	0,037		Algorithm converged.	0,004	0,069	4,71		Algorithm converged.	1,03	21,52	0,0457	0,3045	0,21		Algorithm converged.	0,05	0,97
	CVP	60	10,1	2	3,3	56	9,4	1	1,8	1,90		Convergence criterion (GCONV=1E-8) satisfied.	0,17	21,51	0,015		Algorithm converged.	-0,042	0,073	1,87		Algorithm converged.	0,17	20,02	0,6061		0,54		Algorithm converged.	0,05	5,75
	Bendamustine	338	56,8	14	4,1	338	56,6	9	2,7	1,58		Convergence criterion (GCONV=1E-8) satisfied.	0,67	3,70	0,015		Algorithm converged.	-0,013	0,042	1,56		Algorithm converged.	0,68	3,54	0,2931		0,64		Algorithm converged.	0,28	1,47
	No Chemo	3	0,5	1	33,3																											
FLIPI	Low (0-1)	128	21,5	2	1,6	121	20,3	2	1,7	0,94		Convergence criterion (GCONV=1E-8) satisfied.	0,13	6,81	-0,001		Algorithm converged.	-0,032	0,030	0,95		Algorithm converged.	0,14	6,61	0,9548	0,0754	1,06		Algorithm converged.	0,15	7,39
	Intermediate (2)	221	37,1	14	6,3	222	37,2	2	0,9	7,44		Convergence criterion (GCONV=1E-8) satisfied.	1,67	33,13	0,054		Algorithm converged.	0,020	0,089	7,03		Algorithm converged.	1,62	30,58	0,0093		0,14		Algorithm converged.	0,03	0,62
	High (>=3)	246	41,3	10	4,1	254	42,5	8	3,1	1,30		Convergence criterion (GCONV=1E-8) satisfied.	0,51	3,36	0,009		Algorithm converged.	-0,024	0,042	1,29		Algorithm converged.	0,52	3,22	0,5839		0,77		Algorithm converged.	0,31	1,93

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae_soc.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_soc_sg_SOC02_COMPL_ASAE_FOLY_SE_03MAR2017_21223.xls
10OCT2019 18:29

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade >= 3, Complete Study Duration, CARDIAC DISORDERS
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	24	4,0	597	100,0	17	2,8	1,43		Convergence criterion (GCONV=1E-8) satisfied.	0,76	2,70	0,012		Algorithm converged.	-0,009	0,033	1,42		Algorithm converged.	0,77	2,61	0,2639		0,71		Algorithm converged.	0,38	1,30
Sex	Male	281	47,2	15	5,3	278	46,6	8	2,9	1,90		Convergence criterion (GCONV=1E-8) satisfied.	0,79	4,56	0,025		Algorithm converged.	-0,008	0,057	1,85		Algorithm converged.	0,80	4,30	0,1503	0,3391	0,54		Algorithm converged.	0,23	1,25
	Female	314	52,8	9	2,9	319	53,4	9	2,8	1,02		Convergence criterion (GCONV=1E-8) satisfied.	0,40	2,60	0,000		Algorithm converged.	-0,025	0,026	1,02		Algorithm converged.	0,41	2,53	0,9729		0,98		Algorithm converged.	0,40	2,45
Age	< 60 years	298	50,1	11	3,7	320	53,6	7	2,2	1,71		Convergence criterion (GCONV=1E-8) satisfied.	0,66	4,48	0,015		Algorithm converged.	-0,012	0,042	1,69		Algorithm converged.	0,66	4,30	0,2724	0,5992	0,59		Algorithm converged.	0,23	1,51
	>= 60 years	297	49,9	13	4,4	277	46,4	10	3,6	1,22		Convergence criterion (GCONV=1E-8) satisfied.	0,53	2,83	0,008		Algorithm converged.	-0,024	0,040	1,21		Algorithm converged.	0,54	2,72	0,6403		0,82		Algorithm converged.	0,37	1,85
Geographic region	North America	73	12,3	3	4,1	77	12,9	4	5,2	0,78		Convergence criterion (GCONV=1E-8) satisfied.	0,17	3,62	-0,011		Algorithm converged.	-0,078	0,056	0,79		Algorithm converged.	0,18	3,41	0,7535	0,6829	1,26		Algorithm converged.	0,29	5,46
	Western Europe	293	49,2	9	3,1	282	47,2	7	2,5	1,24		Convergence criterion (GCONV=1E-8) satisfied.	0,46	3,39	0,006		Algorithm converged.	-0,021	0,033	1,24		Algorithm converged.	0,47	3,28	0,6682		0,81		Algorithm converged.	0,31	2,14
	Asia-Pacific	150	25,2	9	6,0	155	26,0	5	3,2	1,91		Convergence criterion (GCONV=1E-8) satisfied.	0,63	5,85	0,028		Algorithm converged.	-0,019	0,075	1,86		Algorithm converged.	0,64	5,42	0,2556		0,54		Algorithm converged.	0,18	1,57
	Other	79	13,3	3	3,8	83	13,9	1	1,2	3,24		Convergence criterion (GCONV=1E-8) satisfied.	0,33	31,78	0,026		Algorithm converged.	-0,022	0,074	3,15		Algorithm converged.	0,33	29,67	0,3156		0,32		Algorithm converged.	0,03	2,99
Actual Chemotherapy regimen	CHOP	194	32,6	7	3,6	203	34,0	5	2,5	1,48		Convergence criterion (GCONV=1E-8) satisfied.	0,46	4,75	0,011		Algorithm converged.	-0,022	0,045	1,46		Algorithm converged.	0,47	4,54	0,5080		0,68		Algorithm converged.	0,22	2,11
	CVP	60	10,1	3	5,0	56	9,4				*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 4.6588036355 is greater than the limit of 0.0001. The convergence is questionable.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	Bendamustine	338	56,8	14	4,1	338	56,6	12	3,6	1,17		Convergence criterion (GCONV=1E-8) satisfied.	0,53	2,58	0,006		Algorithm converged.	-0,023	0,035	1,17		Algorithm converged.	0,55	2,49	0,6895		0,86		Algorithm converged.	0,40	1,83
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	3	2,3	121	20,3	3	2,5	0,94		Convergence criterion (GCONV=1E-8) satisfied.	0,19	4,77	-0,001		Algorithm converged.	-0,039	0,037	0,95		Algorithm converged.	0,19	4,59	0,9444	0,0125	1,06		Algorithm converged.	0,22	5,14
	Intermediate (2)	221	37,1	13	5,9	222	37,2	2	0,9	6,87		Convergence criterion (GCONV=1E-8) satisfied.	1,53	30,83	0,050		Algorithm converged.	0,016	0,083	6,53		Algorithm converged.	1,49	28,60	0,0128		0,15		Algorithm converged.	0,03	0,67
	High (>=3)	246	41,3	8	3,3	254	42,5	12	4,7	0,68		Convergence criterion (GCONV=1E-8) satisfied.	0,27	1,69	-0,015		Algorithm converged.	-0,049	0,020	0,69		Algorithm converged.	0,29	1,65	0,4041		1,45		Algorithm converged.	0,60	3,49

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae_soc.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_soc_sg_SOC02_COMPL_AEG345_FOLY_SE_03MAR2017_21223.xls
01OCT2019 17:51

33 (Anhang): Ergebnisse für Zweitmalignom nach UE, SUE, UE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Second malignancies, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	76	12,8	597	100,0	54	9,0	1,47		Convergence criterion (GCONV=1E-8) satisfied.	1,02	2,13	0,037		Algorithm converged.	0,002	0,073	1,41		Algorithm converged.	1,02	1,96	0,0403		0,71		Algorithm converged.	0,51	0,98
Sex	Male	281	47,2	44	15,7	278	46,6	34	12,2	1,33		Convergence criterion (GCONV=1E-8) satisfied.	0,82	2,16	0,034		Algorithm converged.	-0,023	0,092	1,28		Algorithm converged.	0,84	1,94	0,2440	0,4894	0,78		Algorithm converged.	0,52	1,18
	Female	314	52,8	32	10,2	319	53,4	20	6,3	1,70		Convergence criterion (GCONV=1E-8) satisfied.	0,95	3,04	0,039		Algorithm converged.	-0,004	0,082	1,63		Algorithm converged.	0,95	2,78	0,0759		0,62		Algorithm converged.	0,36	1,05
Age	< 60 years	298	50,1	30	10,1	320	53,6	19	5,9	1,77		Convergence criterion (GCONV=1E-8) satisfied.	0,98	3,22	0,041		Algorithm converged.	-0,002	0,084	1,70		Algorithm converged.	0,98	2,95	0,0611	0,3528	0,59		Algorithm converged.	0,34	1,02
	>= 60 years	297	49,9	46	15,5	277	46,4	35	12,6	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,79	2,04	0,029		Algorithm converged.	-0,028	0,085	1,23		Algorithm converged.	0,82	1,84	0,3281		0,82		Algorithm converged.	0,54	1,23
Geographic region	North America	73	12,3	16	21,9	77	12,9	11	14,3	1,68		Convergence criterion (GCONV=1E-8) satisfied.	0,72	3,92	0,076		Algorithm converged.	-0,047	0,199	1,53		Algorithm converged.	0,76	3,08	0,2292	0,5106	0,65		Algorithm converged.	0,32	1,31
	Western Europe	293	49,2	36	12,3	282	47,2	19	6,7	1,94		Convergence criterion (GCONV=1E-8) satisfied.	1,08	3,47	0,055		Algorithm converged.	0,008	0,103	1,82		Algorithm converged.	1,07	3,10	0,0266		0,55		Algorithm converged.	0,32	0,93
	Asia-Pacific	150	25,2	13	8,7	155	26,0	14	9,0	0,96		Convergence criterion (GCONV=1E-8) satisfied.	0,43	2,11	-0,004		Algorithm converged.	-0,067	0,060	0,96		Algorithm converged.	0,47	1,97	0,9105		1,04		Algorithm converged.	0,51	2,14
	Other	79	13,3	11	13,9	83	13,9	10	12,0	1,18		Convergence criterion (GCONV=1E-8) satisfied.	0,47	2,96	0,019		Algorithm converged.	-0,085	0,122	1,16		Algorithm converged.	0,52	2,57	0,7226		0,87		Algorithm converged.	0,39	1,92
Actual Chemotherapy regimen	CHOP	194	32,6	15	7,7	203	34,0	12	5,9	1,33		Convergence criterion (GCONV=1E-8) satisfied.	0,61	2,93	0,018		Algorithm converged.	-0,031	0,068	1,31		Algorithm converged.	0,63	2,72	0,4729	0,8898	0,76		Algorithm converged.	0,37	1,59
	CVP	60	10,1	4	6,7	56	9,4	4	7,1	0,93		Convergence criterion (GCONV=1E-8) satisfied.	0,22	3,91	-0,005		Algorithm converged.	-0,097	0,088	0,93		Algorithm converged.	0,25	3,55	0,9195		1,07		Algorithm converged.	0,28	4,08
	Bendamustine	338	56,8	57	16,9	338	56,6	38	11,2	1,60		Convergence criterion (GCONV=1E-8) satisfied.	1,03	2,49	0,056		Algorithm converged.	0,004	0,108	1,50		Algorithm converged.	1,02	2,20	0,0374		0,67		Algorithm converged.	0,46	0,98
	No Chemo	3	0,5																												
FLIPI	Low (0-1)	128	21,5	15	11,7	121	20,3	13	10,7	1,10		Convergence criterion (GCONV=1E-8) satisfied.	0,50	2,43	0,010		Algorithm converged.	-0,069	0,088	1,09		Algorithm converged.	0,54	2,20	0,8078	0,6405	0,92		Algorithm converged.	0,46	1,85
	Intermediate (2)	221	37,1	33	14,9	222	37,2	20	9,0	1,77		Convergence criterion (GCONV=1E-8) satisfied.	0,98	3,20	0,059		Algorithm converged.	-0,001	0,119	1,66		Algorithm converged.	0,98	2,80	0,0584		0,60		Algorithm converged.	0,36	1,02
	High (>=3)	246	41,3	28	11,4	254	42,5	21	8,3	1,43		Convergence criterion (GCONV=1E-8) satisfied.	0,79	2,58	0,031		Algorithm converged.	-0,021	0,083	1,38		Algorithm converged.	0,80	2,36	0,2441		0,73		Algorithm converged.	0,42	1,24

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIMAL_FOLY_SE_03MAR2017_21223.xls 01OCT2019 14:02

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Second malignancies Serious, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	34	5,7	597	100,0	26	4,4	1,33		Convergence criterion (GCONV=1E-8) satisfied.	0,79	2,25	0,014		Algorithm converged.	-0,011	0,038	1,31		Algorithm converged.	0,80	2,16	0,2849		0,76		Algorithm converged.	0,46	1,25
Sex	Male	281	47,2	19	6,8	278	46,6	19	6,8	0,99		Convergence criterion (GCONV=1E-8) satisfied.	0,51	1,91	-0,001		Algorithm converged.	-0,042	0,041	0,99		Algorithm converged.	0,54	1,83	0,9727	0,1434	1,01		Algorithm converged.	0,55	1,87
	Female	314	52,8	15	4,8	319	53,4	7	2,2	2,24		Convergence criterion (GCONV=1E-8) satisfied.	0,90	5,56	0,026		Algorithm converged.	-0,003	0,054	2,18		Algorithm converged.	0,90	5,27	0,0844		0,46		Algorithm converged.	0,19	1,11
Age	< 60 years	298	50,1	7	2,3	320	53,6	7	2,2	1,08		Convergence criterion (GCONV=1E-8) satisfied.	0,37	3,10	0,002		Algorithm converged.	-0,022	0,025	1,07		Algorithm converged.	0,38	3,03	0,8928	0,7265	0,93		Algorithm converged.	0,33	2,62
	>= 60 years	297	49,9	27	9,1	277	46,4	19	6,9	1,36		Convergence criterion (GCONV=1E-8) satisfied.	0,74	2,50	0,022		Algorithm converged.	-0,022	0,067	1,33		Algorithm converged.	0,75	2,33	0,3273		0,75		Algorithm converged.	0,43	1,33
Geographic region	North America	73	12,3	8	11,0	77	12,9	5	6,5	1,77		Convergence criterion (GCONV=1E-8) satisfied.	0,55	5,69	0,045		Algorithm converged.	-0,046	0,135	1,69		Algorithm converged.	0,58	4,92	0,3380	0,6782	0,59		Algorithm converged.	0,20	1,73
	Western Europe	293	49,2	17	5,8	282	47,2	10	3,5	1,68		Convergence criterion (GCONV=1E-8) satisfied.	0,75	3,72	0,023		Algorithm converged.	-0,012	0,057	1,64		Algorithm converged.	0,76	3,51	0,2064		0,61		Algorithm converged.	0,28	1,31
	Asia-Pacific	150	25,2	5	3,3	155	26,0	6	3,9	0,86		Convergence criterion (GCONV=1E-8) satisfied.	0,26	2,87	-0,005		Algorithm converged.	-0,047	0,036	0,86		Algorithm converged.	0,27	2,76	0,8014		1,16		Algorithm converged.	0,36	3,72
	Other	79	13,3	4	5,1	83	13,9	5	6,0	0,83		Convergence criterion (GCONV=1E-8) satisfied.	0,22	3,22	-0,010		Algorithm converged.	-0,080	0,061	0,84		Algorithm converged.	0,23	3,02	0,7899		1,19		Algorithm converged.	0,33	4,27
Actual Chemotherapy regimen	CHOP	194	32,6	10	5,2	203	34,0	10	4,9	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,43	2,58	0,002		Algorithm converged.	-0,041	0,045	1,05		Algorithm converged.	0,45	2,46	0,9171		0,96		Algorithm converged.	0,41	2,25
	CVP	60	10,1			56	0,4	3	5,4		*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 5.0826409936 is greater than the limit of 0.0001. The convergence is questionable.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
	Bendamustine	338	56,8	24	7,1	338	56,6	13	3,8	1,91		Convergence criterion (GCONV=1E-8) satisfied.	0,96	3,82	0,033		Algorithm converged.	-0,002	0,067	1,85		Algorithm converged.	0,96	3,56	0,0678		0,54		Algorithm converged.	0,28	1,05
	No Chemo	3	0,5																												
FLIPI	Low (0-1)	128	21,5	7	5,5	121	20,3	4	3,3	1,69		Convergence criterion (GCONV=1E-8) satisfied.	0,48	5,93	0,022		Algorithm converged.	-0,029	0,072	1,65		Algorithm converged.	0,50	5,51	0,4122	0,9127	0,60		Algorithm converged.	0,18	2,01
	Intermediate (2)	221	37,1	14	6,3	222	37,2	11	5,0	1,30		Convergence criterion (GCONV=1E-8) satisfied.	0,58	2,92	0,014		Algorithm converged.	-0,029	0,057	1,28		Algorithm converged.	0,59	2,75	0,5304		0,78		Algorithm converged.	0,36	1,68
	High (>=3)	246	41,3	13	5,3	254	42,5	11	4,3	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,54	2,81	0,010		Algorithm converged.	-0,028	0,047	1,22		Algorithm converged.	0,56	2,67	0,6186		0,82		Algorithm converged.	0,37	1,79

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIMALS_FOLY_SE_03MAR2017_21223.xls 01OCT2019
14:17

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Second malignancies Grade >= 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	33	5,5	597	100,0	26	4,4	1,29		Convergence criterion (GCONV=1E-8) satisfied.	0,76	2,18	0,012		Algorithm converged.	-0,013	0,037	1,27		Algorithm converged.	0,77	2,10	0,3445		0,79		Algorithm converged.	0,48	1,30
Sex	Male	281	47,2	19	6,8	278	46,6	18	6,5	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,54	2,04	0,003		Algorithm converged.	-0,038	0,044	1,04		Algorithm converged.	0,56	1,95	0,8916	0,3199	0,96		Algorithm converged.	0,51	1,79
	Female	314	52,8	14	4,5	319	53,4	8	2,5	1,81		Convergence criterion (GCONV=1E-8) satisfied.	0,75	4,39	0,020		Algorithm converged.	-0,009	0,048	1,78		Algorithm converged.	0,76	4,18	0,1869		0,56		Algorithm converged.	0,24	1,32
Age	< 60 years	298	50,1	6	2,0	320	53,6	7	2,2	0,92		Convergence criterion (GCONV=1E-8) satisfied.	0,31	2,77	-0,002		Algorithm converged.	-0,024	0,021	0,92		Algorithm converged.	0,31	2,71	0,8803	0,5563	1,09		Algorithm converged.	0,37	3,20
	>= 60 years	297	49,9	27	9,1	277	46,4	19	6,9	1,36		Convergence criterion (GCONV=1E-8) satisfied.	0,74	2,50	0,022		Algorithm converged.	-0,022	0,067	1,33		Algorithm converged.	0,75	2,33	0,3273		0,75		Algorithm converged.	0,43	1,33
Geographic region	North America	73	12,3	8	11,0	77	12,9	5	6,5	1,77		Convergence criterion (GCONV=1E-8) satisfied.	0,55	5,69	0,045		Algorithm converged.	-0,046	0,135	1,69		Algorithm converged.	0,58	4,92	0,3380	0,8346	0,59		Algorithm converged.	0,20	1,73
	Western Europe	293	49,2	16	5,5	282	47,2	11	3,9	1,42		Convergence criterion (GCONV=1E-8) satisfied.	0,65	3,12	0,016		Algorithm converged.	-0,019	0,050	1,40		Algorithm converged.	0,66	2,96	0,3793		0,71		Algorithm converged.	0,34	1,51
	Asia-Pacific	150	25,2	4	2,7	155	26,0	5	3,2	0,82		Convergence criterion (GCONV=1E-8) satisfied.	0,22	3,12	-0,006		Algorithm converged.	-0,044	0,032	0,83		Algorithm converged.	0,23	3,02	0,7734		1,21		Algorithm converged.	0,33	4,42
	Other	79	13,3	5	6,3	83	13,9	5	6,0	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,29	3,79	0,003		Algorithm converged.	-0,071	0,077	1,05		Algorithm converged.	0,32	3,49	0,9357		0,95		Algorithm converged.	0,29	3,16
Actual Chemotherapy regimen	CHOP	194	32,6	8	4,1	203	34,0	8	3,9	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,39	2,85	0,002		Algorithm converged.	-0,037	0,041	1,05		Algorithm converged.	0,40	2,73	0,9262	0,4639	0,96		Algorithm converged.	0,37	2,50
	CVP	60	10,1	1	1,7	56	9,4	3	5,4	0,30		Convergence criterion (GCONV=1E-8) satisfied.	0,03	2,97	-0,037		Algorithm converged.	-0,104	0,030	0,31		Algorithm converged.	0,03	2,90	0,3056		3,21		Algorithm converged.	0,34	30,00
	Bendamustine	338	56,8	24	7,1	338	56,6	15	4,4	1,65		Convergence criterion (GCONV=1E-8) satisfied.	0,85	3,20	0,027		Algorithm converged.	-0,008	0,062	1,60		Algorithm converged.	0,85	3,00	0,1419		0,63		Algorithm converged.	0,33	1,17
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	6	4,7	121	20,3	5	4,1	1,14		Convergence criterion (GCONV=1E-8) satisfied.	0,34	3,84	0,006		Algorithm converged.	-0,045	0,057	1,13		Algorithm converged.	0,36	3,62	0,8314	0,7226	0,88		Algorithm converged.	0,28	2,81
	Intermediate (2)	221	37,1	16	7,2	222	37,2	10	4,5	1,65		Convergence criterion (GCONV=1E-8) satisfied.	0,73	3,73	0,027		Algorithm converged.	-0,016	0,071	1,61		Algorithm converged.	0,75	3,46	0,2258		0,62		Algorithm converged.	0,29	1,34
	High (>=3)	246	41,3	11	4,5	254	42,5	11	4,3	1,03		Convergence criterion (GCONV=1E-8) satisfied.	0,44	2,43	0,001		Algorithm converged.	-0,035	0,037	1,03		Algorithm converged.	0,46	2,34	0,9388		0,97		Algorithm converged.	0,43	2,19

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIMAL3_FOLY_SE_03MAR2017_21223.xls 01OCT2019
13:50

34 (Anhang): Ergebnisse für Hepatitis-B (HBV) Reaktivierung nach UE aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Hepatitis B reactivation (based on laboratory values), Complete Study Duration MODEL:
Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
		Patients		Patients		Patients		Patients		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	10	2	597	100,0	4	0,7	0,25		Convergence criterion (GCONV=1E-8) satisfied.	0,03	2,24	-0,005		Algorithm converged.	-0,012	0,002	0,25		Algorithm converged.	0,03	2,24	0,2155		3,99		Algorithm converged.	0,45	35,56
Sex	Male	281	47,2	10	4	278	46,6	1	0,4	0,99		Convergence criterion (GCONV=1E-8) satisfied.	0,06	15,89	0,000		Algorithm converged.	-0,010	0,010	0,99		Algorithm converged.	0,06	15,74	0,9939	0,1376	1,01		Algorithm converged.	0,06	16,08
	Female	314	52,8			319	53,4	3	0,9		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
Age	< 60 years	298	50,1	10	3	320	53,6	2	0,6	0,54		Convergence criterion (GCONV=1E-8) satisfied.	0,05	6,93	-0,003		Algorithm converged.	-0,014	0,008	0,54		Algorithm converged.	0,05	6,89	0,6108	0,2535	1,86		Algorithm converged.	0,17	20,43
	>= 60 years	297	49,9			277	46,4	2	0,7		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
Geographic region	North America	73	12,3			77	12,9																								
	Western Europe	293	49,2			282	47,2																								
	Asia-Pacific	150	25,2	10	7	155	26,0	4	2,6	0,25		Convergence criterion (GCONV=1E-8) satisfied.	0,03	2,29	-0,019		Algorithm converged.	-0,047	0,009	0,26		Algorithm converged.	0,03	2,28	0,2236		3,87		Algorithm converged.	0,44	34,24
	Other	79	13,3			83	13,9																								
Actual Chemotherapy regimen	CHOP	194	32,6	10	5	203	34,0	3	1,5	0,35		Convergence criterion (GCONV=1E-8) satisfied.	0,04	3,35	-0,010		Algorithm converged.	-0,029	0,010	0,35		Algorithm converged.	0,04	3,32	0,3599		2,87		Algorithm converged.	0,30	27,33
	CVP	60	10,1			66	0,4																								
	Bendamustine	338	56,8			338	56,6	1	0,3		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
	No Chemo	3	0,5																												
FLIPI	Low (0-1)	128	21,5	10	8	121	20,3				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE	0,0864	NE		Algorithm converged.	NE	NE
	Intermediate (2)	221	37,1			222	37,2	2	0,9		*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE
	High (>=3)	246	41,3			254	42,5	2	0,8		*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			<0.01		Algorithm converged.	0,00	NE	0,9999		>999.99		Algorithm converged.	0,00	NE

Hepatitis B DNA positive is considered HBV-DNA >= 100 IU/mL Test for
interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical
cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIHEP_FOLY_SE_03MAR2017_21223.xls 01OCT2019
13:09

35 (Anhang): Ergebnisse für Spät einsetzende Neutropenie nach UE aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Late Onset Neutropenia, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																			R-Chemo vs. G-Chemo				
		Patients		with Event		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk									Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	24	4,0	597	100,0	23	3,9	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,59	1,88	0,002		Algorithm converged.	-0,020	0,024	1,05		Algorithm converged.	0,60	1,83	0,8724		0,96		Algorithm converged.	0,55	1,67
Sex	Male	281	47,2	10	3,6	278	46,6	9	3,2	1,10		Convergence criterion (GCONV=1E-8) satisfied.	0,44	2,76	0,003		Algorithm converged.	-0,027	0,033	1,10		Algorithm converged.	0,45	2,66	0,8340	0,8925	0,91		Algorithm converged.	0,38	2,20
	Female	314	52,8	14	4,5	319	53,4	14	4,4	1,02		Convergence criterion (GCONV=1E-8) satisfied.	0,48	2,17	0,001		Algorithm converged.	-0,031	0,033	1,02		Algorithm converged.	0,49	2,10	0,9659		0,98		Algorithm converged.	0,48	2,03
Age	< 60 years	298	50,1	10	3,4	320	53,6	12	3,8	0,89		Convergence criterion (GCONV=1E-8) satisfied.	0,38	2,09	-0,004		Algorithm converged.	-0,033	0,025	0,89		Algorithm converged.	0,39	2,04	0,7917	0,6232	1,12		Algorithm converged.	0,49	2,55
	>= 60 years	297	49,9	14	4,7	277	46,4	11	4,0	1,20		Convergence criterion (GCONV=1E-8) satisfied.	0,53	2,68	0,007		Algorithm converged.	-0,026	0,041	1,19		Algorithm converged.	0,55	2,57	0,6636		0,84		Algorithm converged.	0,39	1,82
Geographic region	North America	73	12,3	1	1,4	77	12,9	5	6,5	0,20		Convergence criterion (GCONV=1E-8) satisfied.	0,02	1,75	-0,051		Algorithm converged.	-0,112	0,010	0,21		Algorithm converged.	0,03	1,76	0,1508	0,2160	4,74		Algorithm converged.	0,57	39,61
	Western Europe	293	49,2	11	3,8	282	47,2	9	3,2	1,18		Convergence criterion (GCONV=1E-8) satisfied.	0,48	2,90	0,006		Algorithm converged.	-0,024	0,036	1,18		Algorithm converged.	0,49	2,80	0,7131		0,85		Algorithm converged.	0,36	2,02
	Asia-Pacific	150	25,2	7	4,7	155	26,0	7	4,5	1,03		Convergence criterion (GCONV=1E-8) satisfied.	0,35	3,02	0,002		Algorithm converged.	-0,045	0,048	1,03		Algorithm converged.	0,37	2,88	0,9499		0,97		Algorithm converged.	0,35	2,69
	Other	79	13,3	5	6,3	83	13,9	2	2,4	2,74		Convergence criterion (GCONV=1E-8) satisfied.	0,52	14,53	0,039		Algorithm converged.	-0,024	0,102	2,63		Algorithm converged.	0,52	13,15	0,2399		0,38		Algorithm converged.	0,08	1,91
Actual Chemotherapy regimen	CHOP	194	32,6	5	2,6	203	34,0	3	1,5	1,76		Convergence criterion (GCONV=1E-8) satisfied.	0,42	7,48	0,011		Algorithm converged.	-0,017	0,039	1,74		Algorithm converged.	0,42	7,20	0,4420		0,57		Algorithm converged.	0,14	2,37
	CVP	60	10,1			56	0,4	1	1,8		*	Quasi-complete separation of data points detected.				*	WARNING: The relative Hessian convergence criterion of 11.232968477 is greater than the limit of 0.0001. The convergence is questionable.			<0.01		Algorithm converged.	0,00	NE	1,0000		>999.99		Algorithm converged.	0,00	NE
	Bendamustine	338	56,8	19	5,6	338	56,6	19	5,6	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,52	1,92	0,000		Algorithm converged.	-0,035	0,035	1,00		Algorithm converged.	0,54	1,85	1,0000		1,00		Algorithm converged.	0,54	1,85
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	2	1,6	121	20,3	3	2,5	0,62		Convergence criterion (GCONV=1E-8) satisfied.	0,10	3,80	-0,009		Algorithm converged.	-0,044	0,026	0,63		Algorithm converged.	0,11	3,71	0,6095	0,3506	1,59		Algorithm converged.	0,27	9,33
	Intermediate (2)	221	37,1	9	4,1	222	37,2	12	5,4	0,74		Convergence criterion (GCONV=1E-8) satisfied.	0,31	1,80	-0,013		Algorithm converged.	-0,053	0,026	0,75		Algorithm converged.	0,32	1,75	0,5108		1,33		Algorithm converged.	0,57	3,09
	High (>=3)	246	41,3	13	5,3	254	42,5	8	3,1	1,72		Convergence criterion (GCONV=1E-8) satisfied.	0,70	4,21	0,021		Algorithm converged.	-0,014	0,057	1,68		Algorithm converged.	0,71	3,98	0,2399		0,60		Algorithm converged.	0,25	1,41

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPILONEU_FOLY_SE_03MAR2017_21223.xls 01OCT2019 13:21

36 (Anhang): Ergebnisse für Verlängerte Neutropenie nach UE aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Prolonged Neutropenia, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

		G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																		R-Chemo vs. G-Chemo				
		Patients		with Event		Patients		with Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
Name	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
All	n/a	595	100,0	5	0,8	597	100,0	3	0,5	1,68		Convergence criterion (GCONV=1E-8) satisfied.	0,40	7,05	0,003		Algorithm converged.	-0,006	0,013	1,67		Algorithm converged.	0,40	6,97	0,4800		0,60		Algorithm converged.	0,14	2,49
Sex	Male	281	47,2	2	0,7	278	46,6	2	0,7	0,99		Convergence criterion (GCONV=1E-8) satisfied.	0,14	7,07	0,000		Algorithm converged.	-0,014	0,014	0,99		Algorithm converged.	0,14	6,97	0,9914	0,4496	1,01		Algorithm converged.	0,14	7,13
	Female	314	52,8	3	1,0	319	53,4	1	0,3	3,07		Convergence criterion (GCONV=1E-8) satisfied.	0,32	29,64	0,006		Algorithm converged.	-0,006	0,019	3,05		Algorithm converged.	0,32	29,14	0,3333		0,33		Algorithm converged.	0,03	3,14
Age	< 60 years	298	50,1	3	1,0	320	53,6	1	0,3	3,24		Convergence criterion (GCONV=1E-8) satisfied.	0,34	31,35	0,007		Algorithm converged.	-0,006	0,020	3,22		Algorithm converged.	0,34	30,80	0,3098	0,4042	0,31		Algorithm converged.	0,03	2,97
	>= 60 years	297	49,9	2	0,7	277	46,4	2	0,7	0,93		Convergence criterion (GCONV=1E-8) satisfied.	0,13	6,66	0,000		Algorithm converged.	-0,014	0,013	0,93		Algorithm converged.	0,13	6,58	0,9442		1,07		Algorithm converged.	0,15	7,56
Geographic region	North America	73	12,3			77	12,9																									
	Western Europe	293	49,2	2	0,7	282	47,2	2	0,7	0,96		Convergence criterion (GCONV=1E-8) satisfied.	0,13	6,88	0,000		Algorithm converged.	-0,014	0,013	0,96		Algorithm converged.	0,14	6,79	0,9694		1,04		Algorithm converged.	0,15	7,33
	Asia-Pacific	150	25,2	3	2,0	155	26,0	1	0,6	3,14		Convergence criterion (GCONV=1E-8) satisfied.	0,32	30,55	0,014		Algorithm converged.	-0,012	0,039	3,10		Algorithm converged.	0,33	29,47	0,3248		0,32		Algorithm converged.	0,03	3,07
	Other	79	13,3			83	13,9																									
Actual Chemotherapy regimen	CHOP	194	32,6	2	1,0	203	34,0				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
	CVP	60	10,1			56	9,4																									
	Bendamustine	338	56,8	3	0,9	338	56,6	3	0,9	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,20	4,99	0,000		Algorithm converged.	-0,014	0,014	1,00		Algorithm converged.	0,20	4,92	1,0000		1,00		Algorithm converged.	0,20	4,92
	No Chemo	3	0,5																													
FLIPI	Low (0-1)	128	21,5	1	0,8	121	20,3				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE	0,5962	NE		Algorithm converged.	NE	NE
	Intermediate (2)	221	37,1	1	0,5	222	37,2	1	0,5	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,06	16,16	0,000		Algorithm converged.	-0,012	0,013	1,00		Algorithm converged.	0,06	15,96	0,9974		1,00		Algorithm converged.	0,06	15,82
	High (>=3)	246	41,3	3	1,2	254	42,5	2	0,8	1,56		Convergence criterion (GCONV=1E-8) satisfied.	0,26	9,39	0,004		Algorithm converged.	-0,013	0,022	1,55		Algorithm converged.	0,26	9,19	0,6301		0,65		Algorithm converged.	0,11	3,83

Test for interaction based on RR (Log-binomial regression)
* indicates convergence problem. Result is uninterpretable. Clinical cut-off: 03MAR2017

Program: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/program/t_s_ae.sas
Output: root/clinical_studies/RO5072759/CDPT7499/BO21223/data_analysis/ACE_SafetyUpdate/qa/output/t_s_ae_sg_COMPL_AEPIPNEU_FOLY_SE_03MAR2017_21223.xls 01OCT2019 13:16

Anhang 4-G5: Spezifische Verträglichkeit: UE nach SOC/PT

SOC/PT ohne aufgetretene Ereignisse werden im Folgendem nicht dargestellt.

37 (Anhang): Ergebnisse für UE bei ≥ 10 % der Patienten in einem Studienarm nach SOC/PT aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Any AEs, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

All

			G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo															R-Chemo vs. G-Chemo			
			Patients		Patients with Event		Patients		Patients with Event		Odds Ratio				Absolute Risk Difference				Relative Risk							Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	n/a	595	100,0	366	61,5	597	100	331	55,4	1,28	Convergence criterion (GCONV=1E-8) satisfied.	1,02	1,62	0,061	Algorithm converged.	0,005	0,117	1,11	Algorithm converged.	1,01	1,22	0,0339		0,90	Algorithm converged.	0,82	0,99
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	n/a	595	100,0	56	9,4	597	100	66	11,1	0,84	Convergence criterion (GCONV=1E-8) satisfied.	0,57	1,22	-0,016	Algorithm converged.	-0,051	0,018	0,85	Algorithm converged.	0,61	1,19	0,3500		1,17	Algorithm converged.	0,84	1,65
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	n/a	595	100,0	74	12,4	597	100	75	12,6	0,99	Convergence criterion (GCONV=1E-8) satisfied.	0,70	1,39	-0,001	Algorithm converged.	-0,039	0,036	0,99	Algorithm converged.	0,73	1,34	0,9476		1,01	Algorithm converged.	0,75	1,36
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	n/a	595	100,0	303	50,9	597	100	273	45,7	1,23	Convergence criterion (GCONV=1E-8) satisfied.	0,98	1,55	0,052	Algorithm converged.	-0,005	0,109	1,11	Algorithm converged.	0,99	1,25	0,0732		0,90	Algorithm converged.	0,80	1,01
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	n/a	595	100,0	74	12,4	597	100	48	8,0	1,62	Convergence criterion (GCONV=1E-8) satisfied.	1,11	2,38	0,044	Algorithm converged.	0,010	0,078	1,55	Algorithm converged.	1,10	2,18	0,0132		0,65	Algorithm converged.	0,46	0,91
CARDIAC DISORDERS	ALL	n/a	595	100,0	86	14,5	597	100	62	10,4	1,46	Convergence criterion (GCONV=1E-8) satisfied.	1,03	2,07	0,041	Algorithm converged.	0,003	0,078	1,39	Algorithm converged.	1,02	1,89	0,0343		0,72	Algorithm converged.	0,53	0,98
EAR AND LABYRINTH DISORDERS	ALL	n/a	595	100,0	52	8,7	597	100	62	10,4	0,83	Convergence criterion (GCONV=1E-8) satisfied.	0,56	1,22	-0,016	Algorithm converged.	-0,050	0,017	0,84	Algorithm converged.	0,59	1,19	0,3348		1,19	Algorithm converged.	0,84	1,69
EYE DISORDERS	ALL	n/a	595	100,0	85	14,3	597	100	72	12,1	1,22	Convergence criterion (GCONV=1E-8) satisfied.	0,87	1,70	0,022	Algorithm converged.	-0,016	0,061	1,18	Algorithm converged.	0,88	1,59	0,2568		0,84	Algorithm converged.	0,63	1,13
GASTROINTESTINAL DISORDERS	ALL	n/a	595	100,0	495	83,2	597	100	470	78,7	1,34	Convergence criterion (GCONV=1E-8) satisfied.	1,00	1,79	0,045	Algorithm converged.	0,000	0,089	1,06	Algorithm converged.	1,00	1,12	0,0499		0,95	Algorithm converged.	0,90	1,00
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	n/a	595	100,0	63	10,6	597	100	70	11,7	0,89	Convergence criterion (GCONV=1E-8) satisfied.	0,62	1,28	-0,011	Algorithm converged.	-0,047	0,024	0,9	Algorithm converged.	0,66	1,24	0,5332		1,11	Algorithm converged.	0,80	1,53
GASTROINTESTINAL DISORDERS	CONSTIPATION	n/a	595	100,0	218	36,6	597	100	197	33,0	1,17	Convergence criterion (GCONV=1E-8) satisfied.	0,92	1,49	0,036	Algorithm converged.	-0,018	0,090	1,11	Algorithm converged.	0,95	1,30	0,1876		0,90	Algorithm converged.	0,77	1,05
GASTROINTESTINAL DISORDERS	DIARRHOEA	n/a	595	100,0	179	30,1	597	100	143	24,0	1,37	Convergence criterion (GCONV=1E-8) satisfied.	1,06	1,77	0,061	Algorithm converged.	0,011	0,112	1,26	Algorithm converged.	1,04	1,52	0,0176		0,80	Algorithm converged.	0,66	0,96
GASTROINTESTINAL DISORDERS	NAUSEA	n/a	595	100,0	297	49,9	597	100	294	49,2	1,03	Convergence criterion (GCONV=1E-8) satisfied.	0,82	1,29	0,007	Algorithm converged.	-0,050	0,063	1,01	Algorithm converged.	0,90	1,14	0,8171		0,99	Algorithm converged.	0,88	1,11
GASTROINTESTINAL DISORDERS	VOMITING	n/a	595	100,0	153	25,7	597	100	132	22,1	1,22	Convergence criterion (GCONV=1E-8) satisfied.	0,93	1,59	0,036	Algorithm converged.	-0,012	0,084	1,16	Algorithm converged.	0,95	1,43	0,1454		0,86	Algorithm converged.	0,70	1,05
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	n/a	595	100,0	465	78,2	597	100	430	72,0	1,39	Convergence criterion (GCONV=1E-8) satisfied.	1,07	1,81	0,061	Algorithm converged.	0,012	0,110	1,09	Algorithm converged.	1,02	1,16	0,0148		0,92	Algorithm converged.	0,86	0,98
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	n/a	595	100,0	103	17,3	597	100	59	9,9	1,91	Convergence criterion (GCONV=1E-8) satisfied.	1,36	2,69	0,074	Algorithm converged.	0,036	0,113	1,75	Algorithm converged.	1,30	2,36	0,0002		0,57	Algorithm converged.	0,42	0,77
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	n/a	595	100,0	227	38,2	597	100	240	40,2	0,92	Convergence criterion (GCONV=1E-8) satisfied.	0,73	1,16	-0,020	Algorithm converged.	-0,076	0,035	0,95	Algorithm converged.	0,82	1,09	0,4687		1,05	Algorithm converged.	0,91	1,21
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	n/a	595	100,0	171	28,7	597	100	132	22,1	1,42	Convergence criterion (GCONV=1E-8) satisfied.	1,09	1,85	0,066	Algorithm converged.	0,017	0,116	1,3	Algorithm converged.	1,07	1,58	0,0090		0,77	Algorithm converged.	0,63	0,94
INFECTIONS AND INFESTATIONS	ALL	n/a	595	100,0	481	80,8	597	100	440	73,7	1,51	Convergence criterion (GCONV=1E-8) satisfied.	1,15	1,98	0,071	Algorithm converged.	0,024	0,119	1,1	Algorithm converged.	1,03	1,17	0,0034		0,91	Algorithm converged.	0,86	0,97
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	n/a	595	100,0	63	10,6	597	100	40	6,7	1,65	Convergence criterion (GCONV=1E-8) satisfied.	1,09	2,49	0,039	Algorithm converged.	0,007	0,071	1,58	Algorithm converged.	1,08	2,31	0,0181		0,63	Algorithm converged.	0,43	0,92
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	n/a	595	100,0	132	22,2	597	100	118	19,8	1,16	Convergence criterion (GCONV=1E-8) satisfied.	0,88	1,53	0,024	Algorithm converged.	-0,022	0,070	1,12	Algorithm converged.	0,90	1,40	0,3054		0,89	Algorithm converged.	0,71	1,11
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	n/a	595	100,0	67	11,3	597	100	61	10,2	1,12	Convergence criterion (GCONV=1E-8) satisfied.	0,77	1,61	0,010	Algorithm converged.	-0,025	0,046	1,1	Algorithm converged.	0,79	1,53	0,5612		0,91	Algorithm converged.	0,65	1,26
INFECTIONS AND INFESTATIONS	VIRAL UPPER RESPIRATORY TRACT INFECTION	n/a	595	100,0	116	19,5	597	100	127	21,3	0,9	Convergence criterion (GCONV=1E-8) satisfied.	0,68	1,19	-0,018	Algorithm converged.	-0,063	0,028	0,92	Algorithm converged.	0,73	1,15	0,4466		1,09	Algorithm converged.	0,87	1,37
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	n/a	595	100,0	400	67,2	597	100	347	58,1	1,48	Convergence criterion (GCONV=1E-8) satisfied.	1,17	1,87	0,091	Algorithm converged.	0,036	0,146	1,16	Algorithm converged.	1,06	1,26	0,0012		0,86	Algorithm converged.	0,79	0,94
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	n/a	595	100,0	364	61,2	597	100	304	50,9	1,52	Convergence criterion (GCONV=1E-8) satisfied.	1,21	1,91	0,103	Algorithm converged.	0,047	0,159	1,2	Algorithm converged.	1,09	1,33	0,0004		0,83	Algorithm converged.	0,75	0,92
INVESTIGATIONS	ALL	n/a	595	100,0	137	23,0	597	100	125	20,9	1,13	Convergence criterion (GCONV=1E-8) satisfied.	0,86	1,49	0,021	Algorithm converged.	-0,026	0,068	1,1	Algorithm converged.	0,89	1,36	0,3846		0,91	Algorithm converged.	0,73	1,13
METABOLISM AND NUTRITION DISORDERS	ALL	n/a	595	100,0	173	29,1	597	100	168	28,1	1,05	Convergence criterion (GCONV=1E-8) satisfied.	0,81	1,35	0,009	Algorithm converged.	-0,042	0,061	1,03	Algorithm converged.	0,86	1,24	0,7210		0,97	Algorithm converged.	0,81	1,16
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	n/a	595	100,0	76	12,8	597	100	83	13,9	0,91	Convergence criterion (GCONV=1E-8) satisfied.	0,65	1,27	-0,011	Algorithm converged.	-0,050	0,027	0,92	Algorithm converged.	0,69	1,23	0,5664		1,09	Algorithm converged.	0,81	1,45
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ALL	n/a	595	100,0	317	53,3	597	100	292	48,9	1,19	Convergence criterion (GCONV=1E-8) satisfied.	0,95	1,49	0,044	Algorithm converged.	-0,013	0,100	1,09	Algorithm converged.	0,97	1,22	0,1321		0,92	Algorithm converged.	0,82	1,03
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	n/a	595	100,0	100	16,8	597	100	84	14,1	1,23	Convergence criterion (GCONV=1E-8) satisfied.	0,90	1,69	0,027	Algorithm converged.	-0,014	0,068	1,19	Algorithm converged.	0,91	1,56	0,1920		0,84	Algorithm converged.	0,64	1,09
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	n/a	595	100,0	82	13,8	597	100	101	16,9	0,78	Convergence criterion (GCONV=1E-8) satisfied.	0,57	1,08	-0,031	Algorithm converged.	-0,072	0,010	0,81	Algorithm converged.	0,62	1,07	0,1342		1,23	Algorithm converged.	0,94	1,61
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	n/a	595	100,0	91	15,3	597	100	61	10,2	1,59	Convergence criterion (GCONV=1E-8) satisfied.	1,12	2,24	0,051	Algorithm converged.	0,013	0,089	1,5	Algorithm converged.	1,10	2,03	0,0093		0,67	Algorithm converged.	0,49	0,91
NERVOUS SYSTEM DISORDERS	ALL	n/a	595	100,0	362	60,8	597	100	319	53,4	1,35	Convergence criterion (GCONV=1E-8) satisfied.	1,08	1,70	0,074	Algorithm converged.	0,018	0,130	1,14	Algorithm converged.	1,03	1,26	0,0100		0,88	Algorithm converged.	0,80	0,97
NERVOUS SYSTEM DISORDERS	HEADACHE	n/a	595	100,0	133	22,4	597	100	104	17,4	1,36	Convergence criterion (GCONV=1E-8) satisfied.	1,02	1,82	0,049	Algorithm converged.	0,004	0,095	1,28	Algorithm converged.	1,02	1,62	0,0337		0,78	Algorithm converged.	0,62	0,98

PSYCHIATRIC DISORDERS	ALL	n/a	595	100,0	150	25,2	597	100	150	25,1	1		Convergence criterion (GCONV=1E-8) satisfied.	0,77	1,30	0,001	Algorithm converged.	-0,048	0,050	1	Algorithm converged.	0,82	1,22	0,9732		1,00	Algorithm converged.	0,82	1,21
PSYCHIATRIC DISORDERS	INSOMNIA	n/a	595	100,0	89	15	597	100	79	13,2	1,15		Convergence criterion (GCONV=1E-8) satisfied.	0,83	1,60	0,017	Algorithm converged.	-0,022	0,057	1,13	Algorithm converged.	0,85	1,50	0,3925		0,88	Algorithm converged.	0,67	1,17
RENAL AND URINARY DISORDERS	ALL	n/a	595	100,0	79	13,3	597	100	69	11,6	1,17		Convergence criterion (GCONV=1E-8) satisfied.	0,83	1,65	0,017	Algorithm converged.	-0,020	0,055	1,15	Algorithm converged.	0,85	1,55	0,3686		0,87	Algorithm converged.	0,64	1,18
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	n/a	595	100,0	346	58,2	597	100	336	56,3	1,08		Convergence criterion (GCONV=1E-8) satisfied.	0,86	1,36	0,019	Algorithm converged.	-0,037	0,075	1,03	Algorithm converged.	0,94	1,14	0,5142		0,97	Algorithm converged.	0,88	1,07
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	n/a	595	100,0	174	29,2	597	100	161	27,0	1,12		Convergence criterion (GCONV=1E-8) satisfied.	0,87	1,44	0,023	Algorithm converged.	-0,028	0,074	1,08	Algorithm converged.	0,90	1,30	0,3825		0,92	Algorithm converged.	0,77	1,11
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	n/a	595	100,0	89	15	597	100	76	12,7	1,21		Convergence criterion (GCONV=1E-8) satisfied.	0,87	1,68	0,022	Algorithm converged.	-0,017	0,061	1,17	Algorithm converged.	0,88	1,56	0,2662		0,85	Algorithm converged.	0,64	1,13
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	n/a	595	100,0	70	11,8	597	100	61	10,2	1,17		Convergence criterion (GCONV=1E-8) satisfied.	0,81	1,69	0,015	Algorithm converged.	-0,020	0,051	1,15	Algorithm converged.	0,83	1,59	0,3937		0,87	Algorithm converged.	0,63	1,20
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	n/a	595	100,0	338	56,8	597	100	328	54,9	1,08		Convergence criterion (GCONV=1E-8) satisfied.	0,86	1,36	0,019	Algorithm converged.	-0,038	0,075	1,03	Algorithm converged.	0,93	1,14	0,5167		0,97	Algorithm converged.	0,87	1,07
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	n/a	595	100,0	82	13,8	597	100	69	11,6	1,22		Convergence criterion (GCONV=1E-8) satisfied.	0,87	1,72	0,022	Algorithm converged.	-0,016	0,060	1,19	Algorithm converged.	0,88	1,61	0,2493		0,84	Algorithm converged.	0,62	1,13
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	n/a	595	100,0	81	13,6	597	100	86	14,4	0,94		Convergence criterion (GCONV=1E-8) satisfied.	0,68	1,30	-0,008	Algorithm converged.	-0,047	0,031	0,95	Algorithm converged.	0,71	1,25	0,6937		1,06	Algorithm converged.	0,80	1,40
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	n/a	595	100,0	98	16,5	597	100	113	18,9	0,84		Convergence criterion (GCONV=1E-8) satisfied.	0,63	1,14	-0,025	Algorithm converged.	-0,068	0,019	0,87	Algorithm converged.	0,68	1,11	0,2670		1,15	Algorithm converged.	0,90	1,47
VASCULAR DISORDERS	ALL	n/a	595	100,0	197	33,1	597	100	183	30,7	1,12		Convergence criterion (GCONV=1E-8) satisfied.	0,88	1,43	0,025	Algorithm converged.	-0,028	0,077	1,08	Algorithm converged.	0,91	1,28	0,3632		0,93	Algorithm converged.	0,78	1,09

38 (Anhang): Ergebnisse für UE bei ≥ 10 % der Patienten in einem Studienarm nach SOC/PT und mit statistisch signifikantem Ergebnis für die Gesamtpopulation nach Subgruppen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Any AEs, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

All

			G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo															R-Chemo vs. G-Chemo			
			Patients		Patients with		Patients		Patients with		Odds Ratio				Absolute Risk Difference				Relative Risk							Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Male	281	47,2	165	58,7	278	46,6	144	51,8	1,32		Convergence criterion (GCONV=1E-8) satisfied.	0,95	1,85	0,069	Algorithm converged.	-0,013	0,151	1,13	Algorithm converged.	0,98	1,32	0,1011	0,70620000000000005	0,88	Algorithm converged.	0,76	1,02
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	281	47,2	33	11,7	278	46,6	22	7,9	1,55		Convergence criterion (GCONV=1E-8) satisfied.	0,88	2,73	0,038	Algorithm converged.	-0,011	0,088	1,48	Algorithm converged.	0,89	2,48	0,1318	0,82869999999999999	0,67	Algorithm converged.	0,4	1,13
CARDIAC DISORDERS	ALL	Male	281	47,2	46	16,4	278	46,6	28	10,1	1,75		Convergence criterion (GCONV=1E-8) satisfied.	1,06	2,89	0,063	Algorithm converged.	0,007	0,119	1,63	Algorithm converged.	1,05	2,52	0,0303	0,32600000000000001	0,62	Algorithm converged.	0,4	0,95
GASTROINTESTINAL DISORDERS	ALL	Male	281	47,2	227	80,8	278	46,6	215	77,3	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,82	1,85	0,034	Algorithm converged.	-0,033	0,102	1,04	Algorithm converged.	0,96	1,14	0,3175	0,69969999999999999	0,96	Algorithm converged.	0,88	1,04
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	281	47,2	77	27,4	278	46,6	63	22,7	1,29		Convergence criterion (GCONV=1E-8) satisfied.	0,88	1,89	0,047	Algorithm converged.	-0,024	0,119	1,21	Algorithm converged.	0,91	1,61	0,1973	0,72309999999999997	0,83	Algorithm converged.	0,62	1,1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Male	281	47,2	221	78,6	278	46,6	188	67,6	1,76		Convergence criterion (GCONV=1E-8) satisfied.	1,21	2,58	0,11	Algorithm converged.	0,037	0,183	1,16	Algorithm converged.	1,05	1,29	0,0036	0,06019999999999997	0,86	Algorithm converged.	0,78	0,95
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Male	281	47,2	56	19,9	278	46,6	25	9	2,52		Convergence criterion (GCONV=1E-8) satisfied.	1,52	4,17	0,109	Algorithm converged.	0,052	0,167	2,22	Algorithm converged.	1,43	3,45	0,0004	0,13689999999999999	0,45	Algorithm converged.	0,29	0,7
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	281	47,2	78	27,8	278	46,6	48	17,3	1,84		Convergence criterion (GCONV=1E-8) satisfied.	1,23	2,76	0,105	Algorithm converged.	0,036	0,174	1,61	Algorithm converged.	1,17	2,21	0,0035	0,08250000000000004	0,62	Algorithm converged.	0,45	0,86
INFECTIONS AND INFESTATIONS	ALL	Male	281	47,2	223	79,4	278	46,6	190	68,3	1,78		Convergence criterion (GCONV=1E-8) satisfied.	1,21	2,61	0,11	Algorithm converged.	0,038	0,182	1,16	Algorithm converged.	1,05	1,28	0,0033	0,1116	0,86	Algorithm converged.	0,78	0,95
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	281	47,2	23	8,2	278	46,6	19	6,8	1,22		Convergence criterion (GCONV=1E-8) satisfied.	0,65	2,29	0,014	Algorithm converged.	-0,03	0,057	1,2	Algorithm converged.	0,67	2,15	0,5454	0,223	0,84	Algorithm converged.	0,47	1,5
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Male	281	47,2	176	62,6	278	46,6	153	55	1,37		Convergence criterion (GCONV=1E-8) satisfied.	0,98	1,92	0,076	Algorithm converged.	-0,005	0,157	1,14	Algorithm converged.	0,99	1,31	0,0691	0,74070000000000003	0,88	Algorithm converged.	0,76	1,01
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Male	281	47,2	159	56,6	278	46,6	128	46	1,53		Convergence criterion (GCONV=1E-8) satisfied.	1,09	2,13	0,105	Algorithm converged.	0,023	0,188	1,23	Algorithm converged.	1,04	1,45	0,0134	0,72050000000000003	0,81	Algorithm converged.	0,69	0,96
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Male	281	47,2	50	17,8	278	46,6	36	12,9	1,45		Convergence criterion (GCONV=1E-8) satisfied.	0,91	2,32	0,048	Algorithm converged.	-0,011	0,108	1,37	Algorithm converged.	0,93	2,04	0,1149	0,53890000000000005	0,73	Algorithm converged.	0,49	1,08
NERVOUS SYSTEM DISORDERS	ALL	Male	281	47,2	152	54,1	278	46,6	139	50	1,18		Convergence criterion (GCONV=1E-8) satisfied.	0,85	1,64	0,041	Algorithm converged.	-0,042	0,124	1,08	Algorithm converged.	0,92	1,27	0,3335	0,37590000000000001	0,92	Algorithm converged.	0,79	1,08
NERVOUS SYSTEM DISORDERS	HEADACHE	Male	281	47,2	43	15,3	278	46,6	29	10,4	1,55		Convergence criterion (GCONV=1E-8) satisfied.	0,94	2,57	0,049	Algorithm converged.	-0,007	0,104	1,47	Algorithm converged.	0,94	2,28	0,0884	0,47870000000000001	0,68	Algorithm converged.	0,44	1,06
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Female	314	52,8	201	64	319	53,4	187	58,6	1,26		Convergence criterion (GCONV=1E-8) satisfied.	0,91	1,73	0,054	Algorithm converged.	-0,022	0,13	1,09	Algorithm converged.	0,96	1,24	0,1643		0,92	Algorithm converged.	0,81	1,04
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	314	52,8	41	13,1	319	53,4	26	8,2	1,69		Convergence criterion (GCONV=1E-8) satisfied.	1,01	2,84	0,049	Algorithm converged.	0,001	0,097	1,6	Algorithm converged.	1,01	2,55	0,0475		0,62	Algorithm converged.	0,39	0,99
CARDIAC DISORDERS	ALL	Female	314	52,8	40	12,7	319	53,4	34	10,7	1,22		Convergence criterion (GCONV=1E-8) satisfied.	0,75	1,99	0,021	Algorithm converged.	-0,029	0,071	1,2	Algorithm converged.	0,78	1,84	0,4161		0,84	Algorithm converged.	0,54	1,29
GASTROINTESTINAL DISORDERS	ALL	Female	314	52,8	268	85,4	319	53,4	255	79,9	1,46		Convergence criterion (GCONV=1E-8) satisfied.	0,96	2,22	0,054	Algorithm converged.	-0,005	0,113	1,07	Algorithm converged.	0,99	1,15	0,0728		0,94	Algorithm converged.	0,87	1,01
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	314	52,8	102	32,5	319	53,4	80	25,1	1,44		Convergence criterion (GCONV=1E-8) satisfied.	1,02	2,03	0,074	Algorithm converged.	0,004	0,144	1,3	Algorithm converged.	1,01	1,66	0,0407		0,77	Algorithm converged.	0,6	0,99
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Female	314	52,8	244	77,7	319	53,4	242	75,9	1,11		Convergence criterion (GCONV=1E-8) satisfied.	0,77	1,6	0,018	Algorithm converged.	-0,047	0,084	1,02	Algorithm converged.	0,94	1,12	0,5826		0,98	Algorithm converged.	0,9	1,06
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Female	314	52,8	47	15	319	53,4	34	10,7	1,48		Convergence criterion (GCONV=1E-8) satisfied.	0,92	2,36	0,043	Algorithm converged.	-0,009	0,095	1,4	Algorithm converged.	0,93	2,12	0,1069		0,71	Algorithm converged.	0,47	1,08
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	314	52,8	93	29,6	319	53,4	84	26,3	1,18		Convergence criterion (GCONV=1E-8) satisfied.	0,83	1,67	0,033	Algorithm converged.	-0,037	0,103	1,12	Algorithm converged.	0,88	1,44	0,3576		0,89	Algorithm converged.	0,69	1,14
INFECTIONS AND INFESTATIONS	ALL	Female	314	52,8	258	82,2	319	53,4	250	78,4	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,86	1,88	0,038	Algorithm converged.	-0,024	0,1	1,05	Algorithm converged.	0,97	1,13	0,2306		0,95	Algorithm converged.	0,88	1,03
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	314	52,8	40	12,7	319	53,4	21	6,6	2,07		Convergence criterion (GCONV=1E-8) satisfied.	1,19	3,6	0,062	Algorithm converged.	0,016	0,107	1,94	Algorithm converged.	1,17	3,21	0,0104		0,52	Algorithm converged.	0,31	0,86
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Female	314	52,8	224	71,3	319	53,4	194	60,8	1,6		Convergence criterion (GCONV=1E-8) satisfied.	1,15	2,24	0,105	Algorithm converged.	0,032	0,179	1,17	Algorithm converged.	1,05	1,31	0,0055		0,85	Algorithm converged.	0,76	0,95
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Female	314	52,8	205	65,3	319	53,4	176	55,2	1,53		Convergence criterion (GCONV=1E-8) satisfied.	1,11	2,11	0,101	Algorithm converged.	0,025	0,177	1,18	Algorithm converged.	1,04	1,34	0,0097		0,85	Algorithm converged.	0,74	0,96
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Female	314	52,8	41	13,1	319	53,4	25	7,8	1,77		Convergence criterion (GCONV=1E-8) satisfied.	1,05	2,98	0,052	Algorithm converged.	0,005	0,1	1,67	Algorithm converged.	1,04	2,67	0,0341		0,6	Algorithm converged.	0,37	0,96
NERVOUS SYSTEM DISORDERS	ALL	Female	314	52,8	210	66,9	319	53,4	180	56,4	1,56		Convergence criterion (GCONV=1E-8) satisfied.	1,13	2,15	0,105	Algorithm converged.	0,029	0,18	1,19	Algorithm converged.	1,05	1,34	0,0072		0,84	Algorithm converged.	0,75	0,96
NERVOUS SYSTEM DISORDERS	HEADACHE	Female	314	52,8	90	28,7	319	53,4	75	23,5	1,31		Convergence criterion (GCONV=1E-8) satisfied.	0,92	1,87	0,052	Algorithm converged.	-0,017	0,12	1,22	Algorithm converged.	0,94	1,59	0,1411		0,82	Algorithm converged.	0,63	1,07
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	< 60 years	298	50,1	177	59,4	320	53,6	169	52,8	1,31		Convergence criterion (GCONV=1E-8) satisfied.	0,95	1,8	0,066	Algorithm converged.	-0,012	0,144	1,12	Algorithm converged.	0,98	1,29	0,0995	0,73570000000000002	0,89	Algorithm converged.	0,77	1,02
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 60 years	298	50,1	32	10,7	320	53,6	20	6,3	1,8		Convergence criterion (GCONV=1E-8) satisfied.	1,01	3,23	0,045	Algorithm converged.	0,001	0,089	1,72	Algorithm converged.	1,01	2,94	0,0478	0,56420000000000003	0,58	Algorithm converged.	0,34	0,99
CARDIAC DISORDERS	ALL	< 60 years	298	50,1	32	10,7	320	53,6	25	7,8	1,42		Convergence criterion (GCONV=1E-8) satisfied.	0,82	2,46	0,029	Algorithm converged.	-0,017	0,075	1,37	Algorithm converged.	0,83	2,26	0,2113	0,9758	0,73	Algorithm converged.	0,44	1,2
GASTROINTESTINAL DISORDERS	ALL	< 60 years	298	50,1	244	81,9	320	53,6	244	76,3	1,41		Convergence criterion (GCONV=1E-8) satisfied.	0,95	2,08	0,056	Algorithm converged.	-0,008	0,12	1,07	Algorithm converged.	0,99	1,16	0,0855	0,52110000000000001	0,93	Algorithm converged.	0,86	1,01
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 60 years	298	50,1	83	27,9	320	53,6	64	20	1,54		Convergence criterion (GCONV=1E-8) satisfied.	1,06	2,24	0,079	Algorithm converged.	0,011	0,146	1,39	Algorithm converged.	1,05	1,85	0,0229	0,2858	0,72	Algorithm converged.	0,54	0,96
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	< 60 years	298	50,1	235	78,9	320	53,6	226	70,6	1,55		Convergence criterion (GCONV=1E-8) satisfied.	1,07	2,24	0,082	Algorithm converged.	0,014	0,15	1,12	Algorithm converged.	1,02	1,22	0,0187	0,36980000000000002	0,9	Algorithm converged.	0,82	0,98
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	< 60 years	298	50,1	58	19,5	320	53,6	27	8,4	2,62		Convergence criterion (GCONV=1E-8) satisfied.	1,61	4,27	0,11	Algorithm converged.	0,056	0,165	2,31	Algorithm converged.	1,5	3,54	0,0001	0,06510000000000005	0,43	Algorithm converged.	0,28	0,67
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 60 years	298	50,1	97	32,6	320	53,6	73	22,8	1,63		Convergence criterion (GCONV=1E-8) satisfied.	1,14	2,33	0,097	Algorithm converged.	0,027	0,168	1,43	Algorithm converged.	1,1	1,85	0,0073	0,32700000000000001	0,7	Algorithm converged.	0,54	0,91

INFECTIONS AND INFESTATIONS	ALL	< 60 years	298	50,1	240	80,5	320	53,6	230	71,9	1,62		Convergence criterion (GCONV=1E-8) satisfied.	1,11	2,36	0,087	Algorithm converged.	0,02	0,153	1,12	Algorithm converged.	1,03	1,22	0,0116	0,46739999999999998	0,89	Algorithm converged.	0,82	0,97
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 60 years	298	50,1	22	7,4	320	53,6	15	4,7	1,62		Convergence criterion (GCONV=1E-8) satisfied.	0,82	3,19	0,027	Algorithm converged.	-0,011	0,065	1,57	Algorithm converged.	0,83	2,98	0,1623	0,94230000000000003	0,63	Algorithm converged.	0,34	1,2
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	< 60 years	298	50,1	205	68,8	320	53,6	190	59,4	1,51		Convergence criterion (GCONV=1E-8) satisfied.	1,08	2,1	0,094	Algorithm converged.	0,019	0,169	1,16	Algorithm converged.	1,03	1,3	0,015	0,99850000000000005	0,86	Algorithm converged.	0,77	0,97
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	< 60 years	298	50,1	188	63,1	320	53,6	169	52,8	1,53		Convergence criterion (GCONV=1E-8) satisfied.	1,11	2,11	0,103	Algorithm converged.	0,025	0,18	1,19	Algorithm converged.	1,04	1,37	0,0099	0,86499999999999999	0,84	Algorithm converged.	0,73	0,96
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	< 60 years	298	50,1	35	11,7	320	53,6	22	6,9	1,8		Convergence criterion (GCONV=1E-8) satisfied.	1,03	3,15	0,049	Algorithm converged.	0,003	0,095	1,71	Algorithm converged.	1,03	2,84	0,0393	0,4491	0,59	Algorithm converged.	0,35	0,97
NERVOUS SYSTEM DISORDERS	ALL	< 60 years	298	50,1	178	59,7	320	53,6	173	54,1	1,26		Convergence criterion (GCONV=1E-8) satisfied.	0,92	1,73	0,057	Algorithm converged.	-0,021	0,135	1,1	Algorithm converged.	0,96	1,27	0,155	0,54010000000000002	0,91	Algorithm converged.	0,79	1,04
NERVOUS SYSTEM DISORDERS	HEADACHE	< 60 years	298	50,1	76	25,5	320	53,6	61	19,1	1,45		Convergence criterion (GCONV=1E-8) satisfied.	0,99	2,13	0,064	Algorithm converged.	-0,001	0,13	1,34	Algorithm converged.	0,99	1,8	0,0553	0,74080000000000001	0,75	Algorithm converged.	0,56	1,01
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	>= 60 years	297	49,9	189	63,6	277	46,4	162	58,5	1,24		Convergence criterion (GCONV=1E-8) satisfied.	0,89	1,74	0,052	Algorithm converged.	-0,028	0,131	1,09	Algorithm converged.	0,95	1,24	0,2075		0,92	Algorithm converged.	0,81	1,05
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 60 years	297	49,9	42	14,1	277	46,4	28	10,1	1,46		Convergence criterion (GCONV=1E-8) satisfied.	0,88	2,44	0,04	Algorithm converged.	-0,013	0,094	1,4	Algorithm converged.	0,89	2,19	0,143		0,71	Algorithm converged.	0,46	1,12
CARDIAC DISORDERS	ALL	>= 60 years	297	49,9	54	18,2	277	46,4	37	13,4	1,44		Convergence criterion (GCONV=1E-8) satisfied.	0,91	2,27	0,048	Algorithm converged.	-0,011	0,108	1,36	Algorithm converged.	0,93	2	0,1164		0,73	Algorithm converged.	0,5	1,08
GASTROINTESTINAL DISORDERS	ALL	>= 60 years	297	49,9	251	84,5	277	46,4	226	81,6	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,8	1,91	0,029	Algorithm converged.	-0,032	0,091	1,04	Algorithm converged.	0,96	1,12	0,3522		0,97	Algorithm converged.	0,9	1,04
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 60 years	297	49,9	96	32,3	277	46,4	79	28,5	1,2		Convergence criterion (GCONV=1E-8) satisfied.	0,84	1,71	0,038	Algorithm converged.	-0,037	0,113	1,13	Algorithm converged.	0,88	1,45	0,3238		0,88	Algorithm converged.	0,69	1,13
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	>= 60 years	297	49,9	230	77,4	277	46,4	204	73,6	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,84	1,8	0,038	Algorithm converged.	-0,032	0,108	1,05	Algorithm converged.	0,96	1,15	0,2919		0,95	Algorithm converged.	0,87	1,04
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>= 60 years	297	49,9	45	15,2	277	46,4	32	11,6	1,37		Convergence criterion (GCONV=1E-8) satisfied.	0,84	2,22	0,036	Algorithm converged.	-0,02	0,091	1,31	Algorithm converged.	0,86	2	0,2085		0,76	Algorithm converged.	0,5	1,16
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 60 years	297	49,9	74	24,9	277	46,4	59	21,3	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,83	1,81	0,036	Algorithm converged.	-0,033	0,105	1,17	Algorithm converged.	0,87	1,58	0,3062		0,85	Algorithm converged.	0,63	1,15
INFECTIONS AND INFESTATIONS	ALL	>= 60 years	297	49,9	241	81,1	277	46,4	210	75,8	1,37		Convergence criterion (GCONV=1E-8) satisfied.	0,92	2,05	0,053	Algorithm converged.	-0,014	0,121	1,07	Algorithm converged.	0,98	1,17	0,1222		0,93	Algorithm converged.	0,86	1,02
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 60 years	297	49,9	41	13,8	277	46,4	25	9	1,61		Convergence criterion (GCONV=1E-8) satisfied.	0,95	2,73	0,048	Algorithm converged.	-0,004	0,1	1,53	Algorithm converged.	0,96	2,45	0,0761		0,65	Algorithm converged.	0,41	1,05
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	>= 60 years	297	49,9	195	65,7	277	46,4	157	56,7	1,46		Convergence criterion (GCONV=1E-8) satisfied.	1,04	2,05	0,09	Algorithm converged.	0,01	0,169	1,16	Algorithm converged.	1,02	1,32	0,0287		0,86	Algorithm converged.	0,76	0,98
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>= 60 years	297	49,9	176	59,3	277	46,4	135	48,7	1,53		Convergence criterion (GCONV=1E-8) satisfied.	1,1	2,13	0,105	Algorithm converged.	0,024	0,186	1,22	Algorithm converged.	1,04	1,42	0,0124		0,82	Algorithm converged.	0,71	0,96
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	>= 60 years	297	49,9	56	18,9	277	46,4	39	14,1	1,42		Convergence criterion (GCONV=1E-8) satisfied.	0,91	2,22	0,048	Algorithm converged.	-0,013	0,108	1,34	Algorithm converged.	0,92	1,95	0,1264		0,75	Algorithm converged.	0,51	1,09
NERVOUS SYSTEM DISORDERS	ALL	>= 60 years	297	49,9	184	62	277	46,4	146	52,7	1,46		Convergence criterion (GCONV=1E-8) satisfied.	1,05	2,04	0,092	Algorithm converged.	0,012	0,173	1,18	Algorithm converged.	1,02	1,36	0,0265		0,85	Algorithm converged.	0,74	0,98
NERVOUS SYSTEM DISORDERS	HEADACHE	>= 60 years	297	49,9	57	19,2	277	46,4	43	15,5	1,29		Convergence criterion (GCONV=1E-8) satisfied.	0,84	2	0,037	Algorithm converged.	-0,025	0,099	1,24	Algorithm converged.	0,86	1,77	0,2487		0,81	Algorithm converged.	0,56	1,16
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	North America	73	12,3	37	50,7	77	12,9	29	37,7	1,7		Convergence criterion (GCONV=1E-8) satisfied.	0,89	3,26	0,13	Algorithm converged.	-0,027	0,288	1,35	Algorithm converged.	0,93	1,94	0,1115	0,69089999999999996	0,74	Algorithm converged.	0,52	1,07
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	North America	73	12,3	11	15,1	77	12,9	7	9,1	1,77		Convergence criterion (GCONV=1E-8) satisfied.	0,65	4,86	0,06	Algorithm converged.	-0,044	0,164	1,66	Algorithm converged.	0,68	4,04	0,2668	0,98729999999999996	0,6	Algorithm converged.	0,25	1,47
CARDIAC DISORDERS	ALL	North America	73	12,3	8	11	77	12,9	12	15,6	0,67		Convergence criterion (GCONV=1E-8) satisfied.	0,26	1,74	-0,046	Algorithm converged.	-0,154	0,062	0,7	Algorithm converged.	0,3	1,62	0,4087	0,15659999999999999	1,42	Algorithm converged.	0,62	3,28
GASTROINTESTINAL DISORDERS	ALL	North America	73	12,3	65	89	77	12,9	70	90,9	0,81		Convergence criterion (GCONV=1E-8) satisfied.	0,28	2,37	-0,019	Algorithm converged.	-0,115	0,078	0,98	Algorithm converged.	0,88	1,09	0,7039	0,1497	1,02	Algorithm converged.	0,92	1,14
GASTROINTESTINAL DISORDERS	DIARRHOEA	North America	73	12,3	31	42,5	77	12,9	26	33,8	1,45		Convergence criterion (GCONV=1E-8) satisfied.	0,75	2,81	0,087	Algorithm converged.	-0,068	0,242	1,26	Algorithm converged.	0,83	1,9	0,2746	0,62580000000000002	0,8	Algorithm converged.	0,53	1,2
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	North America	73	12,3	64	87,7	77	12,9	69	89,6	0,82		Convergence criterion (GCONV=1E-8) satisfied.	0,3	2,27	-0,019	Algorithm converged.	-0,121	0,082	0,98	Algorithm converged.	0,87	1,1	0,7088	0,24590000000000001	1,02	Algorithm converged.	0,91	1,15
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	North America	73	12,3	19	26	77	12,9	10	13	2,36		Convergence criterion (GCONV=1E-8) satisfied.	1,01	5,49	0,13	Algorithm converged.	0,005	0,256	2	Algorithm converged.	1	4,02	0,0501	0,89739999999999998	0,5	Algorithm converged.	0,25	1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	North America	73	12,3	18	24,7	77	12,9	15	19,5	1,35		Convergence criterion (GCONV=1E-8) satisfied.	0,62	2,94	0,052	Algorithm converged.	-0,081	0,184	1,27	Algorithm converged.	0,69	2,32	0,4458	0,98819999999999997	0,79	Algorithm converged.	0,43	1,45
INFECTIONS AND INFESTATIONS	ALL	North America	73	12,3	67	91,8	77	12,9	59	76,6	3,41		Convergence criterion (GCONV=1E-8) satisfied.	1,27	3,15	0,152	Algorithm converged.	0,038	0,265	1,2	Algorithm converged.	1,04	1,38	0,0122	0,1003	0,83	Algorithm converged.	0,72	0,96
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	North America	73	12,3	12	16,4	77	12,9	8	10,4	1,7		Convergence criterion (GCONV=1E-8) satisfied.	0,65	4,43	0,06	Algorithm converged.	-0,048	0,169	1,58	Algorithm converged.	0,69	3,65	0,2817	0,94510000000000005	0,63	Algorithm converged.	0,27	1,46
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	North America	73	12,3	52	71,2	77	12,9	52	67,5	1,19		Convergence criterion (GCONV=1E-8) satisfied.	0,59	2,39	0,037	Algorithm converged.	-0,11	0,184	1,05	Algorithm converged.	0,85	1,3	0,623	0,60499999999999998	0,95	Algorithm converged.	0,77	1,17
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	North America	73	12,3	46	63	77	12,9	46	59,7	1,15		Convergence criterion (GCONV=1E-8) satisfied.	0,59	2,22	0,033	Algorithm converged.	-0,123	0,189	1,05	Algorithm converged.	0,82	1,36	0,6806	0,6976	0,95	Algorithm converged.	0,74	1,22
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	North America	73	12,3	18	24,7	77	12,9	12	15,6	1,77		Convergence criterion (GCONV=1E-8) satisfied.	0,79	4	0,091	Algorithm converged.	-0,037	0,219	1,58	Algorithm converged.	0,82	3,05	0,1708	0,36209999999999998	0,63	Algorithm converged.	0,33	1,22
NERVOUS SYSTEM DISORDERS	ALL	North America	73	12,3	46	63	77	12,9	47	61	3,09		Convergence criterion (GCONV=1E-8) satisfied.	0,56	2,1	0,02	Algorithm converged.	-0,136	0,175	1,03	Algorithm converged.	0,8	1,33	0,8032	0,54990000000000006	0,97	Algorithm converged.	0,75	1,24
NERVOUS SYSTEM DISORDERS	HEADACHE	North America	73	12,3	23	31,5	77	12,9	17	22,1	1,62		Convergence criterion (GCONV=1E-8) satisfied.	0,78	3,37	0,094	Algorithm converged.	-0,047	0,235	1,43	Algorithm converged.	0,83	2,45	0,1959	0,54730000000000001	0,7	Algorithm converged.	0,41	1,2
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Western Europe	293	49,2	163	55,6	282	47,2	143	50,7	1,22		Convergence criterion (GCONV=1E-8) satisfied.	0,88	1,69	0,049	Algorithm converged.	-0,032	0,131	1,1	Algorithm converged.	0,94	1,28	0,2382		0,91	Algorithm converged.	0,78	1,06
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Western Europe	293	49,2	30	10,2	282	47,2	19	6,7	1,58		Convergence criterion (GCONV=1E-8) satisfied.	0,87	2,88	0,035	Algorithm converged.	-0,01	0,08	1,52	Algorithm converged.	0,88	2,64	0,1365		0,66	Algorithm converged.	0,38	1,14
CARDIAC DISORDERS	ALL	Western Europe	293	49,2	47	16	282	47,2	34	12,1	1,39		Convergence criterion (GCONV=1E-8) satisfied.	0,87	2,24	0,04	Algorithm converged.	-0,017	0,097	1,33	Algorithm converged.	0,88	2	0,1721		0,75	Algorithm converged.	0,5	1,13
GASTROINTESTINAL DISORDERS	ALL	Western Europe	293	49,2	246	84	282	47,2	233	82,6	1,1		Convergence criterion (GCONV=1E-8) satisfied.	0,71	1,71	0,013	Algorithm converged.	-0,048	0,074	1,02	Algorithm converged.	0,94	1,09	0,6682		0,98	Algorithm converged.	0,91	1,06
GASTROINTESTINAL DISORDERS	DIARRHOEA	Western Europe	293	49,2	92	31,4	282	47,2	63	22,3	1,59		Convergence criterion (GCONV=1E-8) satisfied.	1,1	2,31	0,091	Algorithm converged.	0,019	0,163	1,41	Algorithm converged.	1,07	1,85	0,0155		0,71	Algorithm converged.	0,54	0,94
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Western Europe	293	49,2	235	80,2	282	47,2	210	74,5	1,39		Convergence criterion (GCONV=1E-8) satisfied.	0,94	2,06	0,057	Algorithm converged.	-0,011	0,126	1,08	Algorithm converged.	0,99	1,18	0,1019		0,93	Algorithm converged.	0,85	1,01
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Western Europe	293	49,2	49	16,7	282	47,2	29	10,3	1,75		Convergence criterion (GCONV=1E-8) satisfied.	1,07	2,86	0,064	Algorithm converged.	0,009	0,12	1,63	Algorithm converged.	1,06	2,5	0,0263		0,61	Algorithm converged.	0,4	0,94
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Western Europe	293	49,2	81	27,6	282	47,2	61	21,6	1,38		Convergence criterion (GCONV=1E-8) satisfied.	0,94	2,03	0,06	Algorithm converged.	-0,01	0,13	1,28	Algorithm converged.	0,96	1,71	0,0965		0,78	Algorithm converged.	0,59	1,04
INFECTIONS AND INFESTATIONS	ALL	Western Europe	293	49,2	235	80,2	282	47,2	220	78	1,14		Convergence criterion (GCONV=1E-8) satisfied.	0,76	1,71	0,022	Algorithm converged.	-0,045	0,088	1,03	Algorithm converged.	0,95	1,12	0,5187		0,97	Algorithm converged.	0,89	1,06
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Western Europe	293	49,2	25	8,5	282	47,2	17	6	1,45		Convergence criterion (GCONV=1E-8) satisfied.	0,77	2,76	0,025	Algorithm converged.	-0,017	0,067	1,42	Algorithm converged.	0,78	2,56	0,2517		0,71	Algorithm converged.	0,39	1,28
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Western Europe	293	49,2	201	68,6	282	47,2	166	58,9	1,53		Convergence criterion (GCONV=1E-8) satisfied.	1,08	2,15	0,097	Algorithm converged.	0,019	0,176	1,17	Algorithm converged.	1,03	1,32	0,016		0,86	Algorithm converged.	0,76	0,97

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Western Europe	293	49,2	185	63,1	282	47,2	145	51,4	1,62		Convergence criterion (GCONV=1E-8) satisfied.	1,16	2,26	0,117		Algorithm converged.	0,037	0,198	1,23		Algorithm converged.	1,06	1,42	0,005		0,81		Algorithm converged.	0,71	0,94
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Western Europe	293	49,2	41	14	282	47,2	20	7,1	2,13		Convergence criterion (GCONV=1E-8) satisfied.	1,22	3,74	0,069		Algorithm converged.	0,019	0,119	1,97		Algorithm converged.	1,19	3,28	0,0089		0,51		Algorithm converged.	0,3	0,84
NERVOUS SYSTEM DISORDERS	ALL	Western Europe	293	49,2	181	61,8	282	47,2	151	53,5	1,4		Convergence criterion (GCONV=1E-8) satisfied.	1,01	1,95	0,082		Algorithm converged.	0,002	0,163	1,15		Algorithm converged.	1	1,33	0,0472		0,87		Algorithm converged.	0,75	1
NERVOUS SYSTEM DISORDERS	HEADACHE	Western Europe	293	49,2	59	20,1	282	47,2	50	17,7	1,17		Convergence criterion (GCONV=1E-8) satisfied.	0,77	1,78	0,024		Algorithm converged.	-0,04	0,088	1,14		Algorithm converged.	0,81	1,59	0,4625		0,88		Algorithm converged.	0,63	1,24
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Asia-Pacific	150	25,2	117	78	155	26	109	70,3	1,5		Convergence criterion (GCONV=1E-8) satisfied.	0,89	2,51	0,077		Algorithm converged.	-0,021	0,175	1,11		Algorithm converged.	0,97	1,27	0,1267		0,9		Algorithm converged.	0,79	1,03
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Asia-Pacific	150	25,2	21	14	155	26	13	8,4	1,78		Convergence criterion (GCONV=1E-8) satisfied.	0,86	3,7	0,056		Algorithm converged.	-0,014	0,127	1,67		Algorithm converged.	0,87	3,21	0,1248		0,6		Algorithm converged.	0,31	1,15
CARDIAC DISORDERS	ALL	Asia-Pacific	150	25,2	25	16,7	155	26	11	7,1	2,62		Convergence criterion (GCONV=1E-8) satisfied.	1,24	6,53	0,096		Algorithm converged.	0,024	0,168	2,35		Algorithm converged.	1,2	4,6	0,0129		0,43		Algorithm converged.	0,22	0,83
GASTROINTESTINAL DISORDERS	ALL	Asia-Pacific	150	25,2	137	91,3	155	26	129	83,2	2,12		Convergence criterion (GCONV=1E-8) satisfied.	1,05	4,31	0,081		Algorithm converged.	0,007	0,155	1,1		Algorithm converged.	1,01	1,2	0,0345		0,91		Algorithm converged.	0,84	0,99
GASTROINTESTINAL DISORDERS	DIARRHOEA	Asia-Pacific	150	25,2	42	28	155	26	42	27,1	1,05		Convergence criterion (GCONV=1E-8) satisfied.	0,63	1,73	0,009		Algorithm converged.	-0,091	0,109	1,03		Algorithm converged.	0,72	1,49	0,8599		0,97		Algorithm converged.	0,67	1,39
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Asia-Pacific	150	25,2	125	83,3	155	26	111	71,6	1,98		Convergence criterion (GCONV=1E-8) satisfied.	1,14	3,45	0,117		Algorithm converged.	0,024	0,21	1,16		Algorithm converged.	1,03	1,31	0,0151		0,86		Algorithm converged.	0,76	0,97
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Asia-Pacific	150	25,2	24	16	155	26	15	9,7	1,78		Convergence criterion (GCONV=1E-8) satisfied.	0,89	3,54	0,063		Algorithm converged.	-0,012	0,138	1,65		Algorithm converged.	0,9	3,03	0,1032		0,6		Algorithm converged.	0,33	1,11
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Asia-Pacific	150	25,2	58	38,7	155	26	44	28,4	1,59		Convergence criterion (GCONV=1E-8) satisfied.	0,98	2,57	0,103		Algorithm converged.	-0,003	0,208	1,36		Algorithm converged.	0,99	1,88	0,0593		0,73		Algorithm converged.	0,53	1,01
INFECTIONS AND INFESTATIONS	ALL	Asia-Pacific	150	25,2	112	74,7	155	26	105	67,7	1,4		Convergence criterion (GCONV=1E-8) satisfied.	0,85	2,31	0,069		Algorithm converged.	-0,032	0,171	1,1		Algorithm converged.	0,96	1,27	0,1827		0,91		Algorithm converged.	0,79	1,05
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Asia-Pacific	150	25,2	15	10	155	26	8	5,2	2,04		Convergence criterion (GCONV=1E-8) satisfied.	0,84	4,97	0,048		Algorithm converged.	-0,011	0,108	1,94		Algorithm converged.	0,85	4,44	0,1175		0,52		Algorithm converged.	0,23	1,18
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Asia-Pacific	150	25,2	104	69,3	155	26	96	61,9	1,39		Convergence criterion (GCONV=1E-8) satisfied.	0,86	2,23	0,074		Algorithm converged.	-0,032	0,18	1,12		Algorithm converged.	0,95	1,32	0,1748		0,89		Algorithm converged.	0,76	1,05
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Asia-Pacific	150	25,2	96	64	155	26	84	54,2	1,5		Convergence criterion (GCONV=1E-8) satisfied.	0,95	2,38	0,098		Algorithm converged.	-0,012	0,208	1,18		Algorithm converged.	0,98	1,43	0,083		0,85		Algorithm converged.	0,7	1,02
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Asia-Pacific	150	25,2	21	14	155	26	16	10,3	1,41		Convergence criterion (GCONV=1E-8) satisfied.	0,71	2,83	0,037		Algorithm converged.	-0,037	0,11	1,36		Algorithm converged.	0,74	2,5	0,3279		0,74		Algorithm converged.	0,4	1,36
NERVOUS SYSTEM DISORDERS	ALL	Asia-Pacific	150	25,2	109	72,7	155	26	92	59,4	1,82		Convergence criterion (GCONV=1E-8) satisfied.	1,12	2,95	0,133		Algorithm converged.	0,028	0,238	1,22		Algorithm converged.	1,04	1,44	0,015		0,82		Algorithm converged.	0,69	0,96
NERVOUS SYSTEM DISORDERS	HEADACHE	Asia-Pacific	150	25,2	43	28,7	155	26	28	18,1	1,82		Convergence criterion (GCONV=1E-8) satisfied.	1,06	3,13	0,106		Algorithm converged.	0,012	0,2	1,59		Algorithm converged.	1,04	2,41	0,031		0,63		Algorithm converged.	0,41	0,96
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Other	79	13,3	49	62	83	13,9	50	60,2	1,08		Convergence criterion (GCONV=1E-8) satisfied.	0,57	2,03	0,018		Algorithm converged.	-0,132	0,168	1,03		Algorithm converged.	0,81	1,32	0,8158		0,97		Algorithm converged.	0,76	1,24
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Other	79	13,3	12	15,2	83	13,9	9	10,8	1,47		Convergence criterion (GCONV=1E-8) satisfied.	0,58	3,71	0,043		Algorithm converged.	-0,06	0,147	1,4		Algorithm converged.	0,62	3,14	0,4133		0,71		Algorithm converged.	0,32	1,6
CARDIAC DISORDERS	ALL	Other	79	13,3	6	7,6	83	13,9	5	6	1,28		Convergence criterion (GCONV=1E-8) satisfied.	0,38	4,38	0,016		Algorithm converged.	-0,062	0,093	1,26		Algorithm converged.	0,4	3,97	0,6919		0,79		Algorithm converged.	0,25	2,5
GASTROINTESTINAL DISORDERS	ALL	Other	79	13,3	47	59,5	83	13,9	38	45,8	1,74		Convergence criterion (GCONV=1E-8) satisfied.	0,93	3,24	0,137		Algorithm converged.	-0,015	0,289	1,3		Algorithm converged.	0,97	1,75	0,0833		0,77		Algorithm converged.	0,57	1,04
GASTROINTESTINAL DISORDERS	DIARRHOEA	Other	79	13,3	14	17,7	83	13,9	12	14,5	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,55	2,96	0,033		Algorithm converged.	-0,081	0,146	1,23		Algorithm converged.	0,6	2,49	0,5725		0,82		Algorithm converged.	0,4	1,65
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Other	79	13,3	41	51,9	83	13,9	40	48,2	1,16		Convergence criterion (GCONV=1E-8) satisfied.	0,63	2,15	0,037		Algorithm converged.	-0,117	0,191	1,08		Algorithm converged.	0,79	1,47	0,6372		0,93		Algorithm converged.	0,68	1,26
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Other	79	13,3	11	13,9	83	13,9	5	6	2,52		Convergence criterion (GCONV=1E-8) satisfied.	0,83	7,63	0,079		Algorithm converged.	-0,013	0,171	2,31		Algorithm converged.	0,84	6,35	0,1044		0,43		Algorithm converged.	0,16	1,19
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Other	79	13,3	14	17,7	83	13,9	12	14,5	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,55	2,96	0,033		Algorithm converged.	-0,081	0,146	1,23		Algorithm converged.	0,6	2,49	0,5725		0,82		Algorithm converged.	0,4	1,65
INFECTIONS AND INFESTATIONS	ALL	Other	79	13,3	67	84,8	83	13,9	56	67,5	2,69		Convergence criterion (GCONV=1E-8) satisfied.	1,25	5,8	0,173		Algorithm converged.	0,045	0,302	1,26		Algorithm converged.	1,05	1,5	0,0109		0,8		Algorithm converged.	0,67	0,95
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Other	79	13,3	11	13,9	83	13,9	7	8,4	1,76		Convergence criterion (GCONV=1E-8) satisfied.	0,64	4,79	0,055		Algorithm converged.	-0,042	0,152	1,65		Algorithm converged.	0,67	4,05	0,2728		0,61		Algorithm converged.	0,25	1,48
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Other	79	13,3	43	54,4	83	13,9	33	39,8	1,81		Convergence criterion (GCONV=1E-8) satisfied.	0,97	3,38	0,147		Algorithm converged.	-0,005	0,299	1,37		Algorithm converged.	0,98	1,91	0,0644		0,73		Algorithm converged.	0,52	1,02
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Other	79	13,3	37	46,8	83	13,9	29	34,9	1,64		Convergence criterion (GCONV=1E-8) satisfied.	0,87	3,08	0,119		Algorithm converged.	-0,031	0,269	1,34		Algorithm converged.	0,92	1,95	0,1267		0,75		Algorithm converged.	0,51	1,09
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Other	79	13,3	11	13,9	83	13,9	13	15,7	0,87		Convergence criterion (GCONV=1E-8) satisfied.	0,37	2,08	-0,017		Algorithm converged.	-0,127	0,092	0,89		Algorithm converged.	0,42	1,87	0,7558		1,12		Algorithm converged.	0,54	2,36
NERVOUS SYSTEM DISORDERS	ALL	Other	79	13,3	26	32,9	83	13,9	29	34,9	0,91		Convergence criterion (GCONV=1E-8) satisfied.	0,48	1,75	-0,02		Algorithm converged.	-0,166	0,126	0,94		Algorithm converged.	0,61	1,45	0,7854		1,06		Algorithm converged.	0,69	1,63
NERVOUS SYSTEM DISORDERS	HEADACHE	Other	79	13,3	8	10,1	83	13,9	9	10,8	0,93		Convergence criterion (GCONV=1E-8) satisfied.	0,34	2,53	-0,007		Algorithm converged.	-0,102	0,087	0,93		Algorithm converged.	0,38	2,3	0,8818		1,07		Algorithm converged.	0,43	2,64
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	CHOP	194	32,6	166	85,6	203	34	153	75,4	1,94		Convergence criterion (GCONV=1E-8) satisfied.	1,16	3,23	0,102		Algorithm converged.	0,025	0,179	1,14		Algorithm converged.	1,03	1,25	0,0108		0,88		Algorithm converged.	0,8	0,97
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	CHOP	194	32,6	30	15,5	203	34	16	7,9	2,14		Convergence criterion (GCONV=1E-8) satisfied.	1,13	4,06	0,076		Algorithm converged.	0,013	0,139	1,96		Algorithm converged.	1,11	3,48	0,0214		0,51		Algorithm converged.	0,29	0,9
CARDIAC DISORDERS	ALL	CHOP	194	32,6	33	17	203	34	15	7,4	2,57		Convergence criterion (GCONV=1E-8) satisfied.	1,35	4,9	0,096		Algorithm converged.	0,032	0,16	2,3		Algorithm converged.	1,29	4,1	0,0047	0,0853000000000000001	0,43		Algorithm converged.	0,24	0,77
GASTROINTESTINAL DISORDERS	ALL	CHOP	194	32,6	148	76,3	203	34	143	70,4	1,35		Convergence criterion (GCONV=1E-8) satisfied.	0,86	2,11	0,058		Algorithm converged.	-0,028	0,145	1,08		Algorithm converged.	0,96	1,22	0,1882	0,4605000000000000002	0,92		Algorithm converged.	0,82	1,04
GASTROINTESTINAL DISORDERS	DIARRHOEA	CHOP	194	32,6	44	22,7	203	34	30	14,8	1,69		Convergence criterion (GCONV=1E-8) satisfied.	1,01	2,83	0,079		Algorithm converged.	0,002	0,156	1,53		Algorithm converged.	1,01	2,34	0,0458	0,37109999999999999	0,65		Algorithm converged.	0,43	0,99
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	CHOP	194	32,6	145	74,7	203	34	132	65	1,59		Convergence criterion (GCONV=1E-8) satisfied.	1,03	2,46	0,097		Algorithm converged.	0,008	0,187	1,15		Algorithm converged.	1,01	1,31	0,0356	0,07660000000000000001	0,87		Algorithm converged.	0,76	0,99
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	CHOP	194	32,6	33	17	203	34	15	7,4	2,57		Convergence criterion (GCONV=1E-8) satisfied.	1,35	4,9	0,096		Algorithm converged.	0,032	0,16	2,3		Algorithm converged.	1,29	4,1	0,0047	0,64449999999999996	0,43		Algorithm converged.	0,24	0,77
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	CHOP	194	32,6	69	35,6	203	34	51	25,1	1,65		Convergence criterion (GCONV=1E-8) satisfied.	1,07	2,54	0,104		Algorithm converged.	0,014	0,194	1,42		Algorithm converged.	1,04	1,92	0,0249	0,1226	0,71		Algorithm converged.	0,52	0,96
INFECTIONS AND INFESTATIONS	ALL	CHOP	194	32,6	148	76,3	203	34	138	68	1,52		Convergence criterion (GCONV=1E-8) satisfied.	0,97	2,36	0,083		Algorithm converged.	-0,005	0,171	1,12		Algorithm converged.	0,99	1,27	0,0656	0,32769999999999999	0,89		Algorithm converged.	0,79	1,01
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	CHOP	194	32,6	17	8,8	203	34	12	5,9	1,53		Convergence criterion (GCONV=1E-8) satisfied.	0,71	3,29	0,029		Algorithm converged.	-0,023	0,08	1,48		Algorithm converged.	0,73	3,02	0,2787	0,97929999999999995	0,67		Algorithm converged.	0,33	1,38
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	CHOP	194	32,6	125	64,4	203	34	121	59,6	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,82	1,84	0,048		Algorithm converged.	-0,047	0,144	1,08		Algorithm converged.	0,93	1,26	0,322		0,93		Algorithm converged.	0,79	1,08
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	CHOP	194	32,6	118	60,8	203	34	108	53,2	1,37		Convergence criterion (GCONV=1E-8) satisfied.	0,92	2,04	0,076		Algorithm converged.	-0,021	0,173	1,14		Algorithm converged.	0,96	1,36	0,1259		0,87		Algorithm converged.	0,74	1,04
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	CHOP	194	32,6	18	9,3	203	34	16	7,9	1,2		Convergence criterion (GCONV=1E-8) satisfied.	0,59	2,42	0,014		Algorithm converged.	-0,041	0,069	1,18		Algorithm converged.	0,62	2,24	0,6196	0,82140000000000002	0,85		Algorithm converged.	0,45	1,62
NERVOUS SYSTEM DISORDERS	ALL	CHOP	194	32,6	124	63,9	203	34	120	59,1	1,23		Convergence criterion (GCONV=1E-8) satisfied.	0,82	1,84	0,048		Algorithm converged.	-0,048	0,144	1,08		Algorithm converged.	0,93	1,26	0,3256		0,92		Algorithm converged.	0,79	1,08

NERVOUS SYSTEM DISORDERS	HEADACHE	CHOP	194	32,6	34	17,5	203	34	29	14,3	1,27		Convergence criterion (GCONV=1E-8) satisfied.	0,74	2,19	0,032		Algorithm converged.	-0,04	0,104	1,23		Algorithm converged.	0,78	1,93	0,3782	0,65410000000000001	0,82		Algorithm converged.	0,52	1,28
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	CVP	60	10,1	37	61,7	56	9,4	18	32,1	3,4		Convergence criterion (GCONV=1E-8) satisfied.	1,58	7,3	0,295		Algorithm converged.	0,122	0,469	1,92		Algorithm converged.	1,25	2,95	0,003		0,52		Algorithm converged.	0,34	0,8
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	CVP	60	10,1	2	3,3	56	9,4				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
CARDIAC DISORDERS	ALL	CVP	60	10,1	10	16,7	56	9,4	5	8,9	2,04		Convergence criterion (GCONV=1E-8) satisfied.	0,65	6,39	0,077		Algorithm converged.	-0,043	0,198	1,87		Algorithm converged.	0,68	5,12	0,2258		0,54		Algorithm converged.	0,2	1,47
GASTROINTESTINAL DISORDERS	ALL	CVP	60	10,1	54	90	56	9,4	44	78,6	2,45		Convergence criterion (GCONV=1E-8) satisfied.	0,85	7,07	0,114		Algorithm converged.	-0,017	0,246	1,15		Algorithm converged.	0,98	1,35	0,0976		0,87		Algorithm converged.	0,74	1,03
GASTROINTESTINAL DISORDERS	DIARRHOEA	CVP	60	10,1	18	30	56	9,4	20	35,7	0,77		Convergence criterion (GCONV=1E-8) satisfied.	0,35	1,68	-0,057		Algorithm converged.	-0,228	0,114	0,84		Algorithm converged.	0,5	1,42	0,513		1,19		Algorithm converged.	0,71	2,01
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	CVP	60	10,1	54	90	56	9,4	39	69,6	3,92		Convergence criterion (GCONV=1E-8) satisfied.	1,42	10,85	0,204		Algorithm converged.	0,061	0,346	1,29		Algorithm converged.	1,07	1,57	0,009		0,77		Algorithm converged.	0,64	0,94
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	CVP	60	10,1	9	15	56	9,4	5	8,9	1,8		Convergence criterion (GCONV=1E-8) satisfied.	0,56	5,74	0,061		Algorithm converged.	-0,057	0,178	1,68		Algorithm converged.	0,6	4,71	0,3239		0,6		Algorithm converged.	0,21	1,67
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	CVP	60	10,1	16	26,7	56	9,4	6	10,7	3,03		Convergence criterion (GCONV=1E-8) satisfied.	1,09	8,42	0,16		Algorithm converged.	0,021	0,298	2,49		Algorithm converged.	1,05	5,91	0,0388		0,4		Algorithm converged.	0,17	0,95
INFECTIONS AND INFESTATIONS	ALL	CVP	60	10,1	45	75	56	9,4	38	67,9	1,42		Convergence criterion (GCONV=1E-8) satisfied.	0,63	3,19	0,071		Algorithm converged.	-0,093	0,236	1,11		Algorithm converged.	0,88	1,39	0,3979		0,9		Algorithm converged.	0,72	1,14
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	CVP	60	10,1	6	10	56	9,4	3	5,4	1,96		Convergence criterion (GCONV=1E-8) satisfied.	0,47	8,26	0,046		Algorithm converged.	-0,05	0,143	1,87		Algorithm converged.	0,49	7,11	0,3603		0,54		Algorithm converged.	0,14	2,04
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	CVP	60	10,1	42	70	56	9,4	31	55,4	1,88		Convergence criterion (GCONV=1E-8) satisfied.	0,88	4,04	0,146		Algorithm converged.	-0,028	0,321	1,26		Algorithm converged.	0,95	1,69	0,1098		0,79		Algorithm converged.	0,59	1,05
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	CVP	60	10,1	39	65	56	9,4	28	50	1,86		Convergence criterion (GCONV=1E-8) satisfied.	0,88	3,91	0,15		Algorithm converged.	-0,028	0,328	1,3		Algorithm converged.	0,94	1,79	0,1092		0,77		Algorithm converged.	0,56	1,06
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	CVP	60	10,1	6	10	56	9,4	4	7,1	1,44		Convergence criterion (GCONV=1E-8) satisfied.	0,39	6,41	0,029		Algorithm converged.	-0,073	0,13	1,4		Algorithm converged.	0,42	4,7	0,5862		0,71		Algorithm converged.	0,21	2,4
NERVOUS SYSTEM DISORDERS	ALL	CVP	60	10,1	50	83,3	56	9,4	40	71,4	2		Convergence criterion (GCONV=1E-8) satisfied.	0,82	4,88	0,119		Algorithm converged.	-0,032	0,27	1,17		Algorithm converged.	0,95	1,43	0,1321		0,86		Algorithm converged.	0,7	1,05
NERVOUS SYSTEM DISORDERS	HEADACHE	CVP	60	10,1	10	16,7	56	9,4	11	19,6	0,82		Convergence criterion (GCONV=1E-8) satisfied.	0,32	2,11	-0,03		Algorithm converged.	-0,17	0,111	0,85		Algorithm converged.	0,39	1,84	0,6778		1,18		Algorithm converged.	0,54	2,56
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Bendamustine	338	56,8	163	48,2	338	56,6	160	47,3	1,04		Convergence criterion (GCONV=1E-8) satisfied.	0,77	1,4	0,009		Algorithm converged.	-0,066	0,084	1,02		Algorithm converged.	0,87	1,19	0,8173		0,98		Algorithm converged.	0,84	1,15
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Bendamustine	338	56,8	42	12,4	338	56,6	32	9,5	1,36		Convergence criterion (GCONV=1E-8) satisfied.	0,83	2,21	0,03		Algorithm converged.	-0,017	0,077	1,31		Algorithm converged.	0,85	2,03	0,2199		0,76		Algorithm converged.	0,49	1,18
CARDIAC DISORDERS	ALL	Bendamustine	338	56,8	42	12,4	338	56,6	42	12,4	1		Convergence criterion (GCONV=1E-8) satisfied.	0,63	1,58	0		Algorithm converged.	-0,05	0,05	1		Algorithm converged.	0,67	1,49	1		1		Algorithm converged.	0,67	1,49
GASTROINTESTINAL DISORDERS	ALL	Bendamustine	338	56,8	291	86,1	338	56,6	283	83,7	1,2		Convergence criterion (GCONV=1E-8) satisfied.	0,79	1,84	0,024		Algorithm converged.	-0,03	0,078	1,03		Algorithm converged.	0,96	1,1	0,3903		0,97		Algorithm converged.	0,91	1,04
GASTROINTESTINAL DISORDERS	DIARRHOEA	Bendamustine	338	56,8	116	34,3	338	56,6	93	27,5	1,38		Convergence criterion (GCONV=1E-8) satisfied.	0,99	1,91	0,068		Algorithm converged.	-0,001	0,138	1,25		Algorithm converged.	0,99	1,57	0,0568		0,8		Algorithm converged.	0,64	1,01
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Bendamustine	338	56,8	264	78,1	338	56,6	259	76,6	1,09		Convergence criterion (GCONV=1E-8) satisfied.	0,76	1,56	0,015		Algorithm converged.	-0,048	0,078	1,02		Algorithm converged.	0,94	1,11	0,6459		0,98		Algorithm converged.	0,9	1,06
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Bendamustine	338	56,8	60	17,8	338	56,6	39	11,5	1,65		Convergence criterion (GCONV=1E-8) satisfied.	1,07	2,56	0,062		Algorithm converged.	0,009	0,115	1,54		Algorithm converged.	1,06	2,24	0,0239		0,65		Algorithm converged.	0,45	0,94
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Bendamustine	338	56,8	84	24,9	338	56,6	75	22,2	1,16		Convergence criterion (GCONV=1E-8) satisfied.	0,81	1,66	0,027		Algorithm converged.	-0,037	0,091	1,12		Algorithm converged.	0,85	1,47	0,4149		0,89		Algorithm converged.	0,68	1,17
INFECTIONS AND INFESTATIONS	ALL	Bendamustine	338	56,8	287	84,9	338	56,6	264	78,1	1,58		Convergence criterion (GCONV=1E-8) satisfied.	1,06	2,34	0,068		Algorithm converged.	0,01	0,126	1,09		Algorithm converged.	1,01	1,17	0,0233		0,92		Algorithm converged.	0,86	0,99
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Bendamustine	338	56,8	40	11,8	338	56,6	25	7,4	1,68		Convergence criterion (GCONV=1E-8) satisfied.	0,99	2,84	0,044		Algorithm converged.	0	0,089	1,6		Algorithm converged.	0,99	2,58	0,0532		0,63		Algorithm converged.	0,39	1,01
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Bendamustine	338	56,8	230	68	338	56,6	195	57,7	1,56		Convergence criterion (GCONV=1E-8) satisfied.	1,14	2,14	0,104		Algorithm converged.	0,031	0,176	1,18		Algorithm converged.	1,05	1,33	0,0057		0,85		Algorithm converged.	0,75	0,95
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Bendamustine	338	56,8	204	60,4	338	56,6	168	49,7	1,54		Convergence criterion (GCONV=1E-8) satisfied.	1,14	2,09	0,107		Algorithm converged.	0,032	0,181	1,21		Algorithm converged.	1,06	1,39	0,0057		0,82		Algorithm converged.	0,72	0,95
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Bendamustine	338	56,8	67	19,8	338	56,6	41	12,1	1,79		Convergence criterion (GCONV=1E-8) satisfied.	1,17	2,73	0,077		Algorithm converged.	0,022	0,132	1,63		Algorithm converged.	1,14	2,34	0,0072		0,61		Algorithm converged.	0,43	0,88
NERVOUS SYSTEM DISORDERS	ALL	Bendamustine	338	56,8	188	55,6	338	56,6	159	47	1,41		Convergence criterion (GCONV=1E-8) satisfied.	1,04	1,91	0,086		Algorithm converged.	0,011	0,161	1,18		Algorithm converged.	1,02	1,37	0,0264		0,85		Algorithm converged.	0,73	0,98
NERVOUS SYSTEM DISORDERS	HEADACHE	Bendamustine	338	56,8	89	26,3	338	56,6	64	18,9	1,53		Convergence criterion (GCONV=1E-8) satisfied.	1,06	2,2	0,074		Algorithm converged.	0,011	0,137	1,39		Algorithm converged.	1,05	1,85	0,0227		0,72		Algorithm converged.	0,54	0,95
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	No Chemo	3	0,5																												
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	No Chemo	3	0,5																												
CARDIAC DISORDERS	ALL	No Chemo	3	0,5	1	33,3																										
GASTROINTESTINAL DISORDERS	ALL	No Chemo	3	0,5	2	66,7																										
GASTROINTESTINAL DISORDERS	DIARRHOEA	No Chemo	3	0,5	1	33,3																										
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	No Chemo	3	0,5	2	66,7																										
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	No Chemo	3	0,5	1	33,3																										
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	No Chemo	3	0,5	2	66,7																										
INFECTIONS AND INFESTATIONS	ALL	No Chemo	3	0,5	1	33,3																										
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	No Chemo	3	0,5																												
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	No Chemo	3	0,5	3	100																										
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	No Chemo	3	0,5	3	100																										
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	No Chemo	3	0,5																												
NERVOUS SYSTEM DISORDERS	ALL	No Chemo	3	0,5																												
NERVOUS SYSTEM DISORDERS	HEADACHE	No Chemo	3	0,5																												
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Low (0-1)	128	21,5	68	53,1	121	20,3	54	44,6	1,41		Convergence criterion (GCONV=1E-8) satisfied.	0,85	2,32	0,085		Algorithm converged.	-0,039	0,209	1,19		Algorithm converged.	0,92	1,54	0,1832	0,4698	0,84		Algorithm converged.	0,65	1,09
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Low (0-1)	128	21,5	10	7,8	121	20,3	1	0,8	10,16		Convergence criterion (GCONV=1E-8) satisfied.	1,28	80,6	0,07		Algorithm converged.	0,021	0,119	9,45		Algorithm converged.	1,23	72,74	0,031	0,07030000000000001	0,11		Algorithm converged.	0,01	0,81
CARDIAC DISORDERS	ALL	Low (0-1)	128	21,5	12	9,4	121	20,3	7	5,8	1,68		Convergence criterion (GCONV=1E-8) satisfied.	0,64	4,43	0,036		Algorithm converged.	-0,03	0,101	1,62		Algorithm converged.	0,66	3,98	0,2923	0,62380000000000002	0,62		Algorithm converged.	0,25	1,52
GASTROINTESTINAL DISORDERS	ALL	Low (0-1)	128	21,5	110	85,9	121	20,3	92	76	1,93		Convergence criterion (GCONV=1E-8) satisfied.	1,01	3,69	0,099		Algorithm converged.	0,002	0,196	1,13		Algorithm converged.	1	1,28	0,0494	0,22789999999999999	0,88		Algorithm converged.	0,78	1
GASTROINTESTINAL DISORDERS	DIARRHOEA	Low (0-1)	128	21,5	42	32,8	121	20,3	23	19	2,08		Convergence criterion (GCONV=1E-8) satisfied.	1,16	3,74	0,138		Algorithm converged.	0,031	0,245	1,73		Algorithm converged.	1,11	2,69	0,0158	0,2611	0,58		Algorithm converged.	0,37	0,9
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Low (0-1)	128	21,5	101	78,9	121	20,3	86	71,1	1,52		Convergence criterion (GCONV=1E-8) satisfied.	0,85	2,72	0,078		Algorithm converged.	-0,029	0,186	1,11		Algorithm converged.	0,96	1,28	0,1569	0,62909999999999999	0,9		Algorithm converged.	0,78	1,04

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Low (0-1)	128	21,5	20	15,6	121	20,3	6	5	3,55	Convergence criterion (GCONV=1E-8) satisfied.	1,37	3,17	0,107	Algorithm converged.	0,033	0,181	3,15	Algorithm converged.	1,31	7,58	0,0104	0,2041	0,32	Algorithm converged.	0,13	0,76
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Low (0-1)	128	21,5	41	32	121	20,3	27	22,3	1,64	Convergence criterion (GCONV=1E-8) satisfied.	0,93	2,89	0,097	Algorithm converged.	-0,013	0,207	1,44	Algorithm converged.	0,95	2,18	0,0896	0,8659999999999999	0,7	Algorithm converged.	0,46	1,06
INFECTIONS AND INFESTATIONS	ALL	Low (0-1)	128	21,5	104	81,3	121	20,3	82	67,8	2,06	Convergence criterion (GCONV=1E-8) satisfied.	1,15	3,7	0,135	Algorithm converged.	0,028	0,242	1,2	Algorithm converged.	1,03	1,39	0,0166	0,40060000000000001	0,83	Algorithm converged.	0,72	0,97
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Low (0-1)	128	21,5	13	10,2	121	20,3	4	3,3	3,31	Convergence criterion (GCONV=1E-8) satisfied.	1,05	10,44	0,069	Algorithm converged.	0,007	0,13	3,07	Algorithm converged.	1,03	8,16	0,0441	0,3095999999999999	0,33	Algorithm converged.	0,11	0,97
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Low (0-1)	128	21,5	78	60,9	121	20,3	66	54,5	1,3	Convergence criterion (GCONV=1E-8) satisfied.	0,79	2,15	0,064	Algorithm converged.	-0,059	0,186	1,12	Algorithm converged.	0,9	1,38	0,3096	0,9013999999999998	0,9	Algorithm converged.	0,72	1,11
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Low (0-1)	128	21,5	68	53,1	121	20,3	56	46,3	1,32	Convergence criterion (GCONV=1E-8) satisfied.	0,8	2,16	0,068	Algorithm converged.	-0,056	0,192	1,15	Algorithm converged.	0,89	1,48	0,2828	0,4754999999999998	0,87	Algorithm converged.	0,68	1,12
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Low (0-1)	128	21,5	15	11,7	121	20,3	15	12,4	0,94	Convergence criterion (GCONV=1E-8) satisfied.	0,44	2,01	-0,007	Algorithm converged.	-0,088	0,074	0,95	Algorithm converged.	0,48	1,85	0,8695	0,2691999999999999	1,06	Algorithm converged.	0,54	2,07
NERVOUS SYSTEM DISORDERS	ALL	Low (0-1)	128	21,5	85	66,4	121	20,3	57	47,1	2,22	Convergence criterion (GCONV=1E-8) satisfied.	1,33	3,7	0,193	Algorithm converged.	0,072	0,314	1,41	Algorithm converged.	1,13	1,77	0,0028	0,044200000000000003	0,71	Algorithm converged.	0,57	0,89
NERVOUS SYSTEM DISORDERS	HEADACHE	Low (0-1)	128	21,5	34	26,6	121	20,3	14	11,6	2,76	Convergence criterion (GCONV=1E-8) satisfied.	1,4	5,46	0,15	Algorithm converged.	0,055	0,245	2,3	Algorithm converged.	1,3	4,06	0,0043	0,055100000000000003	0,44	Algorithm converged.	0,25	0,77
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Intermediate (2)	221	37,1	129	58,4	222	37,2	126	56,8	1,07	Convergence criterion (GCONV=1E-8) satisfied.	0,73	1,56	0,016	Algorithm converged.	-0,076	0,108	1,03	Algorithm converged.	0,88	1,21	0,7311		0,97	Algorithm converged.	0,83	1,14
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Intermediate (2)	221	37,1	23	10,4	222	37,2	16	7,2	1,5	Convergence criterion (GCONV=1E-8) satisfied.	0,77	2,91	0,032	Algorithm converged.	-0,021	0,085	1,44	Algorithm converged.	0,78	2,66	0,238		0,69	Algorithm converged.	0,38	1,27
CARDIAC DISORDERS	ALL	Intermediate (2)	221	37,1	37	16,7	222	37,2	23	10,4	1,74	Convergence criterion (GCONV=1E-8) satisfied.	1	3,04	0,064	Algorithm converged.	0	0,127	1,62	Algorithm converged.	0,99	2,63	0,0529		0,62	Algorithm converged.	0,38	1,01
GASTROINTESTINAL DISORDERS	ALL	Intermediate (2)	221	37,1	182	82,4	222	37,2	183	82,4	0,99	Convergence criterion (GCONV=1E-8) satisfied.	0,61	1,62	-0,001	Algorithm converged.	-0,072	0,07	1	Algorithm converged.	0,92	1,09	0,9825		1	Algorithm converged.	0,92	1,09
GASTROINTESTINAL DISORDERS	DIARRHOEA	Intermediate (2)	221	37,1	65	29,4	222	37,2	54	24,3	1,3	Convergence criterion (GCONV=1E-8) satisfied.	0,85	1,98	0,051	Algorithm converged.	-0,032	0,133	1,21	Algorithm converged.	0,89	1,65	0,2285		0,83	Algorithm converged.	0,61	1,13
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	Intermediate (2)	221	37,1	171	77,4	222	37,2	165	74,3	1,18	Convergence criterion (GCONV=1E-8) satisfied.	0,76	1,83	0,031	Algorithm converged.	-0,049	0,11	1,04	Algorithm converged.	0,94	1,16	0,4534		0,96	Algorithm converged.	0,86	1,07
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Intermediate (2)	221	37,1	30	13,6	222	37,2	23	10,4	1,36	Convergence criterion (GCONV=1E-8) satisfied.	0,76	2,42	0,032	Algorithm converged.	-0,028	0,093	1,31	Algorithm converged.	0,79	2,18	0,2993		0,76	Algorithm converged.	0,46	1,27
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Intermediate (2)	221	37,1	56	25,3	222	37,2	45	20,3	1,33	Convergence criterion (GCONV=1E-8) satisfied.	0,85	2,09	0,051	Algorithm converged.	-0,027	0,129	1,25	Algorithm converged.	0,89	1,77	0,2053		0,8	Algorithm converged.	0,57	1,13
INFECTIONS AND INFESTATIONS	ALL	Intermediate (2)	221	37,1	174	78,7	222	37,2	164	73,9	1,31	Convergence criterion (GCONV=1E-8) satisfied.	0,84	2,03	0,049	Algorithm converged.	-0,03	0,128	1,07	Algorithm converged.	0,96	1,18	0,2299		0,94	Algorithm converged.	0,85	1,04
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Intermediate (2)	221	37,1	19	8,6	222	37,2	11	5	1,8	Convergence criterion (GCONV=1E-8) satisfied.	0,84	3,89	0,036	Algorithm converged.	-0,01	0,083	1,74	Algorithm converged.	0,85	3,56	0,133		0,58	Algorithm converged.	0,28	1,18
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Intermediate (2)	221	37,1	148	67	222	37,2	129	58,1	1,46	Convergence criterion (GCONV=1E-8) satisfied.	0,99	2,15	0,089	Algorithm converged.	-0,001	0,178	1,15	Algorithm converged.	1	1,33	0,0552		0,87	Algorithm converged.	0,75	1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Intermediate (2)	221	37,1	131	59,3	222	37,2	116	52,3	1,33	Convergence criterion (GCONV=1E-8) satisfied.	0,91	1,94	0,07	Algorithm converged.	-0,022	0,163	1,13	Algorithm converged.	0,96	1,34	0,1379		0,88	Algorithm converged.	0,75	1,04
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	Intermediate (2)	221	37,1	41	18,6	222	37,2	22	9,9	2,07	Convergence criterion (GCONV=1E-8) satisfied.	1,19	3,61	0,086	Algorithm converged.	0,022	0,151	1,87	Algorithm converged.	1,15	3,04	0,011		0,53	Algorithm converged.	0,33	0,87
NERVOUS SYSTEM DISORDERS	ALL	Intermediate (2)	221	37,1	133	60,2	222	37,2	133	59,9	1,01	Convergence criterion (GCONV=1E-8) satisfied.	0,69	1,48	0,003	Algorithm converged.	-0,089	0,094	1	Algorithm converged.	0,86	1,17	0,9536		1	Algorithm converged.	0,86	1,16
NERVOUS SYSTEM DISORDERS	HEADACHE	Intermediate (2)	221	37,1	55	24,9	222	37,2	46	20,7	1,27	Convergence criterion (GCONV=1E-8) satisfied.	0,81	1,98	0,042	Algorithm converged.	-0,036	0,12	1,2	Algorithm converged.	0,85	1,7	0,2972		0,83	Algorithm converged.	0,59	1,18
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	High (>=3)	246	41,3	169	68,7	254	42,5	151	59,4	1,5	Convergence criterion (GCONV=1E-8) satisfied.	1,04	2,16	0,093	Algorithm converged.	0,009	0,176	1,16	Algorithm converged.	1,01	1,32	0,0318		0,87	Algorithm converged.	0,76	0,99
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	High (>=3)	246	41,3	41	16,7	254	42,5	31	12,2	1,44	Convergence criterion (GCONV=1E-8) satisfied.	0,87	2,38	0,045	Algorithm converged.	-0,017	0,106	1,37	Algorithm converged.	0,89	2,1	0,1577		0,73	Algorithm converged.	0,48	1,13
CARDIAC DISORDERS	ALL	High (>=3)	246	41,3	37	15	254	42,5	32	12,6	1,23	Convergence criterion (GCONV=1E-8) satisfied.	0,74	2,04	0,024	Algorithm converged.	-0,036	0,085	1,19	Algorithm converged.	0,77	1,85	0,4294		0,84	Algorithm converged.	0,54	1,3
GASTROINTESTINAL DISORDERS	ALL	High (>=3)	246	41,3	203	82,5	254	42,5	195	76,8	1,43	Convergence criterion (GCONV=1E-8) satisfied.	0,92	2,22	0,057	Algorithm converged.	-0,013	0,128	1,07	Algorithm converged.	0,98	1,17	0,1109		0,93	Algorithm converged.	0,85	1,02
GASTROINTESTINAL DISORDERS	DIARRHOEA	High (>=3)	246	41,3	72	29,3	254	42,5	66	26	1,18	Convergence criterion (GCONV=1E-8) satisfied.	0,8	1,75	0,033	Algorithm converged.	-0,046	0,111	1,13	Algorithm converged.	0,85	1,5	0,4119		0,89	Algorithm converged.	0,67	1,18
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	High (>=3)	246	41,3	193	78,5	254	42,5	179	70,5	1,53	Convergence criterion (GCONV=1E-8) satisfied.	1,02	2,29	0,08	Algorithm converged.	0,004	0,156	1,11	Algorithm converged.	1	1,23	0,0413		0,9	Algorithm converged.	0,81	1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	High (>=3)	246	41,3	53	21,5	254	42,5	30	11,8	2,05	Convergence criterion (GCONV=1E-8) satisfied.	1,26	3,34	0,097	Algorithm converged.	0,032	0,162	1,82	Algorithm converged.	1,21	2,75	0,0042		0,55	Algorithm converged.	0,36	0,83
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	High (>=3)	246	41,3	74	30,1	254	42,5	60	23,6	1,39	Convergence criterion (GCONV=1E-8) satisfied.	0,93	2,07	0,065	Algorithm converged.	-0,013	0,142	1,27	Algorithm converged.	0,95	1,71	0,1046		0,79	Algorithm converged.	0,59	1,05
INFECTIONS AND INFESTATIONS	ALL	High (>=3)	246	41,3	203	82,5	254	42,5	194	76,4	1,46	Convergence criterion (GCONV=1E-8) satisfied.	0,94	2,26	0,061	Algorithm converged.	-0,009	0,132	1,08	Algorithm converged.	0,99	1,18	0,0898		0,93	Algorithm converged.	0,85	1,01
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	High (>=3)	246	41,3	31	12,6	254	42,5	25	9,8	1,32	Convergence criterion (GCONV=1E-8) satisfied.	0,76	2,31	0,028	Algorithm converged.	-0,028	0,083	1,28	Algorithm converged.	0,78	2,1	0,3296		0,78	Algorithm converged.	0,48	1,28
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	High (>=3)	246	41,3	174	70,7	254	42,5	152	59,8	1,62	Convergence criterion (GCONV=1E-8) satisfied.	1,12	2,35	0,109	Algorithm converged.	0,026	0,192	1,18	Algorithm converged.	1,04	1,34	0,011		0,85	Algorithm converged.	0,74	0,96
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	High (>=3)	246	41,3	165	67,1	254	42,5	132	52	1,88	Convergence criterion (GCONV=1E-8) satisfied.	1,31	2,7	0,151	Algorithm converged.	0,066	0,236	1,29	Algorithm converged.	1,11	1,5	0,0007		0,77	Algorithm converged.	0,67	0,9
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	High (>=3)	246	41,3	35	14,2	254	42,5	24	9,4	1,59	Convergence criterion (GCONV=1E-8) satisfied.	0,92	2,76	0,048	Algorithm converged.	-0,009	0,104	1,51	Algorithm converged.	0,92	2,46	0,1009		0,66	Algorithm converged.	0,41	1,08
NERVOUS SYSTEM DISORDERS	ALL	High (>=3)	246	41,3	144	58,5	254	42,5	129	50,8	1,37	Convergence criterion (GCONV=1E-8) satisfied.	0,96	1,95	0,077	Algorithm converged.	-0,01	0,164	1,15	Algorithm converged.	0,98	1,35	0,0826		0,87	Algorithm converged.	0,74	1,02
NERVOUS SYSTEM DISORDERS	HEADACHE	High (>=3)	246	41,3	44	17,9	254	42,5	44	17,3	1,04	Convergence criterion (GCONV=1E-8) satisfied.	0,66	1,65	0,006	Algorithm converged.	-0,061	0,072	1,03	Algorithm converged.	0,71	1,51	0,8687		0,97	Algorithm converged.	0,66	1,42

39 (Anhang): Ergebnisse für SUE bei ≥ 5 % der Patienten in einem Studienarm nach SOC/PT aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Any SAEs, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

All

			G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo			
			Patients		with Event		Patients		with		Odds Ratio					Absolute Risk Difference				Relative Risk								Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	n/a	595	100	58	9,7	597	100,0	49	8,2	1,21		Convergence criterion (GCONV=1E-8) satisfied.	0,81	1,8	0,015	Algorithm converged.	-0,02	0,048	1,19	Algorithm converged.	0,83	1,71	0,3531		0,86	Algorithm converged.	0,77	0,97
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	n/a	595	100	30	5	597	100	18	3	1,71		Convergence criterion (GCONV=1E-8) satisfied.	0,94	3,1	0,02	Algorithm converged.	-0	0,043	1,67	Algorithm converged.	0,94	2,97	0,0787		0,63	Algorithm converged.	0,4	1
GASTROINTESTINAL DISORDERS	ALL	n/a	595	100	45	7,6	597	100	31	5,2	1,49		Convergence criterion (GCONV=1E-8) satisfied.	0,93	2,4	0,024	Algorithm converged.	-0	0,051	1,46	Algorithm converged.	0,94	2,27	0,0963		0,98	Algorithm converged.	0,68	1,4
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	n/a	595	100	30	5	597	100	32	5,4	0,94		Convergence criterion (GCONV=1E-8) satisfied.	0,56	1,56	-0,003	Algorithm converged.	-0,03	0,022	0,94	Algorithm converged.	0,58	1,53	0,8047		0,84	Algorithm converged.	0,53	1,32
INFECTIONS AND INFESTATIONS	ALL	n/a	595	100	114	19,2	597	100	95	15,9	1,25		Convergence criterion (GCONV=1E-8) satisfied.	0,93	1,69	0,032	Algorithm converged.	-0,01	0,076	1,2	Algorithm converged.	0,94	1,54	0,1414		0,84	Algorithm converged.	0,67	1,06
INFECTIONS AND INFESTATIONS	PNEUMONIA	n/a	595	100	30	5	597	100	29	4,9	1,04		Convergence criterion (GCONV=1E-8) satisfied.	0,62	1,76	0,002	Algorithm converged.	-0,02	0,026	1,04	Algorithm converged.	0,63	1,71	0,8833		1,07	Algorithm converged.	0,65	1,76
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	n/a	595	100	42	7,1	597	100	24	4	1,81		Convergence criterion (GCONV=1E-8) satisfied.	1,08	3,03	0,03	Algorithm converged.	0,004	0,056	1,76	Algorithm converged.	1,08	2,86	0,0239		0,66	Algorithm converged.	0,44	1
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	n/a	595	100	38	6,4	597	100	29	4,9	1,34		Convergence criterion (GCONV=1E-8) satisfied.	0,81	2,2	0,015	Algorithm converged.	-0,01	0,041	1,31	Algorithm converged.	0,82	2,1	0,2536		0,78	Algorithm converged.	0,49	1,25
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	n/a	595	100	35	5,9	597	100	31	5,2	1,14		Convergence criterion (GCONV=1E-8) satisfied.	0,69	1,88	0,007	Algorithm converged.	-0,02	0,033	1,13	Algorithm converged.	0,71	1,81	0,6029		0,5	Algorithm converged.	0,32	0,77

40 (Anhang): Ergebnisse für SUE bei ≥ 5 % der Patienten in einem Studienarm nach SOC/PT und mit statistisch signifikantem Ergebnis für die Gesamtpopulation nach Subgruppen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: Any SAEs, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

All

			G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo															R-Chemo vs. G-Chemo			
			Patients		with		Patients		with		Odds Ratio				Absolute Risk Difference				Relative Risk							Relative Risk			
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk	Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk	Convergence Reason	95% Lower CL	95% Upper CL
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Male	281	47,2	22	7,8	278	46,6	9	3,2	2,54	Convergence criterion (GCONV=1E-8) satisfied.	1,15	5,62	0,046	Algorithm converged.	0,008	0,084	2,42	Algorithm converged.	1,13	5,16	0,0223	0,251	0,41	Algorithm converged.	0,19	0,88
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Female	314	52,8	20	6,4	319	53,4	15	4,7	1,38	Convergence criterion (GCONV=1E-8) satisfied.	0,69	2,74	0,017	Algorithm converged.	-0,02	0,052	1,35	Algorithm converged.	0,71	2,6	0,3609		0,74	Algorithm converged.	0,38	1,42
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	< 60 years	298	50,1	21	7	320	53,6	13	4,1	1,79	Convergence criterion (GCONV=1E-8) satisfied.	0,88	3,64	0,03	Algorithm converged.	-0,01	0,066	1,73	Algorithm converged.	0,88	3,4	0,1089	0,95830000000000004	0,58	Algorithm converged.	0,29	1,13
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	>= 60 years	297	49,9	21	7,1	277	46,4	11	4	1,84	Convergence criterion (GCONV=1E-8) satisfied.	0,87	3,89	0,031	Algorithm converged.	-0,01	0,068	1,78	Algorithm converged.	0,87	3,62	0,1117		0,56	Algorithm converged.	0,28	1,14
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	North America	73	12,3	3	4,1	77	12,9	1	1,3	3,26	Convergence criterion (GCONV=1E-8) satisfied.	0,33	32,04	0,028	Algorithm converged.	-0,02	0,08	3,16	Algorithm converged.	0,34	29,74	0,3136	0,72489999999999999	0,32	Algorithm converged.	0,03	2,97
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Western Europe	293	49,2	25	8,5	282	47,2	17	6	1,45	Convergence criterion (GCONV=1E-8) satisfied.	0,77	2,76	0,025	Algorithm converged.	-0,02	0,067	1,42	Algorithm converged.	0,78	2,56	0,2517		0,71	Algorithm converged.	0,39	1,28
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Asia-Pacific	150	25,2	11	7,3	155	26	5	3,2	2,37	Convergence criterion (GCONV=1E-8) satisfied.	0,8	7	0,041	Algorithm converged.	-0,01	0,091	2,27	Algorithm converged.	0,81	6,39	0,1192		0,44	Algorithm converged.	0,16	1,24
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Other	79	13,3	3	3,8	83	13,9	1	1,2	3,24	Convergence criterion (GCONV=1E-8) satisfied.	0,33	31,78	0,026	Algorithm converged.	-0,02	0,074	3,15	Algorithm converged.	0,33	29,67	0,3156		0,32	Algorithm converged.	0,03	2,99
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	CHOP	194	32,6	12	6,2	203	34	8	3,9	1,61	Convergence criterion (GCONV=1E-8) satisfied.	0,64	4,02	0,022	Algorithm converged.	-0,02	0,066	1,57	Algorithm converged.	0,66	3,76	0,3113		0,64	Algorithm converged.	0,27	1,52
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	CVP	60	10,1	3	5	56	9,4	4	7,1	0,68	Convergence criterion (GCONV=1E-8) satisfied.	0,15	3,2	-0,021	Algorithm converged.	-0,11	0,066	0,7	Algorithm converged.	0,16	2,99	0,6302		1,43	Algorithm converged.	0,33	6,1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Bendamustine	338	56,8	24	7,1	338	56,6	12	3,6	2,08	Convergence criterion (GCONV=1E-8) satisfied.	1,02	4,22	0,036	Algorithm converged.	0,002	0,069	2	Algorithm converged.	1,02	3,93	0,0446		0,5	Algorithm converged.	0,25	0,98
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	No Chemo	3	0,5	3	100																							
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Low (0-1)	128	21,5	7	5,5	121	20,3	6	5	1,11	Convergence criterion (GCONV=1E-8) satisfied.	0,36	3,4	0,005	Algorithm converged.	-0,05	0,06	1,1	Algorithm converged.	0,38	3,19	0,8566	0,51539999999999997	0,91	Algorithm converged.	0,31	2,62
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Intermediate (2)	221	37,1	19	8,6	222	37,2	8	3,6	2,52	Convergence criterion (GCONV=1E-8) satisfied.	1,08	5,88	0,05	Algorithm converged.	0,006	0,094	2,39	Algorithm converged.	1,07	5,34	0,0342		0,42	Algorithm converged.	0,19	0,94
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	High (>=3)	246	41,3	16	6,5	254	42,5	10	3,9	1,7	Convergence criterion (GCONV=1E-8) satisfied.	0,75	3,82	0,026	Algorithm converged.	-0,01	0,065	1,65	Algorithm converged.	0,76	3,57	0,2015		0,61	Algorithm converged.	0,28	1,31

41 (Anhang): Ergebnisse für UE Grad ≥ 3 bei ≥ 5 % der Patienten in einem Studienarm nach SOC/PT aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade >= 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

All

			G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
			Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	n/a	595	100,0	317	53,3	597	100	274	45,9	1,34		Convergence criterion (GCONV=1E-8) satisfied.	1,07	1,69	0,074		Algorithm converged.	0,017	0,130	1,16		Algorithm converged.	1,03	1,30	0,0111		0,86		Algorithm converged.	0,77	0,97
GASTROINTESTINAL DISORDERS	ALL	n/a	595	100,0	55	9,2	597	100	54	9,0	1,02		Convergence criterion (GCONV=1E-8) satisfied.	0,69	1,52	0,002		Algorithm converged.	-0,031	0,035	1,02		Algorithm converged.	0,71	1,46	0,9054		0,98		Algorithm converged.	0,68	1,40
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	n/a	595	100,0	38	6,4	597	100	32	5,4	1,20		Convergence criterion (GCONV=1E-8) satisfied.	0,74	1,96	0,010		Algorithm converged.	-0,016	0,037	1,19		Algorithm converged.	0,75	1,88	0,4517		0,84		Algorithm converged.	0,53	1,32
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	n/a	595	100,0	54	9,1	597	100	36	6,0	1,56		Convergence criterion (GCONV=1E-8) satisfied.	1,00	2,41	0,030		Algorithm converged.	0,000	0,060	1,51		Algorithm converged.	1,00	2,26	0,0485		0,66		Algorithm converged.	0,44	1,00
METABOLISM AND NUTRITION DISORDERS	ALL	n/a	595	100,0	34	5,7	597	100	27	4,5	1,28		Convergence criterion (GCONV=1E-8) satisfied.	0,76	2,15	0,012		Algorithm converged.	-0,013	0,037	1,26		Algorithm converged.	0,77	2,07	0,3518		0,79		Algorithm converged.	0,48	1,29
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	n/a	595	100,0	37	6,2	597	100	29	4,9	1,30		Convergence criterion (GCONV=1E-8) satisfied.	0,79	2,14	0,014		Algorithm converged.	-0,012	0,040	1,28		Algorithm converged.	0,80	2,05	0,3058		0,78		Algorithm converged.	0,49	1,25
NERVOUS SYSTEM DISORDERS	ALL	n/a	595	100,0	23	3,9	597	100	30	5,0	0,76		Convergence criterion (GCONV=1E-8) satisfied.	0,44	1,32	-0,012		Algorithm converged.	-0,035	0,012	0,77		Algorithm converged.	0,45	1,31	0,3331		1,30		Algorithm converged.	0,76	2,21
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	n/a	595	100,0	56	9,4	597	100	28	4,7	2,11		Convergence criterion (GCONV=1E-8) satisfied.	1,32	3,37	0,047		Algorithm converged.	0,018	0,076	2,01		Algorithm converged.	1,29	3,11	0,0019		0,50		Algorithm converged.	0,32	0,77
VASCULAR DISORDERS	ALL	n/a	595	100,0	31	5,2	597	100	21	3,5	1,51		Convergence criterion (GCONV=1E-8) satisfied.	0,86	2,65	0,017		Algorithm converged.	-0,006	0,040	1,48		Algorithm converged.	0,86	2,55	0,1556		0,68		Algorithm converged.	0,39	1,16
INFECTIONS AND INFESTATIONS	ALL	n/a	595	100,0	127	21,3	597	100	107	17,9	1,24		Convergence criterion (GCONV=1E-8) satisfied.	0,93	1,66	0,034		Algorithm converged.	-0,011	0,079	1,19		Algorithm converged.	0,95	1,50	0,1379		0,84		Algorithm converged.	0,67	1,06
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	n/a	595	100,0	44	7,4	597	100	28	4,7	1,62		Convergence criterion (GCONV=1E-8) satisfied.	1,00	2,64	0,027		Algorithm converged.	0,000	0,054	1,58		Algorithm converged.	1,00	2,50	0,0524		0,63		Algorithm converged.	0,40	1,00
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	n/a	595	100,0	54	9,1	597	100	54	9,0	1,00		Convergence criterion (GCONV=1E-8) satisfied.	0,68	1,49	0,000		Algorithm converged.	-0,032	0,033	1		Algorithm converged.	0,70	1,44	0,9854		1,00		Algorithm converged.	0,70	1,43
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	n/a	595	100,0	277	46,6	597	100	238	39,9	1,31		Convergence criterion (GCONV=1E-8) satisfied.	1,04	1,65	0,067		Algorithm converged.	0,011	0,123	1,17		Algorithm converged.	1,02	1,33	0,0202		0,86		Algorithm converged.	0,75	0,98
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	n/a	595	100,0	36	6,1	597	100	17	2,8	2,20		Convergence criterion (GCONV=1E-8) satisfied.	1,22	3,96	0,032		Algorithm converged.	0,009	0,055	2,12		Algorithm converged.	1,21	3,74	0,0090		0,47		Algorithm converged.	0,27	0,83
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	n/a	595	100,0	41	6,9	597	100	24	4,0	1,77		Convergence criterion (GCONV=1E-8) satisfied.	1,05	2,96	0,029		Algorithm converged.	0,003	0,054	1,71		Algorithm converged.	1,05	2,80	0,0314		0,58		Algorithm converged.	0,36	0,95
INFECTIONS AND INFESTATIONS	PNEUMONIA	n/a	595	100,0	28	4,7	597	100	30	5,0	0,93		Convergence criterion (GCONV=1E-8) satisfied.	0,55	1,58	-0,003		Algorithm converged.	-0,028	0,021	0,94		Algorithm converged.	0,57	1,55	0,7979		1,07		Algorithm converged.	0,65	1,76

42 (Anhang): Ergebnisse für UE Grad ≥ 3 bei ≥ 5 % der Patienten in einem Studienarm nach SOC/PT und mit statistisch signifikantem Ergebnis für die Gesamtpopulation nach Subgruppen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs Grade >= 3, Complete Study Duration
MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

All

			G-chemo (N=595)				R-chemo (N=597)				G-Chemo vs. R-Chemo																	R-Chemo vs. G-Chemo				
			Patients		Event		Patients		Event		Odds Ratio					Absolute Risk Difference					Relative Risk							Relative Risk				
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL	p-value (Wald)	Interaction Test p-value (likelihood ratio)	Relative Risk		Convergence Reason	95% Lower CL	95% Upper CL
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Male	281	47,2	142	50,5	278	46,6	118	42,4	1,39		Convergence criterion	0,99	1,93	0,081		Algorithm	-0	0,163	1,19		Algorithm	1	1,42	0,0565	0,713500	0,84		Algorithm	0,7	1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Male	281	47,2	25	8,9	278	46,6	17	6,1	1,5		Convergence criterion (GCONV=1E-8)satisfied.	0,79	2,84	0,028		Algorithm converged.	-0,02	0,071	1,45		Algorithm converged.	0,8	2,63	0,2156	0,878099 9999999	0,69		Algorithm converged.	0,38	1,24
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Male	281	47,2	22	7,8	278	46,6	8	2,9	2,87		Convergence criterion (GCONV=1E-8)satisfied.	1,25	6,55	0,05		Algorithm converged.	0,012	0,087	2,72		Algorithm converged.	1,23	6,01	0,0133	0,343100 0000000	0,37		Algorithm converged.	0,17	0,81
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	281	47,2	19	6,8	278	46,6	12	4,3	1,61		Convergence criterion (GCONV=1E-8)satisfied.	0,76	3,38	0,024		Algorithm converged.	-0,01	0,062	1,57		Algorithm converged.	0,78	3,17	0,2111	0,977700 0000000 0001	0,64		Algorithm converged.	0,32	1,29
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	281	47,2	125	44,5	278	46,6	103	37,1	1,36		Convergence criterion (GCONV=1E-8)satisfied.	0,97	1,91	0,074		Algorithm converged.	-0,01	0,156	1,2		Algorithm converged.	0,98	1,47	0,0751	0,719600 0000000 0002	0,83		Algorithm converged.	0,68	1,02
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	281	47,2	14	5	278	46,6	5	1,8	2,86		Convergence criterion (GCONV=1E-8)satisfied.	1,02	8,06	0,032		Algorithm converged.	0,002	0,062	2,77		Algorithm converged.	1,01	7,59	0,0475	0,518299 9999999 9998	0,36		Algorithm converged.	0,13	0,99
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Male	281	47,2	20	7,1	278	46,6	11	4	1,86		Convergence criterion (GCONV=1E-8)satisfied.	0,87	3,96	0,032		Algorithm converged.	-0,01	0,069	1,8		Algorithm converged.	0,88	3,68	0,1084	0,854899 9999999	0,56		Algorithm converged.	0,27	1,14
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Female	314	52,8	175	55,7	319	53,4	156	48,9	1,32		Convergence criterion (GCONV=1E-8)satisfied.	0,96	1,8	0,068		Algorithm converged.	-0,01	0,146	1,14		Algorithm converged.	0,98	1,32	0,0862		0,88		Algorithm converged.	0,76	1,02
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Female	314	52,8	29	9,2	319	53,4	19	6	1,61		Convergence criterion (GCONV=1E-8)satisfied.	0,88	2,93	0,033		Algorithm converged.	-0,01	0,074	1,55		Algorithm converged.	0,89	2,71	0,1228		0,64		Algorithm converged.	0,37	1,13
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Female	314	52,8	34	10,8	319	53,4	20	6,3	1,82		Convergence criterion (GCONV=1E-8)satisfied.	1,02	3,23	0,046		Algorithm converged.	0,002	0,089	1,73		Algorithm converged.	1,02	2,93	0,0433		0,58		Algorithm converged.	0,34	0,98
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	314	52,8	25	8	319	53,4	16	5	1,64		Convergence criterion (GCONV=1E-8)satisfied.	0,86	3,13	0,029		Algorithm converged.	-0,01	0,068	1,59		Algorithm converged.	0,86	2,92	0,1362		0,63		Algorithm converged.	0,34	1,16
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	314	52,8	152	48,4	319	53,4	135	42,3	1,28		Convergence criterion (GCONV=1E-8)satisfied.	0,93	1,75	0,061		Algorithm converged.	-0,02	0,138	1,14		Algorithm converged.	0,96	1,36	0,1248		0,87		Algorithm converged.	0,74	1,04
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	314	52,8	22	7	319	53,4	12	3,8	1,93		Convergence criterion (GCONV=1E-8)satisfied.	0,94	3,97	0,032		Algorithm converged.	-0	0,068	1,86		Algorithm converged.	0,94	3,7	0,0755		0,54		Algorithm converged.	0,27	1,07
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Female	314	52,8	21	6,7	319	53,4	13	4,1	1,69		Convergence criterion (GCONV=1E-8)satisfied.	0,83	3,43	0,026		Algorithm converged.	-0,01	0,061	1,64		Algorithm converged.	0,84	3,22	0,1497		0,61		Algorithm converged.	0,31	1,2
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	< 60 years	298	50,1	155	52	320	53,6	141	44,1	1,38		Convergence criterion (GCONV=1E-8)satisfied.	1	1,89	0,08		Algorithm converged.	0,001	0,158	1,18		Algorithm converged.	1	1,39	0,0484	0,743900 0000000 0001	0,85		Algorithm converged.	0,72	1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	< 60 years	298	50,1	25	8,4	320	53,6	22	6,9	1,24		Convergence criterion (GCONV=1E-8)satisfied.	0,68	2,25	0,015		Algorithm converged.	-0,03	0,057	1,22		Algorithm converged.	0,7	2,12	0,4787	0,272799 9999999 9999	0,82		Algorithm converged.	0,47	1,42
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	< 60 years	298	50,1	25	8,4	320	53,6	14	4,4	2		Convergence criterion (GCONV=1E-8)satisfied.	1,02	3,93	0,04		Algorithm converged.	0,002	0,079	1,92		Algorithm converged.	1,02	3,62	0,0445	0,868800 0000000 0002	0,52		Algorithm converged.	0,28	0,98
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 60 years	298	50,1	22	7,4	320	53,6	14	4,4	1,74		Convergence criterion (GCONV=1E-8)satisfied.	0,87	3,47	0,03		Algorithm converged.	-0,01	0,067	1,69		Algorithm converged.	0,88	3,24	0,1153	0,764000 0000000 0001	0,59		Algorithm converged.	0,31	1,14
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 60 years	298	50,1	133	44,6	320	53,6	124	38,8	1,27		Convergence criterion (GCONV=1E-8)satisfied.	0,92	1,76	0,059		Algorithm converged.	-0,02	0,136	1,15		Algorithm converged.	0,96	1,39	0,1386	0,865600 0000000 0004	0,87		Algorithm converged.	0,72	1,05
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 60 years	298	50,1	15	5	320	53,6	4	1,3	4,19		Convergence criterion (GCONV=1E-8)satisfied.	1,37	12,76	0,038		Algorithm converged.	0,01	0,065	4,03		Algorithm converged.	1,35	12	0,0124	0,1178	0,25		Algorithm converged.	0,08	0,74
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	< 60 years	298	50,1	19	6,4	320	53,6	16	5	1,29		Convergence criterion (GCONV=1E-8)satisfied.	0,65	2,57	0,014		Algorithm converged.	-0,02	0,05	1,28		Algorithm converged.	0,67	2,43	0,4609	0,173499 9999999 9999	0,78		Algorithm converged.	0,41	1,5

BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	>= 60 years	297	49,9	162	54,5	277	46,4	133	48	1,3		Convergence criterion (GCONV=1E-8)satisfied.	0,94	1,8	0,065		Algorithm converged.	-0,02	0,147	1,14		Algorithm converged.	0,97	1,33	0,1196		0,88		Algorithm converged.	0,75	1,03
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	>= 60 years	297	49,9	29	9,8	277	46,4	14	5,1	2,03		Convergence criterion (GCONV=1E-8)satisfied.	1,05	3,93	0,047		Algorithm converged.	0,005	0,09	1,93		Algorithm converged.	1,04	3,58	0,0363		0,52		Algorithm converged.	0,28	0,96
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	>= 60 years	297	49,9	31	10,4	277	46,4	14	5,1	2,19		Convergence criterion (GCONV=1E-8)satisfied.	1,14	4,21	0,054		Algorithm converged.	0,011	0,097	2,07		Algorithm converged.	1,12	3,8	0,0197		0,48		Algorithm converged.	0,26	0,89
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 60 years	297	49,9	22	7,4	277	46,4	14	5,1	1,5		Convergence criterion (GCONV=1E-8)satisfied.	0,75	3	0,024		Algorithm converged.	-0,02	0,063	1,47		Algorithm converged.	0,77	2,81	0,2489		0,68		Algorithm converged.	0,36	1,31
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 60 years	297	49,9	144	48,5	277	46,4	114	41,2	1,35		Convergence criterion (GCONV=1E-8)satisfied.	0,97	1,87	0,073		Algorithm converged.	-0,01	0,154	1,18		Algorithm converged.	0,98	1,41	0,0796		0,85		Algorithm converged.	0,71	1,02
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 60 years	297	49,9	21	7,1	277	46,4	13	4,7	1,54		Convergence criterion (GCONV=1E-8)satisfied.	0,76	3,15	0,024		Algorithm converged.	-0,02	0,062	1,51		Algorithm converged.	0,77	2,95	0,232		0,66		Algorithm converged.	0,34	1,3
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>= 60 years	297	49,9	22	7,4	277	46,4	8	2,9	2,69		Convergence criterion (GCONV=1E-8)satisfied.	1,18	6,15	0,045		Algorithm converged.	0,009	0,081	2,56		Algorithm converged.	1,16	5,67	0,0198		0,39		Algorithm converged.	0,18	0,86
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	North America	73	12,3	29	39,7	77	12,9	23	29,9	1,55		Convergence criterion (GCONV=1E-8)satisfied.	0,79	3,04	0,099		Algorithm converged.	-0,05	0,25	1,33		Algorithm converged.	0,85	2,07	0,2079	0,3315000000000002	0,75		Algorithm converged.	0,48	1,17
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	North America	73	12,3	7	9,6	77	12,9	1	1,3	8,06		Convergence criterion (GCONV=1E-8)satisfied.	0,97	67,22	0,083		Algorithm converged.	0,011	0,155	7,38		Algorithm converged.	0,93	58,55	0,0584	0,1650000000000001	0,14		Algorithm converged.	0,02	1,07
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	North America	73	12,3	7	9,6	77	12,9	3	3,9	2,62		Convergence criterion (GCONV=1E-8)satisfied.	0,65	10,53	0,057		Algorithm converged.	-0,02	0,137	2,46		Algorithm converged.	0,66	9,16	0,1792	0,9761999999999996	0,41		Algorithm converged.	0,11	1,51
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	North America	73	12,3	2	2,7	77	12,9	3	3,9	0,69		Convergence criterion (GCONV=1E-8)satisfied.	0,11	4,28	-0,01		Algorithm converged.	-0,07	0,046	0,7		Algorithm converged.	0,12	4,09	0,695	0,7917999999999995	1,42		Algorithm converged.	0,24	8,27
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	North America	73	12,3	25	34,2	77	12,9	19	24,7	1,59		Convergence criterion (GCONV=1E-8)satisfied.	0,78	3,23	0,096		Algorithm converged.	-0,05	0,241	1,39		Algorithm converged.	0,84	2,3	0,2018	0,3559999999999998	0,72		Algorithm converged.	0,44	1,19
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	North America	73	12,3	5	6,8	77	12,9	5	6,5	1,06		Convergence criterion (GCONV=1E-8)satisfied.	0,29	3,82	0,004		Algorithm converged.	-0,08	0,083	1,05		Algorithm converged.	0,32	3,49	0,9304	0,1307000000000001	0,95		Algorithm converged.	0,29	3,14
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	North America	73	12,3	3	4,1	77	12,9				*	Quasi-complete separation of data points detected.				*	ERROR: Error in computing the link function, its derivatives, or the variance function.			NE		Algorithm converged.	NE	NE	NE	0,0701999999999999	NE		Algorithm converged.	NE	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Western Europe	293	49,2	142	48,5	282	47,2	107	37,9	1,54		Convergence criterion (GCONV=1E-8)satisfied.	1,1	2,14	0,105		Algorithm converged.	0,025	0,186	1,28		Algorithm converged.	1,06	1,55	0,0117		0,78		Algorithm converged.	0,65	0,95
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Western Europe	293	49,2	28	9,6	282	47,2	21	7,4	1,31		Convergence criterion (GCONV=1E-8)satisfied.	0,73	2,37	0,021		Algorithm converged.	-0,02	0,067	1,28		Algorithm converged.	0,75	2,21	0,3668		0,78		Algorithm converged.	0,45	1,34
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Western Europe	293	49,2	32	10,9	282	47,2	15	5,3	2,18		Convergence criterion (GCONV=1E-8)satisfied.	1,15	4,12	0,056		Algorithm converged.	0,012	0,1	2,05		Algorithm converged.	1,14	3,71	0,0171		0,49		Algorithm converged.	0,27	0,88
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Western Europe	293	49,2	15	5,1	282	47,2	9	3,2	1,64		Convergence criterion (GCONV=1E-8)satisfied.	0,7	3,8	0,019		Algorithm converged.	-0,01	0,052	1,6		Algorithm converged.	0,71	3,61	0,2529		0,62		Algorithm converged.	0,28	1,4
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Western Europe	293	49,2	121	41,3	282	47,2	89	31,6	1,53		Convergence criterion (GCONV=1E-8)satisfied.	1,08	2,15	0,097		Algorithm converged.	0,019	0,176	1,31		Algorithm converged.	1,05	1,63	0,0163		0,76		Algorithm converged.	0,61	0,95
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Western Europe	293	49,2	16	5,5	282	47,2	3	1,1	5,37		Convergence criterion (GCONV=1E-8)satisfied.	1,55	18,64	0,044		Algorithm converged.	0,015	0,073	5,13		Algorithm converged.	1,51	17,43	0,0087		0,19		Algorithm converged.	0,06	0,66
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Western Europe	293	49,2	20	6,8	282	47,2	14	5	1,4		Convergence criterion (GCONV=1E-8)satisfied.	0,69	2,83	0,019		Algorithm converged.	-0,02	0,057	1,37		Algorithm converged.	0,71	2,67	0,3466		0,73		Algorithm converged.	0,37	1,41
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Asia-Pacific	150	25,2	103	68,7	155	26	103	66,5	1,11		Convergence criterion (GCONV=1E-8)satisfied.	0,68	1,79	0,022		Algorithm converged.	-0,08	0,127	1,03		Algorithm converged.	0,88	1,21	0,6795		0,97		Algorithm converged.	0,83	1,13
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Asia-Pacific	150	25,2	12	8	155	26	6	3,9	2,16		Convergence criterion (GCONV=1E-8)satisfied.	0,79	5,91	0,041		Algorithm converged.	-0,01	0,094	2,07		Algorithm converged.	0,8	5,36	0,1358		0,48		Algorithm converged.	0,19	1,26
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Asia-Pacific	150	25,2	12	8	155	26	7	4,5	1,84		Convergence criterion (GCONV=1E-8)satisfied.	0,7	4,8	0,035		Algorithm converged.	-0,02	0,089	1,77		Algorithm converged.	0,72	4,38	0,2155		0,56		Algorithm converged.	0,23	1,4
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Asia-Pacific	150	25,2	21	14	155	26	13	8,4	1,78		Convergence criterion (GCONV=1E-8)satisfied.	0,86	3,7	0,056		Algorithm converged.	-0,01	0,127	1,67		Algorithm converged.	0,87	3,21	0,1248			0,6	Algorithm converged.	0,31	1,15
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Asia-Pacific	150	25,2	95	63,3	155	26	93	60	1,15		Convergence criterion (GCONV=1E-8)satisfied.	0,73	1,83	0,033		Algorithm converged.	-0,08	0,142	1,06		Algorithm converged.	0,88	1,26	0,5495		0,95		Algorithm converged.	0,79	1,13

BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Asia-Pacific	150	25,2	9	6	155	26	3	1,9	3,23		Convergence criterion (GCONV=1E-8)satisfied.	0,86	12,18	0,041		Algorithm converged.	-0	0,084	3,1		Algorithm converged.	0,86	11,23	0,0849		0,32		Algorithm converged.	0,09	1,17
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Asia-Pacific	150	25,2	12	8	155	26	3	1,9	4,41		Convergence criterion (GCONV=1E-8)satisfied.	1,22	15,94	0,061		Algorithm converged.	0,012	0,109	4,13		Algorithm converged.	1,19	14,36	0,0255		0,24		Algorithm converged.	0,07	0,84
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Other	79	13,3	43	54,4	83	13,9	41	49,4	1,22		Convergence criterion (GCONV=1E-8)satisfied.	0,66	2,27	0,05		Algorithm converged.	-0,1	0,204	1,1		Algorithm converged.	0,82	1,48	0,5218		0,91		Algorithm converged.	0,67	1,22
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Other	79	13,3	7	8,9	83	13,9	8	9,6	0,91		Convergence criterion (GCONV=1E-8)satisfied.	0,31	2,64	-0,01		Algorithm converged.	-0,1	0,081	0,92		Algorithm converged.	0,35	2,42	0,8645		1,09		Algorithm converged.	0,41	2,86
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Other	79	13,3	5	6,3	83	13,9	3	3,6	1,8		Convergence criterion (GCONV=1E-8)satisfied.	0,42	7,8	0,027		Algorithm converged.	-0,04	0,094	1,75		Algorithm converged.	0,43	7,09	0,4321		0,57		Algorithm converged.	0,14	2,31
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Other	79	13,3	6	7,6	83	13,9	3	3,6	2,19		Convergence criterion (GCONV=1E-8)satisfied.	0,53	9,08	0,04		Algorithm converged.	-0,03	0,111	2,1		Algorithm converged.	0,54	8,12	0,2815		0,48		Algorithm converged.	0,12	1,84
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Other	79	13,3	36	45,6	83	13,9	37	44,6	1,04		Convergence criterion (GCONV=1E-8)satisfied.	0,56	1,93	0,01		Algorithm converged.	-0,14	0,163	1,02		Algorithm converged.	0,73	1,44	0,8991		0,98		Algorithm converged.	0,7	1,37
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Other	79	13,3	6	7,6	83	13,9	6	7,2	1,05		Convergence criterion (GCONV=1E-8)satisfied.	0,33	3,42	0,004		Algorithm converged.	-0,08	0,084	1,05		Algorithm converged.	0,35	3,12	0,9292		0,95		Algorithm converged.	0,32	2,83
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Other	79	13,3	6	7,6	83	13,9	7	8,4	0,89		Convergence criterion (GCONV=1E-8)satisfied.	0,29	2,78	-0,01		Algorithm converged.	-0,09	0,075	0,9		Algorithm converged.	0,32	2,56	0,8444		1,11		Algorithm converged.	0,39	3,16
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	CHOP	194	32,6	155	79,9	203	34	135	66,5	2		Convergence criterion (GCONV=1E-8)satisfied.	1,27	3,16	0,134		Algorithm converged.	0,048	0,22	1,2		Algorithm converged.	1,07	1,36	0,0028		0,83		Algorithm converged.	0,74	0,94
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	CHOP	194	32,6	22	11,3	203	34	16	7,9	1,49		Convergence criterion (GCONV=1E-8)satisfied.	0,76	2,94	0,035		Algorithm converged.	-0,02	0,093	1,44		Algorithm converged.	0,78	2,66	0,2449		0,7		Algorithm converged.	0,38	1,28
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	CHOP	194	32,6	24	12,4	203	34	9	4,4	3,04		Convergence criterion (GCONV=1E-8)satisfied.	1,38	6,73	0,079		Algorithm converged.	0,025	0,134	2,79		Algorithm converged.	1,33	5,85	0,0066	0,0119000000000001	0,36		Algorithm converged.	0,17	0,75
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	CHOP	194	32,6	24	12,4	203	34	13	6,4	2,06		Convergence criterion (GCONV=1E-8)satisfied.	1,02	4,18	0,06		Algorithm converged.	0,002	0,117	1,93		Algorithm converged.	1,01	3,68	0,0456	0,8375000000000002	0,52		Algorithm converged.	0,27	0,99
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	CHOP	194	32,6	141	72,7	203	34	117	57,6	1,96		Convergence criterion (GCONV=1E-8)satisfied.	1,28	2,98	0,15		Algorithm converged.	0,058	0,243	1,26		Algorithm converged.	1,09	1,46	0,0019		0,79		Algorithm converged.	0,69	0,92
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	CHOP	194	32,6	15	7,7	203	34	5	2,5	3,32		Convergence criterion (GCONV=1E-8)satisfied.	1,18	9,31	0,053		Algorithm converged.	0,009	0,096	3,14		Algorithm converged.	1,16	8,47	0,0239		0,32		Algorithm converged.	0,12	0,86
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	CHOP	194	32,6	20	10,3	203	34	10	4,9	2,22		Convergence criterion (GCONV=1E-8)satisfied.	1,01	4,87	0,054		Algorithm converged.	0,002	0,106	2,09		Algorithm converged.	1,01	4,36	0,0483		0,48		Algorithm converged.	0,23	0,99
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	CVP	60	10,1	31	51,7	56	9,4	14	25	3,21		Convergence criterion (GCONV=1E-8)satisfied.	1,46	7,06	0,267		Algorithm converged.	0,097	0,437	2,07		Algorithm converged.	1,23	3,46	0,0058		0,48		Algorithm converged.	0,29	0,81
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	CVP	60	10,1	2	3,3	56	9,4	5	8,9	0,35		Convergence criterion (GCONV=1E-8)satisfied.	0,07	1,89	-0,06		Algorithm converged.	-0,14	0,031	0,37		Algorithm converged.	0,08	1,85	0,2271		2,68		Algorithm converged.	0,54	13,25
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	CVP	60	10,1	2	3,3	56	9,4	5	8,9	0,35		Convergence criterion (GCONV=1E-8)satisfied.	0,07	1,89	-0,06		Algorithm converged.	-0,14	0,031	0,37		Algorithm converged.	0,08	1,85	0,2271		2,68		Algorithm converged.	0,54	13,25
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	CVP	60	10,1	2	3,3	56	9,4	2	3,6	0,93		Convergence criterion (GCONV=1E-8)satisfied.	0,13	6,84	-0		Algorithm converged.	-0,07	0,064	0,93		Algorithm converged.	0,14	6,4	0,944		1,07		Algorithm converged.	0,16	7,35
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	CVP	60	10,1	30	50	56	9,4	13	23,2	3,31		Convergence criterion (GCONV=1E-8)satisfied.	1,49	7,37	0,268		Algorithm converged.	0,1	0,436	2,15		Algorithm converged.	1,26	3,69	0,0053		0,46		Algorithm converged.	0,27	0,8
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	CVP	60	10,1	1	1,7	56	9,4				*	Quasi-complete separation of data points detected.				*	ERROR: The mean parameter is either invalid or at a limit of its range for some observations.			NE		Algorithm converged.	NE	NE	NE		NE		Algorithm converged.	NE	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	CVP	60	10,1	1	1,7	56	9,4	3	5,4	0,3		Convergence criterion (GCONV=1E-8)satisfied.	0,03	2,97	-0,04		Algorithm converged.	-0,1	0,03	0,31		Algorithm converged.	0,03	2,9	0,3056		3,21		Algorithm converged.	0,34	30
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Bendamustine	338	56,8	131	38,8	338	56,6	125	37	1,08		Convergence criterion (GCONV=1E-8)satisfied.	0,79	1,47	0,018		Algorithm converged.	-0,06	0,091	1,05		Algorithm converged.	0,86	1,27	0,6343		0,95		Algorithm converged.	0,79	1,16
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Bendamustine	338	56,8	27	8	338	56,6	15	4,4	1,87		Convergence criterion (GCONV=1E-8)satisfied.	0,98	3,58	0,036		Algorithm converged.	-0	0,072	1,8		Algorithm converged.	0,98	3,32	0,0602		0,56		Algorithm converged.	0,3	1,03

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Bendamustine	338	56,8	28	8,3	338	56,6	14	4,1	2,09		Convergence criterion (GCONV=1E-8)satisfied.	1,08	4,05	0,041		Algorithm converged.	0,005	0,078	2		Algorithm converged.	1,07	3,73	0,0294		0,5		Algorithm converged.	0,27	0,93
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Bendamustine	338	56,8	18	5,3	338	56,6	13	3,8	1,41		Convergence criterion (GCONV=1E-8)satisfied.	0,68	2,92	0,015		Algorithm converged.	-0,02	0,046	1,38		Algorithm converged.	0,69	2,78	0,3603		0,72		Algorithm converged.	0,36	1,45
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Bendamustine	338	56,8	106	31,4	338	56,6	108	32	0,97		Convergence criterion (GCONV=1E-8)satisfied.	0,7	1,35	-0,01		Algorithm converged.	-0,08	0,064	0,98		Algorithm converged.	0,79	1,22	0,8687		1,02		Algorithm converged.	0,82	1,27
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Bendamustine	338	56,8	20	5,9	338	56,6	12	3,6	1,71		Convergence criterion (GCONV=1E-8)satisfied.	0,82	3,55	0,024		Algorithm converged.	-0,01	0,056	1,67		Algorithm converged.	0,83	3,35	0,1524		0,6		Algorithm converged.	0,3	1,21
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Bendamustine	338	56,8	17	5	338	56,6	11	3,3	1,57		Convergence criterion (GCONV=1E-8)satisfied.	0,73	3,41	0,018		Algorithm converged.	-0,01	0,048	1,55		Algorithm converged.	0,73	3,25	0,251		0,65		Algorithm converged.	0,31	1,36
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	No Chemo	3	0,5																													
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	No Chemo	3	0,5	3	100																											
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	No Chemo	3	0,5	2	66,7																											
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	No Chemo	3	0,5																													
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	No Chemo	3	0,5																													
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	No Chemo	3	0,5																													
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	No Chemo	3	0,5	3	100																											
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Low (0-1)	128	21,5	60	46,9	121	20,3	45	37,2	1,49		Convergence criterion (GCONV=1E-8)satisfied.	0,9	2,47	0,097		Algorithm converged.	-0,03	0,219	1,26		Algorithm converged.	0,94	1,69	0,1254	0,3118000000000002	0,79		Algorithm converged.	0,59	1,07
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Low (0-1)	128	21,5	8	6,3	121	20,3	9	7,4	0,83		Convergence criterion (GCONV=1E-8)satisfied.	0,31	2,23	-0,01		Algorithm converged.	-0,08	0,051	0,84		Algorithm converged.	0,34	2,11	0,7106	0,3019999999999999	1,19		Algorithm converged.	0,47	2,98
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Low (0-1)	128	21,5	8	6,3	121	20,3	5	4,1	1,55		Convergence criterion (GCONV=1E-8)satisfied.	0,49	4,87	0,021		Algorithm converged.	-0,03	0,076	1,51		Algorithm converged.	0,51	4,5	0,4566	0,7572999999999997	0,66		Algorithm converged.	0,22	1,97
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Low (0-1)	128	21,5	6	4,7	121	20,3	5	4,1	1,14		Convergence criterion (GCONV=1E-8)satisfied.	0,34	3,84	0,006		Algorithm converged.	-0,05	0,057	1,13		Algorithm converged.	0,36	3,62	0,8314	0,0367999999999999	0,88		Algorithm converged.	0,28	2,81
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Low (0-1)	128	21,5	57	44,5	121	20,3	41	33,9	1,57		Convergence criterion (GCONV=1E-8)satisfied.	0,94	2,62	0,106		Algorithm converged.	-0,01	0,227	1,31		Algorithm converged.	0,96	1,8	0,0893	0,1202	0,76		Algorithm converged.	0,56	1,04
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Low (0-1)	128	21,5	4	3,1	121	20,3				*	Quasi-complete separation of data points detected.				*	WARNING: Negative of Hessian not positive definite.			NF		Algorithm converged.	NF	NF	NF	0,2127999999999999	NF		Algorithm converged.	NF	NF
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Low (0-1)	128	21,5	4	3,1	121	20,3	3	2,5	1,27		Convergence criterion (GCONV=1E-8)satisfied.	0,28	5,79	0,006		Algorithm converged.	-0,03	0,047	1,26		Algorithm converged.	0,29	5,52	0,7586	0,8555000000000004	0,79		Algorithm converged.	0,18	3,47
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	Intermediate (2)	221	37,1	108	48,9	222	37,2	105	47,3	1,06		Convergence criterion (GCONV=1E-8)satisfied.	0,73	1,55	0,016		Algorithm converged.	-0,08	0,109	1,03		Algorithm converged.	0,85	1,25	0,7407		0,97		Algorithm converged.	0,8	1,17
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	Intermediate (2)	221	37,1	21	9,5	222	37,2	10	4,5	2,23		Convergence criterion (GCONV=1E-8)satisfied.	1,02	4,84	0,05		Algorithm converged.	0,003	0,097	2,11		Algorithm converged.	1,02	4,38	0,045		0,47		Algorithm converged.	0,23	0,98
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	Intermediate (2)	221	37,1	22	10	222	37,2	9	4,1	2,62		Convergence criterion (GCONV=1E-8)satisfied.	1,18	5,82	0,059		Algorithm converged.	0,012	0,106	2,46		Algorithm converged.	1,16	5,21	0,0193		0,41		Algorithm converged.	0,19	0,86
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Intermediate (2)	221	37,1	13	5,9	222	37,2	15	6,8	0,86		Convergence criterion (GCONV=1E-8)satisfied.	0,4	1,86	-0,01		Algorithm converged.	-0,05	0,037	0,87		Algorithm converged.	0,42	1,79	0,7056		1,15		Algorithm converged.	0,56	2,36
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Intermediate (2)	221	37,1	90	40,7	222	37,2	93	41,9	0,95		Convergence criterion (GCONV=1E-8)satisfied.	0,65	1,39	-0,01		Algorithm converged.	-0,1	0,08	0,97		Algorithm converged.	0,78	1,21	0,8029		1,03		Algorithm converged.	0,82	1,28
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Intermediate (2)	221	37,1	9	4,1	222	37,2	5	2,3	1,84		Convergence criterion (GCONV=1E-8)satisfied.	0,61	5,59	0,018		Algorithm converged.	-0,01	0,051	1,81		Algorithm converged.	0,62	5,31	0,2812		0,55		Algorithm converged.	0,19	1,62
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Intermediate (2)	221	37,1	16	7,2	222	37,2	8	3,6	2,09		Convergence criterion (GCONV=1E-8)satisfied.	0,87	4,98	0,036		Algorithm converged.	-0,01	0,078	2,01		Algorithm converged.	0,88	4,6	0,0987		0,5		Algorithm converged.	0,22	1,14
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	High (>=3)	246	41,3	149	60,6	254	42,5	124	48,8	1,61		Convergence criterion (GCONV=1E-8)satisfied.	1,13	2,3	0,118		Algorithm converged.	0,031	0,204	1,24		Algorithm converged.	1,06	1,46	0,0088		0,81		Algorithm converged.	0,69	0,95
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	High (>=3)	246	41,3	25	10,2	254	42,5	17	6,7	1,58		Convergence criterion (GCONV=1E-8)satisfied.	0,83	3	0,035		Algorithm converged.	-0,01	0,083	1,52		Algorithm converged.	0,84	2,74	0,1658		0,66		Algorithm converged.	0,36	1,19
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	High (>=3)	246	41,3	26	10,6	254	42,5	14	5,5	2,03		Convergence criterion (GCONV=1E-8)satisfied.	1,03	3,98	0,051		Algorithm converged.	0,003	0,098	1,92		Algorithm converged.	1,03	3,58	0,0414		0,52		Algorithm converged.	0,28	0,97
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	High (>=3)	246	41,3	25	10,2	254	42,5	8	3,1	3,48		Convergence criterion (GCONV=1E-8)satisfied.	1,54	7,87	0,07		Algorithm converged.	0,027	0,114	3,23		Algorithm converged.	1,48	7,01	0,0031		0,31		Algorithm converged.	0,14	0,67

BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	High (>=3)	246	41,3	130	52,8	254	42,5	104	40,9	1,62		Convergence criterion (GCONV=1E-8)satisfied.	1,13	2,3	0,119		Algorithm converged.	0,032	0,206	1,29		Algorithm converged.	1,07	1,56	0,0082		0,77		Algorithm converged.	0,64	0,94
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	High (>=3)	246	41,3	23	9,3	254	42,5	12	4,7	2,08		Convergence criterion (GCONV=1E-8)satisfied.	1,01	4,28	0,046		Algorithm converged.	0,001	0,091	1,98		Algorithm converged.	1,01	3,89	0,0477		0,51		Algorithm converged.	0,26	0,99
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	High (>=3)	246	41,3	21	8,5	254	42,5	13	5,1	1,73		Convergence criterion (GCONV=1E-8)satisfied.	0,85	3,54	0,034		Algorithm converged.	-0,01	0,078	1,67		Algorithm converged.	0,85	3,26	0,134		0,6		Algorithm converged.	0,31	1,17

43 (Anhang): Ergebnisse für Abbruchgründe (UE) nach SOC aus RCT mit dem zu bewertenden Arzneimittel

		G-chemo (n= 595)	R-chemo (n= 597)
MedDRA System Organ Class	MedDRA Preferred Term	Patients with events n (%)	Patients with events n (%)2
INFECTIONS AND INFESTATIONS	ALL	28 (4,7)	23 (3,9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ALL	17 (2,9)	14 (2,3)
NERVOUS SYSTEM DISORDERS	ALL	17 (2,9)	20 (3,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	ALL	15 (2,5)	8 (1,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ALL	7 (1,2)	7 (1,2)
GASTROINTESTINAL DISORDERS	ALL	6 (1,0)	7 (1,2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ALL	4 (0,7)	1 (0,2)
HEPATOBILIARY DISORDERS	ALL	3 (0,5)	3 (0,5)
INVESTIGATIONS	ALL	3 (0,5)	3 (0,5)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ALL	3 (0,5)	0 (0,0)
CARDIAC DISORDERS	ALL	2 (0,3)	1 (0,2)
EYE DISORDERS	ALL	2 (0,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ALL	2 (0,3)	1 (0,2)
PSYCHIATRIC DISORDERS	ALL	2 (0,3)	0 (0,0)
RENAL AND URINARY DISORDERS	ALL	2 (0,3)	1 (0,2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALL	2 (0,3)	1 (0,2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ALL	1 (0,2)	4 (0,7)
METABOLISM AND NUTRITION DISORDERS	ALL	1 (0,2)	0 (0,0)
VASCULAR DISORDERS	ALL	0 (0,0)	2 (0,3)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	ALL	0 (0,0)	1 (0,2)

44 (Anhang): Ergebnisse für Abbruchgründe (UE) nach SOC/PT aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients

ENDPOINT: AEs leading to treatment discontinuation, Complete Study Duration MODEL: Unstratified Analysis

STUDY: BO21223

Dichotomous Analysis by Subgroups (Safety)

		G-chemo (n= 595)	R-chemo (n= 597)
MedDRA System Organ Class	**MedDRA Preferred Term**	**Patients with events n (%)**	**Patients with events n (%)2**
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	13 (2,2)	12 (2,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	10 (1,7)	3 (0,5)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	6 (1,0)	8 (1,3)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	4 (0,7)	0 (0,0)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	4 (0,7)	4 (0,7)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	4 (0,7)	3 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	3 (0,5)	1 (0,2)
GASTROINTESTINAL DISORDERS	DIARRHOEA	3 (0,5)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	3 (0,5)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	3 (0,5)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	3 (0,5)	1 (0,2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	2 (0,3)	1 (0,2)
GASTROINTESTINAL DISORDERS	NAUSEA	2 (0,3)	1 (0,2)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	2 (0,3)	0 (0,0)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	2 (0,3)	1 (0,2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	ACUTE MYELOID LEUKAEMIA	2 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	BREAST CANCER	2 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	2 (0,3)	3 (0,5)

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	2 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	2 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	2 (0,3)	1 (0,2)
CARDIAC DISORDERS	TACHYCARDIA	1 (0,2)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	1 (0,2)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	1 (0,2)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	1 (0,2)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	1 (0,2)	0 (0,0)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	1 (0,2)	1 (0,2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	1 (0,2)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	1 (0,2)	1 (0,2)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	1 (0,2)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	1 (0,2)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	1 (0,2)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	1 (0,2)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	1 (0,2)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	1 (0,2)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	1 (0,2)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	FLANK PAIN	1 (0,2)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	1 (0,2)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	1 (0,2)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOSITIS	1 (0,2)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	1 (0,2)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	ACUTE LYMPHOCYTIC LEUKAEMIA	1 (0,2)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	COLON CANCER	1 (0,2)	2 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	HEPATIC CANCER	1 (0,2)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	HODGKIN'S DISEASE NODULAR SCLEROSIS	1 (0,2)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	INVASIVE DUCTAL BREAST CARCINOMA	1 (0,2)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	MENINGIOMA	1 (0,2)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	OESTROGEN RECEPTOR POSITIVE BREAST CANCER	1 (0,2)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	PAPILLARY THYROID CANCER	1 (0,2)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	PROSTATE CANCER	1 (0,2)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	RECTAL ADENOCARCINOMA	1 (0,2)	1 (0,2)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	SQUAMOUS CELL CARCINOMA	1 (0,2)	1 (0,2)
NERVOUS SYSTEM DISORDERS	DIZZINESS	1 (0,2)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	1 (0,2)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	1 (0,2)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	1 (0,2)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	1 (0,2)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	1 (0,2)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	1 (0,2)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	1 (0,2)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	BRONCHOSPASM	1 (0,2)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	1 (0,2)	2 (0,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	1 (0,2)	2 (0,3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	1 (0,2)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	1 (0,2)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	1 (0,2)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	1 (0,2)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	1 (0,2)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	1 (0,2)	0 (0,0)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	1 (0,2)	4 (0,7)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	1 (0,2)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	1 (0,2)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	1 (0,2)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	1 (0,2)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	0 (0,0)	1 (0,2)
CARDIAC DISORDERS	CARDIAC FAILURE	0 (0,0)	1 (0,2)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	0 (0,0)	1 (0,2)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	0 (0,0)	1 (0,2)
GASTROINTESTINAL DISORDERS	COLITIS	0 (0,0)	1 (0,2)
GASTROINTESTINAL DISORDERS	CONSTIPATION	0 (0,0)	1 (0,2)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	0 (0,0)	1 (0,2)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	0 (0,0)	1 (0,2)
GASTROINTESTINAL DISORDERS	VOMITING	0 (0,0)	1 (0,2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	0 (0,0)	1 (0,2)

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	0 (0,0)	1 (0,2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	0 (0,0)	1 (0,2)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	0 (0,0)	1 (0,2)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	0 (0,0)	2 (0,3)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	0 (0,0)	1 (0,2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	ANKLE FRACTURE	0 (0,0)	1 (0,2)
INVESTIGATIONS	TRANSAMINASES INCREASED	0 (0,0)	1 (0,2)
INVESTIGATIONS	WEIGHT DECREASED	0 (0,0)	1 (0,2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	COLORECTAL CANCER	0 (0,0)	1 (0,2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	INTRAOCULAR MELANOMA	0 (0,0)	1 (0,2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	MALIGNANT MELANOMA	0 (0,0)	1 (0,2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	NEUROENDOCRINE CARCINOMA OF THE SKIN	0 (0,0)	1 (0,2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND	RENAL CELL CARCINOMA	0 (0,0)	1 (0,2)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	0 (0,0)	1 (0,2)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	0 (0,0)	1 (0,2)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	0 (0,0)	1 (0,2)
NERVOUS SYSTEM DISORDERS	HEADACHE	0 (0,0)	1 (0,2)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	0 (0,0)	1 (0,2)
RENAL AND URINARY DISORDERS	RENAL INFARCT	0 (0,0)	1 (0,2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	0 (0,0)	2 (0,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	0 (0,0)	1 (0,2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	0 (0,0)	1 (0,2)
VASCULAR DISORDERS	EMBOLISM	0 (0,0)	1 (0,2)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	0 (0,0)	1 (0,2)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	0 (0,0)	1 (0,2)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	0 (0,0)	1 (0,2)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	0 (0,0)	1 (0,2)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	0 (0,0)	2 (0,3)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	0 (0,0)	1 (0,2)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	0 (0,0)	1 (0,2)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	0 (0,0)	1 (0,2)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	0 (0,0)	1 (0,2)
INFECTIONS AND INFESTATIONS	SINUSITIS	0 (0,0)	1 (0,2)

INFECTIONS AND INFESTATIONS	VIRAL INFECTION	0 (0,0)	1 (0,2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPATHY	0 (0,0)	1 (0,2)

45 (Anhang): Ergebnisse für Abbruchgründe (UE) nach SOC/PT nach Subgruppen aus RCT mit dem zu bewertenden Arzneimittel

POPULATION: Safety Evaluable Patients, Follicular Lymphoma Patients
ENDPOINT: AEs leading to treatment discontinuation, Complete Study Duration, SOC01,02,04,05,07-17,20,22-24,27 MODEL: Unstratified Analysis
STUDY: BO21223
Dichotomous Analysis by Subgroups (Safety)

				G-chemo (N=595)	R-chemo (N=597)
MedDRA System Organ Class	MedDRA Preferred Term	Level		Patients with events n (%)	Patients with events n (%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	Male	sex	7 (2,5)	6 (2,2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	Female	sex	10 (3,2)	8 (2,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	sex	1 (0,4)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	sex	2 (0,6)	1 (0,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	sex	0 (0,0)	1 (0,4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	sex	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	sex	5 (1,8)	6 (2,2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	sex	8 (2,5)	6 (1,9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	sex	1 (0,4)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	sex	1 (0,3)	1 (0,3)
CARDIAC DISORDERS	All	Male	sex	2 (0,7)	0 (0,0)
CARDIAC DISORDERS	All	Female	sex	0 (0,0)	1 (0,3)
CARDIAC DISORDERS	CARDIAC FAILURE	Male	sex	0 (0,0)	0 (0,0)

CARDIAC DISORDERS	CARDIAC FAILURE	Female	sex	0 (0,0)	1 (0,3)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	Male	sex	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	Female	sex	0 (0,0)	1 (0,3)
CARDIAC DISORDERS	TACHYCARDIA	Male	sex	1 (0,4)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	Female	sex	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	Male	sex	1 (0,4)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	Female	sex	0 (0,0)	0 (0,0)
EYE DISORDERS	All	Male	sex	1 (0,4)	0 (0,0)
EYE DISORDERS	All	Female	sex	1 (0,3)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	Male	sex	0 (0,0)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	Female	sex	1 (0,3)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	Male	sex	1 (0,4)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	Female	sex	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	All	Male	sex	1 (0,4)	2 (0,7)
GASTROINTESTINAL DISORDERS	All	Female	sex	5 (1,6)	5 (1,6)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	sex	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	sex	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	COLITIS	Male	sex	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	Female	sex	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	sex	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	sex	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	sex	1 (0,4)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	sex	2 (0,6)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Male	sex	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Female	sex	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	ILEUS	Male	sex	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	Female	sex	1 (0,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Male	sex	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Female	sex	1 (0,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	NAUSEA	Male	sex	1 (0,4)	0 (0,0)

GASTROINTESTINAL DISORDERS	NAUSEA	Female	sex	1 (0,3)	1 (0,3)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	Male	sex	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	Female	sex	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	VOMITING	Male	sex	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	VOMITING	Female	sex	0 (0,0)	1 (0,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	Male	sex	1 (0,4)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	Female	sex	0 (0,0)	4 (1,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	Male	sex	1 (0,4)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	Female	sex	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	Male	sex	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	Female	sex	0 (0,0)	1 (0,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	Male	sex	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	Female	sex	0 (0,0)	1 (0,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	sex	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	sex	0 (0,0)	1 (0,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	Male	sex	1 (0,4)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	Female	sex	0 (0,0)	1 (0,3)
HEPATOBILIARY DISORDERS	All	Male	sex	1 (0,4)	2 (0,7)
HEPATOBILIARY DISORDERS	All	Female	sex	2 (0,6)	1 (0,3)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	Male	sex	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	Female	sex	0 (0,0)	1 (0,3)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	Male	sex	1 (0,4)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	Female	sex	1 (0,3)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Male	sex	0 (0,0)	2 (0,7)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Female	sex	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	Male	sex	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	Female	sex	1 (0,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	Male	sex	1 (0,4)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	Female	sex	1 (0,3)	1 (0,3)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Male	sex	1 (0,4)	0 (0,0)

IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Female	sex	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Male	sex	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Female	sex	1 (0,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	Male	sex	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	Female	sex	0 (0,0)	1 (0,3)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	Male	sex	2 (0,7)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	Female	sex	2 (0,6)	1 (0,3)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	Male	sex	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	Female	sex	0 (0,0)	1 (0,3)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	Male	sex	2 (0,7)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	Female	sex	2 (0,6)	0 (0,0)
INVESTIGATIONS	All	Male	sex	1 (0,4)	0 (0,0)
INVESTIGATIONS	All	Female	sex	2 (0,6)	3 (0,9)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Male	sex	1 (0,4)	0 (0,0)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Female	sex	1 (0,3)	1 (0,3)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Male	sex	0 (0,0)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Female	sex	1 (0,3)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	Male	sex	0 (0,0)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	Female	sex	1 (0,3)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	Male	sex	0 (0,0)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	Female	sex	1 (0,3)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	Male	sex	0 (0,0)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	Female	sex	0 (0,0)	1 (0,3)
INVESTIGATIONS	WEIGHT DECREASED	Male	sex	0 (0,0)	0 (0,0)
INVESTIGATIONS	WEIGHT DECREASED	Female	sex	0 (0,0)	1 (0,3)
METABOLISM AND NUTRITION DISORDERS	All	Male	sex	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	Female	sex	1 (0,3)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Male	sex	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Female	sex	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	Male	sex	3 (1,1)	0 (0,0)

MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	Female	sex	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	Male	sex	1 (0,4)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	Female	sex	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	Male	sex	1 (0,4)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	Female	sex	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	Male	sex	1 (0,4)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	Female	sex	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	Male	sex	1 (0,4)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	Female	sex	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	Male	sex	1 (0,4)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	Male	sex	7 (2,5)	6 (2,2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	Female	sex	8 (2,5)	2 (0,6)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	Male	sex	1 (0,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	Male	sex	2 (0,7)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	Male	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	Female	sex	2 (0,6)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	Male	sex	0 (0,0)	2 (0,7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	Female	sex	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	Male	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	Female	sex	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	Male	sex	1 (0,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	Male	sex	1 (0,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	Male	sex	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	Male	sex	0 (0,0)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	Female	sex	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	Male	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	Female	sex	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	Male	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	Female	sex	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	Male	sex	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	Male	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	Female	sex	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	Male	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	Female	sex	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	Male	sex	1 (0,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	Male	sex	1 (0,4)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	Male	sex	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	Female	sex	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	Male	sex	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	Female	sex	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	All	Male	sex	5 (1,8)	7 (2,5)
NERVOUS SYSTEM DISORDERS	All	Female	sex	12 (3,8)	13 (4,1)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	Male	sex	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	Female	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	Male	sex	1 (0,4)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	Female	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	Male	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	Female	sex	0 (0,0)	1 (0,3)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Male	sex	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Female	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HEADACHE	Male	sex	0 (0,0)	0 (0,0)

NERVOUS SYSTEM DISORDERS	HEADACHE	Female	sex	0 (0,0)	1 (0,3)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Male	sex	1 (0,4)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Female	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	Male	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	Female	sex	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Male	sex	1 (0,4)	2 (0,7)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Female	sex	3 (1,0)	2 (0,6)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Male	sex	2 (0,7)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Female	sex	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	Male	sex	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	Female	sex	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Male	sex	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Female	sex	6 (1,9)	7 (2,2)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	Male	sex	1 (0,4)	1 (0,4)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	Female	sex	1 (0,3)	2 (0,6)
PSYCHIATRIC DISORDERS	All	Male	sex	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	All	Female	sex	2 (0,6)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Male	sex	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Female	sex	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	Male	sex	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	Female	sex	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	Male	sex	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	Female	sex	1 (0,3)	0 (0,0)
RENAL AND URINARY DISORDERS	All	Male	sex	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	All	Female	sex	2 (0,6)	1 (0,3)
RENAL AND URINARY DISORDERS	POLLAKIURIA	Male	sex	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	Female	sex	1 (0,3)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	sex	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	sex	1 (0,3)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	Male	sex	0 (0,0)	0 (0,0)

RENAL AND URINARY DISORDERS	RENAL INFARCT	Female	sex	0 (0,0)	1 (0,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	Male	sex	2 (0,7)	1 (0,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	Female	sex	5 (1,6)	6 (1,9)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	Male	sex	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	Female	sex	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	Male	sex	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	Female	sex	1 (0,3)	2 (0,6)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	Male	sex	1 (0,4)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	Female	sex	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	Male	sex	1 (0,4)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	Female	sex	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	Male	sex	0 (0,0)	1 (0,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	Female	sex	0 (0,0)	1 (0,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	Male	sex	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	Female	sex	1 (0,3)	2 (0,6)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	Male	sex	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	Female	sex	0 (0,0)	1 (0,3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	Male	sex	1 (0,4)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	Female	sex	1 (0,3)	1 (0,3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	Male	sex	1 (0,4)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	Female	sex	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	Male	sex	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	Female	sex	1 (0,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	sex	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	sex	0 (0,0)	1 (0,3)
VASCULAR DISORDERS	All	Male	sex	0 (0,0)	1 (0,4)
VASCULAR DISORDERS	All	Female	sex	0 (0,0)	1 (0,3)
VASCULAR DISORDERS	EMBOLISM	Male	sex	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	EMBOLISM	Female	sex	0 (0,0)	1 (0,3)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	Male	sex	0 (0,0)	1 (0,4)

VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	All	Male	sex	14 (5,0)	6 (2,2)
INFECTIONS AND INFESTATIONS	All	Female	sex	14 (4,5)	17 (5,3)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	Male	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	Female	sex	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Male	sex	1 (0,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Female	sex	2 (0,6)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	Male	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	Female	sex	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	Male	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	Female	sex	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	Male	sex	1 (0,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	Male	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	Female	sex	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	Male	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	Female	sex	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	HEPATITIS B	Male	sex	1 (0,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	sex	0 (0,0)	2 (0,6)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Male	sex	1 (0,4)	1 (0,4)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Female	sex	3 (1,0)	2 (0,6)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	Male	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	Female	sex	1 (0,3)	4 (1,3)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	Male	sex	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	Male	sex	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	Male	sex	0 (0,0)	0 (0,0)

INFECTIONS AND INFESTATIONS	OTITIS MEDIA	Female	sex	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	Male	sex	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	sex	6 (2,1)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	sex	4 (1,3)	3 (0,9)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	Male	sex	1 (0,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	Male	sex	1 (0,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	Female	sex	1 (0,3)	1 (0,3)
INFECTIONS AND INFESTATIONS	SINUSITIS	Male	sex	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	SINUSITIS	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Male	sex	1 (0,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	Male	sex	1 (0,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	Female	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Male	sex	1 (0,4)	1 (0,4)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Female	sex	2 (0,6)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	Male	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	Female	sex	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	Male	sex	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	Female	sex	1 (0,3)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	Male	sex	0 (0,0)	1 (0,4)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	Female	sex	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	Male	sex	0 (0,0)	1 (0,4)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	Female	sex	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	< 60 years	age60	7 (2,3)	9 (2,8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	>= 60 year	sage60	10 (3,4)	5 (1,8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 60 years	age60	3 (1,0)	1 (0,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 60 years	age60	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 60 years	age60	0 (0,0)	1 (0,3)

BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 60 yearsage60	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 60 years age60	5 (1,7)	8 (2,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 60 yearsage60	8 (2,7)	4 (1,4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 60 years age60	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 60 yearsage60	2 (0,7)	1 (0,4)
CARDIAC DISORDERS	All	< 60 years age60	2 (0,7)	0 (0,0)
CARDIAC DISORDERS	All	>= 60 yearsage60	0 (0,0)	1 (0,4)
CARDIAC DISORDERS	CARDIAC FAILURE	< 60 years age60	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIAC FAILURE	>= 60 yearsage60	0 (0,0)	1 (0,4)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	< 60 years age60	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	>= 60 yearsage60	0 (0,0)	1 (0,4)
CARDIAC DISORDERS	TACHYCARDIA	< 60 years age60	1 (0,3)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	>= 60 yearsage60	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	< 60 years age60	1 (0,3)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	>= 60 yearsage60	0 (0,0)	0 (0,0)
EYE DISORDERS	All	< 60 years age60	0 (0,0)	0 (0,0)
EYE DISORDERS	All	>= 60 yearsage60	2 (0,7)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	< 60 years age60	0 (0,0)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	>= 60 yearsage60	1 (0,3)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	< 60 years age60	0 (0,0)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	>= 60 yearsage60	1 (0,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	All	< 60 years age60	2 (0,7)	4 (1,3)
GASTROINTESTINAL DISORDERS	All	>= 60 yearsage60	4 (1,3)	3 (1,1)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 60 years age60	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 60 yearsage60	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	< 60 years age60	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	>= 60 yearsage60	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 60 years age60	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 60 yearsage60	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 60 years age60	1 (0,3)	0 (0,0)

GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 60 yearsage60	2 (0,7)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	< 60 years age60	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	>= 60 yearsage60	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	ILEUS	< 60 years age60	1 (0,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	>= 60 yearsage60	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	< 60 years age60	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	>= 60 yearsage60	1 (0,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	NAUSEA	< 60 years age60	1 (0,3)	1 (0,3)
GASTROINTESTINAL DISORDERS	NAUSEA	>= 60 yearsage60	1 (0,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	< 60 years age60	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	>= 60 yearsage60	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	VOMITING	< 60 years age60	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	VOMITING	>= 60 yearsage60	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	< 60 years age60	1 (0,3)	1 (0,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	>= 60 yearsage60	0 (0,0)	3 (1,1)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	< 60 years age60	1 (0,3)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	>= 60 yearsage60	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	< 60 years age60	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	>= 60 yearsage60	0 (0,0)	1 (0,4)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	< 60 years age60	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	>= 60 yearsage60	0 (0,0)	1 (0,4)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 60 years age60	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 60 yearsage60	0 (0,0)	1 (0,4)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	< 60 years age60	1 (0,3)	1 (0,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	>= 60 yearsage60	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	All	< 60 years age60	2 (0,7)	1 (0,3)
HEPATOBILIARY DISORDERS	All	>= 60 yearsage60	1 (0,3)	2 (0,7)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	< 60 years age60	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	>= 60 yearsage60	0 (0,0)	1 (0,4)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	< 60 years age60	1 (0,3)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	>= 60 yearsage60	1 (0,3)	0 (0,0)

HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	< 60 years age60	0 (0,0)	1 (0,3)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	>= 60 yearsage60	0 (0,0)	1 (0,4)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	< 60 years age60	1 (0,3)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	>= 60 yearsage60	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	< 60 years age60	2 (0,7)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	>= 60 yearsage60	0 (0,0)	1 (0,4)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	< 60 years age60	1 (0,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	>= 60 yearsage60	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	< 60 years age60	1 (0,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	>= 60 yearsage60	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	< 60 years age60	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	>= 60 yearsage60	0 (0,0)	1 (0,4)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	< 60 years age60	3 (1,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	>= 60 yearsage60	1 (0,3)	1 (0,4)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	< 60 years age60	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	>= 60 yearsage60	0 (0,0)	1 (0,4)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	< 60 years age60	3 (1,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	>= 60 yearsage60	1 (0,3)	0 (0,0)
INVESTIGATIONS	All	< 60 years age60	1 (0,3)	1 (0,3)
INVESTIGATIONS	All	>= 60 yearsage60	2 (0,7)	2 (0,7)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	< 60 years age60	1 (0,3)	1 (0,3)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>= 60 yearsage60	1 (0,3)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	< 60 years age60	0 (0,0)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>= 60 yearsage60	1 (0,3)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	< 60 years age60	0 (0,0)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	>= 60 yearsage60	1 (0,3)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	< 60 years age60	0 (0,0)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	>= 60 yearsage60	1 (0,3)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	< 60 years age60	0 (0,0)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	>= 60 yearsage60	0 (0,0)	1 (0,4)

INVESTIGATIONS	WEIGHT DECREASED	< 60 years age60	0 (0,0)	0 (0,0)
INVESTIGATIONS	WEIGHT DECREASED	>= 60 yearsage60	0 (0,0)	1 (0,4)
METABOLISM AND NUTRITION DISORDERS	All	< 60 years age60	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	>= 60 yearsage60	1 (0,3)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	< 60 years age60	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	>= 60 yearsage60	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	< 60 years age60	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	>= 60 yearsage60	2 (0,7)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	< 60 years age60	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	>= 60 yearsage60	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	< 60 years age60	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	>= 60 yearsage60	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	< 60 years age60	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	>= 60 yearsage60	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	< 60 years age60	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	>= 60 yearsage60	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	< 60 years age60	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	>= 60 yearsage60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	< 60 years age60	4 (1,3)	2 (0,6)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	>= 60 yearsage60	11 (3,7)	6 (2,2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	< 60 years age60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	>= 60 yearsage60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	>= 60 yearsage60	2 (0,7)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	< 60 years age60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	>= 60 yearsage60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	>= 60 yearsage60	1 (0,3)	2 (0,7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	>= 60 yearsage60	0 (0,0)	1 (0,4)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	< 60 years age60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	>= 60 yearsage60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	>= 60 yearsage60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	>= 60 yearsage60	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	>= 60 yearsage60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	< 60 years age60	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	>= 60 yearsage60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	>= 60 yearsage60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	< 60 years age60	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	>= 60 yearsage60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	>= 60 yearsage60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	>= 60 yearsage60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	>= 60 yearsage60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	>= 60 yearsage60	1 (0,3)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	< 60 years age60	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	>= 60 yearsage60	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	< 60 years age60	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	>= 60 yearsage60	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	All	< 60 years age60	6 (2,0)	7 (2,2)
NERVOUS SYSTEM DISORDERS	All	>= 60 yearsage60	11 (3,7)	13 (4,7)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	< 60 years age60	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	>= 60 yearsage60	0 (0,0)	1 (0,4)

NERVOUS SYSTEM DISORDERS	DIZZINESS	< 60 years age60	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	>= 60 yearsage60	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	< 60 years age60	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	>= 60 yearsage60	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	< 60 years age60	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>= 60 yearsage60	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	HEADACHE	< 60 years age60	0 (0,0)	1 (0,3)
NERVOUS SYSTEM DISORDERS	HEADACHE	>= 60 yearsage60	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	< 60 years age60	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	>= 60 yearsage60	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	< 60 years age60	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	>= 60 yearsage60	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	< 60 years age60	2 (0,7)	1 (0,3)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>= 60 yearsage60	2 (0,7)	3 (1,1)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	< 60 years age60	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>= 60 yearsage60	2 (0,7)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	< 60 years age60	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	>= 60 yearsage60	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	< 60 years age60	2 (0,7)	3 (0,9)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	>= 60 yearsage60	4 (1,3)	5 (1,8)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	< 60 years age60	1 (0,3)	2 (0,6)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	>= 60 yearsage60	1 (0,3)	1 (0,4)
PSYCHIATRIC DISORDERS	All	< 60 years age60	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	All	>= 60 yearsage60	2 (0,7)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	< 60 years age60	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>= 60 yearsage60	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	< 60 years age60	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	>= 60 yearsage60	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	< 60 years age60	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	>= 60 yearsage60	1 (0,3)	0 (0,0)

RENAL AND URINARY DISORDERS	All	< 60 years age60	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	All	>= 60 yearsage60	2 (0,7)	1 (0,4)
RENAL AND URINARY DISORDERS	POLLAKIURIA	< 60 years age60	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	>= 60 yearsage60	1 (0,3)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 60 years age60	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 60 yearsage60	1 (0,3)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	< 60 years age60	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	>= 60 yearsage60	0 (0,0)	1 (0,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	< 60 years age60	3 (1,0)	4 (1,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	>= 60 yearsage60	4 (1,3)	3 (1,1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	< 60 years age60	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	>= 60 yearsage60	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	< 60 years age60	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	>= 60 yearsage60	1 (0,3)	2 (0,7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	< 60 years age60	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	>= 60 yearsage60	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	< 60 years age60	2 (0,7)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	>= 60 yearsage60	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	< 60 years age60	0 (0,0)	2 (0,6)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	>= 60 yearsage60	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	< 60 years age60	0 (0,0)	1 (0,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	>= 60 yearsage60	1 (0,3)	1 (0,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	< 60 years age60	0 (0,0)	1 (0,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	>= 60 yearsage60	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	< 60 years age60	2 (0,7)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	>= 60 yearsage60	0 (0,0)	1 (0,4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	< 60 years age60	1 (0,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	>= 60 yearsage60	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	< 60 years age60	1 (0,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	>= 60 yearsage60	0 (0,0)	0 (0,0)

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 60 years age60	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 60 yearsage60	0 (0,0)	1 (0,4)
VASCULAR DISORDERS	All	< 60 years age60	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	All	>= 60 yearsage60	0 (0,0)	2 (0,7)
VASCULAR DISORDERS	EMBOLISM	< 60 years age60	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	EMBOLISM	>= 60 yearsage60	0 (0,0)	1 (0,4)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	< 60 years age60	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	>= 60 yearsage60	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	All	< 60 years age60	9 (3,0)	12 (3,8)
INFECTIONS AND INFESTATIONS	All	>= 60 yearsage60	19 (6,4)	11 (4,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	< 60 years age60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	>= 60 yearsage60	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	BRONCHITIS	< 60 years age60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	>= 60 yearsage60	3 (1,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	< 60 years age60	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	>= 60 yearsage60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	< 60 years age60	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	>= 60 yearsage60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	< 60 years age60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	>= 60 yearsage60	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	< 60 years age60	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	>= 60 yearsage60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	< 60 years age60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	>= 60 yearsage60	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	HEPATITIS B	< 60 years age60	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	>= 60 yearsage60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 60 years age60	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 60 yearsage60	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	< 60 years age60	1 (0,3)	1 (0,3)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>= 60 yearsage60	3 (1,0)	2 (0,7)

INFECTIONS AND INFESTATIONS	LUNG INFECTION	< 60 years age60	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	>= 60 yearsage60	1 (0,3)	3 (1,1)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	< 60 years age60	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	>= 60 yearsage60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	< 60 years age60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	>= 60 yearsage60	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	< 60 years age60	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	>= 60 yearsage60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	< 60 years age60	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	>= 60 yearsage60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 60 years age60	3 (1,0)	2 (0,6)
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 60 yearsage60	7 (2,4)	1 (0,4)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	< 60 years age60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	>= 60 yearsage60	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	< 60 years age60	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	>= 60 yearsage60	1 (0,3)	1 (0,4)
INFECTIONS AND INFESTATIONS	SINUSITIS	< 60 years age60	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	SINUSITIS	>= 60 yearsage60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	< 60 years age60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	>= 60 yearsage60	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	< 60 years age60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	>= 60 yearsage60	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	< 60 years age60	1 (0,3)	1 (0,3)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>= 60 yearsage60	2 (0,7)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	< 60 years age60	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	>= 60 yearsage60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	< 60 years age60	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	>= 60 yearsage60	1 (0,3)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	< 60 years age60	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	>= 60 yearsage60	0 (0,0)	1 (0,4)

CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	< 60 years	age60	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	>= 60 years	age60	0 (0,0)	1 (0,4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	North Ame	region	2 (2,7)	1 (1,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	Western E	region	7 (2,4)	7 (2,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	Asia-Pacific	region	8 (5,3)	5 (3,2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	Other	region	0 (0,0)	1 (1,2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	North Ame	region	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Western E	region	1 (0,3)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Asia-Pacific	region	2 (1,3)	1 (0,6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Other	region	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	North Ame	region	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Western E	region	0 (0,0)	1 (0,4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Asia-Pacific	region	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Other	region	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	North Ame	region	1 (1,4)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Western E	region	5 (1,7)	7 (2,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Asia-Pacific	region	7 (4,7)	4 (2,6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Other	region	0 (0,0)	1 (1,2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	North Ame	region	1 (1,4)	1 (1,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Western E	region	1 (0,3)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Asia-Pacific	region	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Other	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	All	North Ame	region	0 (0,0)	1 (1,3)
CARDIAC DISORDERS	All	Western E	region	1 (0,3)	0 (0,0)
CARDIAC DISORDERS	All	Asia-Pacific	region	1 (0,7)	0 (0,0)
CARDIAC DISORDERS	All	Other	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIAC FAILURE	North Ame	region	0 (0,0)	1 (1,3)
CARDIAC DISORDERS	CARDIAC FAILURE	Western E	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIAC FAILURE	Asia-Pacific	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIAC FAILURE	Other	region	0 (0,0)	0 (0,0)

CARDIAC DISORDERS	CARDIOGENIC SHOCK	North Ame	region	0 (0,0)	1 (1,3)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	Western E	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	Asia-Pacific	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	Other	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	North Ame	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	Western E	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	Asia-Pacific	region	1 (0,7)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	Other	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	North Ame	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	Western E	region	1 (0,3)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	Asia-Pacific	region	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	Other	region	0 (0,0)	0 (0,0)
EYE DISORDERS	All	North Ame	region	0 (0,0)	0 (0,0)
EYE DISORDERS	All	Western E	region	1 (0,3)	0 (0,0)
EYE DISORDERS	All	Asia-Pacific	region	0 (0,0)	0 (0,0)
EYE DISORDERS	All	Other	region	1 (1,3)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	North Ame	region	0 (0,0)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	Western E	region	1 (0,3)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	Asia-Pacific	region	0 (0,0)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	Other	region	0 (0,0)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	North Ame	region	0 (0,0)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	Western E	region	0 (0,0)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	Asia-Pacific	region	0 (0,0)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	Other	region	1 (1,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	All	North Ame	region	0 (0,0)	1 (1,3)
GASTROINTESTINAL DISORDERS	All	Western E	region	3 (1,0)	2 (0,7)
GASTROINTESTINAL DISORDERS	All	Asia-Pacific	region	2 (1,3)	4 (2,6)
GASTROINTESTINAL DISORDERS	All	Other	region	1 (1,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	North Ame	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Western E	region	0 (0,0)	0 (0,0)

GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Asia-Pacific	region	0 (0,0)	1 (0,6)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Other	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	North Ame	region	0 (0,0)	1 (1,3)
GASTROINTESTINAL DISORDERS	COLITIS	Western E	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	Asia-Pacific	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	Other	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	CONSTIPATION	North Ame	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	CONSTIPATION	Western E	region	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	CONSTIPATION	Asia-Pacific	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	CONSTIPATION	Other	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	North Ame	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	Western E	region	2 (0,7)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	Asia-Pacific	region	1 (0,7)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	Other	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	North Ame	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Western E	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Asia-Pacific	region	0 (0,0)	1 (0,6)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Other	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	North Ame	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	Western E	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	Asia-Pacific	region	1 (0,7)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	Other	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	North Ame	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Western E	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Asia-Pacific	region	0 (0,0)	1 (0,6)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Other	region	1 (1,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	NAUSEA	North Ame	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	NAUSEA	Western E	region	1 (0,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	NAUSEA	Asia-Pacific	region	1 (0,7)	1 (0,6)
GASTROINTESTINAL DISORDERS	NAUSEA	Other	region	0 (0,0)	0 (0,0)

GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	North Ame	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	Western E	region	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	Asia-Pacific	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	Other	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	VOMITING	North Ame	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	VOMITING	Western E	region	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	VOMITING	Asia-Pacific	region	0 (0,0)	1 (0,6)
GASTROINTESTINAL DISORDERS	VOMITING	Other	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	North Ame	region	0 (0,0)	2 (2,6)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	Western E	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	Asia-Pacific	region	1 (0,7)	1 (0,6)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	Other	region	0 (0,0)	1 (1,2)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	North Ame	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	Western E	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	Asia-Pacific	region	1 (0,7)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	Other	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	North Ame	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	Western E	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	Asia-Pacific	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	Other	region	0 (0,0)	1 (1,2)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	North Ame	region	0 (0,0)	1 (1,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	Western E	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	Asia-Pacific	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	Other	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	North Ame	region	0 (0,0)	1 (1,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Western E	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Asia-Pacific	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Other	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	North Ame	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	Western E	region	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	Asia-Pacific	region	1 (0,7)	1 (0,6)

GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	Other	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	All	North Ame	region	1 (1,4)	0 (0,0)
HEPATOBILIARY DISORDERS	All	Western E	region	0 (0,0)	2 (0,7)
HEPATOBILIARY DISORDERS	All	Asia-Pacific	region	2 (1,3)	1 (0,6)
HEPATOBILIARY DISORDERS	All	Other	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	North Ame	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	Western E	region	0 (0,0)	1 (0,4)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	Asia-Pacific	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	Other	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	North Ame	region	1 (1,4)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	Western E	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	Asia-Pacific	region	1 (0,7)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	Other	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	North Ame	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Western E	region	0 (0,0)	1 (0,4)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Asia-Pacific	region	0 (0,0)	1 (0,6)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Other	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	North Ame	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	Western E	region	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	Asia-Pacific	region	1 (0,7)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	Other	region	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	North Ame	region	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	Western E	region	0 (0,0)	1 (0,4)
IMMUNE SYSTEM DISORDERS	All	Asia-Pacific	region	1 (0,7)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	Other	region	1 (1,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	North Ame	region	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Western E	region	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Asia-Pacific	region	1 (0,7)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Other	region	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	North Ame	region	0 (0,0)	0 (0,0)

IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Western E	region	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Asia-Pacific	region	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Other	region	1 (1,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	North Ame	region	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	Western E	region	0 (0,0)	1 (0,4)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	Asia-Pacific	region	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	Other	region	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	North Ame	region	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	Western E	region	2 (0,7)	1 (0,4)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	Asia-Pacific	region	2 (1,3)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	Other	region	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	North Ame	region	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	Western E	region	0 (0,0)	1 (0,4)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	Asia-Pacific	region	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	Other	region	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	North Ame	region	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	Western E	region	2 (0,7)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	Asia-Pacific	region	2 (1,3)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	Other	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	All	North Ame	region	1 (1,4)	1 (1,3)
INVESTIGATIONS	All	Western E	region	0 (0,0)	1 (0,4)
INVESTIGATIONS	All	Asia-Pacific	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	All	Other	region	2 (2,5)	1 (1,2)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	North Ame	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Western E	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Asia-Pacific	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Other	region	2 (2,5)	1 (1,2)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	North Ame	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Western E	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Asia-Pacific	region	0 (0,0)	0 (0,0)

INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Other	region	1 (1,3)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	North Ame	region	1 (1,4)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	Western E	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	Asia-Pacific	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	Other	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	North Ame	region	1 (1,4)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	Western E	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	Asia-Pacific	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	Other	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	North Ame	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	Western E	region	0 (0,0)	1 (0,4)
INVESTIGATIONS	TRANSAMINASES INCREASED	Asia-Pacific	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	Other	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	WEIGHT DECREASED	North Ame	region	0 (0,0)	1 (1,3)
INVESTIGATIONS	WEIGHT DECREASED	Western E	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	WEIGHT DECREASED	Asia-Pacific	region	0 (0,0)	0 (0,0)
INVESTIGATIONS	WEIGHT DECREASED	Other	region	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	North Ame	region	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	Western E	region	1 (0,3)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	Asia-Pacific	region	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	Other	region	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	North Ame	region	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Western E	region	1 (0,3)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Asia-Pacific	region	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Other	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	North Ame	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	Western E	region	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	Asia-Pacific	region	1 (0,7)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	Other	region	1 (1,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	North Ame	region	0 (0,0)	0 (0,0)

MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	Western E	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	Asia-Pacific	region	1 (0,7)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	Other	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	North Ame	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	Western E	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	Asia-Pacific	region	1 (0,7)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	Other	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	North Ame	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	Western E	region	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	Asia-Pacific	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	Other	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	North Ame	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	Western E	region	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	Asia-Pacific	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	Other	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	North Ame	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	Western E	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	Asia-Pacific	region	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	Other	region	1 (1,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	North Ame	region	1 (1,4)	4 (5,2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	Western E	region	6 (2,0)	2 (0,7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	Asia-Pacific	region	4 (2,7)	2 (1,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	Other	region	4 (5,1)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	Western E	region	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	Western E	region	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	Asia-Pacific	region	0 (0,0)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	Other	region	1 (1,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	Western E	region	2 (0,7)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	North Ame	region	0 (0,0)	1 (1,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	Western E	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	Asia-Pacific	region	1 (0,7)	1 (0,6)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	North Ame	region	0 (0,0)	1 (1,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	Western E	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	Western E	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	Other	region	1 (1,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	Western E	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	Other	region	1 (1,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	Western E	region	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	Western E	region	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	North Ame	region	0 (0,0)	1 (1,3)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	Western E	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	Western E	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	Asia-Pacific	region	1 (0,7)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	Western E	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	Asia-Pacific	region	0 (0,0)	1 (0,6)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	Western E	region	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	Western E	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	Asia-Pacific	region	1 (0,7)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	Western E	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	Asia-Pacific	region	1 (0,7)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	North Ame	region	1 (1,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	Western E	region	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	North Ame	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	Western E	region	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	Asia-Pacific	region	0 (0,0)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	Other	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	North Ame	region	0 (0,0)	1 (1,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	Western E	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	Asia-Pacific	region	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	Other	region	1 (1,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	All	North Ame	region	0 (0,0)	2 (2,6)
NERVOUS SYSTEM DISORDERS	All	Western E	region	9 (3,1)	7 (2,5)
NERVOUS SYSTEM DISORDERS	All	Asia-Pacific	region	5 (3,3)	8 (5,2)
NERVOUS SYSTEM DISORDERS	All	Other	region	3 (3,8)	3 (3,6)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	North Ame	region	0 (0,0)	1 (1,3)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	Western E	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	Asia-Pacific	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	Other	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	North Ame	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	Western E	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	Asia-Pacific	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	Other	region	1 (1,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	North Ame	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	Western E	region	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	Asia-Pacific	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	Other	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	North Ame	region	0 (0,0)	1 (1,3)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Western E	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Asia-Pacific	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Other	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HEADACHE	North Ame	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HEADACHE	Western E	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HEADACHE	Asia-Pacific	region	0 (0,0)	1 (0,6)
NERVOUS SYSTEM DISORDERS	HEADACHE	Other	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	North Ame	region	0 (0,0)	0 (0,0)

NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Western E	region	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Asia-Pacific	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Other	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	North Ame	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	Western E	region	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	Asia-Pacific	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	Other	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	North Ame	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Western E	region	3 (1,0)	4 (1,4)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Asia-Pacific	region	1 (0,7)	0 (0,0)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Other	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	North Ame	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Western E	region	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Asia-Pacific	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Other	region	2 (2,5)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	North Ame	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	Western E	region	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	Asia-Pacific	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	Other	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	North Ame	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Western E	region	2 (0,7)	1 (0,4)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Asia-Pacific	region	4 (2,7)	7 (4,5)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Other	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	North Ame	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	Western E	region	2 (0,7)	0 (0,0)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	Asia-Pacific	region	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	Other	region	0 (0,0)	3 (3,6)
PSYCHIATRIC DISORDERS	All	North Ame	region	1 (1,4)	0 (0,0)
PSYCHIATRIC DISORDERS	All	Western E	region	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	All	Asia-Pacific	region	0 (0,0)	0 (0,0)

PSYCHIATRIC DISORDERS	All	Other	region	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	North Ame	region	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Western E	region	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Asia-Pacific	region	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Other	region	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	North Ame	region	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	Western E	region	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	Asia-Pacific	region	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	Other	region	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	North Ame	region	1 (1,4)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	Western E	region	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	Asia-Pacific	region	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	Other	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	All	North Ame	region	1 (1,4)	0 (0,0)
RENAL AND URINARY DISORDERS	All	Western E	region	1 (0,3)	0 (0,0)
RENAL AND URINARY DISORDERS	All	Asia-Pacific	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	All	Other	region	0 (0,0)	1 (1,2)
RENAL AND URINARY DISORDERS	POLLAKIURIA	North Ame	region	1 (1,4)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	Western E	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	Asia-Pacific	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	Other	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	North Ame	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	Western E	region	1 (0,3)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	Asia-Pacific	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	Other	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	North Ame	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	Western E	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	Asia-Pacific	region	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	Other	region	0 (0,0)	1 (1,2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	North Ame	region	2 (2,7)	0 (0,0)

RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	Western E	region	4 (1,4)	4 (1,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	Asia-Pacific	region	1 (0,7)	2 (1,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	Other	region	0 (0,0)	1 (1,2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	North Ame	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	Western E	region	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	Asia-Pacific	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	Other	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	North Ame	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	Western E	region	1 (0,3)	2 (0,7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	Asia-Pacific	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	Other	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	North Ame	region	1 (1,4)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	Western E	region	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	Asia-Pacific	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	Other	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	North Ame	region	1 (1,4)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	Western E	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	Asia-Pacific	region	1 (0,7)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	Other	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	North Ame	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	Western E	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	Asia-Pacific	region	0 (0,0)	2 (1,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	Other	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	North Ame	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	Western E	region	1 (0,3)	1 (0,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	Asia-Pacific	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	Other	region	0 (0,0)	1 (1,2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	North Ame	region	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	Western E	region	0 (0,0)	1 (0,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	Asia-Pacific	region	0 (0,0)	0 (0,0)

RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	Other	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	North Ame	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	Western E	region	1 (0,3)	1 (0,4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	Asia-Pacific	region	1 (0,7)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	Other	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	North Ame	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	Western E	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	Asia-Pacific	region	1 (0,7)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	Other	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	North Ame	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	Western E	region	1 (0,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	Asia-Pacific	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	Other	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	North Ame	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Western E	region	0 (0,0)	1 (0,4)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Asia-Pacific	region	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Other	region	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	All	North Ame	region	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	All	Western E	region	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	All	Asia-Pacific	region	0 (0,0)	1 (0,6)
VASCULAR DISORDERS	All	Other	region	0 (0,0)	1 (1,2)
VASCULAR DISORDERS	EMBOLISM	North Ame	region	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	EMBOLISM	Western E	region	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	EMBOLISM	Asia-Pacific	region	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	EMBOLISM	Other	region	0 (0,0)	1 (1,2)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	North Ame	region	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	Western E	region	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	Asia-Pacific	region	0 (0,0)	1 (0,6)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	All	North Ame	region	4 (5,5)	1 (1,3)
INFECTIONS AND INFESTATIONS	All	Western E	region	12 (4,1)	14 (5,0)

INFECTIONS AND INFESTATIONS	All	Asia-Pacific	region	9 (6,0)	4 (2,6)
INFECTIONS AND INFESTATIONS	All	Other	region	3 (3,8)	4 (4,8)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	Western E	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	Other	region	0 (0,0)	1 (1,2)
INFECTIONS AND INFESTATIONS	BRONCHITIS	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Western E	region	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Other	region	2 (2,5)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	Western E	region	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	Western E	region	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	Western E	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	Asia-Pacific	region	1 (0,7)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	Western E	region	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	Western E	region	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	Other	region	0 (0,0)	0 (0,0)

INFECTIONS AND INFESTATIONS	HEPATITIS B	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	Western E	region	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Western E	region	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Other	region	0 (0,0)	1 (1,2)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Western E	region	4 (1,4)	3 (1,1)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	North Ame	region	1 (1,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	Western E	region	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	Asia-Pacific	region	0 (0,0)	3 (1,9)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	Western E	region	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	Western E	region	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	Western E	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	Other	region	0 (0,0)	1 (1,2)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	Western E	region	0 (0,0)	1 (0,4)

INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	North Ame	region	2 (2,7)	1 (1,3)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Western E	region	3 (1,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Asia-Pacific	region	3 (2,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Other	region	2 (2,5)	1 (1,2)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	Western E	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	Asia-Pacific	region	1 (0,7)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	Western E	region	1 (0,3)	1 (0,4)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	Asia-Pacific	region	1 (0,7)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	SINUSITIS	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	SINUSITIS	Western E	region	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	SINUSITIS	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	SINUSITIS	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	North Ame	region	1 (1,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Western E	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	Western E	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	Asia-Pacific	region	1 (0,7)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Western E	region	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Asia-Pacific	region	2 (1,3)	1 (0,6)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Other	region	0 (0,0)	0 (0,0)

INFECTIONS AND INFESTATIONS	VIRAL INFECTION	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	Western E	region	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	Asia-Pacific	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	Other	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	North Ame	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	Western E	region	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	Asia-Pacific	region	1 (0,7)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	Other	region	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	North Ame	region	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	Western E	region	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	Asia-Pacific	region	0 (0,0)	1 (0,6)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	Other	region	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	North Ame	region	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	Western E	region	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	Asia-Pacific	region	0 (0,0)	1 (0,6)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	Other	region	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	CHOP	chemo_a n	3 (1,5)	3 (1,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	Bendamust	chemo_a n	14 (4,1)	11 (3,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	CHOP	chemo_a n	2 (1,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Bendamust	chemo_a n	1 (0,3)	1 (0,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	CHOP	chemo_a n	0 (0,0)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	CHOP	chemo_a n	1 (0,5)	3 (1,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	CVP	chemo_a n	0 (0,0)	0 (0,0)

BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Bendamust	chemo_a n	12 (3,6)	9 (2,7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Bendamust	chemo_a n	2 (0,6)	1 (0,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	All	CHOP	chemo_a n	1 (0,5)	0 (0,0)
CARDIAC DISORDERS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	All	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
CARDIAC DISORDERS	All	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
CARDIAC DISORDERS	CARDIAC FAILURE	CHOP	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIAC FAILURE	CVP	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIAC FAILURE	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
CARDIAC DISORDERS	CARDIAC FAILURE	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	CHOP	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	CVP	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	CHOP	chemo_a n	1 (0,5)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	CVP	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
EYE DISORDERS	All	CHOP	chemo_a n	1 (0,5)	0 (0,0)
EYE DISORDERS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
EYE DISORDERS	All	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
EYE DISORDERS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)

EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	CHOP	chemo_a n	0 (0,0)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	CVP	chemo_a n	0 (0,0)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	CHOP	chemo_a n	1 (0,5)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	CVP	chemo_a n	0 (0,0)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	All	CHOP	chemo_a n	0 (0,0)	3 (1,5)
GASTROINTESTINAL DISORDERS	All	CVP	chemo_a n	1 (1,7)	0 (0,0)
GASTROINTESTINAL DISORDERS	All	Bendamust	chemo_a n	4 (1,2)	4 (1,2)
GASTROINTESTINAL DISORDERS	All	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	CHOP	chemo_a n	0 (0,0)	1 (0,5)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	CVP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	CHOP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	COLITIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	CONSTIPATION	CHOP	chemo_a n	0 (0,0)	1 (0,5)
GASTROINTESTINAL DISORDERS	CONSTIPATION	CVP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	CONSTIPATION	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	CONSTIPATION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	CVP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	Bendamust	chemo_a n	2 (0,6)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	CVP	chemo_a n	0 (0,0)	0 (0,0)

GASTROINTESTINAL DISORDERS	DYSPHAGIA	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	CHOP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	CVP	chemo_a n	1 (1,7)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	CVP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Bendamust	chemo_a n	1 (0,3)	1 (0,3)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	NAUSEA	CHOP	chemo_a n	0 (0,0)	1 (0,5)
GASTROINTESTINAL DISORDERS	NAUSEA	CVP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	NAUSEA	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	NAUSEA	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	CVP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	VOMITING	CHOP	chemo_a n	0 (0,0)	1 (0,5)
GASTROINTESTINAL DISORDERS	VOMITING	CVP	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	VOMITING	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	VOMITING	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	CHOP	chemo_a n	0 (0,0)	1 (0,5)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	Bendamust	chemo_a n	0 (0,0)	3 (0,9)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	CHOP	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	CVP	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	No Chemo	chemo_a n	1 (33,3)	0 (0,0)

GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	CHOP	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	CVP	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	CHOP	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	CVP	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	CHOP	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	CVP	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	CHOP	chemo_a n	0 (0,0)	1 (0,5)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
HEPATOBILIARY DISORDERS	All	CHOP	chemo_a n	1 (0,5)	0 (0,0)
HEPATOBILIARY DISORDERS	All	CVP	chemo_a n	0 (0,0)	1 (1,8)
HEPATOBILIARY DISORDERS	All	Bendamust	chemo_a n	2 (0,6)	2 (0,6)
HEPATOBILIARY DISORDERS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	CHOP	chemo_a n	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	CVP	chemo_a n	0 (0,0)	1 (1,8)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	CHOP	chemo_a n	1 (0,5)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	CVP	chemo_a n	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	CHOP	chemo_a n	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	CVP	chemo_a n	0 (0,0)	0 (0,0)

HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Bendamust	chemo_a n	0 (0,0)	2 (0,6)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	CHOP	chemo_a n	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	CVP	chemo_a n	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	CHOP	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	Bendamust	chemo_a n	1 (0,3)	1 (0,3)
IMMUNE SYSTEM DISORDERS	All	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	CVP	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	CHOP	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	CVP	chemo_a n	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	CVP	chemo_a n	0 (0,0)	1 (1,8)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	No Chemo	chemo_a n	3 (100,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	CVP	chemo_a n	0 (0,0)	1 (1,8)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	No Chemo	chemo_a n	0 (0,0)	0 (0,0)

INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	CVP	chemo_a n	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	No Chemo	chemo_a n	3 (100,0)	0 (0,0)
INVESTIGATIONS	All	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	All	CVP	chemo_a n	0 (0,0)	1 (1,8)
INVESTIGATIONS	All	Bendamust	chemo_a n	3 (0,9)	2 (0,6)
INVESTIGATIONS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	CVP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Bendamust	chemo_a n	2 (0,6)	1 (0,3)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	CVP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	CVP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	CVP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	CVP	chemo_a n	0 (0,0)	1 (1,8)
INVESTIGATIONS	TRANSAMINASES INCREASED	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	WEIGHT DECREASED	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INVESTIGATIONS	WEIGHT DECREASED	CVP	chemo_a n	0 (0,0)	0 (0,0)

INVESTIGATIONS	WEIGHT DECREASED	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
INVESTIGATIONS	WEIGHT DECREASED	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	CHOP	chemo_a n	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	CHOP	chemo_a n	1 (0,5)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	CHOP	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	CVP	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	CHOP	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	CVP	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	CHOP	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	CVP	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	CHOP	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)

MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	CHOP	chemo_a n	1 (0,5)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	CVP	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	CHOP	chemo_a n	8 (4,1)	3 (1,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	Bendamust	chemo_a n	7 (2,1)	5 (1,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	CHOP	chemo_a n	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	CHOP	chemo_a n	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	CHOP	chemo_a n	2 (1,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	CHOP	chemo_a n	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	Bendamust	chemo_a n	1 (0,3)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	Bendamust	chemo_a n	1 (0,3)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	CHOP	chemo_a n	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	CHOP	chemo_a n	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	CHOP	chemo_a n	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	CHOP	chemo_a n	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	CHOP	chemo_a n	0 (0,0)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	CHOP	chemo_a n	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	CHOP	chemo_a n	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	CHOP	chemo_a n	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	CVP	chemo_a n	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	Bendamust	chemo_a n	1 (0,3)	1 (0,3)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	All	CHOP	chemo_a n	10 (5,2)	11 (5,4)
NERVOUS SYSTEM DISORDERS	All	CVP	chemo_a n	6 (10,0)	4 (7,1)
NERVOUS SYSTEM DISORDERS	All	Bendamust	chemo_a n	1 (0,3)	5 (1,5)
NERVOUS SYSTEM DISORDERS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	CVP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	CHOP	chemo_a n	1 (0,5)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	CVP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	Bendamust	chemo_a n	0 (0,0)	0 (0,0)

NERVOUS SYSTEM DISORDERS	DIZZINESS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	CVP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	CVP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HEADACHE	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HEADACHE	CVP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HEADACHE	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
NERVOUS SYSTEM DISORDERS	HEADACHE	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	CVP	chemo_a n	1 (1,7)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	CHOP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	CVP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	CHOP	chemo_a n	2 (1,0)	1 (0,5)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	CVP	chemo_a n	2 (3,3)	3 (5,4)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	CHOP	chemo_a n	2 (1,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	CVP	chemo_a n	1 (1,7)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	CHOP	chemo_a n	0 (0,0)	0 (0,0)

NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	CVP	chemo_a n	0 (0,0)	1 (1,8)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	CHOP	chemo_a n	3 (1,5)	8 (3,9)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	CVP	chemo_a n	3 (5,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	CHOP	chemo_a n	2 (1,0)	2 (1,0)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	CVP	chemo_a n	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	All	CHOP	chemo_a n	1 (0,5)	0 (0,0)
PSYCHIATRIC DISORDERS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	All	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	CHOP	chemo_a n	1 (0,5)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	CVP	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	CHOP	chemo_a n	1 (0,5)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	CVP	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	CHOP	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	CVP	chemo_a n	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	All	CHOP	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	All	Bendamust	chemo_a n	2 (0,6)	1 (0,3)

RENAL AND URINARY DISORDERS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	CHOP	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	CVP	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	CHOP	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	CVP	chemo_a n	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
RENAL AND URINARY DISORDERS	RENAL INFARCT	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	CHOP	chemo_a n	0 (0,0)	2 (1,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	CVP	chemo_a n	1 (1,7)	1 (1,8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	Bendamust	chemo_a n	3 (0,9)	4 (1,2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	No Chemo	chemo_a n	3 (100,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	CHOP	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	CVP	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	CHOP	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	CVP	chemo_a n	1 (1,7)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	Bendamust	chemo_a n	0 (0,0)	2 (0,6)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	CVP	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	CHOP	chemo_a n	0 (0,0)	0 (0,0)

RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	CHOP	chemo_a n	0 (0,0)	2 (1,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	CVP	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	CHOP	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	CVP	chemo_a n	0 (0,0)	1 (1,8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	Bendamust	chemo_a n	1 (0,3)	1 (0,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	CHOP	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	CVP	chemo_a n	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	CHOP	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	Bendamust	chemo_a n	1 (0,3)	1 (0,3)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	CVP	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	No Chemo	chemo_a n	1 (33,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	CHOP	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	CVP	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	CHOP	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	CVP	chemo_a n	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Bendamust	chemo_a n	0 (0,0)	1 (0,3)

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	All	CHOP	chemo_a n	0 (0,0)	2 (1,0)
VASCULAR DISORDERS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	All	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	EMBOLISM	CHOP	chemo_a n	0 (0,0)	1 (0,5)
VASCULAR DISORDERS	EMBOLISM	CVP	chemo_a n	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	EMBOLISM	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	EMBOLISM	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	CHOP	chemo_a n	0 (0,0)	1 (0,5)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	CVP	chemo_a n	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	All	CHOP	chemo_a n	6 (3,1)	6 (3,0)
INFECTIONS AND INFESTATIONS	All	CVP	chemo_a n	3 (5,0)	3 (5,4)
INFECTIONS AND INFESTATIONS	All	Bendamust	chemo_a n	19 (5,6)	14 (4,1)
INFECTIONS AND INFESTATIONS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	CHOP	chemo_a n	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	CHOP	chemo_a n	2 (1,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	CVP	chemo_a n	1 (1,7)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	CHOP	chemo_a n	0 (0,0)	0 (0,0)

INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	CHOP	chemo_a n	1 (0,5)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Bendamust	chemo_a n	0 (0,0)	2 (0,6)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	CVP	chemo_a n	1 (1,7)	1 (1,8)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Bendamust	chemo_a n	3 (0,9)	2 (0,6)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	CHOP	chemo_a n	0 (0,0)	3 (1,5)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	Bendamust	chemo_a n	1 (0,3)	1 (0,3)

INFECTIONS AND INFESTATIONS	LUNG INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	CHOP	chemo_a n	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	CHOP	chemo_a n	3 (1,5)	1 (0,5)
INFECTIONS AND INFESTATIONS	PNEUMONIA	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Bendamust	chemo_a n	7 (2,1)	2 (0,6)
INFECTIONS AND INFESTATIONS	PNEUMONIA	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	CHOP	chemo_a n	1 (0,5)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	CVP	chemo_a n	0 (0,0)	1 (1,8)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	Bendamust	chemo_a n	2 (0,6)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	SINUSITIS	CHOP	chemo_a n	0 (0,0)	0 (0,0)

INFECTIONS AND INFESTATIONS	SINUSITIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	SINUSITIS	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	SINUSITIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	CVP	chemo_a n	1 (1,7)	1 (1,8)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Bendamust	chemo_a n	2 (0,6)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	Bendamust	chemo_a n	0 (0,0)	1 (0,3)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	CHOP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	CVP	chemo_a n	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	Bendamust	chemo_a n	1 (0,3)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	CHOP	chemo_a n	0 (0,0)	1 (0,5)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	CVP	chemo_a n	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	Bendamust	chemo_a n	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	CHOP	chemo_a n	0 (0,0)	1 (0,5)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	CVP	chemo_a n	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	Bendamust	chemo_a n	0 (0,0)	0 (0,0)

CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	No Chemo	chemo_a n	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	Low (0-1)	flip1g	1 (0,8)	3 (2,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	Intermedia	flip1g	6 (2,7)	6 (2,7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	All	High (>=3)	flip1g	10 (4,1)	5 (2,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Intermedia	flip1g	0 (0,0)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	High (>=3)	flip1g	2 (0,8)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Intermedia	flip1g	0 (0,0)	1 (0,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Low (0-1)	flip1g	0 (0,0)	3 (2,5)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Intermedia	flip1g	6 (2,7)	5 (2,3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	High (>=3)	flip1g	7 (2,8)	4 (1,6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Intermedia	flip1g	0 (0,0)	0 (0,0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	High (>=3)	flip1g	2 (0,8)	1 (0,4)
CARDIAC DISORDERS	All	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
CARDIAC DISORDERS	All	Intermedia	flip1g	1 (0,5)	0 (0,0)
CARDIAC DISORDERS	All	High (>=3)	flip1g	0 (0,0)	1 (0,4)
CARDIAC DISORDERS	CARDIAC FAILURE	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIAC FAILURE	Intermedia	flip1g	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIAC FAILURE	High (>=3)	flip1g	0 (0,0)	1 (0,4)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	Intermedia	flip1g	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	CARDIOGENIC SHOCK	High (>=3)	flip1g	0 (0,0)	1 (0,4)
CARDIAC DISORDERS	TACHYCARDIA	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	Intermedia	flip1g	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	TACHYCARDIA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	Intermedia	flip1g	1 (0,5)	0 (0,0)
CARDIAC DISORDERS	VENTRICULAR DYSFUNCTION	High (>=3)	flip1g	0 (0,0)	0 (0,0)

EYE DISORDERS	All	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
EYE DISORDERS	All	Intermedia	flip1g	0 (0,0)	0 (0,0)
EYE DISORDERS	All	High (>=3)	flip1g	2 (0,8)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	Intermedia	flip1g	0 (0,0)	0 (0,0)
EYE DISORDERS	OPTIC ISCHAEMIC NEUROPATHY	High (>=3)	flip1g	1 (0,4)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	Intermedia	flip1g	0 (0,0)	0 (0,0)
EYE DISORDERS	VISUAL IMPAIRMENT	High (>=3)	flip1g	1 (0,4)	0 (0,0)
GASTROINTESTINAL DISORDERS	All	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
GASTROINTESTINAL DISORDERS	All	Intermedia	flip1g	4 (1,8)	3 (1,4)
GASTROINTESTINAL DISORDERS	All	High (>=3)	flip1g	1 (0,4)	4 (1,6)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Intermedia	flip1g	0 (0,0)	1 (0,5)
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	High (>=3)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	Intermedia	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	COLITIS	High (>=3)	flip1g	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	CONSTIPATION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	CONSTIPATION	Intermedia	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	CONSTIPATION	High (>=3)	flip1g	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	DIARRHOEA	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	Intermedia	flip1g	2 (0,9)	0 (0,0)
GASTROINTESTINAL DISORDERS	DIARRHOEA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Intermedia	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	DYSPHAGIA	High (>=3)	flip1g	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	ILEUS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	Intermedia	flip1g	1 (0,5)	0 (0,0)
GASTROINTESTINAL DISORDERS	ILEUS	High (>=3)	flip1g	0 (0,0)	0 (0,0)

GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Intermedia	flip1g	0 (0,0)	1 (0,5)
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	High (>=3)	flip1g	1 (0,4)	0 (0,0)
GASTROINTESTINAL DISORDERS	NAUSEA	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
GASTROINTESTINAL DISORDERS	NAUSEA	Intermedia	flip1g	1 (0,5)	1 (0,5)
GASTROINTESTINAL DISORDERS	NAUSEA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	Intermedia	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	TONGUE ULCERATION	High (>=3)	flip1g	0 (0,0)	1 (0,4)
GASTROINTESTINAL DISORDERS	VOMITING	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GASTROINTESTINAL DISORDERS	VOMITING	Intermedia	flip1g	0 (0,0)	1 (0,5)
GASTROINTESTINAL DISORDERS	VOMITING	High (>=3)	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	Intermedia	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	All	High (>=3)	flip1g	0 (0,0)	4 (1,6)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	Intermedia	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	CHILLS	High (>=3)	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	Intermedia	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	DEATH	High (>=3)	flip1g	0 (0,0)	1 (0,4)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	Intermedia	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	FATIGUE	High (>=3)	flip1g	0 (0,0)	1 (0,4)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Intermedia	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	MULTIPLE ORGAN DYSFUNCTION SYNDROME	High (>=3)	flip1g	0 (0,0)	1 (0,4)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	Intermedia	flip1g	0 (0,0)	0 (0,0)
GENERAL DISORDERS AND ADMINISTRATION SITE	PYREXIA	High (>=3)	flip1g	0 (0,0)	1 (0,4)

HEPATOBILIARY DISORDERS	All	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
HEPATOBILIARY DISORDERS	All	Intermedia	flip1g	1 (0,5)	1 (0,5)
HEPATOBILIARY DISORDERS	All	High (>=3)	flip1g	1 (0,4)	2 (0,8)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	Intermedia	flip1g	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	CHOLELITHIASIS	High (>=3)	flip1g	0 (0,0)	1 (0,4)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	Intermedia	flip1g	1 (0,5)	0 (0,0)
HEPATOBILIARY DISORDERS	DRUG-INDUCED LIVER INJURY	High (>=3)	flip1g	1 (0,4)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Intermedia	flip1g	0 (0,0)	1 (0,5)
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	High (>=3)	flip1g	0 (0,0)	1 (0,4)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	Intermedia	flip1g	0 (0,0)	0 (0,0)
HEPATOBILIARY DISORDERS	HEPATITIS ACUTE	High (>=3)	flip1g	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
IMMUNE SYSTEM DISORDERS	All	Intermedia	flip1g	1 (0,5)	1 (0,5)
IMMUNE SYSTEM DISORDERS	All	High (>=3)	flip1g	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Intermedia	flip1g	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	High (>=3)	flip1g	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Intermedia	flip1g	1 (0,5)	0 (0,0)
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	Intermedia	flip1g	0 (0,0)	1 (0,5)
IMMUNE SYSTEM DISORDERS	IMMUNODEFICIENCY	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	Low (0-1)	flip1g	2 (1,6)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	Intermedia	flip1g	2 (0,9)	1 (0,5)
INJURY, POISONING AND PROCEDURAL COMPLICA	All	High (>=3)	flip1g	0 (0,0)	0 (0,0)

INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	Intermedia	flip1g	0 (0,0)	1 (0,5)
INJURY, POISONING AND PROCEDURAL COMPLICA	ANKLE FRACTURE	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	Low (0-1)	flip1g	2 (1,6)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	Intermedia	flip1g	2 (0,9)	0 (0,0)
INJURY, POISONING AND PROCEDURAL COMPLICA	INFUSION RELATED REACTION	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	All	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	All	Intermedia	flip1g	0 (0,0)	1 (0,5)
INVESTIGATIONS	All	High (>=3)	flip1g	3 (1,2)	2 (0,8)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Intermedia	flip1g	0 (0,0)	1 (0,5)
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	High (>=3)	flip1g	2 (0,8)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Intermedia	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	High (>=3)	flip1g	1 (0,4)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	Intermedia	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	RESPIROVIRUS TEST POSITIVE	High (>=3)	flip1g	1 (0,4)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	Intermedia	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	STREPTOCOCCUS TEST POSITIVE	High (>=3)	flip1g	1 (0,4)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	Intermedia	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	TRANSAMINASES INCREASED	High (>=3)	flip1g	0 (0,0)	1 (0,4)
INVESTIGATIONS	WEIGHT DECREASED	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	WEIGHT DECREASED	Intermedia	flip1g	0 (0,0)	0 (0,0)
INVESTIGATIONS	WEIGHT DECREASED	High (>=3)	flip1g	0 (0,0)	1 (0,4)
METABOLISM AND NUTRITION DISORDERS	All	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	Intermedia	flip1g	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	All	High (>=3)	flip1g	1 (0,4)	0 (0,0)

METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Intermedia	flip1g	0 (0,0)	0 (0,0)
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	High (>=3)	flip1g	1 (0,4)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	Intermedia	flip1g	1 (0,5)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	All	High (>=3)	flip1g	1 (0,4)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	Intermedia	flip1g	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	FLANK PAIN	High (>=3)	flip1g	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	Intermedia	flip1g	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MUSCLE SPASMS	High (>=3)	flip1g	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	Intermedia	flip1g	1 (0,5)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOPATHY	High (>=3)	flip1g	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	Intermedia	flip1g	1 (0,5)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	MYOSITIS	High (>=3)	flip1g	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	Intermedia	flip1g	0 (0,0)	0 (0,0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DIS	PAIN IN EXTREMITY	High (>=3)	flip1g	1 (0,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	Low (0-1)	flip1g	2 (1,6)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	Intermedia	flip1g	6 (2,7)	4 (1,8)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	All	High (>=3)	flip1g	7 (2,8)	4 (1,6)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	Intermedia	flip1g	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE LYMPHOCYTIC LEUKAEMIA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	Intermedia	flip1g	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	ACUTE MYELOID LEUKAEMIA	High (>=3)	flip1g	1 (0,4)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	Intermedia	flip1g	2 (0,9)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	BREAST CANCER	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	Intermedia	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLON CANCER	High (>=3)	flip1g	1 (0,4)	2 (0,8)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	Intermedia	flip1g	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	COLORECTAL CANCER	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	Intermedia	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HEPATIC CANCER	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	Intermedia	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	HODGKIN'S DISEASE NODULAR SCLEROSIS	High (>=3)	flip1g	1 (0,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	Intermedia	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INTRAOCULAR MELANOMA	High (>=3)	flip1g	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	Intermedia	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	INVASIVE DUCTAL BREAST CARCINOMA	High (>=3)	flip1g	1 (0,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	Intermedia	flip1g	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MALIGNANT MELANOMA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	Intermedia	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	MENINGIOMA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	Intermedia	flip1g	0 (0,0)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	NEUROENDOCRINE CARCINOMA OF THE SKIN	High (>=3)	flip1g	0 (0,0)	0 (0,0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	Intermedia	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	OESTROGEN RECEPTOR POSITIVE BREAST CANC	High (>=3)	flip1g	1 (0,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	Intermedia	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PAPILLARY THYROID CANCER	High (>=3)	flip1g	1 (0,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	Intermedia	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	PROSTATE CANCER	High (>=3)	flip1g	1 (0,4)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	Intermedia	flip1g	1 (0,5)	1 (0,5)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RECTAL ADENOCARCINOMA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	Intermedia	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	RENAL CELL CARCINOMA	High (>=3)	flip1g	0 (0,0)	1 (0,4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	Intermedia	flip1g	1 (0,5)	0 (0,0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIF	SQUAMOUS CELL CARCINOMA	High (>=3)	flip1g	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	All	Low (0-1)	flip1g	4 (3,1)	1 (0,8)
NERVOUS SYSTEM DISORDERS	All	Intermedia	flip1g	4 (1,8)	9 (4,1)
NERVOUS SYSTEM DISORDERS	All	High (>=3)	flip1g	9 (3,7)	10 (3,9)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	Intermedia	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	BRACHIAL PLEXOPATHY	High (>=3)	flip1g	0 (0,0)	1 (0,4)
NERVOUS SYSTEM DISORDERS	DIZZINESS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	Intermedia	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	DIZZINESS	High (>=3)	flip1g	1 (0,4)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	Intermedia	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	ENCEPHALOPATHY	High (>=3)	flip1g	0 (0,0)	1 (0,4)

NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Intermedia	flip1g	0 (0,0)	1 (0,5)
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HEADACHE	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HEADACHE	Intermedia	flip1g	0 (0,0)	1 (0,5)
NERVOUS SYSTEM DISORDERS	HEADACHE	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Intermedia	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	Intermedia	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	LETHARGY	High (>=3)	flip1g	1 (0,4)	0 (0,0)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Intermedia	flip1g	3 (1,4)	1 (0,5)
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	High (>=3)	flip1g	1 (0,4)	3 (1,2)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Low (0-1)	flip1g	2 (1,6)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Intermedia	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	High (>=3)	flip1g	1 (0,4)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	Intermedia	flip1g	0 (0,0)	1 (0,5)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORIMOTOR NEUROPATHY	High (>=3)	flip1g	0 (0,0)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Intermedia	flip1g	0 (0,0)	4 (1,8)
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	High (>=3)	flip1g	5 (2,0)	4 (1,6)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	Low (0-1)	flip1g	1 (0,8)	1 (0,8)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	Intermedia	flip1g	1 (0,5)	1 (0,5)
NERVOUS SYSTEM DISORDERS	POLYNEUROPATHY	High (>=3)	flip1g	0 (0,0)	1 (0,4)
PSYCHIATRIC DISORDERS	All	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	All	Intermedia	flip1g	1 (0,5)	0 (0,0)
PSYCHIATRIC DISORDERS	All	High (>=3)	flip1g	1 (0,4)	0 (0,0)

PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Intermedia	flip1g	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	High (>=3)	flip1g	1 (0,4)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	Intermedia	flip1g	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	ORGANIC BRAIN SYNDROME	High (>=3)	flip1g	1 (0,4)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	Intermedia	flip1g	1 (0,5)	0 (0,0)
PSYCHIATRIC DISORDERS	PSYCHOTIC DISORDER	High (>=3)	flip1g	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	All	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	All	Intermedia	flip1g	1 (0,5)	0 (0,0)
RENAL AND URINARY DISORDERS	All	High (>=3)	flip1g	1 (0,4)	1 (0,4)
RENAL AND URINARY DISORDERS	POLLAKIURIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	Intermedia	flip1g	1 (0,5)	0 (0,0)
RENAL AND URINARY DISORDERS	POLLAKIURIA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	Intermedia	flip1g	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL FAILURE	High (>=3)	flip1g	1 (0,4)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	Intermedia	flip1g	0 (0,0)	0 (0,0)
RENAL AND URINARY DISORDERS	RENAL INFARCT	High (>=3)	flip1g	0 (0,0)	1 (0,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	Low (0-1)	flip1g	1 (0,8)	3 (2,5)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	Intermedia	flip1g	3 (1,4)	2 (0,9)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	All	High (>=3)	flip1g	3 (1,2)	2 (0,8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	Intermedia	flip1g	1 (0,5)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	BRONCHOSPASM	High (>=3)	flip1g	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	Low (0-1)	flip1g	0 (0,0)	1 (0,8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	Intermedia	flip1g	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	COUGH	High (>=3)	flip1g	1 (0,4)	1 (0,4)

RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	Intermedia	flip1g	1 (0,5)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	DYSPNOEA	High (>=3)	flip1g	1 (0,4)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	Intermedia	flip1g	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	HYPOXIA	High (>=3)	flip1g	1 (0,4)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	Low (0-1)	flip1g	0 (0,0)	1 (0,8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	Intermedia	flip1g	0 (0,0)	1 (0,5)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	INTERSTITIAL LUNG DISEASE	High (>=3)	flip1g	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	Intermedia	flip1g	1 (0,5)	1 (0,5)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PNEUMONITIS	High (>=3)	flip1g	0 (0,0)	1 (0,4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	Low (0-1)	flip1g	0 (0,0)	1 (0,8)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	Intermedia	flip1g	0 (0,0)	0 (0,0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISO	PRODUCTIVE COUGH	High (>=3)	flip1g	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	Intermedia	flip1g	1 (0,5)	1 (0,5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	All	High (>=3)	flip1g	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	Intermedia	flip1g	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	Intermedia	flip1g	1 (0,5)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ERYTHEMA NODOSUM	High (>=3)	flip1g	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Intermedia	flip1g	0 (0,0)	1 (0,5)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	High (>=3)	flip1g	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	All	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	All	Intermedia	flip1g	0 (0,0)	1 (0,5)
VASCULAR DISORDERS	All	High (>=3)	flip1g	0 (0,0)	1 (0,4)

VASCULAR DISORDERS	EMBOLISM	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	EMBOLISM	Intermedia	flip1g	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	EMBOLISM	High (>=3)	flip1g	0 (0,0)	1 (0,4)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	Intermedia	flip1g	0 (0,0)	1 (0,5)
VASCULAR DISORDERS	PERIPHERAL ARTERY ANEURYSM	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	All	Low (0-1)	flip1g	1 (0,8)	7 (5,8)
INFECTIONS AND INFESTATIONS	All	Intermedia	flip1g	9 (4,1)	6 (2,7)
INFECTIONS AND INFESTATIONS	All	High (>=3)	flip1g	18 (7,3)	10 (3,9)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ATYPICAL PNEUMONIA	High (>=3)	flip1g	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	BRONCHITIS	High (>=3)	flip1g	3 (1,2)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	Intermedia	flip1g	1 (0,5)	0 (0,0)
INFECTIONS AND INFESTATIONS	CAMPYLOBACTER INFECTION	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	Low (0-1)	flip1g	1 (0,8)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	CHRONIC SINUSITIS	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	Intermedia	flip1g	1 (0,5)	0 (0,0)
INFECTIONS AND INFESTATIONS	ENDOPHTHALMITIS	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	Low (0-1)	flip1g	0 (0,0)	1 (0,8)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	FUNGAL SKIN INFECTION	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HAEMOPHILUS INFECTION	High (>=3)	flip1g	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	HEPATITIS B	Low (0-1)	flip1g	0 (0,0)	0 (0,0)

INFECTIONS AND INFESTATIONS	HEPATITIS B	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HEPATITIS B	High (>=3)	flip1g	1 (0,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Low (0-1)	flip1g	0 (0,0)	1 (0,8)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	High (>=3)	flip1g	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Low (0-1)	flip1g	0 (0,0)	1 (0,8)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Intermedia	flip1g	1 (0,5)	2 (0,9)
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	High (>=3)	flip1g	3 (1,2)	0 (0,0)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	Low (0-1)	flip1g	0 (0,0)	1 (0,8)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	Intermedia	flip1g	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	LUNG INFECTION	High (>=3)	flip1g	1 (0,4)	2 (0,8)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	Low (0-1)	flip1g	0 (0,0)	1 (0,8)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUROBORRELIOSIS	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	NEUTROPENIC INFECTION	High (>=3)	flip1g	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	Intermedia	flip1g	0 (0,0)	1 (0,5)
INFECTIONS AND INFESTATIONS	OTITIS MEDIA	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	Low (0-1)	flip1g	0 (0,0)	1 (0,8)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PARVOVIRUS INFECTION	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PNEUMONIA	Intermedia	flip1g	1 (0,5)	1 (0,5)
INFECTIONS AND INFESTATIONS	PNEUMONIA	High (>=3)	flip1g	9 (3,7)	2 (0,8)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	PULMONARY MYCOSIS	High (>=3)	flip1g	1 (0,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)

INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	Intermedia	flip1g	2 (0,9)	0 (0,0)
INFECTIONS AND INFESTATIONS	RESPIRATORY TRACT INFECTION	High (>=3)	flip1g	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	SINUSITIS	Low (0-1)	flip1g	0 (0,0)	1 (0,8)
INFECTIONS AND INFESTATIONS	SINUSITIS	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	SINUSITIS	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Intermedia	flip1g	1 (0,5)	0 (0,0)
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	TUBERCULOSIS	High (>=3)	flip1g	1 (0,4)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Intermedia	flip1g	3 (1,4)	1 (0,5)
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	High (>=3)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL INFECTION	High (>=3)	flip1g	0 (0,0)	1 (0,4)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	Intermedia	flip1g	0 (0,0)	0 (0,0)
INFECTIONS AND INFESTATIONS	VIRAL MYOSITIS	High (>=3)	flip1g	1 (0,4)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	Intermedia	flip1g	0 (0,0)	1 (0,5)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	All	High (>=3)	flip1g	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	Low (0-1)	flip1g	0 (0,0)	0 (0,0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	Intermedia	flip1g	0 (0,0)	1 (0,5)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	HEREDITARY MOTOR AND SENSORY NEUROPAT	High (>=3)	flip1g	0 (0,0)	0 (0,0)