Anhang 4-G: Ergänzende Unterlagen

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Anhang 4-G1: EORTC QLQ-C30 – Mittelwert über die Zeit

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Table 2.2.1 OLYMPIA: Summary of EORTC QLQ-C30 results across timepoints, by treatment group
Full Analysis Set, DCO 12JUL2021

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
EORTC QLQ-C30 Global QoL/health status	Olaparib (N=921)	Baseline [a]	877	70.3	19.22	0	66.7	100
		6 months	710	70.1	19.69	17	75.0	100
		12 months	665	71.3	19.19	0	75.0	100
		18 months	573	73.9	18.53	17	75.0	100
		24 months	531	74.3	19.22	17	83.3	100
	Placebo (N=915)	Baseline [a]	881	70.0	19.42	0	75.0	100
		6 months	751	71.6	19.98	0	75.0	100
		12 months	685	73.2	19.81	8	75.0	100
		18 months	558	75.2	18.62	0	83.3	100
		24 months	502	75.5	19.68	8	83.3	100
EORTC QLQ-C30 Functional scale: Physical	Olaparib (N=921)	Baseline [a]	881	86.2	14.63	20	86.7	100
		6 months	715	86.0	14.64	20	86.7	100
		12 months	668	86.1	14.40	20	86.7	100
		18 months	574	88.8	13.07	33	93.3	100
		24 months	534	88.6	14.10	27	93.3	100
	Placebo (N=915)	Baseline [a]	883	85.8	15.17	20	86.7	100
		6 months	752	87.4	14.31	20	93.3	100
		12 months	690	87.8	14.07	20	93.3	100
		18 months	562	88.6	13.86	7	93.3	100
		24 months	503	89.5	12.63	27	93.3	100
EORTC QLQ-C30 Functional scale: Role	Olaparib (N=921)	Baseline [a]	881	79.9	24.43	0	83.3	100
		6 months	714	81.7	23.64	0	100.0	100
		12 months	667	81.9	23.36	0	100.0	100
		18 months	574	85.4	21.34	0	100.0	100
		24 months	534	85.8	21.35	0	100.0	100

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Table 2.2.1 OLYMPIA: Summary of EORTC QLQ-C30 results across timepoints, by treatment group
Full Analysis Set, DCO 12JUL2021

Parameter	Group	Time Point	n	Result Mean	SD	Min	Median	Max
EORTC QLQ-C30 Functional scale: Role	Placebo (N=915)	Baseline [a]	883	80.7	24.68	0	100.0	100
		6 months	752	82.4	23.00	0	100.0	100
		12 months	690	84.1	22.42	0	100.0	100
		18 months	562	86.4	20.60	0	100.0	100
		24 months	503	86.7	20.48	0	100.0	100
EORTC QLQ-C30 Functional scale: Cognitive	Olaparib (N=921)	Baseline [a]	878	81.3	20.97	0	83.3	100
		6 months	711	80.6	21.43	0	83.3	100
		12 months	666	79.7	22.23	0	83.3	100
		18 months	572	80.1	21.48	0	83.3	100
		24 months	531	81.7	20.27	0	83.3	100
	Placebo (N=915)	Baseline [a]	881	82.1	20.96	0	83.3	100
		6 months	751	80.4	21.87	0	83.3	100
		12 months	688	79.4	23.22	0	83.3	100
		18 months	559	82.3	21.55	0	83.3	100
		24 months	503	83.2	20.72	0	83.3	100
EORTC QLQ-C30 Functional scale: Emotional	Olaparib (N=921)	Baseline [a]	878	76.4	22.59	0	83.3	100
		6 months	711	77.5	21.95	0	83.3	100
		12 months	666	77.3	21.65	0	83.3	100
		18 months	572	78.4	21.57	0	83.3	100
		24 months	531	79.6	21.14	0	83.3	100
	Placebo (N=915)	Baseline [a]	881	77.0	21.56	0	83.3	100
		6 months	750	77.0	21.56	0	83.3	100
		12 months	688	77.1	22.31	0	83.3	100

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Table 2.2.1 OLYMPIA: Summary of EORTC QLQ-C30 results across timepoints, by treatment group
Full Analysis Set, DCO 12JUL2021

Parameter	Group	Time Point	n	Result Mean	SD	Min	Median	Max
		18 months	559	80.1	20.33	0	83.3	100
		24 months	503	79.9	21.55	0	83.3	100
EORTC QLQ-C30 Functional scale: Social	Olaparib (N=921)	Baseline [a]	878	78.5	25.25	0	83.3	100
		6 months	711	82.7	22.50	0	100.0	100
		12 months	665	83.6	22.62	0	100.0	100
		18 months	573	86.4	22.11	0	100.0	100
		24 months	531	86.7	21.33	0	100.0	100
	Placebo (N=915)	Baseline [a]	882	79.0	24.34	0	83.3	100
		6 months	750	84.1	22.13	0	100.0	100
		12 months	687	84.7	22.32	0	100.0	100
		18 months	559	86.6	21.16	0	100.0	100
		24 months	503	87.1	20.89	0	100.0	100
EORTC QLQ-C30 Single item symptom scale: Loss of appetite	Olaparib (N=921)	Baseline [a]	880	8.7	18.61	0	0.0	100
		6 months	714	14.1	22.42	0	0.0	100
		12 months	668	13.2	21.74	0	0.0	100
		18 months	573	6.2	16.43	0	0.0	100
		24 months	533	5.4	14.65	0	0.0	100
	Placebo (N=915)	Baseline [a]	882	8.2	18.51	0	0.0	100
		6 months	750	7.5	18.02	0	0.0	100
		12 months	687	7.8	17.58	0	0.0	100
		18 months	561	7.0	17.20	0	0.0	100
		24 months	503	6.4	16.28	0	0.0	100
EORTC QLQ-C30 Single item symptom scale: Constipation	Olaparib (N=921)	Baseline [a]	877	9.7	19.66	0	0.0	100

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Table 2.2.1 OLYMPIA: Summary of EORTC QLQ-C30 results across timepoints, by treatment group
Full Analysis Set, DCO 12JUL2021

Parameter	Group	Time Point	n	Result Mean	SD	Min	Median	Max
		6 months	712	12.2	22.06	0	0.0	100
		12 months	666	14.0	22.77	0	0.0	100
		18 months	572	11.4	20.73	0	0.0	100
		24 months	531	11.9	20.88	0	0.0	100
EORTC QLQ-C30 Single item symptom scale: Constipation	Placebo (N=915)	Baseline [a]	881	9.8	20.57	0	0.0	100
		6 months	749	9.7	18.20	0	0.0	100
		12 months	689	10.5	19.81	0	0.0	100
		18 months	559	9.2	18.93	0	0.0	100
		24 months	502	11.4	20.78	0	0.0	100
EORTC QLQ-C30 Single item symptom scale: Diarrhoea	Olaparib (N=921)	Baseline [a]	878	5.8	15.23	0	0.0	100
		6 months	711	6.8	15.60	0	0.0	100
		12 months	666	8.4	16.93	0	0.0	100
		18 months	572	6.8	17.26	0	0.0	100
		24 months	530	5.7	15.02	0	0.0	100
	Placebo (N=915)	Baseline [a]	881	6.0	15.74	0	0.0	100
		6 months	750	7.6	17.90	0	0.0	100
		12 months	687	7.7	18.01	0	0.0	100
		18 months	559	6.1	15.16	0	0.0	100
		24 months	503	5.3	13.08	0	0.0	67
EORTC QLQ-C30 Single item symptom scale: Dyspnoea	Olaparib (N=921)	Baseline [a]	878	13.9	22.21	0	0.0	100
		6 months	714	14.2	21.86	0	0.0	100
		12 months	668	15.1	21.81	0	0.0	100
		18 months	573	12.3	20.73	0	0.0	100
		24 months	533	11.4	19.27	0	0.0	100

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Table 2.2.1 OLYMPIA: Summary of EORTC QLQ-C30 results across timepoints, by treatment group
Full Analysis Set, DCO 12JUL2021

Parameter	Group	Time Point	n	Result Mean	SD	Min	Median	Max
	Placebo (N=915)	Baseline [a]	879	12.7	21.14	0	0.0	100
		6 months	751	12.5	20.43	0	0.0	100
		12 months	689	12.0	19.72	0	0.0	100
		18 months	561	10.6	19.10	0	0.0	100
		24 months	502	9.9	17.67	0	0.0	100
EORTC QLQ-C30 Symptom scale: Fatigue	Olaparib (N=921)	Baseline [a]	881	29.8	22.84	0	33.3	100
		6 months	715	31.6	22.83	0	33.3	100
		12 months	668	31.5	23.28	0	33.3	100
		18 months	574	25.7	21.99	0	22.2	100
		24 months	534	25.2	21.65	0	22.2	100
	Placebo (N=915)	Baseline [a]	883	29.4	21.65	0	33.3	100
		6 months	752	28.8	22.72	0	22.2	100
		12 months	690	28.5	23.95	0	22.2	100
		18 months	561	24.3	21.45	0	22.2	100
		24 months	503	24.7	22.17	0	22.2	100
EORTC QLQ-C30 Single item symptom scale: Financial difficulties	Olaparib (N=921)	Baseline [a]	876	24.0	30.33	0	0.0	100
		6 months	708	17.9	26.48	0	0.0	100
		12 months	663	16.6	26.29	0	0.0	100
		18 months	571	15.5	26.78	0	0.0	100
		24 months	531	14.8	25.78	0	0.0	100
	Placebo (N=915)	Baseline [a]	881	24.0	30.57	0	0.0	100
		6 months	751	18.6	27.46	0	0.0	100

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Table 2.2.1 OLYMPIA: Summary of EORTC QLQ-C30 results across timepoints, by treatment group
Full Analysis Set, DCO 12JUL2021

Parameter	Group	Time Point	n	Result Mean	SD	Min	Median	Max
		12 months	685	15.6	25.38	0	0.0	100
		18 months	558	15.2	25.75	0	0.0	100
		24 months	500	14.0	23.68	0	0.0	100
EORTC QLQ-C30 Symptom scale: Nausea and vomiting	Olaparib (N=921)	Baseline [a]	881	3.2	9.07	0	0.0	67
		6 months	715	10.3	16.28	0	0.0	100
		12 months	668	9.3	15.17	0	0.0	100
		18 months	573	3.3	8.18	0	0.0	67
		24 months	533	3.7	11.25	0	0.0	100
EORTC QLQ-C30 Symptom scale: Nausea and vomiting	Placebo (N=915)	Baseline [a]	883	3.5	10.37	0	0.0	100
		6 months	751	4.8	11.25	0	0.0	100
		12 months	689	3.9	9.73	0	0.0	67
		18 months	562	3.9	11.68	0	0.0	100
		24 months	503	3.0	9.27	0	0.0	83
EORTC QLQ-C30 Symptom scale: Pain	Olaparib (N=921)	Baseline [a]	881	21.1	24.45	0	16.7	100
		6 months	715	19.7	23.56	0	16.7	100
		12 months	668	18.8	23.55	0	16.7	100
		18 months	574	16.3	21.02	0	16.7	100
		24 months	534	17.6	22.62	0	16.7	100
	Placebo (N=915)	Baseline [a]	884	21.0	23.75	0	16.7	100
		6 months	752	19.9	23.20	0	16.7	100
		12 months	690	19.6	23.29	0	16.7	100
		18 months	562	16.9	22.43	0	0.0	100
		24 months	503	15.7	21.30	0	0.0	100

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Table 2.2.1 OLYMPIA: Summary of EORTC QLQ-C30 results across timepoints, by treatment group
Full Analysis Set, DCO 12JUL2021

Parameter	Group	Time Point	n	Result Mean	SD	Min	Median	Max
EORTC QLQ-C30 Single item symptom scale: Insomnia	Olaparib (N=921)	Baseline [a]	880	28.2	28.67	0	33.3	100
		6 months	713	26.7	28.86	0	33.3	100
		12 months	667	28.7	29.32	0	33.3	100
		18 months	574	25.4	28.95	0	33.3	100
		24 months	532	25.4	28.88	0	33.3	100
	Placebo (N=915)	Baseline [a]	882	28.8	29.76	0	33.3	100
		6 months	752	27.2	29.48	0	33.3	100
		12 months	690	27.5	31.14	0	33.3	100
		18 months	561	25.8	28.65	0	33.3	100
		24 months	503	26.2	29.26	0	33.3	100

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Anhang 4-G2: FACIT-Fatigue – Mittelwert über die Zeit

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Table 2.2.2 OLYMPIA: Summary of FACIT-F Fatigue results across timepoints, by treatment group
Full Analysis Set, DCO 12JUL2021

			Result					
Parameter	Group	Time Point	n	Mean	SD	Min	Median	Max
FACIT-F Fatigue scale	Olaparib (N=921)	Baseline [a]	876	40.1	9.79	6	43.0	52
		6 months	708	39.4	10.10	6	43.0	52
		12 months	665	39.3	10.24	6	42.0	52
		18 months	574	41.8	9.22	7	44.0	52
		24 months	534	42.1	9.03	9	44.0	52
	Placebo (N=915)	Baseline [a]	882	40.1	9.22	4	42.0	52
		6 months	747	40.6	9.47	2	43.0	52
		12 months	683	40.8	9.60	2	44.0	52
		18 months	558	42.0	9.22	0	44.0	52
		24 months	500	42.3	9.18	11	45.0	52

[a] Baseline is defined as last evaluable assessment prior to dosing with olaparib or placebo.
SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
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Anhang 4-G3: Subgruppenanalysen: Gesamtüberleben

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Table 4.1.1 OLYMPIA: Summary of subgroup analysis of Overall survival (OS)
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)					
Subgroup	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	Hazard ratio [b]	95% CI [b]	2-sided p-value [b]
Hormone receptor status (eCRF)									
ER and/or PgR positive/HER2 negative	168	16 (9.5)	NE (NE, NE)	157	17 (10.8)	NE (NE, NE)	0.90	0.45, 1.78	0.7556
TNBC	751	59 (7.9)	NE (NE, NE)	758	92 (12.1)	NE (NE, NE)	0.64	0.46, 0.88	0.0067*
Interaction p-value									0.3817
Sequence Chemo/ surgery (eCRF)									
Adjuvant chemotherapy	461	22 (4.8)	NE (NE, NE)	455	28 (6.2)	NE (NE, NE)	0.78	0.44, 1.36	0.3888
Neoadjuvant	460	53 (11.5)	NE (NE, NE)	460	81 (17.6)	NE (NE, NE)	0.64	0.45, 0.90	0.0102*
Interaction p-value									0.5434
Platinum therapy for current breast cancer (eCRF)									
Yes	247	27 (10.9)	NE (NE, NE)	238	29 (12.2)	NE (NE, NE)	0.88	0.52, 1.49	0.6375
No	674	48 (7.1)	NE (NE, NE)	677	80 (11.8)	NE (NE, NE)	0.60	0.42, 0.85	0.0045*
Interaction p-value									0.2356
Age [years]									
<50	699	54 (7.7)	NE (NE, NE)	673	84 (12.5)	NE (NE, NE)	0.61	0.43, 0.86	0.0046*
50-64	193	18 (9.3)	NE (NE, NE)	210	24 (11.4)	NE (NE, NE)	0.80	0.43, 1.47	0.4792
>=65	29	3 (10.3)	NE (NE, NE)	32	1 (3.1)	NE (NE, NE)	3.66	0.47, 73.96	0.2232
Interaction p-value									0.2038
Menopausal status at screening									
Premenopausal	572	49 (8.6)	NE (NE, NE)	553	66 (11.9)	NE (NE, NE)	0.72	0.49, 1.04	0.0789
Postmenopausal	347	26 (7.5)	NE (NE, NE)	358	43 (12.0)	NE (NE, NE)	0.61	0.37, 0.99	0.0447*
Interaction p-value									0.6035
Type of prior Neo/Adjuvant chemotherapy									

Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.0.
NC = not calculable. NE = not estimable as median (or 95% CLs) not reached.
[a] Median time to event based on the K-M estimate.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgr. levels, >=10 events for 1 subgr. level, >0 events for all subgr. levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgr. with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only. *p-value <0.05. HR >1 favours olaparib.
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Table 4.1.1 OLYMPIA: Summary of subgroup analysis of Overall survival (OS)
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)					
Subgroup	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	Hazard ratio [b]	95% CI [b]	2-sided p-value [b]
Anthracycline	7	0	NE (NE, NE)	13	2 (15.4)	NE (NE, NE)	NC	NC	NC
Taxane	43	1 (2.3)	NE (NE, NE)	52	5 (9.6)	NE (NE, NE)	0.20	0.01, 1.27	0.0927
Anthracycline + Taxane	871	74 (8.5)	NE (NE, NE)	849	102 (12.0)	NE (NE, NE)	0.71	0.52, 0.95	0.0229*
Interaction p-value									0.2061
Type of breast surgery prior to randomisation									
Breast conservation	222	10 (4.5)	NE (NE, NE)	239	25 (10.5)	NE (NE, NE)	0.43	0.19, 0.86	0.0165*
Unilateral mastectomy	361	33 (9.1)	NE (NE, NE)	356	46 (12.9)	NE (NE, NE)	0.70	0.45, 1.09	0.1175
Bilateral mastectomy	338	32 (9.5)	NE (NE, NE)	318	37 (11.6)	NE (NE, NE)	0.81	0.50, 1.30	0.3877
Interaction p-value									0.3288
Bilateral Oophorectomy									
Yes	189	13 (6.9)	NE (NE, NE)	176	20 (11.4)	NE (NE, NE)	0.62	0.30, 1.23	0.1722
No	732	62 (8.5)	NE (NE, NE)	739	89 (12.0)	NE (NE, NE)	0.69	0.50, 0.96	0.0258*
Interaction p-value									0.7696
Axillary nodal status at surgery prior to rand. (post adjuvant only)									
Positive	174	10 (5.7)	NE (NE, NE)	177	16 (9.0)	NE (NE, NE)	0.60	0.26, 1.31	0.2032
Negative	203	6 (3.0)	NE (NE, NE)	192	7 (3.6)	NE (NE, NE)	0.89	0.29, 2.67	0.8285
Interaction p-value									0.5757
Hormone receptor status by prior chemotherapy setting									
ER and/or PgR positive with neoadjuvant chemotherapy	104	11 (10.6)	NE (NE, NE)	92	14 (15.2)	NE (NE, NE)	0.72	0.32, 1.58	0.4078
ER and/or PgR positive with adjuvant chemotherapy	64	5 (7.8)	NE (NE, NE)	65	3 (4.6)	NE (NE, NE)	1.69	0.42, 8.25	0.4642
ER and PgR negative with neoadjuvant chemotherapy	354	42 (11.9)	NE (NE, NE)	368	67 (18.2)	NE (NE, NE)	0.63	0.42, 0.92	0.0165*

Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.0.
NC = not calculable. NE = not estimable as median (or 95% CLs) not reached.
[a] Median time to event based on the K-M estimate.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgr. levels, >=10 events for 1 subgr. level, >0 events for all subgr. levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgr. with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only. *p-value <0.05. HR >1 favours olaparib.
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Table 4.1.1 OLYMPIA: Summary of subgroup analysis of Overall survival (OS)
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)					
Subgroup	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	Hazard ratio [b]	95% CI [b]	2-sided p-value [b]
ER and PgR negative with adjuvant chemotherapy	397	17 (4.3)	NE (NE, NE)	390	25 (6.4)	NE (NE, NE)	0.68	0.36, 1.24	0.2082
Interaction p-value									0.6130
Race									
White	626	56 (8.9)	NE (NE, NE)	599	79 (13.2)	NE (NE, NE)	0.66	0.47, 0.93	0.0161*
Black/African-American	19	3 (15.8)	NE (NE, NE)	29	4 (13.8)	NE (NE, NE)	1.30	0.26, 5.91	0.7312
Asian	259	14 (5.4)	NE (NE, NE)	272	23 (8.5)	NE (NE, NE)	0.66	0.33, 1.27	0.2153
Other	17	2 (11.8)	NE (NE, NE)	15	3 (20.0)	NE (NE, NE)	0.54	0.07, 3.26	0.4953
Interaction p-value									0.8524
Ethnicity									
Hispanic	34	5 (14.7)	NE (NE, NE)	24	6 (25.0)	NE (NE, NE)	0.54	0.16, 1.79	0.3085
Non-hispanic	805	59 (7.3)	NE (NE, NE)	812	91 (11.2)	NE (NE, NE)	0.66	0.47, 0.91	0.0105*
Not known, not recorded or refused	82	11 (13.4)	NE (NE, NE)	79	12 (15.2)	NE (NE, NE)	0.79	0.34, 1.81	0.5819
Interaction p-value									0.8576
Jewish descent									
Yes Ashkenazi	41	5 (12.2)	NE (NE, NE)	36	6 (16.7)	NE (NE, NE)	0.59	0.17, 1.97	0.3868
No	880	70 (8.0)	NE (NE, NE)	876	103 (11.8)	NE (NE, NE)	0.68	0.50, 0.92	0.0114*
Interaction p-value									0.8294
CPS+EG score at baseline (post neoadjuvant only)									
2, 3 or 4	398	39 (9.8)	NE (NE, NE)	387	68 (17.6)	NE (NE, NE)	0.54	0.36, 0.79	0.0017*
5 or 6	22	10 (45.5)	61.4 (15.8, NE)	15	10 (66.7)	28.1 (7.9,55.4)	0.47	0.19, 1.16	0.0999
Interaction p-value									0.7933
Geographic region									

Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.0.
NC = not calculable. NE = not estimable as median (or 95% CLs) not reached.
[a] Median time to event based on the K-M estimate.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgr. levels, >=10 events for 1 subgr. level, >0 events for all subgr. levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgr. with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only. *p-value <0.05. HR >1 favours olaparib.
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Table 4.1.1 OLYMPIA: Summary of subgroup analysis of Overall survival (OS)
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)					
Subgroup	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	Hazard ratio [b]	95% CI [b]	2-sided p-value [b]
North America	122	10 (8.2)	NE (NE, NE)	132	14 (10.6)	NE (NE, NE)	0.73	0.31, 1.63	0.4394
South America	16	2 (12.5)	NE (NE, NE)	12	5 (41.7)	NE (NE, NE)	0.28	0.04, 1.28	0.1013
Europe	481	46 (9.6)	NE (NE, NE)	452	60 (13.3)	NE (NE, NE)	0.71	0.48, 1.04	0.0822
Asia Pacific and South Africa	302	17 (5.6)	NE (NE, NE)	319	30 (9.4)	NE (NE, NE)	0.61	0.33, 1.09	0.0946
Interaction p-value									0.6863
Sponsor									
AZ	810	65 (8.0)	NE (NE, NE)	806	98 (12.2)	NE (NE, NE)	0.66	0.48, 0.90	0.0085*
NRG Oncology	111	10 (9.0)	NE (NE, NE)	109	11 (10.1)	NE (NE, NE)	0.85	0.35, 2.01	0.7050
Interaction p-value									0.5903
BRCA mutation type									
BRCA1	579	49 (8.5)	NE (NE, NE)	588	75 (12.8)	NE (NE, NE)	0.64	0.45, 0.92	0.0150*
BRCA2	235	16 (6.8)	NE (NE, NE)	216	28 (13.0)	NE (NE, NE)	0.52	0.28, 0.95	0.0335*
Interaction p-value									0.5601

Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.0.
NC = not calculable. NE = not estimable as median (or 95% CLs) not reached.
[a] Median time to event based on the K-M estimate.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgr. levels, >=10 events for 1 subgr. level, >0 events for all subgr. levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgr. with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only. *p-value <0.05. HR >1 favours olaparib.
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Anhang 4-G4: Subgruppenanalysen: Rezidive/krankheitsfreies Überleben

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Table 4.2.1 OLYMPIA: Summary of subgroup analysis of Disease-free survival (AMNOG) (DFS)
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)					
Subgroup	Number (%) of patients n with events	Median time (95% CI) (months) [a]		Number (%) of patients n with events	Median time (95% CI) (months) [a]		Hazard ratio [b]	95% CI [b]	2-sided p-value [b]
Hormone receptor status (eCRF)									
ER and/or PgR positive/HER2 negative	168	25 (14.9)	66.3 (NE, NE)	157	36 (22.9)	62.5 (62.5, NE)	0.64	0.38, 1.06	0.0806
TNBC	751	113 (15.0)	NE (NE, NE)	758	174 (23.0)	NE (NE, NE)	0.64	0.50, 0.81	0.0002*
Interaction p-value									0.9909
Sequence Chemo/ surgery (eCRF)									
Adjuvant chemotherapy	461	49 (10.6)	NE (NE, NE)	455	77 (16.9)	NE (NE, NE)	0.64	0.45, 0.91	0.0136*
Neoadjuvant	460	89 (19.3)	NE (NE, NE)	460	133 (28.9)	70.8 (70.8, NE)	0.62	0.47, 0.81	0.0005*
Interaction p-value									0.9001
Platinum therapy for current breast cancer (eCRF)									
Yes	247	44 (17.8)	NE (NE, NE)	238	52 (21.8)	NE (NE, NE)	0.81	0.54, 1.21	0.3130
No	674	94 (13.9)	NE (NE, NE)	677	158 (23.3)	NE (NE, NE)	0.58	0.45, 0.75	<0.0001*
Interaction p-value									0.1614
Age [years]									
<50	699	102 (14.6)	NE (NE, NE)	673	156 (23.2)	NE (NE, NE)	0.61	0.47, 0.78	<0.0001*
50-64	193	31 (16.1)	NE (NE, NE)	210	48 (22.9)	NE (NE, NE)	0.70	0.44, 1.09	0.1184
>=65	29	5 (17.2)	NE (NE, NE)	32	6 (18.8)	70.8 (70.8, NE)	1.07	0.31, 3.56	0.9094
Interaction p-value									0.5950
Menopausal status at screening									
Premenopausal	572	95 (16.6)	NE (NE, NE)	553	125 (22.6)	NE (NE, NE)	0.72	0.55, 0.93	0.0133*
Postmenopausal	347	43 (12.4)	NE (NE, NE)	358	85 (23.7)	NE (NE, NE)	0.51	0.35, 0.73	0.0002*
Interaction p-value									0.1472
Type of prior Neo/Adjuvant chemotherapy									

Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.0.
NC = not calculable. NE = not estimable as median (or 95% CLs) not reached.
[a] Median time to event based on the K-M estimate.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgr. levels, >=10 events for 1 subgr. level, >0 events for all subgr. levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgr. with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only. *p-value <0.05. HR >1 favours olaparib.
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Table 4.2.1 OLYMPIA: Summary of subgroup analysis of Disease-free survival (AMNOG) (DFS)
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)					
Subgroup	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	Hazard ratio [b]	95% CI [b]	2-sided p-value [b]
Anthracycline	7	1 (14.3)	68.0 (NE, NE)	13	2 (15.4)	NE (NE, NE)	0.92	0.04, 9.56	0.9423
Taxane	43	7 (16.3)	NE (NE, NE)	52	9 (17.3)	NE (NE, NE)	0.83	0.30, 2.23	0.7093
Anthracycline + Taxane	871	130 (14.9)	NE (NE, NE)	849	199 (23.4)	NE (NE, NE)	0.62	0.50, 0.78	<0.0001*
Interaction p-value									0.8256
Type of breast surgery prior to randomisation									
Breast conservation	222	30 (13.5)	NE (NE, NE)	239	55 (23.0)	NE (NE, NE)	0.58	0.37, 0.89	0.0135*
Unilateral mastectomy	361	64 (17.7)	NE (NE, NE)	356	85 (23.9)	NE (NE, NE)	0.75	0.54, 1.03	0.0767
Bilateral mastectomy	338	44 (13.0)	NE (NE, NE)	318	69 (21.7)	NE (NE, NE)	0.56	0.38, 0.82	0.0026*
Interaction p-value									0.4702
Bilateral Oophorectomy									
Yes	189	18 (9.5)	NE (NE, NE)	176	44 (25.0)	NE (NE, NE)	0.37	0.21, 0.63	0.0002*
No	732	120 (16.4)	NE (NE, NE)	739	166 (22.5)	NE (NE, NE)	0.71	0.56, 0.90	0.0043*
Interaction p-value									0.0293*
Axillary nodal status at surgery prior to rand. (post adjuvant only)									
Positive	174	20 (11.5)	NE (NE, NE)	177	38 (21.5)	NE (NE, NE)	0.51	0.29, 0.87	0.0125*
Negative	203	21 (10.3)	NE (NE, NE)	192	25 (13.0)	NE (NE, NE)	0.86	0.48, 1.54	0.6106
Interaction p-value									0.1968
Hormone receptor status by prior chemotherapy setting									
ER and/or PgR positive with neoadjuvant chemotherapy	104	19 (18.3)	66.3 (NE, NE)	92	26 (28.3)	NE (NE, NE)	0.60	0.33, 1.07	0.0837
ER and/or PgR positive with adjuvant chemotherapy	64	6 (9.4)	NE (NE, NE)	65	10 (15.4)	62.5 (53.7, NE)	0.65	0.22, 1.76	0.4046
ER and PgR negative with neoadjuvant chemotherapy	354	70 (19.8)	NE (NE, NE)	368	107 (29.1)	70.8 (70.8, NE)	0.64	0.47, 0.86	0.0029*

Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.0.
NC = not calculable. NE = not estimable as median (or 95% CLs) not reached.
[a] Median time to event based on the K-M estimate.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgr. levels, >=10 events for 1 subgr. level, >0 events for all subgr. levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgr. with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only. *p-value <0.05. HR >1 favours olaparib.
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Table 4.2.1 OLYMPIA: Summary of subgroup analysis of Disease-free survival (AMNOG) (DFS)
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)					
Subgroup	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	Hazard ratio [b]	95% CI [b]	2-sided p-value [b]
ER and PgR negative with adjuvant chemotherapy	397	43 (10.8)	NE (NE, NE)	390	67 (17.2)	NE (NE, NE)	0.64	0.43, 0.93	0.0200*
Interaction p-value									0.9973
Race									
White	626	96 (15.3)	NE (NE, NE)	599	144 (24.0)	NE (NE, NE)	0.61	0.47, 0.79	0.0002*
Black/African-American	19	5 (26.3)	NE (NE, NE)	29	5 (17.2)	NE (NE, NE)	1.65	0.46, 5.93	0.4313
Asian	259	35 (13.5)	NE (NE, NE)	272	57 (21.0)	NE (NE, NE)	0.65	0.42, 0.99	0.0432*
Other	17	2 (11.8)	NE (NE, NE)	15	4 (26.7)	NE (NE, NE)	0.36	0.05, 1.85	0.2219
Interaction p-value									0.4340
Ethnicity									
Hispanic	34	8 (23.5)	NE (NE, NE)	24	7 (29.2)	NE (NE, NE)	0.70	0.25, 1.99	0.4921
Non-hispanic	805	118 (14.7)	NE (NE, NE)	812	181 (22.3)	NE (NE, NE)	0.65	0.51, 0.82	0.0002*
Not known, not recorded or refused	82	12 (14.6)	NE (NE, NE)	79	22 (27.8)	NE (NE, NE)	0.46	0.22, 0.92	0.0286*
Interaction p-value									0.6582
Jewish descent									
Yes Ashkenazi	41	8 (19.5)	NE (NE, NE)	36	14 (38.9)	NE (NE, NE)	0.41	0.16, 0.95	0.0371*
No	880	130 (14.8)	NE (NE, NE)	876	196 (22.4)	NE (NE, NE)	0.65	0.52, 0.81	0.0001*
Interaction p-value									0.2974
CPS+EG score at baseline (post neoadjuvant only)									
2, 3 or 4	398	71 (17.8)	NE (NE, NE)	387	111 (28.7)	70.8 (70.8, NE)	0.57	0.42, 0.77	0.0002*
5 or 6	22	12 (54.5)	30.7 (10.4, NE)	15	10 (66.7)	14.9 (1.4,33.9)	0.46	0.20, 1.10	0.0807
Interaction p-value									0.6386
Geographic region									

Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.0.
NC = not calculable. NE = not estimable as median (or 95% CLs) not reached.
[a] Median time to event based on the K-M estimate.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgr. levels, >=10 events for 1 subgr. level, >0 events for all subgr. levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgr. with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only. *p-value <0.05. HR >1 favours olaparib.
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Table 4.2.1 OLYMPIA: Summary of subgroup analysis of Disease-free survival (AMNOG) (DFS)
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)		Placebo (N=915)				
Subgroup	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	n	Number (%) of patients with events	Median time (95% CI) (months) [a]	Hazard ratio [b]	95% CI [b]	2-sided p-value [b]
North America	122	17 (13.9)	NE (NE, NE)	132	25 (18.9)	NE (NE, NE)	0.68	0.36, 1.25	0.2190
South America	16	3 (18.8)	NE (NE, NE)	12	5 (41.7)	NE (NE, NE)	0.39	0.08, 1.60	0.1900
Europe	481	75 (15.6)	NE (NE, NE)	452	110 (24.3)	NE (NE, NE)	0.62	0.46, 0.83	0.0014*
Asia Pacific and South Africa	302	43 (14.2)	NE (NE, NE)	319	70 (21.9)	NE (NE, NE)	0.65	0.44, 0.94	0.0228*
Interaction p-value									0.9139
Sponsor									
AZ	810	121 (14.9)	NE (NE, NE)	806	190 (23.6)	NE (NE, NE)	0.62	0.49, 0.78	<0.0001*
NRG Oncology	111	17 (15.3)	NE (NE, NE)	109	20 (18.3)	NE (NE, NE)	0.78	0.40, 1.48	0.4443
Interaction p-value									0.5265
BRCA mutation type									
BRCA1	579	87 (15.0)	NE (NE, NE)	588	151 (25.7)	NE (NE, NE)	0.55	0.42, 0.71	<0.0001*
BRCA2	235	34 (14.5)	NE (NE, NE)	216	45 (20.8)	NE (NE, NE)	0.68	0.43, 1.05	0.0843
Interaction p-value									0.4334

Includes adverse events with an onset date on or after the date of first dose and up to and including 30 days following the date of last dose of olaparib/placebo. MedDRA version 24.0.
NC = not calculable. NE = not estimable as median (or 95% CLs) not reached.
[a] Median time to event based on the K-M estimate.
[b] HR, 95% profile likelihood CIs and likelihood-ratio test p-values estimated from Cox PH model. Efron method for handling ties. If >=10 patients for all subgr. levels, >=10 events for 1 subgr. level, >0 events for all subgr. levels/treatments, results from model including treatment, subgroup, treatment by subgroup interaction. For subgr. with >2 levels, levels with insufficient data were dropped and, if appropriate, interaction model re-fitted. If interaction model conditions not met but 1 level had >=10 events, and >0 events for both treatments, results from model for 1 level including treatment only. *p-value <0.05. HR >1 favours olaparib.
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Figure 4.2.2 OLYMPIA: Kaplan-Meier plot of Disease-free survival (AMNOG) (DFS) for Bilateral Oophorectomy=Yes
Full Analysis Set, DCO 12JUL2021

Number of patients at risk:

189	171	161	149	138	123	98	77	59	38	21	7	1	1	0	Olaparib
176	154	147	139	129	113	90	69	51	34	21	10	3	0	0	Placebo

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Figure 4.2.3 OLYMPIA: Kaplan-Meier plot of Disease-free survival (AMNOG) (DFS) for Bilateral Oophorectomy=No
Full Analysis Set, DCO 12JUL2021

Number of patients at risk:

732	654	616	589	556	480	396	303	231	165	110	52	5	3	0	Olaparib
739	653	616	574	525	456	368	299	240	152	97	48	7	3	0	Placebo

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Anhang 4-G5: Subgruppenanalysen: EORTC QLQ-C30

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Table 5.1.1.1 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Global QoL/health status (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	136	70.65 (20.209)	0.29 (1.179)	134	70.52 (18.750)	3.50 (1.190)	-3.20 (-6.500, 0.093)	0.0568
Hedges' g SMD							-0.23 (-0.472, 0.007)	0.0573
TNBC	630	70.65 (19.103)	1.90 (0.563)	639	70.14 (19.150)	3.44 (0.558)	-1.54 (-3.093, 0.015)	0.0523
Hedges' g SMD							-0.11 (-0.219, 0.001)	0.0523
Int. p-value								0.2357
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	385	71.47 (19.357)	1.84 (0.681)	410	71.04 (19.381)	3.78 (0.662)	-1.94 (-3.799, -0.072)	0.0418*
Hedges' g SMD							-0.14 (-0.284, -0.005)	0.0420*
Neoadjuvant	383	69.80 (19.247)	1.40 (0.754)	363	69.26 (18.695)	3.10 (0.772)	-1.71 (-3.825, 0.413)	0.1145
Hedges' g SMD							-0.12 (-0.259, 0.028)	0.1147
Int. p-value								0.6286
Platinum therapy for current breast cancer (eCRF)								
Yes	196	68.71 (18.986)	2.54 (0.994)	195	72.65 (17.844)	2.99 (0.993)	-0.45 (-3.225, 2.317)	0.7474
Hedges' g SMD							-0.03 (-0.231, 0.166)	0.7469
No	572	71.30 (19.389)	1.41 (0.589)	578	69.38 (19.412)	3.54 (0.586)	-2.13 (-3.760, -0.497)	0.0106*
Hedges' g SMD							-0.15 (-0.267, -0.035)	0.0106*
Int. p-value								0.3758
Age [years]								
<50	583	72.14 (18.053)	1.52 (0.572)	569	70.83 (18.752)	3.17 (0.581)	-1.65 (-3.253, -0.054)	0.0428*
Hedges' g SMD							-0.12 (-0.235, -0.004)	0.0428*
50-64	161	68.37 (20.940)	0.82 (1.089)	174	69.01 (19.602)	3.81 (1.040)	-2.99 (-5.948, -0.023)	0.0483*
Hedges' g SMD							-0.22 (-0.431, -0.001)	0.0485*

[a] = number of patients with change from baseline in the MMRM analysis.
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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.1 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Global QoL/health status (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	49.31 (23.814)	4.68 (3.831)	30	65.28 (21.452)	8.97 (3.369)	-4.29 (-14.841, 6.270)	0.4187
Hedges' g SMD							-0.23 (-0.766, 0.311)	0.4085
Int. p-value								0.7551
Menopausal status at screening								
Premenopausal	482	72.63 (18.254)	1.37 (0.634)	467	71.23 (18.560)	2.62 (0.644)	-1.26 (-3.031, 0.517)	0.1645
Hedges' g SMD							-0.09 (-0.218, 0.037)	0.1646
Postmenopausal	284	67.14 (20.539)	2.12 (0.844)	302	68.65 (19.692)	4.89 (0.815)	-2.77 (-5.080, -0.469)	0.0184*
Hedges' g SMD							-0.20 (-0.358, -0.033)	0.0185*
Int. p-value								0.2685
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	51.39 (20.012)	0.78 (8.861)	8	77.08 (17.678)	7.22 (7.423)	-6.45 (-34.553, 21.658)	0.6277
Hedges' g SMD							-0.28 (-1.349, 0.782)	0.6021
Taxane	36	67.59 (19.898)	3.24 (1.945)	39	74.57 (19.398)	6.43 (1.897)	-3.19 (-8.658, 2.280)	0.2485
Hedges' g SMD							-0.27 (-0.723, 0.187)	0.2479
Anthracycline + Taxane	726	70.95 (19.207)	1.51 (0.524)	725	69.90 (19.062)	3.27 (0.523)	-1.76 (-3.216, -0.311)	0.0174*
Hedges' g SMD							-0.12 (-0.228, -0.022)	0.0174*
Int. p-value								0.8188
Type of breast surgery prior to randomisation								
Breast conservation	188	69.33 (20.745)	0.72 (1.021)	207	70.45 (18.718)	2.82 (0.978)	-2.10 (-4.879, 0.680)	0.1383
Hedges' g SMD							-0.15 (-0.347, 0.048)	0.1389
Unilateral mastectomy	295	72.01 (18.671)	1.66 (0.804)	299	70.85 (19.302)	2.77 (0.794)	-1.12 (-3.336, 1.103)	0.3236
Hedges' g SMD							-0.08 (-0.242, 0.080)	0.3239
Bilateral mastectomy	285	70.09 (18.952)	2.16 (0.853)	265	69.28 (19.156)	4.92 (0.886)	-2.76 (-5.181, -0.347)	0.0251*
Hedges' g SMD							-0.19 (-0.359, -0.024)	0.0252*

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.1 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Global QoL/health status (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.7340
Bilateral Oophorectomy								
Yes	155	69.03 (17.193)	3.39 (1.105)	146	68.32 (18.169)	6.66 (1.135)	-3.27 (-6.392, -0.149)	0.0401*
Hedges' g SMD							-0.24 (-0.464, -0.011)	0.0403*
No	613	71.04 (19.800)	1.19 (0.569)	627	70.64 (19.262)	2.68 (0.563)	-1.49 (-3.057, 0.084)	0.0635
Hedges' g SMD							-0.11 (-0.217, 0.006)	0.0636
Int. p-value								0.2019
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	73.08 (18.376)	3.13 (1.078)	159	69.76 (18.741)	3.94 (1.076)	-0.80 (-3.808, 2.200)	0.5987
Hedges' g SMD							-0.06 (-0.280, 0.162)	0.5986
Negative	167	69.96 (19.914)	1.13 (1.054)	175	71.24 (19.547)	4.46 (1.028)	-3.33 (-6.229, -0.435)	0.0243*
Hedges' g SMD							-0.24 (-0.457, -0.031)	0.0245*
Int. p-value								0.2716
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	69.13 (20.340)	1.11 (1.585)	73	68.61 (16.983)	5.68 (1.757)	-4.57 (-9.242, 0.105)	0.0553
Hedges' g SMD							-0.30 (-0.617, 0.008)	0.0559
ER and/or PgR positive with adjuvant chemotherapy	48	73.44 (19.874)	-0.78 (1.719)	61	72.81 (20.576)	0.68 (1.507)	-1.46 (-5.991, 3.073)	0.5247
Hedges' g SMD							-0.12 (-0.501, 0.256)	0.5260
ER and PgR negative with neoadjuvant chemotherapy	293	70.02 (18.890)	1.45 (0.863)	290	69.43 (19.125)	2.44 (0.859)	-1.00 (-3.389, 1.394)	0.4130
Hedges' g SMD							-0.07 (-0.230, 0.095)	0.4134

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.1 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Global QoL/health status (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	337	71.19 (19.297)	2.24 (0.738)	349	70.73 (19.178)	4.31 (0.729)	-2.07 (-4.106, -0.032)	0.0466*
Hedges' g SMD							-0.15 (-0.302, -0.002)	0.0467*
Int. p-value								0.2497
Race								
White	508	69.87 (19.131)	1.65 (0.625)	484	70.33 (18.229)	3.24 (0.640)	-1.59 (-3.344, 0.165)	0.0758
Hedges' g SMD							-0.11 (-0.237, 0.012)	0.0759
Black/African-American	11	64.39 (19.397)	1.78 (5.284)	21	69.44 (21.943)	6.88 (3.468)	-5.10 (-18.049, 7.840)	0.4250
Hedges' g SMD							-0.30 (-1.036, 0.431)	0.4192
Asian	237	72.05 (19.650)	1.15 (0.918)	257	70.20 (20.364)	3.58 (0.883)	-2.43 (-4.932, 0.077)	0.0575
Hedges' g SMD							-0.17 (-0.348, 0.006)	0.0576
Other	12	81.25 (16.332)	12.48 (2.666)	11	65.91 (20.566)	2.37 (2.114)	10.11 (2.132, 18.082)	0.0174*
Hedges' g SMD							1.18 (0.281, 2.080)	0.0101*
Int. p-value								NC
Ethnicity								
Hispanic	26	78.85 (20.847)	1.01 (2.362)	17	73.53 (14.801)	5.19 (3.013)	-4.18 (-11.975, 3.622)	0.2853
Hedges' g SMD							-0.34 (-0.952, 0.280)	0.2846
Non-hispanic	682	70.47 (19.216)	1.73 (0.537)	693	70.02 (19.313)	3.71 (0.532)	-1.98 (-3.467, -0.502)	0.0087*
Hedges' g SMD							-0.14 (-0.247, -0.036)	0.0088*
Not known, not recorded or refused	60	69.03 (19.169)	0.43 (1.891)	63	71.30 (17.440)	0.29 (1.868)	0.14 (-5.129, 5.412)	0.9576
Hedges' g SMD							0.01 (-0.344, 0.363)	0.9578
Int. p-value								0.6209
Jewish descent								

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.1 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Global QoL/health status (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Yes Ashkenazi	33	73.48 (19.371)	0.29 (2.108)	25	70.00 (17.347)	1.61 (2.543)	-1.32 (-7.979, 5.338)	0.6914
Hedges' g SMD							-0.11 (-0.625, 0.415)	0.6915
No	735	70.51 (19.309)	1.69 (0.519)	746	70.16 (19.139)	3.51 (0.514)	-1.82 (-3.256, -0.391)	0.0127*
Hedges' g SMD							-0.13 (-0.232, -0.028)	0.0127*
Int. p-value								0.8983
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	333	70.42 (18.937)	1.24 (0.801)	306	68.68 (19.087)	2.91 (0.834)	-1.67 (-3.937, 0.606)	0.1504
Hedges' g SMD							-0.11 (-0.269, 0.041)	0.1506
5 or 6	19	70.61 (20.855)	-3.14 (5.080)	7	75.00 (24.056)	1.10 (8.928)	-4.25 (-27.587, 19.096)	0.6896
Hedges' g SMD							-0.18 (-1.051, 0.686)	0.6802
Int. p-value								0.9324
Geographic region								
North America	83	72.29 (18.639)	4.96 (1.550)	90	71.48 (21.014)	4.68 (1.529)	0.29 (-4.013, 4.587)	0.8953
Hedges' g SMD							0.02 (-0.278, 0.318)	0.8958
South America	13	91.03 (9.293)	-4.25 (3.696)	9	75.93 (16.375)	-0.86 (4.744)	-3.39 (-16.922, 10.144)	0.6058
Hedges' g SMD							-0.24 (-1.091, 0.615)	0.5846
Europe	393	68.51 (19.259)	1.75 (0.712)	373	69.46 (18.111)	3.42 (0.725)	-1.68 (-3.671, 0.321)	0.0998
Hedges' g SMD							-0.12 (-0.261, 0.023)	0.1001
Asia Pacific and South Africa	279	72.19 (19.243)	0.67 (0.843)	301	70.57 (19.714)	3.33 (0.815)	-2.66 (-4.965, -0.357)	0.0237*
Hedges' g SMD							-0.19 (-0.352, -0.025)	0.0238*
Int. p-value								0.4813
Sponsor								
AZ	693	70.42 (19.455)	1.33 (0.535)	702	69.91 (18.986)	3.16 (0.530)	-1.84 (-3.313, -0.358)	0.0149*
Hedges' g SMD							-0.13 (-0.236, -0.025)	0.0149*
NRG Oncology	75	72.67 (17.892)	4.02 (1.499)	71	73.12 (19.780)	6.28 (1.577)	-2.26 (-6.561, 2.051)	0.3022
Hedges' g SMD							-0.17 (-0.496, 0.154)	0.3032

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.1 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Global QoL/health status (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.9256
BRCA mutation type								
BRCA1	491	69.87 (18.520)	1.11 (0.648)	489	69.67 (18.406)	3.10 (0.648)	-1.99 (-3.789, -0.191)	0.0302*
Hedges' g SMD							-0.14 (-0.264, -0.013)	0.0302*
BRCA2	193	68.91 (21.109)	3.44 (1.028)	186	69.13 (20.838)	3.96 (1.050)	-0.52 (-3.407, 2.371)	0.7245
Hedges' g SMD							-0.04 (-0.238, 0.165)	0.7249
Int. p-value								0.4053

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.2 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Physical (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	86.42 (14.335)	-0.14 (0.732)	134	88.20 (12.842)	0.95 (0.741)	-1.09 (-3.142, 0.964)	0.2972
Hedges' g SMD							-0.13 (-0.365, 0.112)	0.2975
TNBC	633	86.27 (14.622)	1.06 (0.397)	640	86.02 (14.727)	1.81 (0.394)	-0.75 (-1.853, 0.343)	0.1778
Hedges' g SMD							-0.08 (-0.185, 0.034)	0.1780
Int. p-value								0.6379
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	387	87.56 (13.242)	1.05 (0.464)	410	86.92 (14.665)	1.70 (0.452)	-0.65 (-1.918, 0.625)	0.3187
Hedges' g SMD							-0.07 (-0.210, 0.068)	0.3190
Neoadjuvant	385	85.07 (15.670)	0.64 (0.529)	364	85.81 (14.166)	1.64 (0.541)	-1.00 (-2.485, 0.486)	0.1870
Hedges' g SMD							-0.10 (-0.240, 0.047)	0.1873
Int. p-value								0.8178
Platinum therapy for current breast cancer (eCRF)								
Yes	198	84.78 (16.496)	0.84 (0.759)	196	87.04 (14.436)	2.27 (0.762)	-1.43 (-3.547, 0.686)	0.1848
Hedges' g SMD							-0.13 (-0.331, 0.064)	0.1847
No	574	86.85 (13.788)	0.84 (0.395)	578	86.18 (14.439)	1.47 (0.393)	-0.63 (-1.720, 0.465)	0.2600
Hedges' g SMD							-0.07 (-0.182, 0.049)	0.2601
Int. p-value								0.3594
Age [years]								
<50	584	87.23 (13.875)	0.94 (0.396)	569	86.98 (14.486)	1.94 (0.402)	-1.00 (-2.105, 0.110)	0.0774
Hedges' g SMD							-0.10 (-0.220, 0.011)	0.0775
50-64	164	84.63 (15.602)	0.61 (0.748)	175	85.13 (14.298)	1.03 (0.719)	-0.42 (-2.458, 1.626)	0.6890
Hedges' g SMD							-0.04 (-0.256, 0.170)	0.6894

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.2 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Physical (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	75.56 (18.089)	-2.40 (2.814)	30	82.67 (13.629)	0.89 (2.495)	-3.29 (-10.952, 4.376)	0.3926
Hedges' g SMD							-0.24 (-0.775, 0.303)	0.3902
Int. p-value								0.5589
Menopausal status at screening								
Premenopausal	483	87.44 (13.766)	1.15 (0.436)	467	87.23 (14.086)	1.85 (0.443)	-0.69 (-1.911, 0.528)	0.2659
Hedges' g SMD							-0.07 (-0.199, 0.055)	0.2661
Postmenopausal	287	84.37 (15.634)	0.22 (0.588)	303	85.15 (14.923)	1.44 (0.570)	-1.21 (-2.823, 0.394)	0.1387
Hedges' g SMD							-0.12 (-0.284, 0.040)	0.1389
Int. p-value								0.7713
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	73.33 (24.944)	8.10 (4.705)	8	89.17 (7.918)	6.71 (4.026)	1.39 (-12.980, 15.753)	0.8368
Hedges' g SMD							0.11 (-0.946, 1.173)	0.8338
Taxane	37	84.50 (16.409)	-3.07 (1.783)	39	90.26 (14.335)	3.66 (1.750)	-6.73 (-11.763, -1.702)	0.0095*
Hedges' g SMD							-0.61 (-1.073, -0.151)	0.0092*
Anthracycline + Taxane	729	86.52 (14.316)	0.92 (0.359)	726	86.14 (14.476)	1.58 (0.359)	-0.66 (-1.657, 0.336)	0.1936
Hedges' g SMD							-0.07 (-0.171, 0.035)	0.1937
Int. p-value								0.0289*
Type of breast surgery prior to randomisation								
Breast conservation	190	86.98 (14.126)	-0.20 (0.664)	207	86.70 (13.818)	0.66 (0.639)	-0.86 (-2.672, 0.953)	0.3515
Hedges' g SMD							-0.09 (-0.291, 0.104)	0.3522
Unilateral mastectomy	295	86.98 (12.971)	0.99 (0.542)	299	86.93 (14.016)	1.19 (0.535)	-0.20 (-1.697, 1.295)	0.7919
Hedges' g SMD							-0.02 (-0.182, 0.139)	0.7920
Bilateral mastectomy	287	85.20 (16.240)	1.41 (0.631)	266	85.64 (15.360)	3.15 (0.655)	-1.74 (-3.524, 0.050)	0.0568
Hedges' g SMD							-0.16 (-0.329, 0.005)	0.0570

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.2 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Physical (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.5161
Bilateral Oophorectomy								
Yes	156	85.38 (14.880)	1.59 (0.786)	147	86.21 (14.549)	2.45 (0.808)	-0.86 (-3.078, 1.358)	0.4461
Hedges' g SMD							-0.09 (-0.313, 0.138)	0.4468
No	616	86.56 (14.465)	0.62 (0.395)	627	86.44 (14.418)	1.49 (0.391)	-0.87 (-1.957, 0.221)	0.1182
Hedges' g SMD							-0.09 (-0.200, 0.023)	0.1183
Int. p-value								0.8884
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	88.03 (11.774)	1.69 (0.725)	159	86.74 (14.827)	0.90 (0.724)	0.79 (-1.234, 2.804)	0.4447
Hedges' g SMD							0.09 (-0.135, 0.307)	0.4451
Negative	168	87.02 (14.357)	1.08 (0.698)	175	86.86 (14.050)	2.40 (0.683)	-1.32 (-3.244, 0.597)	0.1760
Hedges' g SMD							-0.15 (-0.358, 0.066)	0.1766
Int. p-value								0.1117
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	84.55 (15.871)	0.61 (0.950)	73	89.13 (9.970)	0.79 (1.057)	-0.18 (-3.002, 2.651)	0.9026
Hedges' g SMD							-0.02 (-0.330, 0.291)	0.9021
ER and/or PgR positive with adjuvant chemotherapy	49	89.80 (10.373)	-1.14 (1.169)	61	87.08 (15.619)	1.05 (1.034)	-2.19 (-5.295, 0.912)	0.1644
Hedges' g SMD							-0.27 (-0.646, 0.110)	0.1647
ER and PgR negative with neoadjuvant chemotherapy	295	85.17 (15.672)	0.71 (0.629)	291	84.97 (14.934)	1.81 (0.627)	-1.10 (-2.844, 0.644)	0.2158
Hedges' g SMD							-0.10 (-0.264, 0.060)	0.2162

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.2 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Physical (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	338	87.24 (13.591)	1.35 (0.502)	349	86.90 (14.515)	1.84 (0.496)	-0.50 (-1.881, 0.891)	0.4831
Hedges' g SMD							-0.05 (-0.203, 0.096)	0.4834
Int. p-value								0.9342
Race								
White	512	85.75 (15.527)	0.70 (0.463)	485	86.44 (14.554)	1.34 (0.475)	-0.64 (-1.940, 0.666)	0.3374
Hedges' g SMD							-0.06 (-0.185, 0.063)	0.3377
Black/African-American	11	79.39 (18.246)	7.69 (2.792)	21	83.25 (22.904)	5.55 (1.861)	2.15 (-4.745, 9.037)	0.5280
Hedges' g SMD							0.24 (-0.494, 0.970)	0.5236
Asian	237	87.48 (12.069)	0.82 (0.529)	257	86.67 (13.398)	2.13 (0.509)	-1.31 (-2.754, 0.131)	0.0746
Hedges' g SMD							-0.16 (-0.337, 0.016)	0.0748
Other	12	93.89 (7.224)	3.57 (2.233)	11	84.24 (13.424)	1.77 (2.325)	1.79 (-5.424, 9.013)	0.6057
Hedges' g SMD							0.22 (-0.597, 1.045)	0.5929
Int. p-value								0.3091
Ethnicity								
Hispanic	26	93.08 (10.580)	-0.47 (2.053)	17	85.10 (13.850)	1.95 (2.705)	-2.42 (-9.522, 4.678)	0.4948
Hedges' g SMD							-0.22 (-0.835, 0.392)	0.4794
Non-hispanic	685	86.27 (14.643)	0.84 (0.369)	693	86.73 (13.855)	1.67 (0.367)	-0.84 (-1.859, 0.183)	0.1076
Hedges' g SMD							-0.09 (-0.192, 0.019)	0.1077
Not known, not recorded or refused	61	84.04 (14.261)	1.08 (1.370)	64	83.13 (19.661)	1.74 (1.350)	-0.66 (-4.471, 3.157)	0.7333
Hedges' g SMD							-0.06 (-0.412, 0.290)	0.7344
Int. p-value								0.9184
Jewish descent								

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.2 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Physical (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Yes Ashkenazi	33	89.70 (12.920)	0.82 (1.665)	25	85.87 (17.672)	-2.38 (1.973)	3.20 (-2.016, 8.407)	0.2234
Hedges' g SMD							0.33 (-0.198, 0.848)	0.2233
No	739	86.17 (14.606)	0.80 (0.359)	747	86.39 (14.335)	1.83 (0.357)	-1.03 (-2.026, -0.040)	0.0414*
Hedges' g SMD							-0.11 (-0.208, -0.004)	0.0415*
Int. p-value								0.0770
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	335	85.13 (15.845)	0.84 (0.560)	307	85.93 (14.261)	1.41 (0.583)	-0.57 (-2.158, 1.017)	0.4806
Hedges' g SMD							-0.06 (-0.211, 0.099)	0.4810
5 or 6	19	85.61 (14.275)	-0.44 (2.071)	7	86.67 (16.777)	-0.16 (3.415)	-0.29 (-8.555, 7.979)	0.9432
Hedges' g SMD							-0.03 (-0.898, 0.836)	0.9443
Int. p-value								0.8244
Geographic region								
North America	84	89.13 (13.284)	1.93 (1.019)	90	87.80 (16.099)	2.77 (1.004)	-0.84 (-3.665, 1.987)	0.5585
Hedges' g SMD							-0.09 (-0.386, 0.209)	0.5598
South America	13	96.92 (3.459)	1.03 (1.491)	9	88.15 (14.444)	-2.90 (2.065)	3.93 (-1.794, 9.658)	0.1664
Hedges' g SMD							0.66 (-0.215, 1.538)	0.1392
Europe	396	84.54 (16.259)	0.71 (0.550)	374	85.50 (15.310)	1.58 (0.561)	-0.87 (-2.414, 0.673)	0.2687
Hedges' g SMD							-0.08 (-0.221, 0.062)	0.2691
Asia Pacific and South Africa	279	87.50 (12.026)	0.68 (0.504)	301	87.04 (12.682)	1.68 (0.487)	-1.00 (-2.371, 0.381)	0.1561
Hedges' g SMD							-0.12 (-0.281, 0.045)	0.1565
Int. p-value								0.8048
Sponsor								
AZ	696	86.03 (14.617)	0.71 (0.372)	703	86.18 (14.372)	1.53 (0.369)	-0.82 (-1.846, 0.210)	0.1186
Hedges' g SMD							-0.08 (-0.188, 0.021)	0.1187
NRG Oncology	76	88.95 (13.708)	1.63 (1.073)	71	88.57 (14.966)	3.17 (1.129)	-1.53 (-4.611, 1.549)	0.3273
Hedges' g SMD							-0.16 (-0.485, 0.163)	0.3288

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
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Table 5.1.1.2 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Physical (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.7111
BRCA mutation type								
BRCA1	493	86.12 (14.798)	0.71 (0.466)	490	85.62 (14.950)	1.99 (0.466)	-1.28 (-2.572, 0.014)	0.0526
Hedges' g SMD							-0.12 (-0.249, 0.001)	0.0527
BRCA2	195	84.75 (15.539)	1.65 (0.677)	186	87.16 (14.478)	1.38 (0.695)	0.28 (-1.633, 2.188)	0.7753
Hedges' g SMD							0.03 (-0.172, 0.230)	0.7753
Int. p-value								0.1653

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.3 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Role (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	82.00 (25.086)	-0.91 (1.345)	134	83.58 (21.628)	0.91 (1.362)	-1.82 (-5.589, 1.951)	0.3429
Hedges' g SMD							-0.12 (-0.353, 0.123)	0.3436
TNBC	633	79.67 (24.055)	3.16 (0.648)	640	80.83 (24.329)	3.71 (0.643)	-0.55 (-2.341, 1.241)	0.5471
Hedges' g SMD							-0.03 (-0.144, 0.076)	0.5472
Int. p-value								0.5204
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	387	82.21 (23.018)	2.69 (0.744)	410	83.66 (21.802)	2.24 (0.725)	0.45 (-1.586, 2.493)	0.6625
Hedges' g SMD							0.03 (-0.108, 0.170)	0.6626
Neoadjuvant	385	78.01 (25.226)	2.29 (0.908)	364	78.66 (25.823)	4.39 (0.928)	-2.11 (-4.655, 0.444)	0.1053
Hedges' g SMD							-0.12 (-0.262, 0.025)	0.1056
Int. p-value								0.1721
Platinum therapy for current breast cancer (eCRF)								
Yes	198	75.76 (26.793)	4.53 (1.293)	195	79.15 (26.560)	6.40 (1.299)	-1.87 (-5.479, 1.733)	0.3078
Hedges' g SMD							-0.10 (-0.301, 0.095)	0.3080
No	574	81.62 (23.102)	1.80 (0.650)	579	82.04 (22.903)	2.20 (0.646)	-0.40 (-2.201, 1.395)	0.6604
Hedges' g SMD							-0.03 (-0.141, 0.090)	0.6605
Int. p-value								0.3976
Age [years]								
<50	584	81.02 (23.649)	2.84 (0.661)	569	81.34 (24.041)	3.06 (0.671)	-0.22 (-2.065, 1.632)	0.8181
Hedges' g SMD							-0.01 (-0.129, 0.102)	0.8182
50-64	164	78.25 (25.540)	1.35 (1.239)	175	81.24 (22.926)	3.91 (1.187)	-2.56 (-5.939, 0.819)	0.1371
Hedges' g SMD							-0.16 (-0.375, 0.052)	0.1371

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[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.3 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Role (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	70.83 (27.031)	-1.00 (4.132)	30	81.11 (27.240)	3.27 (3.651)	-4.27 (-15.451, 6.907)	0.4462
Hedges' g SMD							-0.21 (-0.748, 0.329)	0.4458
Int. p-value								0.6117
Menopausal status at screening								
Premenopausal	483	81.95 (22.934)	2.57 (0.724)	467	82.08 (23.064)	2.54 (0.736)	0.03 (-1.994, 2.058)	0.9751
Hedges' g SMD							0.00 (-0.125, 0.129)	0.9751
Postmenopausal	287	76.95 (26.034)	2.20 (0.980)	303	80.53 (24.684)	4.34 (0.949)	-2.14 (-4.823, 0.542)	0.1176
Hedges' g SMD							-0.13 (-0.291, 0.033)	0.1174
Int. p-value								0.2310
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	75.00 (32.914)	-11.06 (5.300)	8	85.42 (16.517)	13.82 (4.527)	-24.88 (-41.115, -8.649)	0.0073*
Hedges' g SMD							-1.81 (-3.130, -0.488)	0.0073*
Taxane	37	75.68 (27.665)	0.54 (2.721)	39	80.77 (27.450)	10.20 (2.681)	-9.66 (-17.303, -2.012)	0.0140*
Hedges' g SMD							-0.57 (-1.034, -0.115)	0.0143*
Anthracycline + Taxane	729	80.38 (23.973)	2.54 (0.601)	726	81.27 (23.787)	2.80 (0.600)	-0.26 (-1.928, 1.403)	0.7571
Hedges' g SMD							-0.02 (-0.119, 0.087)	0.7572
Int. p-value								0.0286*
Type of breast surgery prior to randomisation								
Breast conservation	190	82.46 (22.271)	-0.43 (1.109)	206	85.52 (19.037)	0.16 (1.070)	-0.59 (-3.621, 2.447)	0.7037
Hedges' g SMD							-0.04 (-0.235, 0.159)	0.7037
Unilateral mastectomy	295	81.86 (22.329)	2.69 (0.894)	300	83.00 (23.290)	1.63 (0.879)	1.05 (-1.409, 3.515)	0.4011
Hedges' g SMD							0.07 (-0.092, 0.230)	0.4014
Bilateral mastectomy	287	76.77 (26.891)	4.78 (1.049)	266	76.19 (26.994)	7.61 (1.090)	-2.83 (-5.805, 0.139)	0.0616
Hedges' g SMD							-0.16 (-0.326, 0.008)	0.0618

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.3 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Role (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.1826
Bilateral Oophorectomy								
Yes	156	75.75 (26.188)	5.52 (1.307)	147	77.55 (24.648)	7.91 (1.344)	-2.39 (-6.080, 1.304)	0.2040
Hedges' g SMD							-0.15 (-0.372, 0.080)	0.2046
No	616	81.22 (23.591)	1.73 (0.653)	627	82.19 (23.646)	2.12 (0.646)	-0.39 (-2.195, 1.409)	0.6687
Hedges' g SMD							-0.02 (-0.135, 0.087)	0.6688
Int. p-value								0.3213
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	83.65 (19.808)	3.50 (1.148)	159	83.54 (21.461)	-0.80 (1.147)	4.30 (1.104, 7.492)	0.0085*
Hedges' g SMD							0.30 (0.076, 0.520)	0.0086*
Negative	168	81.35 (25.652)	2.49 (1.098)	175	83.52 (22.173)	5.23 (1.074)	-2.74 (-5.762, 0.285)	0.0757
Hedges' g SMD							-0.19 (-0.404, 0.020)	0.0758
Int. p-value								0.0035*
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	80.49 (26.889)	-0.44 (1.723)	73	83.79 (20.967)	2.16 (1.916)	-2.60 (-7.692, 2.500)	0.3157
Hedges' g SMD							-0.16 (-0.470, 0.152)	0.3162
ER and/or PgR positive with adjuvant chemotherapy	49	84.69 (21.473)	-2.01 (2.164)	61	83.33 (22.567)	-0.10 (1.913)	-1.91 (-7.639, 3.823)	0.5105
Hedges' g SMD							-0.13 (-0.502, 0.250)	0.5116
ER and PgR negative with neoadjuvant chemotherapy	295	77.18 (24.757)	2.99 (1.068)	291	77.38 (26.782)	5.05 (1.062)	-2.06 (-5.019, 0.896)	0.1714
Hedges' g SMD							-0.11 (-0.275, 0.049)	0.1718

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.3 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Role (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	338	81.85 (23.242)	3.33 (0.787)	349	83.72 (21.698)	2.75 (0.778)	0.58 (-1.591, 2.757)	0.5987
Hedges' g SMD							0.04 (-0.109, 0.190)	0.5988
Int. p-value								0.5347
Race								
White	512	77.02 (25.652)	3.44 (0.790)	485	78.38 (25.367)	4.56 (0.810)	-1.12 (-3.336, 1.105)	0.3243
Hedges' g SMD							-0.06 (-0.187, 0.062)	0.3244
Black/African-American	11	NC	NC	21	NC	NC	NC	NC
Asian	237	86.92 (18.729)	0.34 (0.822)	257	87.35 (19.349)	0.51 (0.791)	-0.18 (-2.417, 2.066)	0.8778
Hedges' g SMD							-0.01 (-0.190, 0.163)	0.8779
Other	12	93.06 (13.216)	1.44 (4.557)	11	81.82 (25.226)	0.87 (4.727)	0.56 (-13.934, 15.063)	0.9343
Hedges' g SMD							0.03 (-0.784, 0.853)	0.9340
Int. p-value								0.6622
Ethnicity								
Hispanic	26	87.82 (22.389)	4.68 (2.930)	17	80.39 (23.000)	0.80 (3.693)	3.88 (-5.800, 13.566)	0.4215
Hedges' g SMD							0.25 (-0.361, 0.867)	0.4188
Non-hispanic	685	80.24 (23.857)	2.52 (0.604)	693	81.65 (23.476)	3.32 (0.598)	-0.80 (-2.468, 0.867)	0.3463
Hedges' g SMD							-0.05 (-0.156, 0.055)	0.3464
Not known, not recorded or refused	61	75.41 (28.154)	0.09 (2.717)	64	77.86 (28.336)	2.62 (2.673)	-2.53 (-10.094, 5.034)	0.5085
Hedges' g SMD							-0.12 (-0.469, 0.233)	0.5098
Int. p-value								0.7386
Jewish descent								
Yes Ashkenazi	33	84.85 (20.140)	1.01 (2.551)	25	82.00 (20.367)	-3.12 (2.996)	4.13 (-3.791, 12.050)	0.2993

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
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Table 5.1.1.3 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Role (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hedges' g SMD							0.28 (-0.247, 0.798)	0.3014
No	739	79.91 (24.377)	2.50 (0.598)	747	81.26 (24.035)	3.44 (0.592)	-0.94 (-2.594, 0.707)	0.2624
Hedges' g SMD							-0.06 (-0.160, 0.044)	0.2625
Int. p-value								0.2317
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	335	78.21 (25.163)	2.25 (0.966)	307	78.94 (25.381)	4.26 (1.004)	-2.01 (-4.748, 0.724)	0.1492
Hedges' g SMD							-0.11 (-0.269, 0.041)	0.1495
5 or 6	19	82.46 (18.818)	1.56 (4.239)	7	88.10 (15.853)	-18.97 (9.737)	20.53 (-7.449, 48.513)	0.1226
Hedges' g SMD							0.97 (0.055, 1.880)	0.0376*
Int. p-value								0.6192
Geographic region								
North America	84	79.96 (24.239)	7.15 (1.602)	90	81.85 (23.918)	4.58 (1.579)	2.57 (-1.868, 7.015)	0.2544
Hedges' g SMD							0.17 (-0.125, 0.471)	0.2560
South America	13	93.59 (10.841)	3.65 (2.714)	9	87.04 (16.197)	-2.45 (3.384)	6.10 (-3.080, 15.288)	0.1797
Hedges' g SMD							0.59 (-0.280, 1.463)	0.1837
Europe	396	75.04 (27.160)	3.54 (0.966)	375	76.62 (26.285)	5.28 (0.983)	-1.74 (-4.446, 0.967)	0.2075
Hedges' g SMD							-0.09 (-0.232, 0.050)	0.2079
Asia Pacific and South Africa	279	86.74 (17.581)	-0.05 (0.748)	300	86.83 (19.368)	0.83 (0.724)	-0.88 (-2.920, 1.169)	0.4007
Hedges' g SMD							-0.07 (-0.233, 0.093)	0.4012
Int. p-value								0.2811
Sponsor								
AZ	696	80.24 (24.165)	1.82 (0.623)	703	81.20 (23.924)	2.80 (0.617)	-0.98 (-2.703, 0.737)	0.2622
Hedges' g SMD							-0.06 (-0.165, 0.045)	0.2624
NRG Oncology	76	78.95 (24.850)	8.58 (1.522)	71	82.39 (23.719)	8.02 (1.613)	0.55 (-3.839, 4.946)	0.8037
Hedges' g SMD							0.04 (-0.283, 0.365)	0.8038
Int. p-value								0.4899

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.3 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Role (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
BRCA mutation type								
BRCA1	493	79.31 (24.605)	2.77 (0.762)	490	78.61 (25.621)	4.86 (0.762)	-2.09 (-4.208, 0.020)	0.0523
Hedges' g SMD							-0.12 (-0.249, 0.001)	0.0524
BRCA2	195	77.35 (25.408)	3.61 (1.189)	186	83.96 (21.250)	1.49 (1.221)	2.11 (-1.254, 5.482)	0.2179
Hedges' g SMD							0.13 (-0.074, 0.328)	0.2163
Int. p-value								0.0572

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.4 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Cognitive (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	77.74 (25.747)	-2.33 (1.341)	134	82.59 (19.049)	-1.42 (1.353)	-0.91 (-4.673, 2.852)	0.6341
Hedges' g SMD							-0.06 (-0.296, 0.180)	0.6338
TNBC	630	82.43 (19.738)	-1.71 (0.598)	638	82.86 (20.476)	-1.82 (0.593)	0.11 (-1.544, 1.760)	0.8977
Hedges' g SMD							0.01 (-0.103, 0.117)	0.8977
Int. p-value								0.6248
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	386	82.77 (18.621)	-1.71 (0.727)	410	83.21 (19.623)	-1.68 (0.707)	-0.03 (-2.023, 1.961)	0.9758
Hedges' g SMD							0.00 (-0.141, 0.137)	0.9758
Neoadjuvant	383	80.50 (23.102)	-1.89 (0.815)	362	82.37 (20.902)	-1.79 (0.835)	-0.11 (-2.400, 2.183)	0.9261
Hedges' g SMD							-0.01 (-0.150, 0.137)	0.9262
Int. p-value								0.9064
Platinum therapy for current breast cancer (eCRF)								
Yes	196	79.25 (22.653)	-1.37 (1.199)	195	84.96 (19.485)	-3.01 (1.199)	1.64 (-1.708, 4.995)	0.3354
Hedges' g SMD							0.10 (-0.101, 0.296)	0.3337
No	573	82.46 (20.346)	-1.96 (0.606)	577	82.09 (20.434)	-1.32 (0.604)	-0.64 (-2.318, 1.040)	0.4553
Hedges' g SMD							-0.04 (-0.160, 0.072)	0.4554
Int. p-value								0.2895
Age [years]								
<50	584	82.25 (20.633)	-1.52 (0.621)	568	82.83 (20.364)	-1.66 (0.631)	0.14 (-1.595, 1.879)	0.8725
Hedges' g SMD							0.01 (-0.106, 0.125)	0.8726
50-64	161	80.23 (21.667)	-3.11 (1.218)	174	82.57 (19.533)	-2.54 (1.161)	-0.58 (-3.889, 2.739)	0.7329
Hedges' g SMD							-0.04 (-0.252, 0.177)	0.7330

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.4 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Cognitive (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	76.39 (24.533)	-0.82 (2.833)	30	83.89 (22.095)	1.28 (2.501)	-2.10 (-9.758, 5.561)	0.5839
Hedges' g SMD							-0.15 (-0.688, 0.387)	0.5842
Int. p-value								0.7413
Menopausal status at screening								
Premenopausal	483	83.47 (19.502)	-2.05 (0.656)	466	84.19 (18.976)	-1.62 (0.667)	-0.43 (-2.268, 1.406)	0.6454
Hedges' g SMD							-0.03 (-0.157, 0.097)	0.6455
Postmenopausal	284	78.52 (23.029)	-1.46 (0.947)	302	80.68 (21.914)	-1.90 (0.914)	0.44 (-2.149, 3.025)	0.7396
Hedges' g SMD							0.03 (-0.135, 0.189)	0.7396
Int. p-value								0.5923
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	69.44 (22.153)	5.30 (4.200)	8	89.58 (12.400)	3.42 (3.497)	1.88 (-11.070, 14.829)	0.7577
Hedges' g SMD							0.17 (-0.886, 1.236)	0.7467
Taxane	36	77.78 (24.881)	-0.10 (2.481)	39	88.03 (19.098)	0.33 (2.397)	-0.42 (-7.407, 6.559)	0.9039
Hedges' g SMD							-0.03 (-0.481, 0.425)	0.9032
Anthracycline + Taxane	727	81.93 (20.755)	-1.97 (0.563)	724	82.44 (20.322)	-1.91 (0.563)	-0.06 (-1.620, 1.502)	0.9411
Hedges' g SMD							0.00 (-0.107, 0.099)	0.9411
Int. p-value								0.8385
Type of breast surgery prior to randomisation								
Breast conservation	188	82.27 (20.072)	-1.69 (1.082)	207	84.22 (18.154)	-3.01 (1.036)	1.32 (-1.625, 4.270)	0.3780
Hedges' g SMD							0.09 (-0.109, 0.286)	0.3784
Unilateral mastectomy	295	82.26 (19.868)	-2.50 (0.865)	298	83.72 (19.554)	-0.95 (0.855)	-1.56 (-3.946, 0.834)	0.2014
Hedges' g SMD							-0.10 (-0.266, 0.056)	0.2016
Bilateral mastectomy	286	80.59 (22.670)	-1.10 (0.926)	265	81.13 (21.720)	-1.54 (0.962)	0.44 (-2.186, 3.062)	0.7430
Hedges' g SMD							0.03 (-0.139, 0.195)	0.7432

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Table 5.1.1.4 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Cognitive (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.2070
Bilateral Oophorectomy								
Yes	155	79.46 (21.972)	-0.72 (1.345)	146	80.48 (20.748)	-2.60 (1.384)	1.88 (-1.915, 5.685)	0.3297
Hedges' g SMD							0.11 (-0.114, 0.339)	0.3303
No	614	82.19 (20.717)	-2.07 (0.589)	626	83.36 (20.078)	-1.52 (0.583)	-0.55 (-2.172, 1.082)	0.5111
Hedges' g SMD							-0.04 (-0.149, 0.074)	0.5112
Int. p-value								0.2053
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	85.15 (14.856)	-1.57 (1.123)	159	81.66 (21.314)	-3.46 (1.121)	1.89 (-1.239, 5.019)	0.2355
Hedges' g SMD							0.13 (-0.087, 0.355)	0.2351
Negative	167	82.34 (19.335)	-2.28 (1.067)	175	85.24 (18.557)	0.53 (1.039)	-2.81 (-5.745, 0.127)	0.0607
Hedges' g SMD							-0.20 (-0.416, 0.009)	0.0605
Int. p-value								0.0600
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	76.14 (27.075)	-1.99 (1.676)	73	84.25 (19.620)	-0.40 (1.851)	-1.59 (-6.560, 3.378)	0.5279
Hedges' g SMD							-0.10 (-0.411, 0.210)	0.5261
ER and/or PgR positive with adjuvant chemotherapy	49	80.61 (23.161)	-2.57 (2.232)	61	80.60 (18.303)	-3.08 (1.983)	0.51 (-5.421, 6.431)	0.8660
Hedges' g SMD							0.03 (-0.344, 0.408)	0.8665
ER and PgR negative with neoadjuvant chemotherapy	293	81.68 (21.681)	-1.89 (0.938)	289	81.89 (21.220)	-2.18 (0.937)	0.29 (-2.312, 2.898)	0.8251
Hedges' g SMD							0.02 (-0.144, 0.181)	0.8252

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.4 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Cognitive (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	337	83.09 (17.885)	-1.58 (0.770)	349	83.67 (19.834)	-1.49 (0.760)	-0.09 (-2.213, 2.036)	0.9351
Hedges' g SMD							-0.01 (-0.156, 0.143)	0.9351
Int. p-value								0.8168
Race								
White	509	80.12 (23.280)	-2.08 (0.741)	483	81.85 (21.913)	-2.45 (0.760)	0.37 (-1.716, 2.450)	0.7297
Hedges' g SMD							0.02 (-0.103, 0.146)	0.7297
Black/African-American	11	86.36 (16.361)	2.96 (6.586)	21	85.71 (16.060)	-5.88 (3.898)	8.84 (-6.648, 24.332)	0.2519
Hedges' g SMD							0.45 (-0.292, 1.186)	0.2357
Asian	237	84.25 (15.044)	-1.66 (0.740)	257	84.44 (16.985)	-0.32 (0.713)	-1.34 (-3.355, 0.684)	0.1944
Hedges' g SMD							-0.12 (-0.294, 0.060)	0.1949
Other	12	90.28 (16.603)	5.56 (2.988)	11	81.82 (18.936)	-0.31 (3.039)	5.87 (-3.274, 15.020)	0.1943
Hedges' g SMD							0.55 (-0.283, 1.391)	0.1946
Int. p-value								0.3882
Ethnicity								
Hispanic	26	91.67 (14.337)	-3.65 (2.920)	17	89.22 (20.362)	-4.66 (3.668)	1.01 (-8.494, 10.511)	0.8309
Hedges' g SMD							0.07 (-0.545, 0.678)	0.8322
Non-hispanic	683	81.53 (20.973)	-1.96 (0.567)	692	82.95 (19.641)	-1.56 (0.562)	-0.40 (-1.966, 1.167)	0.6169
Hedges' g SMD							-0.03 (-0.133, 0.079)	0.6169
Not known, not recorded or refused	60	78.61 (22.569)	0.31 (2.297)	63	79.63 (25.654)	-2.39 (2.261)	2.70 (-3.692, 9.087)	0.4046
Hedges' g SMD							0.15 (-0.204, 0.504)	0.4064
Int. p-value								0.4295
Jewish descent								

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.4 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Cognitive (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Yes Ashkenazi	33	79.80 (28.185)	-0.25 (3.018)	25	83.33 (18.634)	-9.85 (3.536)	9.60 (0.279, 18.917)	0.0438*
Hedges' g SMD							0.54 (0.012, 1.071)	0.0451*
No	736	81.73 (20.630)	-1.91 (0.553)	745	82.82 (20.305)	-1.52 (0.549)	-0.38 (-1.912, 1.146)	0.6235
Hedges' g SMD							-0.03 (-0.127, 0.076)	0.6235
Int. p-value								0.0339*
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	333	79.93 (23.819)	-1.10 (0.860)	305	81.64 (21.584)	-1.35 (0.896)	0.24 (-2.197, 2.684)	0.8449
Hedges' g SMD							0.02 (-0.140, 0.171)	0.8450
5 or 6	19	83.33 (15.713)	-8.00 (3.867)	7	90.48 (13.113)	-16.84 (6.976)	8.84 (-9.954, 27.633)	0.3020
Hedges' g SMD							0.50 (-0.383, 1.375)	0.2689
Int. p-value								0.9762
Geographic region								
North America	84	80.16 (21.252)	-2.19 (1.866)	90	82.59 (19.974)	-3.54 (1.823)	1.36 (-3.801, 6.512)	0.6045
Hedges' g SMD							0.08 (-0.219, 0.376)	0.6052
South America	13	94.87 (10.507)	-0.62 (2.761)	9	94.44 (11.785)	-8.22 (3.500)	7.60 (-1.749, 16.948)	0.1052
Hedges' g SMD							0.72 (-0.163, 1.600)	0.1102
Europe	393	79.94 (23.355)	-2.06 (0.842)	372	81.72 (22.238)	-1.80 (0.859)	-0.26 (-2.625, 2.102)	0.8280
Hedges' g SMD							-0.02 (-0.157, 0.126)	0.8280
Asia Pacific and South Africa	279	83.87 (17.043)	-1.28 (0.734)	301	83.89 (17.630)	-0.82 (0.710)	-0.46 (-2.461, 1.550)	0.6556
Hedges' g SMD							-0.04 (-0.200, 0.126)	0.6559
Int. p-value								0.5458
Sponsor								
AZ	693	81.79 (20.937)	-1.75 (0.573)	701	82.67 (20.363)	-1.75 (0.569)	0.00 (-1.586, 1.584)	0.9990
Hedges' g SMD							0.00 (-0.105, 0.105)	0.9990
NRG Oncology	76	80.26 (21.553)	-2.20 (1.740)	71	84.27 (18.875)	-1.80 (1.819)	-0.40 (-5.391, 4.599)	0.8758
Hedges' g SMD							-0.03 (-0.349, 0.298)	0.8757

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.4 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Cognitive (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.6739
BRCA mutation type								
BRCA1	491	82.21 (19.903)	-2.27 (0.718)	488	82.24 (20.983)	-1.75 (0.719)	-0.52 (-2.512, 1.479)	0.6116
Hedges' g SMD							-0.03 (-0.158, 0.093)	0.6118
BRCA2	194	76.98 (25.499)	-0.39 (1.072)	186	83.06 (19.334)	-2.71 (1.093)	2.32 (-0.707, 5.344)	0.1327
Hedges' g SMD							0.16 (-0.046, 0.357)	0.1313
Int. p-value								0.1917

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.5 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Emotional (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	76.76 (23.902)	-0.54 (1.411)	134	75.31 (20.346)	1.99 (1.428)	-2.53 (-6.486, 1.422)	0.2084
Hedges' g SMD							-0.15 (-0.391, 0.086)	0.2092
TNBC	630	77.17 (21.809)	0.05 (0.584)	637	78.29 (20.871)	-0.52 (0.579)	0.57 (-1.046, 2.180)	0.4906
Hedges' g SMD							0.04 (-0.071, 0.149)	0.4908
Int. p-value								0.0671
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	386	78.15 (20.469)	0.15 (0.721)	410	78.16 (20.856)	0.55 (0.702)	-0.41 (-2.383, 1.566)	0.6850
Hedges' g SMD							-0.03 (-0.168, 0.110)	0.6852
Neoadjuvant	383	75.83 (24.025)	-0.20 (0.813)	361	77.33 (20.753)	-0.72 (0.832)	0.53 (-1.759, 2.809)	0.6519
Hedges' g SMD							0.03 (-0.111, 0.177)	0.6522
Int. p-value								0.4950
Platinum therapy for current breast cancer (eCRF)								
Yes	196	72.79 (24.146)	0.01 (1.188)	195	77.69 (20.972)	-0.44 (1.190)	0.45 (-2.866, 3.765)	0.7900
Hedges' g SMD							0.03 (-0.171, 0.225)	0.7897
No	573	78.43 (21.504)	-0.01 (0.605)	576	77.80 (20.758)	0.08 (0.603)	-0.10 (-1.775, 1.578)	0.9083
Hedges' g SMD							-0.01 (-0.122, 0.109)	0.9083
Int. p-value								0.9522
Age [years]								
<50	584	77.54 (21.411)	0.10 (0.616)	568	77.56 (20.699)	-0.59 (0.626)	0.69 (-1.031, 2.417)	0.4306
Hedges' g SMD							0.05 (-0.069, 0.162)	0.4309
50-64	161	74.48 (25.578)	-0.34 (1.175)	173	78.56 (20.376)	1.61 (1.120)	-1.95 (-5.148, 1.250)	0.2315
Hedges' g SMD							-0.13 (-0.346, 0.084)	0.2313

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Olaparib OLYMPIA, German benefit assessment Page 2

Table 5.1.1.5 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Emotional (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	80.56 (20.214)	-1.94 (3.758)	30	77.22 (25.327)	0.38 (3.341)	-2.32 (-12.434, 7.797)	0.6473
Hedges' g SMD							-0.12 (-0.662, 0.413)	0.6497
Int. p-value								0.2782
Menopausal status at screening								
Premenopausal	483	78.09 (20.657)	0.33 (0.670)	466	78.10 (20.501)	-0.39 (0.682)	0.71 (-1.163, 2.591)	0.4556
Hedges' g SMD							0.05 (-0.079, 0.176)	0.4559
Postmenopausal	284	74.99 (24.845)	-0.75 (0.924)	301	77.30 (21.203)	0.48 (0.893)	-1.24 (-3.761, 1.290)	0.3371
Hedges' g SMD							-0.08 (-0.242, 0.083)	0.3373
Int. p-value								0.1849
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	62.50 (20.242)	3.08 (5.146)	8	78.47 (10.784)	2.87 (4.363)	0.20 (-15.677, 16.083)	0.9780
Hedges' g SMD							0.02 (-1.043, 1.074)	0.9774
Taxane	36	73.84 (21.926)	-2.07 (2.348)	39	79.06 (22.852)	5.43 (2.304)	-7.50 (-14.086, -0.920)	0.0261*
Hedges' g SMD							-0.52 (-0.982, -0.060)	0.0267*
Anthracycline + Taxane	727	77.27 (22.339)	0.02 (0.559)	723	77.66 (20.783)	-0.35 (0.559)	0.37 (-1.182, 1.921)	0.6405
Hedges' g SMD							0.02 (-0.078, 0.127)	0.6407
Int. p-value								0.0616
Type of breast surgery prior to randomisation								
Breast conservation	188	76.20 (22.827)	0.32 (1.067)	207	78.22 (20.222)	-0.26 (1.023)	0.58 (-2.326, 3.488)	0.6946
Hedges' g SMD							0.04 (-0.158, 0.237)	0.6949
Unilateral mastectomy	295	79.07 (22.238)	0.01 (0.837)	297	77.85 (21.338)	0.43 (0.830)	-0.43 (-2.740, 1.890)	0.7185
Hedges' g SMD							-0.03 (-0.191, 0.132)	0.7187
Bilateral mastectomy	286	75.38 (21.994)	-0.19 (0.942)	265	77.35 (20.663)	-0.07 (0.980)	-0.12 (-2.791, 2.551)	0.9297
Hedges' g SMD							-0.01 (-0.175, 0.160)	0.9298

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Table 5.1.1.5 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Emotional (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.9114
Bilateral Oophorectomy								
Yes	155	75.57 (22.167)	-1.44 (1.211)	146	76.71 (19.301)	0.15 (1.244)	-1.59 (-5.006, 1.830)	0.3613
Hedges' g SMD							-0.11 (-0.331, 0.121)	0.3620
No	614	77.35 (22.371)	0.27 (0.606)	625	78.02 (21.140)	-0.08 (0.599)	0.35 (-1.320, 2.024)	0.6797
Hedges' g SMD							0.02 (-0.088, 0.135)	0.6798
Int. p-value								0.3968
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	80.34 (17.556)	0.72 (1.014)	159	76.14 (22.623)	-0.14 (1.014)	0.86 (-1.967, 3.697)	0.5483
Hedges' g SMD							0.07 (-0.153, 0.289)	0.5475
Negative	167	76.50 (21.671)	-0.51 (1.162)	175	81.78 (18.072)	0.45 (1.130)	-0.96 (-4.166, 2.238)	0.5542
Hedges' g SMD							-0.06 (-0.276, 0.148)	0.5531
Int. p-value								0.5985
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	75.47 (24.995)	0.00 (1.887)	73	78.42 (17.940)	0.55 (2.080)	-0.54 (-6.095, 5.012)	0.8474
Hedges' g SMD							-0.03 (-0.341, 0.280)	0.8478
ER and/or PgR positive with adjuvant chemotherapy	49	79.08 (21.858)	-0.82 (2.170)	61	71.58 (22.483)	3.12 (1.937)	-3.94 (-9.753, 1.874)	0.1819
Hedges' g SMD							-0.26 (-0.636, 0.119)	0.1803
ER and PgR negative with neoadjuvant chemotherapy	293	76.19 (23.433)	-0.39 (0.898)	288	77.05 (21.427)	-1.17 (0.896)	0.78 (-1.707, 3.276)	0.5367
Hedges' g SMD							0.05 (-0.111, 0.214)	0.5371

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.5 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Emotional (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	337	78.02 (20.290)	0.40 (0.764)	349	79.31 (20.376)	0.02 (0.755)	0.38 (-1.730, 2.489)	0.7241
Hedges' g SMD							0.03 (-0.123, 0.177)	0.7242
Int. p-value								0.2097
Race								
White	509	73.59 (24.403)	0.06 (0.741)	482	75.29 (22.012)	-0.13 (0.761)	0.19 (-1.892, 2.276)	0.8565
Hedges' g SMD							0.01 (-0.113, 0.136)	0.8565
Black/African-American	11	NC	NC	21	NC	NC	NC	NC
Asian	237	83.72 (15.500)	-0.42 (0.727)	257	82.49 (17.550)	0.26 (0.701)	-0.68 (-2.663, 1.308)	0.5029
Hedges' g SMD							-0.06 (-0.237, 0.116)	0.5032
Other	12	87.50 (13.056)	5.95 (3.763)	11	71.97 (18.361)	4.09 (3.366)	1.86 (-9.708, 13.432)	0.7325
Hedges' g SMD							0.15 (-0.672, 0.967)	0.7245
Int. p-value								0.6008
Ethnicity								
Hispanic	26	86.54 (17.172)	-1.82 (2.823)	17	82.84 (18.035)	-2.71 (3.463)	0.89 (-8.247, 10.028)	0.8438
Hedges' g SMD							0.06 (-0.551, 0.672)	0.8452
Non-hispanic	683	76.82 (22.422)	-0.04 (0.568)	691	78.27 (20.423)	-0.01 (0.563)	-0.04 (-1.607, 1.530)	0.9613
Hedges' g SMD							0.00 (-0.108, 0.103)	0.9613
Not known, not recorded or refused	60	74.86 (22.523)	0.77 (2.116)	63	70.90 (24.267)	-0.48 (2.103)	1.25 (-4.672, 7.169)	0.6768
Hedges' g SMD							0.07 (-0.279, 0.429)	0.6777
Int. p-value								0.7698
Jewish descent								
Yes Ashkenazi	33	67.42 (29.710)	0.97 (3.367)	25	77.00 (20.023)	-8.68 (3.971)	9.65 (-0.917, 20.217)	0.0724

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[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.5 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Emotional (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hedges' g SMD							0.49 (-0.041, 1.014)	0.0707
No	736	77.42 (21.866)	-0.11 (0.546)	744	77.78 (20.858)	0.19 (0.542)	-0.30 (-1.808, 1.210)	0.6976
Hedges' g SMD							-0.02 (-0.122, 0.082)	0.6977
Int. p-value								0.0466*
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	333	75.85 (24.216)	0.15 (0.882)	304	76.97 (21.286)	-0.94 (0.919)	1.09 (-1.411, 3.592)	0.3922
Hedges' g SMD							0.07 (-0.088, 0.223)	0.3926
5 or 6	19	78.07 (23.605)	-1.93 (2.649)	7	84.52 (5.751)	3.01 (4.225)	-4.94 (-15.459, 5.576)	0.3366
Hedges' g SMD							-0.42 (-1.293, 0.458)	0.3496
Int. p-value								0.1824
Geographic region								
North America	84	74.40 (22.435)	-1.25 (1.640)	90	80.22 (21.142)	-1.33 (1.617)	0.08 (-4.493, 4.646)	0.9737
Hedges' g SMD							0.01 (-0.292, 0.302)	0.9737
South America	13	91.03 (10.465)	0.97 (3.799)	9	82.41 (8.784)	-7.75 (4.746)	8.72 (-4.711, 22.154)	0.1890
Hedges' g SMD							0.60 (-0.269, 1.475)	0.1755
Europe	393	73.51 (24.538)	0.55 (0.852)	371	73.83 (22.328)	0.62 (0.870)	-0.08 (-2.466, 2.314)	0.9501
Hedges' g SMD							0.00 (-0.146, 0.137)	0.9502
Asia Pacific and South Africa	279	82.03 (17.867)	-0.19 (0.744)	301	81.76 (17.978)	-0.13 (0.719)	-0.07 (-2.097, 1.966)	0.9497
Hedges' g SMD							-0.01 (-0.168, 0.158)	0.9497
Int. p-value								0.6536
Sponsor								
AZ	693	77.31 (22.278)	0.05 (0.574)	700	77.48 (20.826)	-0.08 (0.569)	0.13 (-1.458, 1.713)	0.8745
Hedges' g SMD							0.01 (-0.097, 0.113)	0.8745
NRG Oncology	76	74.12 (22.713)	-0.66 (1.583)	71	80.67 (20.442)	0.51 (1.672)	-1.17 (-5.756, 3.416)	0.6144
Hedges' g SMD							-0.08 (-0.407, 0.240)	0.6130
Int. p-value								0.8513

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.5 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Emotional (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
BRCA mutation type								
BRCA1	491	75.42 (22.602)	0.11 (0.698)	487	76.96 (20.527)	-0.21 (0.699)	0.32 (-1.617, 2.260)	0.7449
Hedges' g SMD							0.02 (-0.105, 0.146)	0.7450
BRCA2	194	76.63 (23.833)	0.05 (1.110)	186	77.15 (21.589)	0.09 (1.136)	-0.05 (-3.169, 3.077)	0.9770
Hedges' g SMD							0.00 (-0.204, 0.198)	0.9770
Int. p-value								0.7467

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.6 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Social (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	77.86 (26.361)	4.20 (1.401)	134	80.22 (22.311)	5.09 (1.413)	-0.89 (-4.811, 3.031)	0.6553
Hedges' g SMD							-0.05 (-0.292, 0.184)	0.6557
TNBC	630	78.99 (24.573)	5.45 (0.629)	639	79.08 (24.382)	6.09 (0.624)	-0.64 (-2.380, 1.097)	0.4691
Hedges' g SMD							-0.04 (-0.151, 0.069)	0.4693
Int. p-value								0.9041
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	386	78.71 (24.726)	6.27 (0.732)	410	80.20 (23.142)	6.28 (0.713)	-0.01 (-2.014, 1.999)	0.9942
Hedges' g SMD							0.00 (-0.140, 0.138)	0.9942
Neoadjuvant	383	78.55 (25.446)	4.38 (0.884)	363	78.24 (24.978)	5.58 (0.903)	-1.21 (-3.687, 1.273)	0.3397
Hedges' g SMD							-0.07 (-0.214, 0.074)	0.3401
Int. p-value								0.3968
Platinum therapy for current breast cancer (eCRF)								
Yes	196	74.91 (26.661)	5.18 (1.300)	195	78.80 (26.341)	7.80 (1.301)	-2.61 (-6.237, 1.009)	0.1568
Hedges' g SMD							-0.14 (-0.342, 0.055)	0.1566
No	573	79.90 (24.397)	5.45 (0.634)	578	79.44 (23.215)	5.32 (0.631)	0.13 (-1.624, 1.887)	0.8831
Hedges' g SMD							0.01 (-0.107, 0.124)	0.8831
Int. p-value								0.1450
Age [years]								
<50	584	79.34 (24.173)	5.81 (0.661)	569	78.12 (24.846)	6.43 (0.672)	-0.62 (-2.469, 1.230)	0.5110
Hedges' g SMD							-0.04 (-0.154, 0.077)	0.5111
50-64	161	77.12 (27.184)	2.91 (1.225)	174	82.47 (20.216)	4.52 (1.162)	-1.60 (-4.936, 1.730)	0.3446
Hedges' g SMD							-0.10 (-0.318, 0.111)	0.3435

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.6 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Social (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	71.53 (30.880)	10.50 (3.322)	30	82.78 (27.152)	5.40 (2.902)	5.11 (-3.849, 14.065)	0.2571
Hedges' g SMD							0.31 (-0.227, 0.854)	0.2556
Int. p-value								0.4013
Menopausal status at screening								
Premenopausal	483	80.26 (23.258)	5.02 (0.732)	467	79.19 (23.761)	5.78 (0.744)	-0.76 (-2.805, 1.291)	0.4685
Hedges' g SMD							-0.05 (-0.174, 0.080)	0.4687
Postmenopausal	284	75.70 (27.714)	5.88 (0.932)	302	79.36 (24.545)	6.38 (0.899)	-0.50 (-3.049, 2.043)	0.6979
Hedges' g SMD							-0.03 (-0.194, 0.130)	0.6977
Int. p-value								0.9104
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	69.44 (19.484)	8.21 (5.444)	8	79.17 (23.146)	11.48 (4.664)	-3.27 (-19.316, 12.778)	0.6630
Hedges' g SMD							-0.23 (-1.294, 0.832)	0.6704
Taxane	36	75.46 (28.027)	2.48 (2.422)	39	80.77 (27.450)	11.03 (2.369)	-8.55 (-15.322, -1.768)	0.0142*
Hedges' g SMD							-0.58 (-1.039, -0.114)	0.0146*
Anthracycline + Taxane	727	78.86 (24.963)	5.45 (0.594)	725	79.17 (23.876)	5.64 (0.594)	-0.19 (-1.842, 1.452)	0.8165
Hedges' g SMD							-0.01 (-0.115, 0.091)	0.8166
Int. p-value								0.0700
Type of breast surgery prior to randomisation								
Breast conservation	188	79.43 (24.549)	4.36 (1.108)	207	82.53 (20.297)	4.33 (1.063)	0.03 (-2.993, 3.053)	0.9844
Hedges' g SMD							0.00 (-0.195, 0.199)	0.9844
Unilateral mastectomy	295	79.89 (24.289)	5.01 (0.880)	299	79.65 (24.943)	5.60 (0.868)	-0.59 (-3.016, 1.841)	0.6350
Hedges' g SMD							-0.04 (-0.200, 0.122)	0.6353
Bilateral mastectomy	286	76.81 (26.160)	6.69 (1.031)	265	76.35 (25.428)	7.76 (1.071)	-1.06 (-3.982, 1.857)	0.4750
Hedges' g SMD							-0.06 (-0.228, 0.106)	0.4754

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Table 5.1.1.6 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Social (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.8166
Bilateral Oophorectomy								
Yes	155	75.05 (27.483)	8.10 (1.298)	146	76.83 (25.248)	9.39 (1.335)	-1.29 (-4.953, 2.379)	0.4901
Hedges' g SMD							-0.08 (-0.306, 0.147)	0.4907
No	614	79.53 (24.365)	4.67 (0.640)	627	79.85 (23.717)	5.15 (0.633)	-0.48 (-2.243, 1.289)	0.5960
Hedges' g SMD							-0.03 (-0.141, 0.081)	0.5962
Int. p-value								0.7601
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	78.10 (23.249)	8.29 (1.170)	159	79.14 (23.192)	4.96 (1.168)	3.33 (0.075, 6.583)	0.0450*
Hedges' g SMD							0.23 (0.005, 0.448)	0.0453*
Negative	167	80.44 (24.949)	4.09 (1.066)	175	81.43 (23.493)	7.46 (1.039)	-3.37 (-6.297, -0.437)	0.0244*
Hedges' g SMD							-0.24 (-0.457, -0.031)	0.0246*
Int. p-value								0.0025*
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	78.41 (26.402)	3.48 (1.790)	73	80.82 (21.637)	5.61 (1.981)	-2.13 (-7.411, 3.147)	0.4261
Hedges' g SMD							-0.13 (-0.437, 0.185)	0.4269
ER and/or PgR positive with adjuvant chemotherapy	49	76.87 (26.531)	5.15 (2.312)	61	79.51 (23.253)	4.20 (2.032)	0.95 (-5.161, 7.066)	0.7580
Hedges' g SMD							0.06 (-0.317, 0.435)	0.7583
ER and PgR negative with neoadjuvant chemotherapy	293	79.01 (24.718)	4.31 (1.017)	290	77.59 (25.744)	5.39 (1.012)	-1.09 (-3.907, 1.731)	0.4487
Hedges' g SMD							-0.06 (-0.225, 0.100)	0.4490

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.6 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Social (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	337	78.98 (24.482)	6.40 (0.770)	349	80.32 (23.154)	6.73 (0.760)	-0.33 (-2.451, 1.799)	0.7633
Hedges' g SMD							-0.02 (-0.173, 0.127)	0.7635
Int. p-value								0.6802
Race								
White	509	76.29 (26.827)	6.11 (0.749)	484	78.24 (24.629)	6.68 (0.767)	-0.56 (-2.666, 1.544)	0.6010
Hedges' g SMD							-0.03 (-0.158, 0.091)	0.6011
Black/African-American	11	72.73 (26.112)	10.64 (5.446)	21	76.98 (26.075)	12.01 (3.125)	-1.37 (-14.114, 11.368)	0.8269
Hedges' g SMD							-0.09 (-0.815, 0.644)	0.8186
Asian	237	83.61 (19.646)	3.85 (0.909)	257	81.19 (22.840)	4.39 (0.876)	-0.54 (-3.021, 1.945)	0.6703
Hedges' g SMD							-0.04 (-0.215, 0.138)	0.6704
Other	12	NC	NC	11	NC	NC	NC	NC
Int. p-value								0.7927
Ethnicity								
Hispanic	26	81.41 (22.768)	8.78 (2.788)	17	77.45 (19.491)	7.26 (3.514)	1.52 (-7.581, 10.628)	0.7361
Hedges' g SMD							0.10 (-0.507, 0.716)	0.7380
Non-hispanic	683	78.75 (25.112)	5.14 (0.609)	693	79.56 (23.887)	5.83 (0.603)	-0.69 (-2.372, 0.991)	0.4206
Hedges' g SMD							-0.04 (-0.149, 0.062)	0.4207
Not known, not recorded or refused	60	76.11 (25.741)	6.31 (2.141)	63	76.72 (26.697)	7.18 (2.126)	-0.87 (-6.849, 5.113)	0.7741
Hedges' g SMD							-0.05 (-0.405, 0.302)	0.7750
Int. p-value								0.8651
Jewish descent								
Yes Ashkenazi	33	77.27 (28.204)	6.69 (3.119)	25	80.67 (24.851)	-0.60 (3.678)	7.29 (-2.415, 16.988)	0.1376

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Table 5.1.1.6 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Social (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hedges' g SMD							0.40 (-0.128, 0.922)	0.1386
No	736	78.69 (24.941)	5.29 (0.585)	746	79.18 (24.022)	6.14 (0.579)	-0.84 (-2.458, 0.770)	0.3053
Hedges' g SMD							-0.05 (-0.155, 0.049)	0.3054
Int. p-value								0.1403
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	333	78.98 (25.452)	4.96 (0.941)	306	78.21 (25.161)	5.07 (0.978)	-0.11 (-2.775, 2.553)	0.9348
Hedges' g SMD							-0.01 (-0.162, 0.149)	0.9349
5 or 6	19	80.70 (20.981)	-3.18 (3.778)	7	88.10 (15.853)	-3.53 (6.613)	0.35 (-16.613, 17.312)	0.9643
Hedges' g SMD							0.02 (-0.846, 0.887)	0.9635
Int. p-value								0.4750
Geographic region								
North America	84	79.76 (26.520)	7.09 (1.591)	90	78.15 (24.940)	7.90 (1.570)	-0.81 (-5.219, 3.609)	0.7192
Hedges' g SMD							-0.05 (-0.352, 0.243)	0.7201
South America	13	93.59 (10.841)	6.11 (2.955)	9	81.48 (13.029)	1.35 (3.639)	4.77 (-5.656, 15.188)	0.3466
Hedges' g SMD							0.43 (-0.435, 1.287)	0.3322
Europe	393	74.94 (27.384)	5.93 (0.881)	373	78.02 (25.001)	6.57 (0.896)	-0.64 (-3.107, 1.831)	0.6121
Hedges' g SMD							-0.04 (-0.178, 0.105)	0.6122
Asia Pacific and South Africa	279	82.80 (20.405)	4.50 (0.854)	301	81.12 (22.703)	4.86 (0.826)	-0.36 (-2.696, 1.973)	0.7612
Hedges' g SMD							-0.03 (-0.188, 0.138)	0.7613
Int. p-value								0.8570
Sponsor								
AZ	693	78.57 (24.891)	5.06 (0.612)	702	79.42 (23.939)	5.46 (0.606)	-0.40 (-2.088, 1.292)	0.6441
Hedges' g SMD							-0.02 (-0.130, 0.080)	0.6442
NRG Oncology	76	79.17 (26.822)	8.32 (1.495)	71	77.93 (25.004)	11.40 (1.580)	-3.08 (-7.382, 1.227)	0.1596
Hedges' g SMD							-0.23 (-0.557, 0.092)	0.1604
Int. p-value								0.3843

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.6 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Functional scale: Social (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
BRCA mutation type								
BRCA1	491	77.33 (25.568)	5.91 (0.746)	489	77.57 (25.143)	7.74 (0.746)	-1.83 (-3.902, 0.242)	0.0834
Hedges' g SMD							-0.11 (-0.236, 0.015)	0.0835
BRCA2	194	77.75 (26.589)	6.79 (1.123)	186	81.63 (22.630)	3.34 (1.145)	3.44 (0.285, 6.604)	0.0327*
Hedges' g SMD							0.22 (0.018, 0.422)	0.0326*
Int. p-value								0.0052*

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.7 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Loss of appetite (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	9.49 (19.364)	2.43 (1.092)	134	7.71 (18.241)	-0.99 (1.109)	3.42 (0.353, 6.486)	0.0290*
Hedges' g SMD							0.27 (0.027, 0.505)	0.0292*
TNBC	632	7.86 (17.598)	1.85 (0.505)	638	8.10 (17.883)	-0.53 (0.501)	2.38 (0.988, 3.778)	0.0008*
Hedges' g SMD							0.19 (0.078, 0.298)	0.0008*
Int. p-value								0.5587
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	386	8.12 (17.250)	1.66 (0.609)	408	7.52 (17.428)	-0.82 (0.593)	2.49 (0.819, 4.157)	0.0035*
Hedges' g SMD							0.21 (0.068, 0.347)	0.0035*
Neoadjuvant	385	8.31 (18.793)	2.28 (0.685)	364	8.61 (18.493)	-0.43 (0.700)	2.71 (0.789, 4.637)	0.0058*
Hedges' g SMD							0.20 (0.059, 0.346)	0.0058*
Int. p-value								0.9221
Platinum therapy for current breast cancer (eCRF)								
Yes	198	7.41 (18.430)	1.80 (0.908)	196	8.67 (19.933)	-1.16 (0.912)	2.96 (0.428, 5.491)	0.0221*
Hedges' g SMD							0.23 (0.033, 0.429)	0.0222*
No	573	8.49 (17.892)	2.01 (0.531)	576	7.81 (17.215)	-0.43 (0.528)	2.45 (0.976, 3.914)	0.0011*
Hedges' g SMD							0.19 (0.077, 0.308)	0.0011*
Int. p-value								0.6374
Age [years]								
<50	584	7.42 (17.629)	1.74 (0.516)	568	7.86 (18.273)	-0.34 (0.524)	2.08 (0.637, 3.525)	0.0048*
Hedges' g SMD							0.17 (0.051, 0.282)	0.0048*
50-64	164	9.96 (18.528)	2.18 (0.980)	174	8.24 (16.497)	-0.93 (0.943)	3.12 (0.438, 5.794)	0.0228*
Hedges' g SMD							0.25 (0.035, 0.463)	0.0228*

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.7 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Loss of appetite (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	23	15.94 (22.178)	7.33 (3.502)	30	10.00 (19.865)	-3.87 (3.037)	11.20 (1.808, 20.583)	0.0205*
Hedges' g SMD							0.66 (0.102, 1.219)	0.0205*
Int. p-value								NC
Menopausal status at screening								
Premenopausal	483	7.52 (17.732)	1.86 (0.552)	466	7.01 (17.031)	0.31 (0.562)	1.56 (0.011, 3.104)	0.0483*
Hedges' g SMD							0.13 (0.001, 0.256)	0.0484*
Postmenopausal	286	9.44 (18.529)	2.26 (0.808)	302	9.60 (19.207)	-2.08 (0.781)	4.35 (2.140, 6.556)	0.0001*
Hedges' g SMD							0.32 (0.156, 0.482)	0.0001*
Int. p-value								0.0315*
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	16.67 (18.257)	-3.40 (5.284)	8	0.00 (0.000)	4.46 (4.350)	-7.86 (-24.914, 9.199)	0.3315
Hedges' g SMD							-0.59 (-1.674, 0.504)	0.2924
Taxane	37	10.81 (23.641)	4.33 (1.925)	39	4.27 (17.404)	-5.00 (1.913)	9.33 (3.886, 14.771)	0.0010*
Hedges' g SMD							0.78 (0.313, 1.248)	0.0011*
Anthracycline + Taxane	728	8.01 (17.698)	1.88 (0.471)	724	8.33 (18.039)	-0.52 (0.471)	2.39 (1.086, 3.701)	0.0003*
Hedges' g SMD							0.19 (0.085, 0.291)	0.0003*
Int. p-value								0.1116
Type of breast surgery prior to randomisation								
Breast conservation	190	7.89 (16.506)	2.93 (0.909)	206	9.22 (18.512)	-1.87 (0.877)	4.80 (2.311, 7.279)	0.0002*
Hedges' g SMD							0.38 (0.182, 0.580)	0.0002*
Unilateral mastectomy	294	8.16 (17.239)	2.71 (0.739)	298	6.15 (16.049)	0.77 (0.729)	1.95 (-0.093, 3.989)	0.0613
Hedges' g SMD							0.15 (-0.007, 0.315)	0.0613
Bilateral mastectomy	287	8.48 (19.753)	0.46 (0.764)	266	9.02 (19.045)	-1.18 (0.794)	1.64 (-0.520, 3.809)	0.1361
Hedges' g SMD							0.13 (-0.040, 0.294)	0.1364

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.7 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Loss of appetite (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.1084
Bilateral Oophorectomy								
Yes	156	5.98 (13.906)	1.87 (1.003)	147	9.30 (20.190)	-1.39 (1.030)	3.26 (0.420, 6.097)	0.0246*
Hedges' g SMD							0.26 (0.034, 0.486)	0.0243*
No	615	8.78 (18.897)	1.97 (0.512)	625	7.73 (17.366)	-0.46 (0.507)	2.43 (1.014, 3.839)	0.0008*
Hedges' g SMD							0.19 (0.080, 0.303)	0.0008*
Int. p-value								0.5032
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	5.34 (12.839)	1.66 (0.928)	159	9.43 (19.171)	-0.48 (0.928)	2.14 (-0.456, 4.733)	0.1058
Hedges' g SMD							0.18 (-0.038, 0.405)	0.1047
Negative	167	9.38 (19.321)	1.04 (0.909)	173	5.97 (15.963)	-1.56 (0.890)	2.60 (0.093, 5.116)	0.0421*
Hedges' g SMD							0.22 (0.008, 0.435)	0.0417*
Int. p-value								0.8084
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	7.95 (18.906)	0.76 (1.267)	73	8.22 (19.068)	-1.61 (1.416)	2.37 (-1.391, 6.123)	0.2152
Hedges' g SMD							0.20 (-0.115, 0.508)	0.2157
ER and/or PgR positive with adjuvant chemotherapy	49	12.24 (20.062)	4.51 (1.772)	61	7.10 (17.336)	-0.45 (1.571)	4.97 (0.252, 9.680)	0.0392*
Hedges' g SMD							0.40 (0.020, 0.780)	0.0390*
ER and PgR negative with neoadjuvant chemotherapy	295	8.25 (18.538)	2.73 (0.804)	291	8.71 (18.378)	-0.13 (0.798)	2.86 (0.634, 5.086)	0.0119*
Hedges' g SMD							0.21 (0.046, 0.371)	0.0119*

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.7 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Loss of appetite (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	337	7.52 (16.752)	1.18 (0.637)	347	7.59 (17.468)	-0.88 (0.631)	2.06 (0.299, 3.819)	0.0220*
Hedges' g SMD							0.18 (0.025, 0.326)	0.0220*
Int. p-value								0.5746
Race								
White	511	8.61 (18.897)	1.83 (0.587)	484	8.26 (18.837)	-1.22 (0.603)	3.05 (1.394, 4.697)	0.0003*
Hedges' g SMD							0.23 (0.105, 0.354)	0.0003*
Black/African-American	11	12.12 (22.473)	-3.09 (4.332)	20	18.33 (25.305)	-7.92 (2.495)	4.83 (-5.559, 15.220)	0.3474
Hedges' g SMD							0.38 (-0.362, 1.123)	0.3151
Asian	237	7.31 (15.735)	2.69 (0.763)	257	7.13 (15.483)	0.17 (0.734)	2.52 (0.441, 4.601)	0.0176*
Hedges' g SMD							0.21 (0.037, 0.391)	0.0177*
Other	12	NC	NC	11	NC	NC	NC	NC
Int. p-value								0.7801
Ethnicity								
Hispanic	26	10.26 (26.279)	0.76 (3.694)	17	3.92 (11.070)	5.99 (4.581)	-5.23 (-17.204, 6.753)	0.3829
Hedges' g SMD							-0.27 (-0.886, 0.342)	0.3854
Non-hispanic	684	7.85 (17.353)	2.54 (0.480)	691	7.81 (17.584)	-0.38 (0.476)	2.92 (1.590, 4.244)	<0.0001*
Hedges' g SMD							0.23 (0.126, 0.339)	<0.0001*
Not known, not recorded or refused	61	11.48 (20.981)	-4.69 (1.359)	64	11.46 (22.395)	-5.49 (1.337)	0.81 (-2.967, 4.579)	0.6733
Hedges' g SMD							0.08 (-0.276, 0.426)	0.6747
Int. p-value								0.1395
Jewish descent								
Yes Ashkenazi	33	8.08 (20.464)	-1.79 (1.998)	25	13.33 (25.459)	2.60 (2.485)	-4.39 (-10.873, 2.090)	0.1779

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
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Table 5.1.1.7 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Loss of appetite (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hedges' g SMD							-0.36 (-0.888, 0.160)	0.1732
No	738	8.22 (17.925)	2.10 (0.468)	745	7.87 (17.643)	-0.75 (0.464)	2.84 (1.553, 4.137)	<0.0001*
Hedges' g SMD							0.22 (0.122, 0.326)	<0.0001*
Int. p-value								0.0401*
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	335	8.26 (18.993)	2.00 (0.725)	307	9.12 (18.961)	-0.37 (0.755)	2.36 (0.306, 4.420)	0.0244*
Hedges' g SMD							0.18 (0.023, 0.333)	0.0245*
5 or 6	19	NC	NC	7	NC	NC	NC	NC
Int. p-value								NC
Geographic region								
North America	84	9.92 (18.498)	1.09 (1.524)	90	10.37 (19.764)	-1.28 (1.507)	2.38 (-1.856, 6.612)	0.2690
Hedges' g SMD							0.17 (-0.130, 0.465)	0.2705
South America	13	NC	NC	9	NC	NC	NC	NC
Europe	395	8.61 (19.269)	2.29 (0.658)	372	7.35 (17.642)	-1.25 (0.671)	3.54 (1.695, 5.386)	0.0002*
Hedges' g SMD							0.27 (0.130, 0.414)	0.0002*
Asia Pacific and South Africa	279	7.41 (16.269)	1.97 (0.705)	301	8.19 (17.827)	-0.01 (0.681)	1.98 (0.049, 3.901)	0.0445*
Hedges' g SMD							0.17 (0.004, 0.330)	0.0446*
Int. p-value								0.4142
Sponsor								
AZ	695	8.06 (17.956)	2.02 (0.478)	701	7.85 (17.646)	-0.45 (0.474)	2.47 (1.153, 3.796)	0.0003*
Hedges' g SMD							0.20 (0.091, 0.302)	0.0003*
NRG Oncology	76	9.65 (18.711)	1.48 (1.537)	71	9.86 (20.621)	-2.38 (1.630)	3.87 (-0.567, 8.300)	0.0869
Hedges' g SMD							0.28 (-0.042, 0.609)	0.0873
Int. p-value								0.4881
BRCA mutation type								

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.7 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Loss of appetite (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
BRCA1	493	8.79 (19.229)	2.05 (0.594)	488	8.33 (18.714)	-1.02 (0.594)	3.07 (1.422, 4.719)	0.0003*
Hedges' g SMD							0.23 (0.108, 0.359)	0.0003*
BRCA2	195	8.55 (17.121)	0.80 (0.909)	186	8.96 (18.102)	-0.14 (0.936)	0.93 (-1.633, 3.500)	0.4750
Hedges' g SMD							0.07 (-0.128, 0.274)	0.4754
Int. p-value								0.1542

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.8 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Constipation (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	8.76 (20.320)	5.52 (1.218)	134	7.96 (17.428)	0.01 (1.240)	5.51 (2.090, 8.939)	0.0017*
Hedges' g SMD							0.38 (0.144, 0.625)	0.0017*
TNBC	630	9.89 (19.329)	1.86 (0.583)	638	10.03 (20.384)	0.45 (0.578)	1.41 (-0.199, 3.022)	0.0858
Hedges' g SMD							0.10 (-0.014, 0.207)	0.0859
Int. p-value								0.0314*
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	385	10.65 (20.391)	0.70 (0.688)	410	10.89 (20.992)	-1.43 (0.671)	2.13 (0.243, 4.016)	0.0270*
Hedges' g SMD							0.16 (0.018, 0.296)	0.0271*
Neoadjuvant	384	8.68 (18.499)	4.40 (0.794)	362	8.29 (18.536)	2.49 (0.814)	1.91 (-0.321, 4.143)	0.0932
Hedges' g SMD							0.12 (-0.021, 0.267)	0.0934
Int. p-value								0.9651
Platinum therapy for current breast cancer (eCRF)								
Yes	197	9.14 (18.319)	4.46 (1.106)	195	6.84 (17.553)	1.93 (1.111)	2.53 (-0.555, 5.613)	0.1077
Hedges' g SMD							0.16 (-0.036, 0.361)	0.1079
No	572	9.85 (19.878)	1.89 (0.601)	577	10.63 (20.569)	-0.07 (0.598)	1.96 (0.294, 3.620)	0.0211*
Hedges' g SMD							0.14 (0.020, 0.252)	0.0212*
Int. p-value								0.7198
Age [years]								
<50	584	8.50 (18.052)	2.88 (0.590)	568	8.92 (19.961)	1.06 (0.600)	1.81 (0.162, 3.464)	0.0314*
Hedges' g SMD							0.13 (0.011, 0.243)	0.0315*
50-64	162	11.73 (20.842)	1.89 (1.193)	174	10.54 (18.207)	-1.05 (1.140)	2.94 (-0.310, 6.187)	0.0761
Hedges' g SMD							0.19 (-0.020, 0.409)	0.0762

[a] = number of patients with change from baseline in the MMRM analysis.
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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.8 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Constipation (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	23	24.64 (33.661)	0.36 (3.749)	30	18.89 (25.795)	-4.27 (3.252)	4.63 (-5.400, 14.651)	0.3576
Hedges' g SMD							0.25 (-0.291, 0.800)	0.3599
Int. p-value								0.6787
Menopausal status at screening								
Premenopausal	483	8.07 (17.749)	3.35 (0.632)	466	7.94 (19.342)	0.82 (0.644)	2.53 (0.756, 4.298)	0.0052*
Hedges' g SMD							0.18 (0.054, 0.309)	0.0052*
Postmenopausal	284	12.44 (21.925)	1.16 (0.927)	302	12.36 (20.556)	-0.50 (0.895)	1.67 (-0.865, 4.198)	0.1966
Hedges' g SMD							0.11 (-0.055, 0.269)	0.1969
Int. p-value								0.6327
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	NC	NC	8	NC	NC	NC	NC
Taxane	37	10.81 (19.332)	3.54 (2.359)	39	8.55 (21.245)	-0.52 (2.358)	4.05 (-2.607, 10.716)	0.2288
Hedges' g SMD							0.28 (-0.176, 0.728)	0.2315
Anthracycline + Taxane	726	9.55 (19.512)	2.45 (0.542)	724	9.58 (19.767)	0.60 (0.542)	1.85 (0.348, 3.357)	0.0159*
Hedges' g SMD							0.13 (0.024, 0.230)	0.0159*
Int. p-value								0.5710
Type of breast surgery prior to randomisation								
Breast conservation	188	9.04 (18.750)	3.26 (1.115)	207	10.47 (19.787)	0.66 (1.071)	2.60 (-0.445, 5.636)	0.0941
Hedges' g SMD							0.17 (-0.029, 0.367)	0.0944
Unilateral mastectomy	294	9.86 (19.401)	2.07 (0.731)	298	8.72 (17.683)	0.22 (0.719)	1.85 (-0.170, 3.860)	0.0726
Hedges' g SMD							0.15 (-0.014, 0.309)	0.0727
Bilateral mastectomy	287	9.87 (20.084)	2.24 (0.939)	265	10.06 (22.271)	0.50 (0.979)	1.74 (-0.928, 4.403)	0.2008
Hedges' g SMD							0.11 (-0.058, 0.276)	0.2011
Int. p-value								0.9704

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.8 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Constipation (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Bilateral Oophorectomy								
Yes	156	11.54 (20.268)	1.77 (1.285)	146	12.79 (21.176)	-1.35 (1.328)	3.12 (-0.516, 6.759)	0.0923
Hedges' g SMD							0.19 (-0.032, 0.420)	0.0927
No	613	9.19 (19.264)	2.67 (0.576)	626	8.95 (19.547)	0.79 (0.570)	1.88 (0.292, 3.474)	0.0204*
Hedges' g SMD							0.13 (0.020, 0.243)	0.0204*
Int. p-value								0.4480
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	8.97 (18.295)	0.25 (0.999)	159	11.53 (21.211)	-0.29 (1.000)	0.54 (-2.250, 3.321)	0.7053
Hedges' g SMD							0.04 (-0.178, 0.264)	0.7054
Negative	166	11.65 (20.717)	-0.17 (1.088)	175	10.67 (21.154)	-2.19 (1.057)	2.02 (-0.965, 5.007)	0.1839
Hedges' g SMD							0.14 (-0.069, 0.357)	0.1842
Int. p-value								0.3513
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	8.71 (19.894)	6.78 (1.632)	73	7.31 (15.954)	0.89 (1.830)	5.88 (1.036, 10.729)	0.0177*
Hedges' g SMD							0.38 (0.066, 0.692)	0.0177*
ER and/or PgR positive with adjuvant chemotherapy	49	8.84 (21.274)	4.04 (1.869)	61	8.74 (19.150)	-0.97 (1.660)	5.02 (0.041, 9.989)	0.0482*
Hedges' g SMD							0.38 (0.003, 0.762)	0.0482*
ER and PgR negative with neoadjuvant chemotherapy	294	8.73 (18.146)	3.79 (0.908)	289	8.54 (19.150)	2.88 (0.905)	0.91 (-1.609, 3.428)	0.4784
Hedges' g SMD							0.06 (-0.104, 0.221)	0.4788

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.8 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Constipation (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	336	10.91 (20.279)	0.22 (0.741)	349	11.27 (21.301)	-1.48 (0.732)	1.70 (-0.346, 3.746)	0.1033
Hedges' g SMD							0.12 (-0.025, 0.274)	0.1036
Int. p-value								0.2208
Race								
White	509	10.67 (21.165)	2.11 (0.682)	483	9.11 (19.908)	0.25 (0.701)	1.86 (-0.057, 3.784)	0.0572
Hedges' g SMD							0.12 (-0.004, 0.246)	0.0572
Black/African-American	11	NC	NC	21	NC	NC	NC	NC
Asian	237	8.16 (15.916)	3.35 (0.819)	257	10.38 (19.884)	0.24 (0.790)	3.11 (0.868, 5.344)	0.0066*
Hedges' g SMD							0.25 (0.068, 0.423)	0.0066*
Other	12	2.78 (9.623)	. (.)	11	3.03 (10.050)	. (.)	-7.86 (-27.070, 11.343)	0.4029
Hedges' g SMD							. (. , .)	
Int. p-value								0.3614
Ethnicity								
Hispanic	26	12.82 (25.081)	-3.08 (3.522)	17	17.65 (20.809)	2.19 (4.378)	-5.27 (-16.707, 6.160)	0.3559
Hedges' g SMD							-0.29 (-0.902, 0.327)	0.3590
Non-hispanic	682	9.87 (19.547)	2.55 (0.554)	692	9.59 (19.799)	0.41 (0.549)	2.13 (0.602, 3.662)	0.0063*
Hedges' g SMD							0.15 (0.042, 0.253)	0.0063*
Not known, not recorded or refused	61	6.01 (15.526)	3.98 (1.880)	63	8.47 (20.712)	0.50 (1.875)	3.48 (-1.778, 8.744)	0.1924
Hedges' g SMD							0.23 (-0.119, 0.587)	0.1940
Int. p-value								0.2465
Jewish descent								
Yes Ashkenazi	33	9.09 (15.076)	-0.86 (2.561)	25	9.33 (24.570)	4.56 (3.060)	-5.42 (-13.436, 2.603)	0.1809

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.8 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Constipation (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hedges' g SMD							-0.36 (-0.881, 0.167)	0.1817
No	736	9.69 (19.664)	2.66 (0.539)	745	9.71 (19.773)	0.28 (0.535)	2.38 (0.893, 3.872)	0.0017*
Hedges' g SMD							0.16 (0.061, 0.265)	0.0017*
Int. p-value								0.0274*
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	334	8.58 (18.794)	4.69 (0.840)	305	8.31 (18.835)	2.20 (0.877)	2.49 (0.107, 4.876)	0.0406*
Hedges' g SMD							0.16 (0.007, 0.318)	0.0407*
5 or 6	19	5.26 (12.488)	5.81 (82.279)	7	4.76 (12.599)	-0.80 (244.48)	6.61 (-3282.4,3295.66)	0.9837
Hedges' g SMD							0.01 (-0.852, 0.881)	0.9742
Int. p-value								0.4836
Geographic region								
North America	84	10.32 (17.143)	4.53 (1.753)	90	11.11 (22.347)	0.02 (1.749)	4.51 (-0.383, 9.403)	0.0706
Hedges' g SMD							0.27 (-0.024, 0.574)	0.0715
South America	13	2.56 (9.245)	0.73 (3.908)	9	14.81 (17.568)	2.62 (4.264)	-1.89 (-15.018, 11.232)	0.7628
Hedges' g SMD							-0.13 (-0.985, 0.717)	0.7575
Europe	393	11.20 (22.441)	2.10 (0.801)	372	8.69 (18.126)	0.51 (0.817)	1.59 (-0.658, 3.839)	0.1654
Hedges' g SMD							0.10 (-0.041, 0.242)	0.1653
Asia Pacific and South Africa	279	7.65 (15.398)	2.43 (0.765)	301	10.30 (21.280)	0.44 (0.740)	1.99 (-0.101, 4.087)	0.0621
Hedges' g SMD							0.16 (-0.008, 0.318)	0.0620
Int. p-value								0.5170
Sponsor								
AZ	693	9.62 (19.724)	2.23 (0.548)	701	9.51 (19.556)	0.50 (0.544)	1.73 (0.215, 3.245)	0.0253*
Hedges' g SMD							0.12 (0.015, 0.225)	0.0253*
NRG Oncology	76	10.09 (17.230)	5.17 (1.895)	71	11.27 (23.193)	-0.45 (2.010)	5.62 (0.151, 11.086)	0.0441*
Hedges' g SMD							0.33 (0.008, 0.660)	0.0444*
Int. p-value								0.0603

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.8 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Constipation (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
BRCA mutation type								
BRCA1	491	10.73 (20.601)	1.72 (0.676)	488	10.18 (20.683)	-0.23 (0.677)	1.95 (0.074, 3.830)	0.0416*
Hedges' g SMD							0.13 (0.005, 0.256)	0.0417*
BRCA2	195	8.72 (18.485)	4.56 (1.052)	186	9.32 (18.898)	1.31 (1.082)	3.25 (0.280, 6.219)	0.0321*
Hedges' g SMD							0.22 (0.019, 0.422)	0.0322*
Int. p-value								0.3119

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.9 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Diarrhoea (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	4.62 (14.677)	2.00 (1.018)	134	6.22 (15.386)	1.41 (1.033)	0.59 (-2.264, 3.453)	0.6823
Hedges' g SMD							0.05 (-0.188, 0.288)	0.6827
TNBC	630	6.03 (15.117)	0.65 (0.457)	638	5.96 (15.153)	0.60 (0.453)	0.05 (-1.215, 1.310)	0.9408
Hedges' g SMD							0.00 (-0.106, 0.114)	0.9408
Int. p-value								0.5930
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	386	5.96 (15.068)	-0.16 (0.557)	410	6.18 (15.277)	0.45 (0.542)	-0.61 (-2.133, 0.919)	0.4350
Hedges' g SMD							-0.06 (-0.194, 0.084)	0.4353
Neoadjuvant	383	5.57 (14.995)	2.04 (0.621)	362	5.80 (15.095)	1.08 (0.635)	0.96 (-0.781, 2.708)	0.2786
Hedges' g SMD							0.08 (-0.064, 0.223)	0.2789
Int. p-value								0.1640
Platinum therapy for current breast cancer (eCRF)								
Yes	196	6.80 (16.161)	1.93 (0.918)	195	5.98 (14.891)	0.45 (0.919)	1.48 (-1.073, 4.040)	0.2544
Hedges' g SMD							0.12 (-0.083, 0.314)	0.2547
No	573	5.41 (14.611)	0.49 (0.463)	577	6.01 (15.294)	0.88 (0.461)	-0.38 (-1.662, 0.900)	0.5595
Hedges' g SMD							-0.03 (-0.150, 0.081)	0.5596
Int. p-value								0.1715
Age [years]								
<50	584	6.16 (15.250)	0.50 (0.471)	568	6.16 (15.050)	0.16 (0.478)	0.34 (-0.980, 1.653)	0.6163
Hedges' g SMD							0.03 (-0.086, 0.145)	0.6165
50-64	161	3.93 (13.632)	2.40 (0.889)	174	4.41 (13.872)	2.86 (0.841)	-0.46 (-2.873, 1.944)	0.7045
Hedges' g SMD							-0.04 (-0.256, 0.173)	0.7047

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.9 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Diarrhoea
(mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	8.33 (17.720)	0.16 (3.182)	30	12.22 (22.289)	-0.31 (2.805)	0.47 (-8.065, 9.015)	0.9116
Hedges' g SMD							0.03 (-0.507, 0.567)	0.9121
Int. p-value								0.6762
Menopausal status at screening								
Premenopausal	483	6.49 (15.757)	0.07 (0.513)	466	6.58 (15.752)	-0.48 (0.523)	0.56 (-0.883, 1.994)	0.4487
Hedges' g SMD							0.05 (-0.078, 0.176)	0.4489
Postmenopausal	284	4.58 (13.677)	2.25 (0.709)	302	5.08 (14.248)	2.71 (0.683)	-0.46 (-2.399, 1.470)	0.6373
Hedges' g SMD							-0.04 (-0.201, 0.123)	0.6375
Int. p-value								0.2712
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	5.56 (13.608)	0.96 (4.239)	8	4.17 (11.785)	4.25 (3.640)	-3.30 (-15.974, 9.380)	0.5733
Hedges' g SMD							-0.30 (-1.365, 0.768)	0.5830
Taxane	36	10.19 (17.493)	5.13 (2.072)	39	2.56 (8.998)	-0.97 (2.028)	6.11 (0.221, 11.990)	0.0422*
Hedges' g SMD							0.48 (0.022, 0.941)	0.0402*
Anthracycline + Taxane	727	5.55 (14.890)	0.73 (0.427)	724	6.17 (15.444)	0.80 (0.427)	-0.07 (-1.255, 1.115)	0.9082
Hedges' g SMD							-0.01 (-0.109, 0.097)	0.9083
Int. p-value								0.2765
Type of breast surgery prior to randomisation								
Breast conservation	188	6.03 (15.769)	2.11 (0.881)	207	5.15 (14.881)	2.10 (0.845)	0.01 (-2.390, 2.414)	0.9921
Hedges' g SMD							0.00 (-0.196, 0.198)	0.9921
Unilateral mastectomy	295	5.42 (14.044)	0.46 (0.641)	298	6.38 (15.485)	0.01 (0.631)	0.46 (-1.311, 2.224)	0.6121
Hedges' g SMD							0.04 (-0.119, 0.203)	0.6123
Bilateral mastectomy	286	5.94 (15.535)	0.65 (0.700)	265	5.79 (13.916)	0.91 (0.730)	-0.26 (-2.246, 1.729)	0.7984
Hedges' g SMD							-0.02 (-0.189, 0.145)	0.7985

[a] = number of patients with change from baseline in the MMRM analysis.
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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.9 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Diarrhoea
(mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.8989
Bilateral Oophorectomy								
Yes	155	3.66 (12.349)	2.51 (0.968)	146	5.48 (13.577)	3.52 (0.993)	-1.01 (-3.746, 1.724)	0.4675
Hedges' g SMD							-0.08 (-0.310, 0.142)	0.4673
No	614	6.30 (15.590)	0.52 (0.460)	626	6.12 (15.542)	0.06 (0.455)	0.46 (-0.807, 1.734)	0.4743
Hedges' g SMD							0.04 (-0.071, 0.152)	0.4744
Int. p-value								0.1579
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	4.91 (12.446)	-0.64 (0.803)	159	7.34 (16.195)	0.39 (0.801)	-1.04 (-3.273, 1.201)	0.3626
Hedges' g SMD							-0.10 (-0.324, 0.118)	0.3626
Negative	167	6.59 (16.049)	-0.51 (0.749)	175	5.14 (14.480)	-0.78 (0.729)	0.26 (-1.793, 2.323)	0.8002
Hedges' g SMD							0.03 (-0.185, 0.239)	0.8003
Int. p-value								0.4516
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	3.03 (10.882)	2.82 (1.121)	73	5.48 (14.713)	1.50 (1.253)	1.32 (-2.015, 4.648)	0.4359
Hedges' g SMD							0.12 (-0.187, 0.434)	0.4355
ER and/or PgR positive with adjuvant chemotherapy	49	7.48 (19.562)	1.08 (1.973)	61	7.10 (16.233)	0.84 (1.751)	0.24 (-5.002, 5.474)	0.9288
Hedges' g SMD							0.02 (-0.359, 0.393)	0.9290
ER and PgR negative with neoadjuvant chemotherapy	293	6.37 (16.002)	1.88 (0.736)	289	5.88 (15.215)	0.92 (0.731)	0.96 (-1.079, 2.996)	0.3558
Hedges' g SMD							0.08 (-0.086, 0.239)	0.3562

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.9 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Diarrhoea (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	337	5.74 (14.321)	-0.33 (0.569)	349	6.02 (15.123)	0.33 (0.562)	-0.66 (-2.233, 0.907)	0.4074
Hedges' g SMD							-0.06 (-0.213, 0.086)	0.4078
Int. p-value								0.5200
Race								
White	509	6.09 (16.201)	0.88 (0.558)	483	6.28 (15.913)	0.91 (0.571)	-0.03 (-1.594, 1.538)	0.9721
Hedges' g SMD							0.00 (-0.127, 0.122)	0.9721
Black/African-American	11	NC	NC	21	NC	NC	NC	NC
Asian	237	5.34 (12.635)	0.88 (0.638)	257	5.71 (14.201)	0.51 (0.615)	0.37 (-1.374, 2.107)	0.6789
Hedges' g SMD							0.04 (-0.139, 0.214)	0.6792
Other	12	2.78 (9.623)	. (.)	11	6.06 (13.484)	. (.)	4.81 (-1.126, 10.737)	0.1067
Hedges' g SMD							. (. , .)	
Int. p-value								NC
Ethnicity								
Hispanic	26	2.56 (9.058)	1.60 (2.186)	17	3.92 (11.070)	0.84 (2.761)	0.76 (-6.394, 7.907)	0.8315
Hedges' g SMD							0.07 (-0.545, 0.678)	0.8323
Non-hispanic	683	6.00 (15.148)	0.89 (0.438)	692	5.83 (15.102)	0.63 (0.434)	0.26 (-0.949, 1.473)	0.6713
Hedges' g SMD							0.02 (-0.083, 0.129)	0.6714
Not known, not recorded or refused	60	4.44 (15.607)	0.38 (1.682)	63	8.47 (16.900)	1.84 (1.659)	-1.46 (-6.153, 3.238)	0.5398
Hedges' g SMD							-0.11 (-0.464, 0.243)	0.5402
Int. p-value								0.6940
Jewish descent								
Yes Ashkenazi	33	6.06 (19.462)	-0.92 (3.431)	25	6.67 (21.517)	8.25 (4.001)	-9.17 (-19.815, 1.466)	0.0892

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
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Table 5.1.1.9 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Diarrhoea (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hedges' g SMD							-0.46 (-0.983, 0.070)	0.0895
No	736	5.75 (14.810)	0.96 (0.418)	745	6.00 (14.962)	0.60 (0.414)	0.36 (-0.797, 1.512)	0.5433
Hedges' g SMD							0.03 (-0.070, 0.133)	0.5434
Int. p-value								0.0425*
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	333	6.01 (15.651)	2.16 (0.687)	305	6.12 (15.498)	1.01 (0.716)	1.15 (-0.800, 3.100)	0.2472
Hedges' g SMD							0.09 (-0.064, 0.247)	0.2475
5 or 6	19	NC	NC	7	NC	NC	NC	NC
Int. p-value								NC
Geographic region								
North America	84	4.76 (14.765)	1.98 (1.359)	90	5.19 (13.136)	2.87 (1.350)	-0.88 (-4.676, 2.912)	0.6461
Hedges' g SMD							-0.07 (-0.367, 0.228)	0.6471
South America	13	NC	NC	9	NC	NC	NC	NC
Europe	393	5.94 (15.570)	1.59 (0.638)	372	6.00 (15.375)	0.96 (0.648)	0.62 (-1.160, 2.409)	0.4922
Hedges' g SMD							0.05 (-0.092, 0.191)	0.4926
Asia Pacific and South Africa	279	5.97 (14.560)	-0.11 (0.596)	301	6.20 (15.585)	0.00 (0.576)	-0.11 (-1.740, 1.516)	0.8925
Hedges' g SMD							-0.01 (-0.174, 0.152)	0.8926
Int. p-value								0.6554
Sponsor								
AZ	693	5.82 (14.986)	0.80 (0.436)	701	6.09 (15.360)	0.65 (0.432)	0.15 (-1.059, 1.349)	0.8130
Hedges' g SMD							0.01 (-0.092, 0.118)	0.8131
NRG Oncology	76	5.26 (15.447)	1.80 (1.382)	71	5.16 (13.390)	1.21 (1.475)	0.59 (-3.419, 4.598)	0.7709
Hedges' g SMD							0.05 (-0.276, 0.372)	0.7713
Int. p-value								0.8303
BRCA mutation type								

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Olaparib OLYMPIA, German benefit assessment Page 6

Table 5.1.1.9 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Diarrhoea
(mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
BRCA1	491	6.25 (15.559)	0.77 (0.542)	488	6.90 (16.134)	0.22 (0.542)	0.56 (-0.948, 2.061)	0.4681
Hedges' g SMD							0.05 (-0.079, 0.172)	0.4683
BRCA2	194	5.33 (14.800)	1.65 (0.897)	186	5.38 (13.680)	2.06 (0.917)	-0.41 (-2.929, 2.117)	0.7518
Hedges' g SMD							-0.03 (-0.234, 0.169)	0.7521
Int. p-value								0.4944

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Olaparib OLYMPIA, German benefit assessment Page 1

Table 5.1.1.10 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Dyspnoea
(mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	12.17 (20.161)	2.66 (1.129)	134	10.95 (19.075)	0.69 (1.147)	1.97 (-1.202, 5.145)	0.2223
Hedges' g SMD							0.15 (-0.090, 0.387)	0.2227
TNBC	630	13.76 (21.867)	0.24 (0.582)	636	12.53 (20.543)	-1.04 (0.578)	1.27 (-0.339, 2.882)	0.1216
Hedges' g SMD							0.09 (-0.023, 0.197)	0.1216
Int. p-value								0.6692
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	385	12.99 (20.663)	0.00 (0.716)	408	10.87 (18.521)	-0.08 (0.697)	0.08 (-1.888, 2.040)	0.9395
Hedges' g SMD							0.01 (-0.134, 0.145)	0.9395
Neoadjuvant	384	13.98 (22.435)	1.32 (0.749)	362	13.81 (22.041)	-1.58 (0.768)	2.90 (0.790, 5.001)	0.0071*
Hedges' g SMD							0.20 (0.054, 0.341)	0.0071*
Int. p-value								0.0588
Platinum therapy for current breast cancer (eCRF)								
Yes	198	13.64 (22.762)	0.29 (1.081)	194	12.54 (20.575)	-1.44 (1.089)	1.73 (-1.287, 4.748)	0.2602
Hedges' g SMD							0.11 (-0.084, 0.312)	0.2607
No	571	13.43 (21.144)	0.76 (0.590)	576	12.15 (20.213)	-0.53 (0.587)	1.29 (-0.345, 2.922)	0.1218
Hedges' g SMD							0.09 (-0.024, 0.207)	0.1219
Int. p-value								0.7444
Age [years]								
<50	582	12.49 (20.897)	0.06 (0.566)	566	11.84 (20.206)	-1.22 (0.575)	1.29 (-0.296, 2.870)	0.1109
Hedges' g SMD							0.09 (-0.022, 0.210)	0.1111
50-64	164	16.87 (23.497)	1.68 (1.193)	174	12.45 (19.748)	0.60 (1.144)	1.09 (-2.175, 4.346)	0.5129
Hedges' g SMD							0.07 (-0.142, 0.285)	0.5122

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Table 5.1.1.10 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Dyspnoea
(mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	23	14.49 (22.079)	8.99 (4.010)	30	18.89 (24.264)	-0.55 (3.449)	9.53 (-1.165, 20.231)	0.0793
Hedges' g SMD							0.49 (-0.059, 1.045)	0.0798
Int. p-value								0.1404
Menopausal status at screening								
Premenopausal	482	12.79 (21.169)	-0.31 (0.618)	463	11.81 (20.451)	-1.30 (0.631)	0.99 (-0.741, 2.725)	0.2616
Hedges' g SMD							0.07 (-0.055, 0.201)	0.2617
Postmenopausal	285	14.74 (22.229)	2.38 (0.910)	303	12.87 (20.101)	0.05 (0.877)	2.32 (-0.161, 4.806)	0.0668
Hedges' g SMD							0.15 (-0.011, 0.313)	0.0669
Int. p-value								0.2865
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	NC	NC	8	NC	NC	NC	NC
Taxane	37	13.51 (26.597)	6.42 (3.035)	39	11.11 (22.076)	-3.47 (2.999)	9.89 (1.372, 18.400)	0.0235*
Hedges' g SMD							0.53 (0.068, 0.984)	0.0243*
Anthracycline + Taxane	726	13.45 (21.326)	0.38 (0.526)	722	12.37 (20.266)	-0.58 (0.526)	0.96 (-0.499, 2.418)	0.1972
Hedges' g SMD							0.07 (-0.035, 0.171)	0.1972
Int. p-value								0.0089*
Type of breast surgery prior to randomisation								
Breast conservation	189	12.17 (19.420)	3.74 (1.077)	207	12.56 (20.591)	0.60 (1.035)	3.14 (0.205, 6.079)	0.0361*
Hedges' g SMD							0.21 (0.013, 0.409)	0.0363*
Unilateral mastectomy	294	15.19 (22.953)	-0.74 (0.826)	297	11.45 (19.079)	-0.22 (0.816)	-0.52 (-2.807, 1.764)	0.6541
Hedges' g SMD							-0.04 (-0.198, 0.124)	0.6538
Bilateral mastectomy	286	12.59 (21.377)	-0.13 (0.826)	264	12.88 (21.419)	-2.57 (0.861)	2.44 (0.097, 4.787)	0.0413*
Hedges' g SMD							0.17 (0.007, 0.342)	0.0414*
Int. p-value								0.0998

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Table 5.1.1.10 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Dyspnoea
(mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Bilateral Oophorectomy								
Yes	156	12.39 (20.467)	1.49 (1.134)	147	11.11 (18.437)	-1.48 (1.167)	2.97 (-0.234, 6.174)	0.0691
Hedges' g SMD							0.21 (-0.017, 0.435)	0.0695
No	613	13.76 (21.834)	0.47 (0.583)	623	12.52 (20.710)	-0.54 (0.578)	1.01 (-0.601, 2.622)	0.2189
Hedges' g SMD							0.07 (-0.042, 0.181)	0.2189
Int. p-value								0.2711
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	155	10.75 (18.585)	-0.69 (1.143)	158	11.39 (19.099)	2.38 (1.139)	-3.07 (-6.244, 0.108)	0.0583
Hedges' g SMD							-0.21 (-0.437, 0.008)	0.0586
Negative	167	14.17 (22.077)	0.07 (1.026)	174	11.30 (18.794)	-2.58 (1.002)	2.65 (-0.175, 5.477)	0.0659
Hedges' g SMD							0.20 (-0.013, 0.413)	0.0659
Int. p-value								0.0117*
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	11.74 (20.241)	1.91 (1.300)	73	12.33 (20.418)	-0.61 (1.463)	2.51 (-1.359, 6.383)	0.2017
Hedges' g SMD							0.20 (-0.108, 0.514)	0.2016
ER and/or PgR positive with adjuvant chemotherapy	49	12.93 (20.203)	3.98 (2.091)	61	9.29 (17.354)	2.22 (1.849)	1.76 (-3.788, 7.306)	0.5305
Hedges' g SMD							0.12 (-0.256, 0.497)	0.5311
ER and PgR negative with neoadjuvant chemotherapy	294	14.63 (23.074)	1.21 (0.896)	289	14.19 (22.451)	-1.84 (0.894)	3.05 (0.566, 5.540)	0.0162*
Hedges' g SMD							0.20 (0.037, 0.362)	0.0163*

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[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.10 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Dyspnoea (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	336	13.00 (20.759)	-0.59 (0.762)	347	11.14 (18.728)	-0.46 (0.752)	-0.13 (-2.233, 1.975)	0.9041
Hedges' g SMD							-0.01 (-0.159, 0.141)	0.9041
Int. p-value								0.2423
Race								
White	509	14.15 (22.832)	0.81 (0.678)	481	13.03 (21.545)	-0.84 (0.697)	1.65 (-0.257, 3.562)	0.0897
Hedges' g SMD							0.11 (-0.017, 0.233)	0.0898
Black/African-American	11	NC	NC	21	NC	NC	NC	NC
Asian	237	11.81 (18.441)	0.76 (0.817)	257	10.77 (17.702)	-0.72 (0.786)	1.48 (-0.750, 3.707)	0.1930
Hedges' g SMD							0.12 (-0.059, 0.294)	0.1933
Other	12	NC	NC	11	NC	NC	NC	NC
Int. p-value								0.9012
Ethnicity								
Hispanic	26	5.13 (12.265)	0.57 (2.735)	17	11.76 (28.726)	-4.04 (3.424)	4.60 (-4.284, 13.494)	0.3021
Hedges' g SMD							0.32 (-0.293, 0.938)	0.3043
Non-hispanic	682	13.69 (21.641)	0.84 (0.545)	690	11.74 (19.318)	-0.25 (0.541)	1.10 (-0.408, 2.607)	0.1526
Hedges' g SMD							0.08 (-0.029, 0.183)	0.1525
Not known, not recorded or refused	61	14.75 (23.194)	-1.62 (2.002)	63	17.99 (26.657)	-5.66 (1.974)	4.04 (-1.538, 9.608)	0.1542
Hedges' g SMD							0.26 (-0.097, 0.610)	0.1556
Int. p-value								0.4472
Jewish descent								
Yes Ashkenazi	33	5.05 (14.722)	2.07 (2.258)	25	5.33 (15.753)	6.55 (2.686)	-4.48 (-11.559, 2.591)	0.2079
Hedges' g SMD							-0.34 (-0.859, 0.188)	0.2086

[a] = number of patients with change from baseline in the MMRM analysis.
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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.10 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Dyspnoea (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
No	736	13.86 (21.745)	0.63 (0.531)	743	12.52 (20.412)	-0.95 (0.528)	1.58 (0.110, 3.049)	0.0351*
Hedges' g SMD							0.11 (0.008, 0.212)	0.0351*
Int. p-value								0.2299
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	334	14.17 (22.493)	1.30 (0.782)	305	13.66 (22.112)	-1.28 (0.816)	2.58 (0.365, 4.803)	0.0225*
Hedges' g SMD							0.18 (0.025, 0.336)	0.0226*
5 or 6	19	NC	NC	7	NC	NC	NC	NC
Int. p-value								NC
Geographic region								
North America	83	10.44 (18.717)	0.79 (1.467)	90	9.63 (17.485)	-1.20 (1.462)	2.00 (-2.092, 6.087)	0.3362
Hedges' g SMD							0.15 (-0.153, 0.445)	0.3383
South America	13	NC	NC	9	NC	NC	NC	NC
Europe	394	16.67 (24.279)	0.13 (0.816)	370	15.23 (23.008)	-1.72 (0.835)	1.85 (-0.439, 4.146)	0.1128
Hedges' g SMD							0.11 (-0.027, 0.257)	0.1130
Asia Pacific and South Africa	279	10.51 (17.684)	1.07 (0.737)	301	9.63 (16.981)	0.38 (0.712)	0.68 (-1.329, 2.698)	0.5046
Hedges' g SMD							0.06 (-0.107, 0.218)	0.5049
Int. p-value								0.6820
Sponsor								
AZ	694	13.78 (21.797)	0.71 (0.550)	699	12.54 (20.733)	-0.60 (0.546)	1.31 (-0.214, 2.827)	0.0920
Hedges' g SMD							0.09 (-0.015, 0.195)	0.0921
NRG Oncology	75	10.67 (19.109)	0.29 (1.484)	71	9.39 (15.101)	-1.87 (1.585)	2.15 (-2.144, 6.448)	0.3237
Hedges' g SMD							0.16 (-0.162, 0.489)	0.3245
Int. p-value								0.5901
BRCA mutation type								
BRCA1	491	13.65 (21.755)	0.07 (0.656)	486	13.51 (21.360)	-1.85 (0.659)	1.92 (0.090, 3.741)	0.0397*

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.10 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Dyspnoea (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hedges' g SMD							0.13 (0.006, 0.257)	0.0398*
BRCA2	194	15.81 (23.309)	0.49 (1.033)	186	11.29 (19.859)	-0.68 (1.057)	1.16 (-1.751, 4.079)	0.4327
Hedges' g SMD							0.08 (-0.121, 0.282)	0.4319
Int. p-value								0.7784

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.11 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Fatigue (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	29.12 (22.632)	2.91 (1.345)	134	26.29 (20.280)	-1.22 (1.363)	4.13 (0.356, 7.908)	0.0321*
Hedges' g SMD							0.26 (0.022, 0.501)	0.0322*
TNBC	633	29.28 (22.654)	-0.52 (0.626)	640	29.69 (21.541)	-1.99 (0.622)	1.46 (-0.267, 3.196)	0.0973
Hedges' g SMD							0.09 (-0.017, 0.203)	0.0975
Int. p-value								0.2399
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	387	27.98 (21.530)	-0.36 (0.778)	410	27.07 (20.680)	-1.61 (0.758)	1.25 (-0.882, 3.383)	0.2500
Hedges' g SMD							0.08 (-0.057, 0.220)	0.2503
Neoadjuvant	385	30.63 (23.642)	0.52 (0.827)	364	31.38 (21.893)	-2.25 (0.847)	2.77 (0.441, 5.090)	0.0198*
Hedges' g SMD							0.17 (0.027, 0.314)	0.0199*
Int. p-value								0.4665
Platinum therapy for current breast cancer (eCRF)								
Yes	198	32.10 (23.881)	-0.25 (1.231)	196	28.94 (22.415)	-1.94 (1.236)	1.69 (-1.749, 5.120)	0.3351
Hedges' g SMD							0.10 (-0.100, 0.295)	0.3352
No	574	28.34 (22.125)	0.19 (0.636)	578	29.15 (21.002)	-1.87 (0.634)	2.05 (0.289, 3.814)	0.0226*
Hedges' g SMD							0.13 (0.019, 0.250)	0.0226*
Int. p-value								0.9916
Age [years]								
<50	584	29.01 (21.996)	-0.21 (0.657)	569	29.59 (21.916)	-2.47 (0.667)	2.26 (0.419, 4.093)	0.0161*
Hedges' g SMD							0.14 (0.026, 0.257)	0.0162*
50-64	164	29.81 (24.738)	0.24 (1.202)	175	28.35 (19.264)	-0.51 (1.152)	0.75 (-2.523, 4.029)	0.6515
Hedges' g SMD							0.05 (-0.164, 0.262)	0.6519

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.11 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Fatigue (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	32.87 (23.508)	6.52 (3.252)	30	24.07 (22.046)	0.88 (2.863)	5.64 (-3.140, 14.424)	0.2028
Hedges' g SMD							0.35 (-0.189, 0.893)	0.2022
Int. p-value								0.4208
Menopausal status at screening								
Premenopausal	483	28.32 (22.255)	-0.41 (0.727)	467	28.97 (21.110)	-2.03 (0.740)	1.62 (-0.417, 3.653)	0.1190
Hedges' g SMD							0.10 (-0.026, 0.228)	0.1192
Postmenopausal	287	31.13 (23.175)	1.03 (0.907)	303	29.35 (21.808)	-1.64 (0.879)	2.67 (0.190, 5.153)	0.0349*
Hedges' g SMD							0.17 (0.012, 0.336)	0.0350*
Int. p-value								0.5565
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	35.19 (16.355)	0.55 (5.572)	8	25.00 (11.501)	-1.66 (4.586)	2.21 (-14.675, 19.097)	0.7746
Hedges' g SMD							0.16 (-0.905, 1.217)	0.7730
Taxane	37	33.48 (25.609)	3.33 (2.748)	39	22.51 (24.514)	-7.81 (2.688)	11.14 (3.361, 18.918)	0.0056*
Hedges' g SMD							0.66 (0.196, 1.121)	0.0053*
Anthracycline + Taxane	729	29.04 (22.516)	-0.01 (0.583)	726	29.52 (21.219)	-1.63 (0.583)	1.62 (0.005, 3.242)	0.0493*
Hedges' g SMD							0.10 (0.000, 0.206)	0.0493*
Int. p-value								0.0647
Type of breast surgery prior to randomisation								
Breast conservation	190	28.68 (22.615)	2.46 (1.091)	207	28.50 (21.213)	-0.22 (1.053)	2.68 (-0.305, 5.659)	0.0783
Hedges' g SMD							0.18 (-0.020, 0.374)	0.0788
Unilateral mastectomy	295	27.76 (21.839)	-0.54 (0.905)	299	27.78 (19.464)	-1.77 (0.894)	1.22 (-1.276, 3.720)	0.3371
Hedges' g SMD							0.08 (-0.082, 0.240)	0.3375
Bilateral mastectomy	287	31.30 (23.365)	-0.93 (0.968)	266	30.72 (23.011)	-3.50 (1.007)	2.57 (-0.175, 5.313)	0.0664
Hedges' g SMD							0.16 (-0.011, 0.323)	0.0666

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
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Table 5.1.1.11 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Fatigue (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.7207
Bilateral Oophorectomy								
Yes	156	30.38 (21.901)	-0.12 (1.225)	147	29.52 (21.505)	-3.40 (1.259)	3.28 (-0.176, 6.738)	0.0628
Hedges' g SMD							0.21 (-0.012, 0.440)	0.0632
No	616	29.03 (22.823)	0.17 (0.639)	627	29.00 (21.334)	-1.54 (0.633)	1.71 (-0.057, 3.473)	0.0579
Hedges' g SMD							0.11 (-0.004, 0.219)	0.0580
Int. p-value								0.5285
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	25.28 (20.413)	-0.80 (1.273)	159	29.28 (22.096)	-0.61 (1.272)	-0.18 (-3.729, 3.367)	0.9201
Hedges' g SMD							-0.01 (-0.232, 0.210)	0.9200
Negative	168	30.06 (23.034)	-1.00 (1.086)	175	26.48 (19.526)	-3.79 (1.061)	2.79 (-0.207, 5.777)	0.0679
Hedges' g SMD							0.20 (-0.014, 0.410)	0.0678
Int. p-value								0.2390
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	29.92 (24.780)	2.55 (1.636)	73	27.85 (19.783)	-3.72 (1.826)	6.27 (1.421, 11.113)	0.0116*
Hedges' g SMD							0.40 (0.090, 0.717)	0.0116*
ER and/or PgR positive with adjuvant chemotherapy	49	27.66 (18.303)	3.08 (2.337)	61	24.41 (20.868)	1.86 (2.068)	1.22 (-4.982, 7.420)	0.6974
Hedges' g SMD							0.07 (-0.302, 0.451)	0.6977
ER and PgR negative with neoadjuvant chemotherapy	295	30.72 (23.354)	-0.11 (0.961)	291	32.26 (22.335)	-1.83 (0.958)	1.72 (-0.947, 4.385)	0.2059
Hedges' g SMD							0.10 (-0.058, 0.267)	0.2061

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Table 5.1.1.11 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Fatigue (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	338	28.02 (21.983)	-0.89 (0.822)	349	27.54 (20.642)	-2.18 (0.813)	1.30 (-0.970, 3.569)	0.2612
Hedges' g SMD							0.09 (-0.064, 0.235)	0.2615
Int. p-value								0.3885
Race								
White	512	30.86 (23.965)	0.19 (0.746)	485	30.29 (22.558)	-1.30 (0.767)	1.49 (-0.612, 3.587)	0.1648
Hedges' g SMD							0.09 (-0.036, 0.212)	0.1650
Black/African-American	11	42.42 (32.515)	-10.42 (7.637)	21	28.57 (23.719)	-9.71 (4.133)	-0.71 (-17.961, 16.535)	0.9331
Hedges' g SMD							-0.03 (-0.762, 0.697)	0.9301
Asian	237	25.64 (18.504)	0.49 (0.870)	257	26.98 (18.826)	-2.72 (0.837)	3.21 (0.836, 5.582)	0.0081*
Hedges' g SMD							0.24 (0.062, 0.416)	0.0082*
Other	12	23.15 (17.381)	-5.24 (5.409)	11	27.27 (15.205)	-0.29 (4.376)	-4.94 (-20.570, 10.687)	0.5046
Hedges' g SMD							-0.28 (-1.106, 0.541)	0.5011
Int. p-value								0.6061
Ethnicity								
Hispanic	26	16.24 (19.684)	2.93 (3.301)	17	26.80 (19.269)	0.48 (4.267)	2.45 (-8.691, 13.595)	0.6583
Hedges' g SMD							0.14 (-0.472, 0.753)	0.6528
Non-hispanic	685	29.33 (22.338)	0.31 (0.596)	693	28.52 (20.640)	-1.77 (0.591)	2.08 (0.438, 3.731)	0.0131*
Hedges' g SMD							0.13 (0.028, 0.239)	0.0132*
Not known, not recorded or refused	61	34.52 (25.115)	-3.13 (2.277)	64	36.02 (27.698)	-4.24 (2.253)	1.11 (-5.239, 7.458)	0.7297
Hedges' g SMD							0.06 (-0.289, 0.412)	0.7308
Int. p-value								0.9839
Jewish descent								

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.11 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Fatigue (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Yes Ashkenazi	33	30.30 (22.096)	-2.57 (3.189)	25	31.56 (24.360)	6.55 (3.814)	-9.12 (-19.108, 0.875)	0.0727
Hedges' g SMD							-0.48 (-1.010, 0.045)	0.0731
No	739	29.26 (22.670)	0.21 (0.576)	747	29.03 (21.285)	-2.05 (0.572)	2.26 (0.672, 3.854)	0.0053*
Hedges' g SMD							0.14 (0.043, 0.246)	0.0054*
Int. p-value								0.0601
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	335	30.36 (23.931)	0.57 (0.880)	307	31.63 (22.079)	-2.04 (0.917)	2.61 (0.116, 5.110)	0.0403*
Hedges' g SMD							0.16 (0.007, 0.317)	0.0404*
5 or 6	19	30.99 (22.092)	-0.71 (3.624)	7	25.40 (23.757)	11.65 (6.510)	-12.36 (-28.555, 3.833)	0.1250
Hedges' g SMD							-0.74 (-1.634, 0.153)	0.1044
Int. p-value								0.4203
Geographic region								
North America	84	31.08 (20.609)	-2.77 (1.758)	90	28.27 (21.663)	-4.40 (1.737)	1.63 (-3.261, 6.514)	0.5119
Hedges' g SMD							0.10 (-0.198, 0.397)	0.5128
South America	13	8.55 (12.133)	-0.15 (3.440)	9	19.75 (19.859)	9.37 (4.572)	-9.52 (-22.161, 3.114)	0.1299
Hedges' g SMD							-0.71 (-1.588, 0.173)	0.1152
Europe	396	32.01 (25.039)	0.02 (0.864)	374	30.90 (23.045)	-1.75 (0.882)	1.77 (-0.653, 4.194)	0.1519
Hedges' g SMD							0.10 (-0.038, 0.245)	0.1523
Asia Pacific and South Africa	279	25.89 (18.797)	0.95 (0.840)	301	27.39 (18.844)	-1.86 (0.812)	2.81 (0.514, 5.107)	0.0165*
Hedges' g SMD							0.20 (0.036, 0.363)	0.0166*
Int. p-value								0.5912
Sponsor								
AZ	696	29.09 (22.786)	0.47 (0.600)	703	29.41 (21.453)	-1.55 (0.596)	2.02 (0.362, 3.678)	0.0170*
Hedges' g SMD							0.13 (0.023, 0.233)	0.0170*
NRG Oncology	76	31.29 (21.215)	-3.35 (1.688)	71	25.98 (20.223)	-5.66 (1.784)	2.31 (-2.576, 7.195)	0.3514
Hedges' g SMD							0.15 (-0.169, 0.478)	0.3500

[a] = number of patients with change from baseline in the MMRM analysis.
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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.11 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Fatigue (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.8953
BRCA mutation type								
BRCA1	493	30.35 (22.096)	0.59 (0.740)	490	31.13 (21.707)	-2.58 (0.741)	3.17 (1.116, 5.228)	0.0025*
Hedges' g SMD							0.19 (0.068, 0.318)	0.0025*
BRCA2	195	31.60 (25.043)	-1.62 (1.127)	186	26.34 (20.850)	-0.63 (1.158)	-0.99 (-4.178, 2.196)	0.5412
Hedges' g SMD							-0.06 (-0.264, 0.138)	0.5406
Int. p-value								0.0361*

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[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.12 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Financial difficulties (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	23.11 (30.934)	-6.99 (1.692)	134	25.62 (31.640)	-7.09 (1.709)	0.10 (-4.641, 4.839)	0.9671
Hedges' g SMD							0.01 (-0.233, 0.243)	0.9671
TNBC	626	23.32 (29.198)	-6.24 (0.703)	638	22.36 (29.499)	-6.75 (0.695)	0.51 (-1.432, 2.450)	0.6070
Hedges' g SMD							0.03 (-0.081, 0.139)	0.6071
Int. p-value								0.9841
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	385	21.82 (26.952)	-6.94 (0.868)	410	23.25 (29.964)	-6.30 (0.843)	-0.64 (-3.018, 1.735)	0.5964
Hedges' g SMD							-0.04 (-0.177, 0.102)	0.5966
Neoadjuvant	380	25.09 (32.067)	-6.08 (0.980)	362	22.56 (29.834)	-7.53 (0.999)	1.45 (-1.299, 4.200)	0.3007
Hedges' g SMD							0.08 (-0.068, 0.220)	0.3009
Int. p-value								0.2251
Platinum therapy for current breast cancer (eCRF)								
Yes	196	24.49 (30.774)	-4.04 (1.374)	195	21.71 (30.299)	-8.37 (1.372)	4.33 (0.510, 8.148)	0.0264*
Hedges' g SMD							0.23 (0.026, 0.424)	0.0265*
No	569	23.08 (29.244)	-7.28 (0.734)	577	23.34 (29.760)	-6.43 (0.729)	-0.85 (-2.882, 1.178)	0.4106
Hedges' g SMD							-0.05 (-0.164, 0.067)	0.4108
Int. p-value								0.0420*
Age [years]								
<50	582	24.00 (29.768)	-6.90 (0.751)	569	23.96 (30.419)	-7.80 (0.761)	0.89 (-1.204, 2.992)	0.4031
Hedges' g SMD							0.05 (-0.066, 0.165)	0.4033
50-64	159	21.59 (29.563)	-5.40 (1.426)	173	21.97 (28.629)	-4.11 (1.357)	-1.29 (-5.162, 2.587)	0.5136
Hedges' g SMD							-0.07 (-0.287, 0.144)	0.5140

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.12 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Financial difficulties (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	22.22 (27.217)	-5.91 (3.036)	30	8.89 (23.050)	-5.06 (2.666)	-0.85 (-9.073, 7.378)	0.8370
Hedges' g SMD							-0.06 (-0.594, 0.480)	0.8359
Int. p-value								0.4580
Menopausal status at screening								
Premenopausal	481	23.35 (29.063)	-6.74 (0.836)	467	23.98 (29.952)	-7.70 (0.848)	0.96 (-1.373, 3.300)	0.4185
Hedges' g SMD							0.05 (-0.075, 0.180)	0.4187
Postmenopausal	282	23.52 (30.585)	-6.25 (1.010)	301	21.48 (29.874)	-5.82 (0.972)	-0.43 (-3.186, 2.321)	0.7578
Hedges' g SMD							-0.03 (-0.188, 0.137)	0.7579
Int. p-value								0.2286
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	22.22 (17.213)	-4.40 (5.532)	8	16.67 (25.198)	-8.68 (4.772)	4.27 (-11.906, 20.451)	0.5719
Hedges' g SMD							0.30 (-0.770, 1.362)	0.5866
Taxane	36	29.63 (33.597)	-7.09 (2.839)	39	19.66 (30.318)	-11.43 (2.770)	4.34 (-3.625, 12.309)	0.2805
Hedges' g SMD							0.25 (-0.205, 0.705)	0.2809
Anthracycline + Taxane	723	23.14 (29.499)	-6.46 (0.673)	724	23.20 (29.936)	-6.65 (0.671)	0.19 (-1.675, 2.053)	0.8423
Hedges' g SMD							0.01 (-0.093, 0.114)	0.8424
Int. p-value								0.8130
Type of breast surgery prior to randomisation								
Breast conservation	186	21.68 (29.233)	-5.22 (1.219)	207	19.32 (28.104)	-4.19 (1.161)	-1.03 (-4.343, 2.283)	0.5412
Hedges' g SMD							-0.06 (-0.260, 0.136)	0.5415
Unilateral mastectomy	294	24.60 (30.095)	-7.19 (1.044)	298	26.62 (31.303)	-8.76 (1.029)	1.56 (-1.317, 4.442)	0.2870
Hedges' g SMD							0.09 (-0.074, 0.249)	0.2872
Bilateral mastectomy	285	23.39 (29.448)	-6.56 (1.127)	265	21.51 (29.349)	-6.64 (1.171)	0.08 (-3.113, 3.275)	0.9605
Hedges' g SMD							0.00 (-0.163, 0.171)	0.9605

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Table 5.1.1.12 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Financial difficulties (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.5736
Bilateral Oophorectomy								
Yes	154	21.65 (28.143)	-6.31 (1.240)	146	19.18 (26.792)	-6.23 (1.271)	-0.08 (-3.571, 3.418)	0.9656
Hedges' g SMD							0.00 (-0.231, 0.221)	0.9657
No	611	23.90 (29.997)	-6.53 (0.751)	626	23.80 (30.516)	-7.05 (0.742)	0.52 (-1.554, 2.588)	0.6245
Hedges' g SMD							0.03 (-0.084, 0.139)	0.6246
Int. p-value								0.5197
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	19.87 (25.338)	-6.08 (1.307)	159	24.32 (29.693)	-5.14 (1.307)	-0.93 (-4.577, 2.710)	0.6144
Hedges' g SMD							-0.06 (-0.278, 0.164)	0.6144
Negative	166	22.29 (27.313)	-5.11 (1.275)	175	20.76 (28.265)	-6.89 (1.239)	1.78 (-1.721, 5.274)	0.3184
Hedges' g SMD							0.11 (-0.104, 0.321)	0.3189
Int. p-value								0.2419
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	23.48 (31.220)	-4.93 (1.995)	73	23.29 (27.602)	-7.66 (2.228)	2.73 (-3.187, 8.648)	0.3633
Hedges' g SMD							0.14 (-0.167, 0.455)	0.3635
ER and/or PgR positive with adjuvant chemotherapy	49	22.45 (30.723)	-10.96 (3.042)	61	28.42 (35.920)	-6.54 (2.690)	-4.42 (-12.489, 3.641)	0.2792
Hedges' g SMD							-0.21 (-0.585, 0.169)	0.2799
ER and PgR negative with neoadjuvant chemotherapy	290	25.17 (32.076)	-6.14 (1.126)	289	22.38 (30.415)	-7.35 (1.117)	1.21 (-1.905, 4.329)	0.4453
Hedges' g SMD							0.06 (-0.100, 0.226)	0.4455

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Table 5.1.1.12 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Financial difficulties (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	336	21.73 (26.408)	-6.39 (0.891)	349	22.35 (28.763)	-6.32 (0.878)	-0.07 (-2.529, 2.382)	0.9533
Hedges' g SMD							0.00 (-0.154, 0.145)	0.9533
Int. p-value								0.4290
Race								
White	505	24.22 (30.871)	-6.30 (0.818)	483	21.67 (30.285)	-7.53 (0.836)	1.23 (-1.067, 3.527)	0.2936
Hedges' g SMD							0.07 (-0.058, 0.192)	0.2936
Black/African-American	11	21.21 (22.473)	-7.72 (6.325)	21	23.81 (23.905)	-3.90 (3.751)	-3.82 (-19.240, 11.600)	0.6127
Hedges' g SMD							-0.20 (-0.932, 0.531)	0.5904
Asian	237	21.52 (26.947)	-6.10 (1.106)	257	25.16 (29.430)	-5.76 (1.066)	-0.34 (-3.360, 2.682)	0.8255
Hedges' g SMD							-0.02 (-0.196, 0.157)	0.8255
Other	12	NC	NC	11	NC	NC	NC	NC
Int. p-value								0.5621
Ethnicity								
Hispanic	26	29.49 (34.418)	-14.77 (2.953)	17	15.69 (29.149)	-12.35 (3.646)	-2.42 (-12.002, 7.167)	0.6124
Hedges' g SMD							-0.16 (-0.770, 0.455)	0.6137
Non-hispanic	679	22.68 (29.070)	-5.68 (0.686)	693	22.41 (29.190)	-6.47 (0.678)	0.79 (-1.105, 2.680)	0.4144
Hedges' g SMD							0.04 (-0.062, 0.150)	0.4146
Not known, not recorded or refused	60	29.44 (33.102)	-12.77 (2.543)	62	30.65 (36.364)	-10.58 (2.521)	-2.19 (-9.291, 4.908)	0.5419
Hedges' g SMD							-0.11 (-0.465, 0.245)	0.5434
Int. p-value								0.5007
Jewish descent								
Yes Ashkenazi	33	23.23 (29.445)	-7.87 (2.543)	25	24.00 (37.908)	-0.24 (3.025)	-7.62 (-15.573, 0.324)	0.0597

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Table 5.1.1.12 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Financial difficulties (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hedges' g SMD							-0.51 (-1.035, 0.021)	0.0600
No	732	23.45 (29.658)	-6.46 (0.669)	745	22.95 (29.627)	-7.08 (0.662)	0.62 (-1.227, 2.465)	0.5107
Hedges' g SMD							0.03 (-0.068, 0.136)	0.5108
Int. p-value								0.1845
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	330	25.15 (32.623)	-6.76 (1.045)	306	23.97 (30.528)	-8.22 (1.082)	1.47 (-1.488, 4.420)	0.3301
Hedges' g SMD							0.08 (-0.078, 0.233)	0.3305
5 or 6	19	22.81 (22.368)	-6.52 (4.995)	7	4.76 (12.599)	-0.21 (8.444)	-6.31 (-27.194, 14.568)	0.5367
Hedges' g SMD							-0.28 (-1.149, 0.592)	0.5300
Int. p-value								0.7255
Geographic region								
North America	83	30.12 (31.067)	-8.20 (2.177)	90	21.48 (27.511)	-8.19 (2.135)	-0.01 (-6.061, 6.045)	0.9979
Hedges' g SMD							0.00 (-0.299, 0.298)	0.9979
South America	13	25.64 (33.758)	-12.61 (4.473)	9	11.11 (23.570)	-6.62 (5.439)	-5.99 (-20.911, 8.934)	0.4123
Hedges' g SMD							-0.36 (-1.213, 0.502)	0.4166
Europe	390	22.99 (31.047)	-5.93 (0.935)	372	21.51 (30.429)	-6.82 (0.948)	0.89 (-1.724, 3.505)	0.5038
Hedges' g SMD							0.05 (-0.094, 0.190)	0.5042
Asia Pacific and South Africa	279	21.98 (26.721)	-6.57 (1.015)	301	25.47 (29.954)	-6.74 (0.982)	0.17 (-2.607, 2.943)	0.9054
Hedges' g SMD							0.01 (-0.153, 0.173)	0.9054
Int. p-value								0.6435
Sponsor								
AZ	690	22.75 (29.331)	-6.31 (0.678)	701	23.06 (30.170)	-6.54 (0.670)	0.23 (-1.641, 2.099)	0.8098
Hedges' g SMD							0.01 (-0.092, 0.118)	0.8099
NRG Oncology	75	29.78 (31.752)	-9.07 (2.311)	71	21.60 (27.079)	-10.28 (2.415)	1.20 (-5.437, 7.844)	0.7205
Hedges' g SMD							0.06 (-0.265, 0.384)	0.7201
Int. p-value								0.5747

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[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.12 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Financial difficulties (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
BRCA mutation type								
BRCA1	489	23.45 (29.569)	-5.80 (0.810)	488	22.40 (29.581)	-8.28 (0.810)	2.48 (0.229, 4.724)	0.0309*
Hedges' g SMD							0.14 (0.013, 0.264)	0.0309*
BRCA2	192	23.09 (30.969)	-8.67 (1.303)	186	22.40 (31.479)	-4.44 (1.323)	-4.23 (-7.880, -0.575)	0.0234*
Hedges' g SMD							-0.23 (-0.436, -0.031)	0.0236*
Int. p-value								0.0049*

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.13 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Nausea and vomiting (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	2.80 (7.166)	3.56 (0.645)	134	3.36 (9.538)	0.22 (0.655)	3.34 (1.533, 5.155)	0.0003*
Hedges' g SMD							0.44 (0.199, 0.682)	0.0003*
TNBC	633	2.98 (8.766)	3.81 (0.341)	640	3.36 (10.193)	1.01 (0.338)	2.80 (1.861, 3.745)	<0.0001*
Hedges' g SMD							0.33 (0.217, 0.438)	<0.0001*
Int. p-value								0.6994
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	387	3.06 (8.896)	3.08 (0.403)	410	3.41 (9.916)	0.93 (0.392)	2.16 (1.053, 3.261)	0.0001*
Hedges' g SMD							0.27 (0.132, 0.411)	0.0001*
Neoadjuvant	385	2.81 (8.070)	4.55 (0.455)	364	3.30 (10.267)	0.75 (0.465)	3.80 (2.522, 5.079)	<0.0001*
Hedges' g SMD							0.43 (0.281, 0.571)	<0.0001*
Int. p-value								0.0757
Platinum therapy for current breast cancer (eCRF)								
Yes	198	1.60 (5.958)	5.51 (0.656)	196	4.08 (11.950)	1.06 (0.659)	4.46 (2.622, 6.293)	<0.0001*
Hedges' g SMD							0.48 (0.282, 0.683)	<0.0001*
No	574	3.40 (9.162)	3.17 (0.337)	578	3.11 (9.356)	0.79 (0.335)	2.37 (1.442, 3.308)	<0.0001*
Hedges' g SMD							0.29 (0.178, 0.410)	<0.0001*
Int. p-value								0.0464*
Age [years]								
<50	584	2.63 (7.482)	3.80 (0.342)	569	3.22 (9.658)	0.97 (0.347)	2.83 (1.874, 3.789)	<0.0001*
Hedges' g SMD							0.34 (0.225, 0.458)	<0.0001*
50-64	164	3.86 (11.015)	3.64 (0.652)	175	3.05 (8.395)	0.87 (0.624)	2.78 (1.001, 4.552)	0.0023*
Hedges' g SMD							0.33 (0.119, 0.548)	0.0023*

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.13 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Nausea and vomiting (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	4.17 (11.261)	4.62 (2.225)	30	7.78 (20.869)	-0.59 (1.970)	5.21 (-0.783, 11.201)	0.0868
Hedges' g SMD							0.47 (-0.071, 1.018)	0.0883
Int. p-value								0.8403
Menopausal status at screening								
Premenopausal	483	2.59 (7.643)	3.45 (0.338)	467	2.93 (9.122)	0.74 (0.343)	2.71 (1.763, 3.655)	<0.0001*
Hedges' g SMD							0.36 (0.236, 0.493)	<0.0001*
Postmenopausal	287	3.54 (9.758)	4.28 (0.565)	303	4.07 (11.426)	0.99 (0.547)	3.28 (1.740, 4.828)	<0.0001*
Hedges' g SMD							0.34 (0.181, 0.506)	<0.0001*
Int. p-value								0.5375
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	5.56 (13.608)	1.27 (2.675)	8	0.00 (0.000)	1.75 (2.225)	-0.48 (-8.912, 7.951)	0.8973
Hedges' g SMD							-0.07 (-1.129, 0.989)	0.8965
Taxane	37	3.60 (8.902)	6.88 (1.739)	39	3.42 (10.935)	0.86 (1.725)	6.02 (1.145, 10.903)	0.0162*
Hedges' g SMD							0.56 (0.099, 1.017)	0.0171*
Anthracycline + Taxane	729	2.88 (8.429)	3.60 (0.302)	726	3.40 (10.092)	0.78 (0.302)	2.81 (1.973, 3.648)	<0.0001*
Hedges' g SMD							0.35 (0.242, 0.449)	<0.0001*
Int. p-value								0.2381
Type of breast surgery prior to randomisation								
Breast conservation	190	3.33 (10.026)	4.05 (0.612)	207	3.38 (10.352)	1.26 (0.590)	2.79 (1.124, 4.465)	0.0011*
Hedges' g SMD							0.33 (0.131, 0.528)	0.0011*
Unilateral mastectomy	295	2.82 (8.335)	4.14 (0.489)	299	2.95 (9.241)	0.73 (0.483)	3.41 (2.056, 4.755)	<0.0001*
Hedges' g SMD							0.41 (0.244, 0.569)	<0.0001*
Bilateral mastectomy	287	2.79 (7.504)	3.00 (0.466)	266	3.63 (10.409)	0.79 (0.483)	2.21 (0.893, 3.533)	0.0011*
Hedges' g SMD							0.28 (0.112, 0.448)	0.0011*

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.13 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Nausea and vomiting (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.6774
Bilateral Oophorectomy								
Yes	156	3.21 (7.832)	3.85 (0.710)	147	4.20 (11.840)	0.51 (0.731)	3.34 (1.331, 5.346)	0.0012*
Hedges' g SMD							0.38 (0.148, 0.603)	0.0012*
No	616	2.87 (8.653)	3.74 (0.333)	627	3.16 (9.617)	0.96 (0.330)	2.79 (1.869, 3.709)	<0.0001*
Hedges' g SMD							0.34 (0.225, 0.449)	<0.0001*
Int. p-value								0.6314
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	1.92 (6.548)	2.25 (0.583)	159	3.77 (8.780)	0.78 (0.583)	1.47 (-0.160, 3.098)	0.0770
Hedges' g SMD							0.20 (-0.021, 0.422)	0.0764
Negative	168	3.97 (10.515)	2.93 (0.624)	175	3.43 (11.343)	0.96 (0.610)	1.97 (0.256, 3.693)	0.0245*
Hedges' g SMD							0.24 (0.031, 0.456)	0.0246*
Int. p-value								0.8893
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	2.65 (6.131)	2.88 (0.794)	73	3.65 (9.721)	0.12 (0.886)	2.77 (0.417, 5.118)	0.0213*
Hedges' g SMD							0.37 (0.054, 0.680)	0.0215*
ER and/or PgR positive with adjuvant chemotherapy	49	3.06 (8.789)	5.00 (1.141)	61	3.01 (9.383)	0.48 (1.015)	4.52 (1.490, 7.546)	0.0038*
Hedges' g SMD							0.56 (0.181, 0.948)	0.0039*
ER and PgR negative with neoadjuvant chemotherapy	295	2.88 (8.595)	5.08 (0.545)	291	3.21 (10.414)	0.96 (0.543)	4.12 (2.607, 5.633)	<0.0001*
Hedges' g SMD							0.44 (0.278, 0.605)	<0.0001*

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.13 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Nausea and vomiting (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	338	3.06 (8.924)	2.84 (0.432)	349	3.49 (10.018)	1.04 (0.427)	1.80 (0.610, 2.994)	0.0031*
Hedges' g SMD							0.23 (0.076, 0.376)	0.0031*
Int. p-value								0.0907
Race								
White	512	3.13 (8.661)	4.09 (0.406)	485	3.71 (11.029)	0.99 (0.416)	3.10 (1.963, 4.244)	<0.0001*
Hedges' g SMD							0.34 (0.213, 0.463)	<0.0001*
Black/African-American	11	NC	NC	21	NC	NC	NC	NC
Asian	237	2.53 (8.157)	3.20 (0.434)	257	2.79 (7.920)	0.36 (0.418)	2.85 (1.661, 4.029)	<0.0001*
Hedges' g SMD							0.42 (0.246, 0.603)	<0.0001*
Other	12	4.17 (10.360)	. (.)	11	0.00 (0.000)	. (.)	-3.94 (-12.847, 4.975)	0.3519
Hedges' g SMD							. (. , .)	
Int. p-value								0.3006
Ethnicity								
Hispanic	26	3.21 (9.451)	8.10 (1.374)	17	0.00 (0.000)	2.66 (1.729)	5.44 (0.873, 9.998)	0.0213*
Hedges' g SMD							0.76 (0.123, 1.390)	0.0193*
Non-hispanic	685	2.97 (8.604)	3.65 (0.322)	693	3.44 (10.206)	0.84 (0.319)	2.81 (1.919, 3.698)	<0.0001*
Hedges' g SMD							0.33 (0.227, 0.440)	<0.0001*
Not known, not recorded or refused	61	2.46 (6.692)	3.47 (1.034)	64	3.39 (9.929)	0.98 (1.017)	2.49 (-0.390, 5.360)	0.0896
Hedges' g SMD							0.30 (-0.048, 0.657)	0.0906
Int. p-value								0.3369
Jewish descent								
Yes Ashkenazi	33	2.53 (9.429)	2.25 (1.597)	25	6.00 (17.267)	3.34 (1.911)	-1.09 (-6.084, 3.908)	0.6641

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
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Table 5.1.1.13 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Nausea and vomiting (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hedges' g SMD							-0.11 (-0.635, 0.405)	0.6649
No	739	2.95 (8.452)	3.82 (0.307)	747	3.28 (9.765)	0.77 (0.304)	3.06 (2.210, 3.903)	<0.0001*
Hedges' g SMD							0.37 (0.265, 0.470)	<0.0001*
Int. p-value								0.0602
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	335	3.03 (8.452)	4.38 (0.489)	307	3.64 (10.711)	0.60 (0.508)	3.78 (2.395, 5.167)	<0.0001*
Hedges' g SMD							0.42 (0.266, 0.579)	<0.0001*
5 or 6	19	1.75 (5.255)	. (.)	7	0.00 (0.000)	. (.)	2.15 (-2.425, 6.726)	0.3365
Hedges' g SMD							. (. , .)	
Int. p-value								0.8665
Geographic region								
North America	84	5.36 (9.736)	2.83 (1.007)	90	4.26 (11.867)	0.90 (1.002)	1.93 (-0.883, 4.741)	0.1773
Hedges' g SMD							0.20 (-0.093, 0.503)	0.1780
South America	13	2.56 (9.245)	. (.)	9	0.00 (0.000)	. (.)	5.73 (1.106, 10.356)	0.0179*
Hedges' g SMD							. (. , .)	
Europe	396	2.82 (8.372)	4.35 (0.479)	374	3.61 (10.620)	0.91 (0.488)	3.45 (2.102, 4.790)	<0.0001*
Hedges' g SMD							0.36 (0.220, 0.505)	<0.0001*
Asia Pacific and South Africa	279	2.39 (8.137)	3.23 (0.400)	301	2.88 (8.872)	0.68 (0.387)	2.55 (1.456, 3.643)	<0.0001*
Hedges' g SMD							0.38 (0.216, 0.545)	<0.0001*
Int. p-value								0.6288
Sponsor								
AZ	696	2.63 (8.258)	3.89 (0.315)	703	3.27 (9.844)	0.92 (0.312)	2.96 (2.096, 3.834)	<0.0001*
Hedges' g SMD							0.36 (0.252, 0.463)	<0.0001*
NRG Oncology	76	5.70 (10.019)	2.33 (1.063)	71	4.23 (12.188)	0.11 (1.131)	2.22 (-0.864, 5.299)	0.1570
Hedges' g SMD							0.23 (-0.090, 0.559)	0.1562
Int. p-value								0.4755

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Table 5.1.1.13 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Nausea and vomiting (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
BRCA mutation type								
BRCA1	493	3.35 (9.237)	4.03 (0.404)	490	3.74 (10.904)	0.60 (0.404)	3.42 (2.302, 4.547)	<0.0001*
Hedges' g SMD							0.38 (0.256, 0.508)	<0.0001*
BRCA2	195	2.74 (7.638)	3.05 (0.560)	186	2.87 (8.533)	1.70 (0.575)	1.36 (-0.221, 2.936)	0.0916
Hedges' g SMD							0.17 (-0.028, 0.374)	0.0919
Int. p-value								0.0232*

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.14 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Pain (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	23.11 (25.345)	-1.36 (1.329)	134	19.90 (23.076)	-0.33 (1.351)	-1.02 (-4.761, 2.719)	0.5912
Hedges' g SMD							-0.07 (-0.303, 0.173)	0.5912
TNBC	633	20.04 (23.646)	-1.90 (0.643)	641	20.93 (23.607)	-2.34 (0.638)	0.44 (-1.337, 2.219)	0.6267
Hedges' g SMD							0.03 (-0.083, 0.137)	0.6268
Int. p-value								0.5643
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	387	18.60 (22.727)	-1.17 (0.747)	410	18.13 (22.970)	-1.62 (0.728)	0.45 (-1.601, 2.496)	0.6681
Hedges' g SMD							0.03 (-0.109, 0.169)	0.6683
Neoadjuvant	385	22.60 (24.975)	-2.52 (0.894)	365	23.70 (23.780)	-2.51 (0.914)	-0.02 (-2.529, 2.492)	0.9886
Hedges' g SMD							0.00 (-0.144, 0.142)	0.9886
Int. p-value								0.7720
Platinum therapy for current breast cancer (eCRF)								
Yes	198	23.15 (25.497)	-2.08 (1.280)	196	22.79 (23.617)	-3.39 (1.287)	1.31 (-2.259, 4.881)	0.4707
Hedges' g SMD							0.07 (-0.125, 0.270)	0.4712
No	574	19.72 (23.341)	-1.68 (0.644)	579	20.06 (23.447)	-1.57 (0.641)	-0.10 (-1.887, 1.679)	0.9088
Hedges' g SMD							-0.01 (-0.122, 0.109)	0.9089
Int. p-value								0.3631
Age [years]								
<50	584	19.89 (23.420)	-2.30 (0.653)	570	20.85 (23.706)	-3.00 (0.663)	0.70 (-1.128, 2.523)	0.4537
Hedges' g SMD							0.04 (-0.071, 0.160)	0.4538
50-64	164	21.24 (24.165)	-0.02 (1.252)	175	21.05 (23.635)	0.07 (1.200)	-0.09 (-3.507, 3.317)	0.9564
Hedges' g SMD							-0.01 (-0.219, 0.207)	0.9564

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.14 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Pain (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	33.33 (31.470)	-0.31 (4.140)	30	17.22 (18.817)	4.29 (3.642)	-4.59 (-15.946, 6.758)	0.4200
Hedges' g SMD							-0.23 (-0.764, 0.313)	0.4123
Int. p-value								0.6270
Menopausal status at screening								
Premenopausal	483	19.22 (22.884)	-2.12 (0.723)	468	19.55 (23.073)	-2.47 (0.734)	0.34 (-1.678, 2.367)	0.7384
Hedges' g SMD							0.02 (-0.105, 0.149)	0.7386
Postmenopausal	287	23.00 (25.540)	-1.09 (0.951)	303	22.55 (24.057)	-1.50 (0.921)	0.42 (-2.185, 3.016)	0.7539
Hedges' g SMD							0.03 (-0.136, 0.187)	0.7541
Int. p-value								0.8586
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	27.78 (31.032)	-4.24 (4.575)	8	14.58 (18.767)	-6.99 (3.885)	2.75 (-10.805, 16.311)	0.6631
Hedges' g SMD							0.23 (-0.831, 1.296)	0.6681
Taxane	37	24.32 (23.764)	3.00 (2.739)	39	17.09 (23.096)	-3.56 (2.722)	6.55 (-1.218, 14.326)	0.0970
Hedges' g SMD							0.39 (-0.069, 0.840)	0.0963
Anthracycline + Taxane	729	20.35 (23.903)	-1.99 (0.596)	727	21.02 (23.589)	-1.85 (0.596)	-0.14 (-1.791, 1.514)	0.8694
Hedges' g SMD							-0.01 (-0.111, 0.094)	0.8695
Int. p-value								0.1236
Type of breast surgery prior to randomisation								
Breast conservation	190	19.47 (22.829)	0.46 (1.113)	207	18.60 (22.373)	-0.37 (1.073)	0.84 (-2.204, 3.876)	0.5891
Hedges' g SMD							0.05 (-0.143, 0.251)	0.5896
Unilateral mastectomy	295	18.59 (21.867)	-2.06 (0.872)	300	18.89 (21.909)	-0.73 (0.858)	-1.33 (-3.737, 1.070)	0.2762
Hedges' g SMD							-0.09 (-0.250, 0.072)	0.2766
Bilateral mastectomy	287	23.40 (26.391)	-3.27 (1.045)	266	24.44 (25.702)	-4.99 (1.087)	1.72 (-1.241, 4.688)	0.2539
Hedges' g SMD							0.10 (-0.070, 0.264)	0.2541

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.14 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Pain (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.3314
Bilateral Oophorectomy								
Yes	156	22.54 (24.959)	-3.59 (1.281)	147	25.06 (23.761)	-5.41 (1.318)	1.82 (-1.806, 5.443)	0.3241
Hedges' g SMD							0.11 (-0.112, 0.339)	0.3240
No	616	20.10 (23.674)	-1.29 (0.650)	628	19.75 (23.349)	-1.24 (0.643)	-0.06 (-1.853, 1.736)	0.9491
Hedges' g SMD							0.00 (-0.115, 0.108)	0.9491
Int. p-value								0.4566
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	16.45 (21.502)	-2.04 (1.145)	159	18.45 (23.837)	0.46 (1.145)	-2.50 (-5.691, 0.686)	0.1235
Hedges' g SMD							-0.17 (-0.395, 0.048)	0.1239
Negative	168	18.85 (22.602)	-0.49 (1.123)	175	16.48 (20.606)	-3.52 (1.097)	3.03 (-0.065, 6.118)	0.0550
Hedges' g SMD							0.21 (-0.004, 0.420)	0.0550
Int. p-value								0.0098*
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	24.43 (25.764)	-2.74 (1.746)	73	19.86 (22.163)	-0.74 (1.956)	-2.01 (-7.211, 3.192)	0.4463
Hedges' g SMD							-0.12 (-0.432, 0.190)	0.4452
ER and/or PgR positive with adjuvant chemotherapy	49	20.75 (24.658)	0.56 (2.058)	61	19.95 (24.309)	0.17 (1.820)	0.39 (-5.063, 5.841)	0.8878
Hedges' g SMD							0.03 (-0.349, 0.403)	0.8881
ER and PgR negative with neoadjuvant chemotherapy	295	22.03 (24.828)	-2.55 (1.045)	292	24.66 (24.108)	-2.93 (1.040)	0.38 (-2.520, 3.277)	0.7975
Hedges' g SMD							0.02 (-0.141, 0.183)	0.7975

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.14 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Pain (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	338	18.29 (22.456)	-1.43 (0.799)	349	17.81 (22.749)	-1.97 (0.791)	0.54 (-1.666, 2.750)	0.6299
Hedges' g SMD							0.04 (-0.113, 0.186)	0.6302
Int. p-value								0.9431
Race								
White	512	23.11 (25.978)	-1.27 (0.783)	486	22.39 (24.425)	-1.22 (0.803)	-0.05 (-2.248, 2.155)	0.9668
Hedges' g SMD							0.00 (-0.127, 0.121)	0.9668
Black/African-American	11	22.73 (25.025)	-6.08 (4.714)	21	34.13 (33.943)	-14.75 (2.992)	8.67 (-2.597, 19.946)	0.1264
Hedges' g SMD							0.59 (-0.158, 1.334)	0.1221
Asian	237	15.40 (18.110)	-2.39 (0.778)	257	16.47 (19.459)	-2.64 (0.749)	0.25 (-1.874, 2.370)	0.8182
Hedges' g SMD							0.02 (-0.156, 0.197)	0.8184
Other	12	13.89 (17.164)	-9.25 (4.877)	11	22.73 (29.129)	-6.88 (4.993)	-2.37 (-17.320, 12.584)	0.7421
Hedges' g SMD							-0.14 (-0.956, 0.683)	0.7443
Int. p-value								0.8975
Ethnicity								
Hispanic	26	16.67 (23.094)	-5.06 (3.269)	17	21.57 (22.642)	-0.38 (4.083)	-4.68 (-15.295, 5.932)	0.3775
Hedges' g SMD							-0.27 (-0.889, 0.340)	0.3809
Non-hispanic	685	20.63 (24.066)	-1.87 (0.602)	694	20.44 (23.050)	-1.99 (0.597)	0.12 (-1.546, 1.778)	0.8912
Hedges' g SMD							0.01 (-0.098, 0.113)	0.8912
Not known, not recorded or refused	61	21.86 (23.082)	0.21 (2.439)	64	23.96 (28.308)	-2.68 (2.410)	2.89 (-3.926, 9.700)	0.4020
Hedges' g SMD							0.15 (-0.202, 0.501)	0.4035
Int. p-value								0.5120
Jewish descent								

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Table 5.1.1.14 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Pain (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Yes Ashkenazi	33	23.74 (32.816)	-3.94 (2.914)	25	26.00 (28.496)	2.26 (3.437)	-6.20 (-15.234, 2.833)	0.1741
Hedges' g SMD							-0.36 (-0.885, 0.163)	0.1767
No	739	20.46 (23.489)	-1.63 (0.591)	748	20.59 (23.337)	-2.16 (0.586)	0.53 (-1.102, 2.161)	0.5246
Hedges' g SMD							0.03 (-0.069, 0.135)	0.5247
Int. p-value								0.1181
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	335	22.94 (25.018)	-2.99 (0.945)	308	23.65 (24.418)	-2.34 (0.983)	-0.65 (-3.326, 2.029)	0.6347
Hedges' g SMD							-0.04 (-0.192, 0.117)	0.6349
5 or 6	19	15.79 (23.878)	1.97 (4.549)	7	23.81 (16.265)	-4.11 (7.917)	6.07 (-13.385, 25.529)	0.5256
Hedges' g SMD							0.29 (-0.579, 1.163)	0.5106
Int. p-value								0.3212
Geographic region								
North America	84	24.21 (26.435)	-5.48 (1.742)	90	20.74 (25.271)	-2.32 (1.731)	-3.16 (-8.016, 1.687)	0.1996
Hedges' g SMD							-0.19 (-0.492, 0.104)	0.2011
South America	13	8.97 (14.618)	-1.72 (3.330)	9	12.96 (18.215)	5.45 (4.049)	-7.17 (-18.154, 3.814)	0.1878
Hedges' g SMD							-0.57 (-1.442, 0.298)	0.1977
Europe	396	23.11 (25.627)	-0.75 (0.932)	375	23.56 (24.962)	-1.91 (0.950)	1.16 (-1.455, 3.769)	0.3847
Hedges' g SMD							0.06 (-0.079, 0.204)	0.3851
Asia Pacific and South Africa	279	16.49 (20.066)	-2.23 (0.751)	301	17.50 (20.688)	-2.49 (0.727)	0.27 (-1.788, 2.319)	0.7997
Hedges' g SMD							0.02 (-0.142, 0.184)	0.7999
Int. p-value								0.3528
Sponsor								
AZ	696	20.16 (23.514)	-1.40 (0.610)	704	20.81 (23.432)	-1.93 (0.605)	0.53 (-1.155, 2.214)	0.5377
Hedges' g SMD							0.03 (-0.072, 0.138)	0.5378
NRG Oncology	76	24.56 (27.416)	-5.21 (1.869)	71	20.19 (24.384)	-3.24 (1.982)	-1.96 (-7.361, 3.435)	0.4732
Hedges' g SMD							-0.12 (-0.442, 0.205)	0.4736

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.14 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Symptom scale: Pain (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.3669
BRCA mutation type								
BRCA1	493	21.40 (24.535)	-1.85 (0.752)	491	21.66 (23.893)	-2.91 (0.752)	1.07 (-1.019, 3.153)	0.3158
Hedges' g SMD							0.06 (-0.061, 0.189)	0.3160
BRCA2	195	23.08 (25.275)	-3.41 (1.171)	186	22.76 (24.725)	-0.93 (1.203)	-2.48 (-5.784, 0.820)	0.1402
Hedges' g SMD							-0.15 (-0.352, 0.050)	0.1406
Int. p-value								0.0754

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.15 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Insomnia (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	137	27.49 (28.839)	4.18 (1.827)	134	29.35 (30.327)	1.04 (1.853)	3.15 (-1.976, 8.275)	0.2274
Hedges' g SMD							0.15 (-0.092, 0.385)	0.2281
TNBC	632	26.95 (27.956)	-0.86 (0.806)	639	28.64 (29.489)	-0.66 (0.800)	-0.20 (-2.433, 2.025)	0.8576
Hedges' g SMD							-0.01 (-0.120, 0.100)	0.8577
Int. p-value								0.2386
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	387	25.15 (26.593)	-0.80 (0.994)	409	27.71 (29.213)	-0.36 (0.971)	-0.44 (-3.164, 2.292)	0.7538
Hedges' g SMD							-0.02 (-0.161, 0.117)	0.7539
Neoadjuvant	384	29.17 (29.599)	0.82 (1.090)	364	29.95 (30.062)	-0.41 (1.115)	1.23 (-1.829, 4.294)	0.4296
Hedges' g SMD							0.06 (-0.086, 0.201)	0.4300
Int. p-value								0.5851
Platinum therapy for current breast cancer (eCRF)								
Yes	197	31.81 (28.630)	-0.12 (1.563)	196	27.38 (28.520)	0.20 (1.567)	-0.33 (-4.688, 4.032)	0.8826
Hedges' g SMD							-0.01 (-0.213, 0.183)	0.8825
No	574	25.55 (27.875)	-0.02 (0.836)	577	29.23 (29.990)	-0.57 (0.834)	0.55 (-1.770, 2.868)	0.6422
Hedges' g SMD							0.03 (-0.088, 0.143)	0.6421
Int. p-value								0.9384
Age [years]								
<50	583	26.99 (27.767)	-0.72 (0.851)	569	28.35 (29.547)	-0.78 (0.864)	0.05 (-2.327, 2.432)	0.9653
Hedges' g SMD							0.00 (-0.113, 0.118)	0.9653
50-64	164	29.47 (30.313)	2.72 (1.579)	175	29.52 (29.002)	-0.01 (1.514)	2.73 (-1.573, 7.036)	0.2127
Hedges' g SMD							0.14 (-0.078, 0.349)	0.2132

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.15 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Insomnia
(mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	15.28 (19.608)	-1.88 (4.210)	29	32.18 (35.054)	4.50 (3.753)	-6.38 (-17.962, 5.210)	0.2735
Hedges' g SMD							-0.31 (-0.852, 0.236)	0.2674
Int. p-value								0.3848
Menopausal status at screening								
Premenopausal	482	25.24 (26.700)	-0.62 (0.903)	467	26.27 (29.217)	-0.64 (0.918)	0.02 (-2.512, 2.544)	0.9903
Hedges' g SMD							0.00 (-0.126, 0.128)	0.9903
Postmenopausal	287	30.55 (30.279)	1.18 (1.263)	302	32.45 (29.752)	-0.24 (1.226)	1.42 (-2.035, 4.882)	0.4192
Hedges' g SMD							0.07 (-0.095, 0.228)	0.4196
Int. p-value								0.4915
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	44.44 (17.213)	-4.35 (5.193)	8	20.83 (17.252)	-12.30 (4.240)	7.95 (-8.199, 24.104)	0.3048
Hedges' g SMD							0.61 (-0.486, 1.696)	0.2769
Taxane	37	27.93 (31.927)	1.44 (3.191)	39	24.79 (30.318)	-4.13 (3.207)	5.57 (-3.475, 14.608)	0.2234
Hedges' g SMD							0.28 (-0.173, 0.731)	0.2261
Anthracycline + Taxane	728	26.97 (28.041)	0.02 (0.766)	725	29.10 (29.689)	-0.08 (0.766)	0.11 (-2.017, 2.233)	0.9206
Hedges' g SMD							0.01 (-0.098, 0.108)	0.9207
Int. p-value								0.4208
Type of breast surgery prior to randomisation								
Breast conservation	190	25.79 (29.022)	-0.26 (1.477)	207	29.15 (27.551)	0.93 (1.428)	-1.18 (-5.227, 2.858)	0.5649
Hedges' g SMD							-0.06 (-0.255, 0.139)	0.5652
Unilateral mastectomy	295	25.42 (28.663)	0.10 (1.126)	298	25.84 (29.329)	-0.52 (1.112)	0.62 (-2.487, 3.732)	0.6942
Hedges' g SMD							0.03 (-0.129, 0.193)	0.6944
Bilateral mastectomy	286	29.84 (26.990)	-0.22 (1.290)	266	31.58 (31.004)	-1.42 (1.340)	1.20 (-2.455, 4.855)	0.5193
Hedges' g SMD							0.05 (-0.112, 0.222)	0.5196

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.15 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Insomnia
(mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.6025
Bilateral Oophorectomy								
Yes	156	29.70 (28.979)	1.46 (1.810)	147	34.69 (28.100)	0.16 (1.861)	1.30 (-3.819, 6.417)	0.6178
Hedges' g SMD							0.06 (-0.168, 0.283)	0.6178
No	615	26.50 (27.966)	-0.34 (0.804)	626	27.37 (29.813)	-0.54 (0.797)	0.19 (-2.028, 2.414)	0.8643
Hedges' g SMD							0.01 (-0.102, 0.121)	0.8644
Int. p-value								0.7126
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	156	23.50 (24.892)	-3.40 (1.523)	159	30.82 (30.594)	0.31 (1.522)	-3.71 (-7.959, 0.547)	0.0874
Hedges' g SMD							-0.19 (-0.415, 0.028)	0.0866
Negative	168	26.39 (27.985)	-0.03 (1.493)	175	24.76 (27.616)	-2.94 (1.458)	2.92 (-1.193, 7.024)	0.1636
Hedges' g SMD							0.15 (-0.061, 0.363)	0.1638
Int. p-value								0.0151*
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	88	28.03 (29.420)	4.39 (2.334)	73	29.68 (30.713)	0.40 (2.602)	3.99 (-2.920, 10.892)	0.2560
Hedges' g SMD							0.18 (-0.131, 0.491)	0.2567
ER and/or PgR positive with adjuvant chemotherapy	49	26.53 (28.037)	3.39 (2.933)	61	28.96 (30.108)	2.39 (2.602)	1.00 (-6.782, 8.782)	0.7993
Hedges' g SMD							0.05 (-0.327, 0.425)	0.7999
ER and PgR negative with neoadjuvant chemotherapy	294	29.25 (29.507)	-0.30 (1.239)	291	30.01 (29.950)	-0.41 (1.232)	0.11 (-3.320, 3.545)	0.9486
Hedges' g SMD							0.01 (-0.157, 0.167)	0.9487

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.15 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Insomnia
(mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	338	24.95 (26.415)	-1.40 (1.054)	348	27.49 (29.092)	-0.87 (1.044)	-0.52 (-3.437, 2.389)	0.7240
Hedges' g SMD							-0.03 (-0.177, 0.123)	0.7241
Int. p-value								0.6218
Race								
White	511	31.05 (29.763)	0.26 (0.979)	484	33.26 (30.972)	-0.76 (1.007)	1.03 (-1.731, 3.782)	0.4657
Hedges' g SMD							0.05 (-0.078, 0.171)	0.4658
Black/African-American	11	NC	NC	21	NC	NC	NC	NC
Asian	237	20.11 (23.037)	-1.01 (1.075)	257	20.88 (25.357)	-0.52 (1.035)	-0.50 (-3.430, 2.435)	0.7390
Hedges' g SMD							-0.03 (-0.206, 0.147)	0.7393
Other	12	5.56 (12.975)	-1.68 (5.591)	11	21.21 (22.473)	10.64 (5.361)	-12.31 (-29.340, 4.714)	0.1448
Hedges' g SMD							-0.64 (-1.480, 0.206)	0.1384
Int. p-value								NC
Ethnicity								
Hispanic	26	15.38 (25.352)	6.10 (3.513)	17	33.33 (28.868)	-2.16 (4.497)	8.26 (-3.600, 20.123)	0.1666
Hedges' g SMD							0.45 (-0.173, 1.066)	0.1576
Non-hispanic	685	27.35 (28.008)	0.27 (0.785)	692	27.65 (28.801)	-0.59 (0.779)	0.87 (-1.304, 3.035)	0.4340
Hedges' g SMD							0.04 (-0.063, 0.148)	0.4342
Not known, not recorded or refused	60	30.00 (30.501)	-4.82 (2.754)	64	39.58 (36.065)	1.74 (2.714)	-6.56 (-14.255, 1.125)	0.0935
Hedges' g SMD							-0.30 (-0.657, 0.051)	0.0936
Int. p-value								0.3061
Jewish descent								
Yes Ashkenazi	33	32.32 (24.274)	-4.24 (4.054)	25	41.33 (33.720)	-5.03 (4.938)	0.78 (-12.115, 13.681)	0.9033

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.15 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Insomnia
(mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hedges' g SMD							0.03 (-0.487, 0.552)	0.9030
No	738	26.92 (28.339)	0.20 (0.753)	746	28.33 (29.441)	-0.23 (0.748)	0.43 (-1.655, 2.511)	0.6869
Hedges' g SMD							0.02 (-0.081, 0.123)	0.6869
Int. p-value								0.8238
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	335	29.55 (30.174)	0.48 (1.160)	307	30.29 (29.854)	-0.61 (1.208)	1.08 (-2.205, 4.375)	0.5175
Hedges' g SMD							0.05 (-0.104, 0.206)	0.5179
5 or 6	19	26.32 (28.499)	-0.33 (5.700)	7	9.52 (16.265)	-6.16 (10.455)	5.83 (-20.858, 32.517)	0.6500
Hedges' g SMD							0.22 (-0.648, 1.090)	0.6186
Int. p-value								0.2679
Geographic region								
North America	83	26.91 (24.115)	3.54 (2.535)	90	31.85 (31.170)	0.45 (2.503)	3.09 (-3.953, 10.137)	0.3873
Hedges' g SMD							0.13 (-0.167, 0.430)	0.3885
South America	13	7.69 (14.618)	-5.51 (3.042)	9	29.63 (30.932)	0.56 (4.254)	-6.07 (-17.658, 5.517)	0.2835
Hedges' g SMD							-0.50 (-1.364, 0.367)	0.2590
Europe	396	32.07 (31.036)	-0.04 (1.111)	373	33.15 (31.299)	-1.06 (1.135)	1.02 (-2.099, 4.137)	0.5212
Hedges' g SMD							0.05 (-0.095, 0.188)	0.5215
Asia Pacific and South Africa	279	21.15 (23.715)	-1.08 (1.045)	301	22.37 (25.708)	0.11 (1.011)	-1.19 (-4.048, 1.665)	0.4131
Hedges' g SMD							-0.07 (-0.231, 0.095)	0.4135
Int. p-value								0.5735
Sponsor								
AZ	696	27.20 (28.567)	-0.49 (0.769)	702	28.63 (29.500)	-0.29 (0.764)	-0.20 (-2.322, 1.931)	0.8570
Hedges' g SMD							-0.01 (-0.114, 0.095)	0.8570
NRG Oncology	75	26.67 (24.507)	4.84 (2.556)	71	30.05 (30.940)	-1.36 (2.704)	6.20 (-1.163, 13.564)	0.0981
Hedges' g SMD							0.27 (-0.051, 0.601)	0.0987
Int. p-value								0.0723

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Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.1.15 OLYMPIA: Summary of subgroup analysis of change from baseline in EORTC QLQ-C30 Single item symptom scale: Insomnia (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
BRCA mutation type								
BRCA1	492	28.12 (28.738)	-0.31 (0.940)	490	31.02 (30.657)	-1.76 (0.940)	1.46 (-1.154, 4.066)	0.2738
Hedges' g SMD							0.07 (-0.055, 0.195)	0.2739
BRCA2	195	29.06 (28.296)	-0.31 (1.522)	185	28.65 (29.319)	1.47 (1.570)	-1.78 (-6.080, 2.522)	0.4165
Hedges' g SMD							-0.08 (-0.285, 0.118)	0.4170
Int. p-value								0.2409

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Figure 5.2.1.1 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Physical across timepoints, by treatment group for Type of prior Neo/Adjuvant chemotherapy=Anthracycline
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.2 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Physical across timepoints, by treatment group for Type of prior Neo/Adjuvant chemotherapy=Taxane
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.3 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Physical across timepoints, by treatment group for Type of prior Neo/Adjuvant chemotherapy=Anthracycline + Taxane
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.4 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Role across timepoints, by treatment group for Type of prior Neo/Adjuvant chemotherapy=Anthracycline
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.5 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Role across timepoints, by treatment group for Type of prior Neo/Adjuvant chemotherapy=Taxane
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.6 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Role across timepoints, by treatment group for Type of prior Neo/Adjuvant chemotherapy=Anthracycline + Taxane
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.7 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Role across timepoints, by treatment group for Axillary nodal status at surgery prior to rand. (post adjuvant only)=Positive
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.8 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Role across timepoints, by treatment group for Axillary nodal status at surgery prior to rand. (post adjuvant only)=Negative
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.9 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Cognitive across timepoints, by treatment group for Jewish descent=Yes Ashkenazi
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.10 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Cognitive across timepoints, by treatment group for Jewish descent=No
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.11 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Emotional across timepoints, by treatment group for Jewish descent=Yes Ashkenazi
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.12 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Emotional across timepoints, by treatment group for Jewish descent=No
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.13 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Social across timepoints, by treatment group for Axillary nodal status at surgery prior to rand. (post adjuvant only)=Positive
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.14 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Social across timepoints, by treatment group for Axillary nodal status at surgery prior to rand. (post adjuvant only)=Negative
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.15 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Social across timepoints, by treatment group for BRCA mutation type=BRCA1
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.16 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Functional scale: Social across timepoints, by treatment group for BRCA mutation type=BRCA2
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.17 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Loss of appetite across timepoints, by treatment group for Menopausal status at screening=Premenopausal
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.18 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Loss of appetite across timepoints, by treatment group for Menopausal status at screening=Postmenopausal
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.19 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Loss of appetite across timepoints, by treatment group for Jewish descent=Yes Ashkenazi
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.20 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Loss of appetite across timepoints, by treatment group for Jewish descent=No
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.21 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Constipation across timepoints, by treatment group for Hormone receptor status (eCRF)=ER and/or PgR positive/HER2 negative
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.22 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Constipation across timepoints, by treatment group for Hormone receptor status (eCRF)=TNBC
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.23 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Constipation across timepoints, by treatment group for Jewish descent=Yes Ashkenazi
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.24 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Constipation across timepoints, by treatment group for Jewish descent=No
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.25 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Diarrhoea across timepoints, by treatment group for Jewish descent=Yes Ashkenazi
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.26 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Diarrhoea across timepoints, by treatment group for Jewish descent=No
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.27 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Dyspnoea across timepoints, by treatment group for Type of prior Neo/Adjuvant chemotherapy=Anthracycline
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.28 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Dyspnoea across timepoints, by treatment group for Type of prior Neo/Adjuvant chemotherapy=Taxane
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.29 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Dyspnoea across timepoints, by treatment group for Type of prior Neo/Adjuvant chemotherapy=Anthracycline + Taxane
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.30 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Dyspnoea across timepoints, by treatment group for Axillary nodal status at surgery prior to rand. (post adjuvant only)=Positive
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.31 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Dyspnoea across timepoints, by treatment group for Axillary nodal status at surgery prior to rand. (post adjuvant only)=Negative
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.32 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Symptom scale: Fatigue across timepoints, by treatment group for BRCA mutation type=BRCA1
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.33 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Symptom scale: Fatigue across timepoints, by treatment group for BRCA mutation type=BRCA2
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.34 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Financial difficulties across timepoints, by treatment group for Platinum therapy for current breast cancer (eCRF)=Yes
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.35 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Financial difficulties across timepoints, by treatment group for Platinum therapy for current breast cancer (eCRF)=No
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.36 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Financial difficulties across timepoints, by treatment group for BRCA mutation type=BRCA1
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.37 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Financial difficulties across timepoints, by treatment group for BRCA mutation type=BRCA2
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.38 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Symptom scale: Nausea and vomiting across timepoints, by treatment group for Platinum therapy for current breast cancer (eCRF)=Yes
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.39 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Symptom scale: Nausea and vomiting across timepoints, by treatment group
for Platinum therapy for current breast cancer (eCRF)=No
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.40 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Symptom scale: Nausea and vomiting across timepoints, by treatment group
for BRCA mutation type=BRCA1
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.41 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Symptom scale: Nausea and vomiting across timepoints, by treatment group for BRCA mutation type=BRCA2
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.42 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Symptom scale: Pain across timepoints, by treatment group for Axillary nodal status at surgery prior to rand. (post adjuvant only)=Positive
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.43 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Symptom scale: Pain across timepoints, by treatment group for Axillary nodal status at surgery prior to rand. (post adjuvant only)=Negative
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.44 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Insomnia across timepoints, by treatment group for Axillary nodal status at surgery prior to rand. (post adjuvant only)=Positive
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Figure 5.2.1.45 OLYMPIA: Mean (+/- SD) for EORTC QLQ-C30 Single item symptom scale: Insomnia across timepoints, by treatment group for Axillary nodal status at surgery prior to rand. (post adjuvant only)=Negative
Full Analysis Set, DCO 12JUL2021

Only subgroups with interaction p-value <= 0.05 in MMRM analysis are presented.
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Anhang 4-G6: Subgruppenanalysen: FACIT-Fatigue

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Table 5.1.2.1 OLYMPIA: Summary of subgroup analysis of change from baseline in FACIT-F Fatigue scale (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Hormone receptor status (eCRF)								
ER and/or PgR positive/HER2 negative	136	40.09 (10.636)	-0.63 (0.552)	135	40.64 (8.715)	0.62 (0.557)	-1.25 (-2.794, 0.296)	0.1125
Hedges' g SMD							-0.19 (-0.432, 0.046)	0.1130
TNBC	628	40.32 (9.465)	0.09 (0.257)	638	40.39 (8.919)	0.82 (0.255)	-0.73 (-1.437, -0.016)	0.0450*
Hedges' g SMD							-0.11 (-0.223, -0.002)	0.0451*
Int. p-value								0.4633
Sequence Chemo/ surgery (eCRF)								
Adjuvant chemotherapy	384	40.77 (9.088)	0.15 (0.322)	409	40.81 (8.718)	0.86 (0.313)	-0.71 (-1.592, 0.172)	0.1142
Hedges' g SMD							-0.11 (-0.252, 0.027)	0.1145
Neoadjuvant	382	39.76 (10.204)	-0.15 (0.335)	364	40.01 (9.049)	0.70 (0.342)	-0.85 (-1.789, 0.090)	0.0763
Hedges' g SMD							-0.13 (-0.274, 0.014)	0.0765
Int. p-value								0.8473
Platinum therapy for current breast cancer (eCRF)								
Yes	198	39.33 (10.017)	0.17 (0.483)	197	40.88 (8.966)	0.34 (0.484)	-0.17 (-1.515, 1.180)	0.8070
Hedges' g SMD							-0.02 (-0.222, 0.173)	0.8068
No	568	40.59 (9.530)	-0.06 (0.266)	576	40.28 (8.851)	0.92 (0.264)	-0.98 (-1.712, -0.242)	0.0092*
Hedges' g SMD							-0.15 (-0.270, -0.038)	0.0093*
Int. p-value								0.4639
Age [years]								
<50	578	40.69 (9.382)	0.13 (0.264)	568	40.37 (9.123)	0.89 (0.267)	-0.76 (-1.495, -0.019)	0.0443*
Hedges' g SMD							-0.12 (-0.235, -0.003)	0.0444*
50-64	164	39.32 (10.306)	-0.22 (0.517)	175	40.37 (8.171)	0.75 (0.497)	-0.97 (-2.379, 0.446)	0.1791
Hedges' g SMD							-0.15 (-0.359, 0.067)	0.1792

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.2.1 OLYMPIA: Summary of subgroup analysis of change from baseline in FACIT-F Fatigue scale (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
>=65	24	36.59 (11.072)	-2.04 (1.459)	30	41.93 (8.246)	-0.94 (1.273)	-1.10 (-5.052, 2.858)	0.5799
Hedges' g SMD							-0.15 (-0.691, 0.384)	0.5762
Int. p-value								0.8671
Menopausal status at screening								
Premenopausal	479	40.98 (9.195)	0.06 (0.289)	466	40.96 (8.490)	0.81 (0.293)	-0.75 (-1.557, 0.056)	0.0683
Hedges' g SMD							-0.12 (-0.246, 0.009)	0.0684
Postmenopausal	285	39.03 (10.342)	-0.17 (0.393)	303	39.62 (9.379)	0.77 (0.380)	-0.94 (-2.015, 0.135)	0.0865
Hedges' g SMD							-0.14 (-0.303, 0.020)	0.0867
Int. p-value								0.8217
Type of prior Neo/Adjuvant chemotherapy								
Anthracycline	6	33.33 (9.136)	5.49 (3.403)	8	45.00 (3.854)	-1.81 (2.579)	7.30 (-3.634, 18.234)	0.1712
Hedges' g SMD							0.88 (-0.244, 2.009)	0.1247
Taxane	37	38.12 (10.338)	-0.34 (1.042)	39	42.48 (9.268)	3.12 (1.022)	-3.45 (-6.401, -0.500)	0.0226*
Hedges' g SMD							-0.54 (-0.995, -0.079)	0.0216*
Anthracycline + Taxane	723	40.43 (9.615)	-0.04 (0.240)	725	40.27 (8.883)	0.70 (0.240)	-0.74 (-1.408, -0.078)	0.0286*
Hedges' g SMD							-0.12 (-0.218, -0.012)	0.0286*
Int. p-value								0.0579
Type of breast surgery prior to randomisation								
Breast conservation	188	40.62 (9.677)	-0.78 (0.472)	207	40.98 (8.134)	0.21 (0.453)	-0.98 (-2.272, 0.302)	0.1332
Hedges' g SMD							-0.15 (-0.349, 0.046)	0.1338
Unilateral mastectomy	293	40.84 (9.535)	0.37 (0.363)	298	41.02 (8.786)	0.79 (0.358)	-0.42 (-1.419, 0.582)	0.4116
Hedges' g SMD							-0.07 (-0.229, 0.094)	0.4120
Bilateral mastectomy	285	39.45 (9.773)	0.12 (0.397)	266	39.42 (9.445)	1.33 (0.411)	-1.20 (-2.327, -0.083)	0.0354*
Hedges' g SMD							-0.18 (-0.347, -0.012)	0.0355*

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.2.1 OLYMPIA: Summary of subgroup analysis of change from baseline in FACIT-F Fatigue scale (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.5586
Bilateral Oophorectomy								
Yes	154	39.77 (9.731)	0.18 (0.543)	147	39.29 (9.069)	1.45 (0.556)	-1.27 (-2.803, 0.258)	0.1028
Hedges' g SMD							-0.19 (-0.415, 0.038)	0.1032
No	612	40.39 (9.655)	-0.06 (0.258)	626	40.70 (8.819)	0.64 (0.255)	-0.70 (-1.409, 0.015)	0.0550
Hedges' g SMD							-0.11 (-0.221, 0.002)	0.0551
Int. p-value								0.4095
Axillary nodal status at surgery prior to rand. (post adjuvant only)								
Positive	155	41.38 (8.078)	0.56 (0.524)	158	40.25 (8.822)	0.38 (0.523)	0.18 (-1.277, 1.641)	0.8060
Hedges' g SMD							0.03 (-0.194, 0.249)	0.8061
Negative	166	40.42 (9.849)	-0.01 (0.460)	175	41.22 (8.414)	1.52 (0.448)	-1.53 (-2.792, -0.264)	0.0180*
Hedges' g SMD							-0.26 (-0.470, -0.044)	0.0181*
Int. p-value								0.1029
Hormone receptor status by prior chemotherapy setting								
ER and/or PgR positive with neoadjuvant chemotherapy	87	39.48 (11.381)	-0.24 (0.710)	74	40.28 (8.741)	1.54 (0.779)	-1.78 (-3.864, 0.302)	0.0932
Hedges' g SMD							-0.27 (-0.578, 0.045)	0.0938
ER and/or PgR positive with adjuvant chemotherapy	49	41.17 (9.179)	-1.22 (0.842)	61	41.08 (8.736)	-0.50 (0.745)	-0.72 (-2.954, 1.514)	0.5241
Hedges' g SMD							-0.12 (-0.498, 0.254)	0.5250
ER and PgR negative with neoadjuvant chemotherapy	293	39.87 (9.876)	-0.20 (0.381)	290	39.94 (9.139)	0.51 (0.379)	-0.71 (-1.766, 0.347)	0.1876
Hedges' g SMD							-0.11 (-0.272, 0.053)	0.1880

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.2.1 OLYMPIA: Summary of subgroup analysis of change from baseline in FACIT-F Fatigue scale (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
ER and PgR negative with adjuvant chemotherapy	335	40.71 (9.087)	0.36 (0.344)	348	40.76 (8.727)	1.08 (0.339)	-0.72 (-1.664, 0.232)	0.1384
Hedges' g SMD							-0.11 (-0.264, 0.037)	0.1387
Int. p-value								0.8291
Race								
White	506	39.54 (10.344)	-0.14 (0.310)	485	39.86 (9.259)	0.60 (0.317)	-0.73 (-1.604, 0.136)	0.0981
Hedges' g SMD							-0.11 (-0.230, 0.019)	0.0983
Black/African-American	11	33.36 (14.590)	5.35 (2.539)	20	37.37 (11.556)	5.45 (1.592)	-0.09 (-6.347, 6.157)	0.9750
Hedges' g SMD							-0.01 (-0.748, 0.724)	0.9741
Asian	237	42.03 (7.376)	-0.11 (0.342)	257	41.65 (7.808)	1.05 (0.329)	-1.16 (-2.094, -0.229)	0.0148*
Hedges' g SMD							-0.22 (-0.397, -0.043)	0.0149*
Other	12	42.42 (9.080)	2.30 (1.910)	11	42.45 (6.654)	-2.28 (1.734)	4.57 (-0.939, 10.084)	0.0982
Hedges' g SMD							0.71 (-0.140, 1.557)	0.1017
Int. p-value								0.1951
Ethnicity								
Hispanic	26	43.96 (7.040)	-0.27 (1.238)	17	40.22 (9.192)	0.94 (1.560)	-1.21 (-5.292, 2.865)	0.5512
Hedges' g SMD							-0.19 (-0.800, 0.425)	0.5491
Non-hispanic	682	40.30 (9.569)	-0.07 (0.246)	692	40.62 (8.579)	0.84 (0.244)	-0.91 (-1.586, -0.226)	0.0091*
Hedges' g SMD							-0.14 (-0.247, -0.035)	0.0091*
Not known, not recorded or refused	58	38.20 (11.317)	0.51 (0.899)	64	38.43 (11.525)	0.20 (0.873)	0.31 (-2.176, 2.790)	0.8070
Hedges' g SMD							0.04 (-0.311, 0.399)	0.8080
Int. p-value								0.7892
Jewish descent								

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ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.2.1 OLYMPIA: Summary of subgroup analysis of change from baseline in FACIT-F Fatigue scale (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Yes Ashkenazi	32	39.75 (8.455)	0.83 (1.251)	26	38.93 (10.259)	-1.36 (1.445)	2.18 (-1.663, 6.029)	0.2588
Hedges' g SMD							0.30 (-0.222, 0.819)	0.2606
No	734	40.29 (9.721)	-0.05 (0.237)	745	40.47 (8.837)	0.84 (0.235)	-0.89 (-1.546, -0.235)	0.0078*
Hedges' g SMD							-0.14 (-0.241, -0.037)	0.0078*
Int. p-value								0.1451
CPS+EG score at baseline (post neoadjuvant only)								
2, 3 or 4	332	39.85 (10.237)	-0.07 (0.357)	307	39.80 (9.245)	0.77 (0.370)	-0.84 (-1.851, 0.169)	0.1024
Hedges' g SMD							-0.13 (-0.285, 0.026)	0.1027
5 or 6	19	39.79 (8.561)	-0.73 (1.755)	7	39.14 (11.246)	-3.40 (3.066)	2.66 (-4.803, 10.132)	0.4655
Hedges' g SMD							0.33 (-0.540, 1.204)	0.4553
Int. p-value								0.5910
Geographic region								
North America	84	39.12 (9.376)	1.68 (0.754)	90	39.88 (10.536)	1.81 (0.744)	-0.13 (-2.220, 1.965)	0.9043
Hedges' g SMD							-0.02 (-0.316, 0.279)	0.9046
South America	13	46.62 (3.709)	0.05 (1.528)	9	43.52 (7.757)	-2.78 (1.900)	2.84 (-2.429, 8.105)	0.2694
Hedges' g SMD							0.49 (-0.376, 1.353)	0.2680
Europe	391	39.07 (10.992)	-0.08 (0.356)	372	39.67 (9.250)	0.69 (0.362)	-0.76 (-1.759, 0.235)	0.1339
Hedges' g SMD							-0.11 (-0.251, 0.033)	0.1341
Asia Pacific and South Africa	278	42.00 (7.330)	-0.36 (0.337)	302	41.44 (7.758)	0.81 (0.324)	-1.16 (-2.081, -0.245)	0.0131*
Hedges' g SMD							-0.21 (-0.370, -0.043)	0.0132*
Int. p-value								0.3580
Sponsor								
AZ	690	40.39 (9.677)	-0.19 (0.245)	702	40.42 (8.760)	0.63 (0.243)	-0.82 (-1.496, -0.142)	0.0178*
Hedges' g SMD							-0.13 (-0.232, -0.022)	0.0178*
NRG Oncology	76	39.18 (9.578)	1.77 (0.726)	71	40.57 (10.043)	2.53 (0.769)	-0.76 (-2.855, 1.334)	0.4743
Hedges' g SMD							-0.12 (-0.442, 0.206)	0.4744

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
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Table 5.1.2.1 OLYMPIA: Summary of subgroup analysis of change from baseline in FACIT-F Fatigue scale (mixed model for repeated measures) - average over all visits
Full Analysis Set, DCO 12JUL2021

	Olaparib (N=921)			Placebo (N=915)			Difference between groups	
Subgroup	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	n [a]	Mean (SD) at Baseline [b]	Mean (SE) Change from baseline	Estimated difference (95% CI)	p-value
Int. p-value								0.9380
BRCA mutation type								
BRCA1	488	40.25 (9.395)	-0.45 (0.294)	490	40.18 (8.927)	0.69 (0.293)	-1.14 (-1.951, -0.325)	0.0061*
Hedges' g SMD							-0.18 (-0.301, -0.050)	0.0062*
BRCA2	194	38.64 (11.066)	1.14 (0.505)	185	40.33 (9.542)	0.99 (0.518)	0.16 (-1.266, 1.582)	0.8275
Hedges' g SMD							0.02 (-0.179, 0.224)	0.8274
Int. p-value								0.0801

[a] = number of patients with change from baseline in the MMRM analysis.
[b] = mean baseline for patients with change from baseline in the MMRM analysis.
ID = insufficient data. NC = not calculable due to convergence issues. Results for subgroup levels from separate models including treatment, visit, baseline, treatment by visit interaction and baseline by visit interaction for each subgroup level (ID where <10 patients with data for a subgroup level). Interaction p-values from models including the above terms plus subgroup and treatment by subgroup interaction (ID where <=1 subgroup level with >=10 patients).
Only visits included in the related main analysis for this endpoint are included. An unstructured covariance matrix is used to model within-subject error, p-values from type 3 tests. SMD = standardised mean difference.
root/cdar/d081/_iemt/ar/iemt_payer_olympia_germany/tlf/prod/program/mmrmsubpr.sas emmrmsubprba 06APR2022:09:42 khcs324

Anhang 4-G7: Subgruppenanalysen: Gesamtraten unerwünschter Ereignisse

Tabelle 6.1.1: Subgruppenergebnisse für Gesamtraten unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
UE					
Alter (Interaktionstest: p=0,8684)					
<50	690	630 (91,3)	663	553 (83,4)	2,09 [1,49; 2,92]; <0,0001 1,09 [1,05; 1,14]; <0,0001 0,08 [0,04; 0,11]; <0,0001
50-64	192	177 (92,2)	209	175 (83,7)	2,29 [1,21; 4,36]; 0,0114 1,10 [1,02; 1,18]; 0,0094 0,08 [0,02; 0,15]; 0,0083
≥65	29	29 (100,0)	32	30 (93,8)	4,84 [0,22; 105,04]; 0,3156 1,06 [0,95; 1,19]; 0,2617 0,06 [-0,04; 0,16]; 0,2263
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6164)					
Anthrazyklin	7	6 (85,7)	13	9 (69,2)	2,67 [0,24; 30,07]; 0,4275 1,24 [0,77; 1,98]; 0,3752 0,16 [-0,20; 0,53]; 0,3705
Anthrazyklin und Taxan	861	791 (91,9)	840	704 (83,8)	2,18 [1,61; 2,96]; <0,0001 1,10 [1,06; 1,14]; <0,0001 0,08 [0,05; 0,11]; <0,0001
Taxan	43	39 (90,7)	50	44 (88,0)	1,33 [0,35; 5,06]; 0,6762 1,03 [0,90; 1,19]; 0,6728 0,03 [-0,10; 0,15]; 0,6726
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0123)					
Brusterhaltend	220	197 (89,5)	235	189 (80,4)	2,08 [1,22; 3,57]; 0,0075 1,11 [1,03; 1,20]; 0,0066 0,09 [0,03; 0,16]; 0,0059
Einseitige Mastektomie	355	324 (91,3)	352	280 (79,6)	2,69 [1,71; 4,22]; <0,0001 1,15 [1,08; 1,22]; <0,0001 0,12 [0,07; 0,17]; <0,0001
Beidseitige Mastektomie	336	315 (93,8)	315	287 (91,1)	1,46 [0,81; 2,63]; 0,2043 1,03 [0,98; 1,08]; 0,2053 0,03 [-0,01; 0,07]; 0,2039
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,1445)					
Ja	41	41 (100,0)	35	34 (97,1)	3,61 [0,14; 91,44]; 0,4365 1,03 [0,96; 1,11]; 0,4289 0,03 [-0,04; 0,10]; 0,4433
Nein	870	795 (91,4)	866	721 (83,3)	2,13 [1,58; 2,87]; <0,0001 1,10 [1,06; 1,14]; <0,0001 0,08 [0,05; 0,11]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,4562)					
Positiv	173	160 (92,5)	176	148 (84,1)	2,33 [1,16; 4,66]; 0,0171 1,10 [1,02; 1,19]; 0,0155 0,08 [0,02; 0,15]; 0,0138
Negativ	200	185 (92,5)	191	154 (80,6)	2,96 [1,57; 5,60]; 0,0008 1,15 [1,06; 1,24]; 0,0008 0,12 [0,05; 0,19]; 0,0005
Bilaterale Oophorektomie (Interaktionstest: p=0,0696)					
Ja	189	177 (93,7)	176	159 (90,3)	1,58 [0,73; 3,40]; 0,2458 1,04 [0,98; 1,10]; 0,2470 0,03 [-0,02; 0,09]; 0,2450
Nein	722	659 (91,3)	728	599 (82,3)	2,25 [1,63; 3,11]; <0,0001 1,11 [1,07; 1,16]; <0,0001 0,09 [0,06; 0,12]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,9229)					
BRCA1	574	527 (91,8)	580	491 (84,7)	2,03 [1,40; 2,95]; 0,0002 1,08 [1,04; 1,13]; 0,0002 0,07 [0,03; 0,11]; 0,0001
BRCA2	232	215 (92,7)	215	183 (85,1)	2,21 [1,19; 4,11]; 0,0122 1,09 [1,02; 1,16]; 0,0123 0,08 [0,02; 0,13]; 0,0109
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,8746)					
2, 3 oder 4	392	354 (90,3)	383	323 (84,3)	1,73 [1,12; 2,67]; 0,0131 1,07 [1,01; 1,13]; 0,0130 0,06 [0,01; 0,11]; 0,0122
5 oder 6	22	19 (86,4)	14	11 (78,6)	1,73 [0,30; 10,08]; 0,5437 1,10 [0,80; 1,51]; 0,5625 0,08 [-0,18; 0,34]; 0,5545
Ethnie (Interaktionstest: p=0,7276)					
Andere	16	14 (87,5)	15	13 (86,7)	1,08 [0,13; 8,80]; 0,9449 1,01 [0,77; 1,32]; 0,9449 0,01 [-0,23; 0,24]; 0,9449
Asiatisch	259	245 (94,6)	271	228 (84,1)	3,30 [1,76; 6,19]; 0,0002 1,12 [1,06; 1,19]; 0,0001 0,10 [0,05; 0,16]; <0,0001
Kaukasisch	617	560 (90,8)	589	493 (83,7)	1,91 [1,35; 2,71]; 0,0003 1,08 [1,04; 1,13]; 0,0003 0,07 [0,03; 0,11]; 0,0002
Schwarz oder afroamerikanisch	19	17 (89,5)	29	24 (82,8)	1,77 [0,31; 10,23]; 0,5230 1,08 [0,86; 1,36]; 0,5000 0,07 [-0,13; 0,26]; 0,4993

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,8118)					
Hispanisch	34	26 (76,5)	24	15 (62,5)	1,95 [0,62; 6,13]; 0,2529 1,22 [0,85; 1,76]; 0,2743 0,14 [-0,10; 0,38]; 0,2549
Nicht-hispanisch	798	738 (92,5)	803	678 (84,4)	2,27 [1,64; 3,14]; <0,0001 1,10 [1,06; 1,14]; <0,0001 0,08 [0,05; 0,11]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	72 (91,1)	77	65 (84,4)	1,90 [0,71; 5,11]; 0,2045 1,08 [0,96; 1,21]; 0,2033 0,07 [-0,04; 0,17]; 0,1982
Hormonrezeptorstatus (Interaktionstest: p=0,8079)					
ER- und/oder PgR-positiv, HER2-positiv	168	159 (94,6)	155	133 (85,8)	2,92 [1,30; 6,56]; 0,0094 1,10 [1,02; 1,19]; 0,0089 0,09 [0,02; 0,15]; 0,0074
TNBC	741	675 (91,1)	749	625 (83,4)	2,03 [1,48; 2,79]; <0,0001 1,09 [1,05; 1,14]; <0,0001 0,08 [0,04; 0,11]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,4997)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	97 (93,3)	92	80 (87,0)	2,08 [0,78; 5,53]; 0,1426 1,07 [0,98; 1,18]; 0,1460 0,06 [-0,02; 0,15]; 0,1407
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	62 (96,9)	63	53 (84,1)	5,85 [1,23; 27,89]; 0,0267 1,15 [1,03; 1,29]; 0,0171 0,13 [0,03; 0,23]; 0,0123
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	311 (89,4)	362	304 (84,0)	1,60 [1,03; 2,49]; 0,0361 1,06 [1,00; 1,13]; 0,0348 0,05 [0,00; 0,10]; 0,0338
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	364 (92,6)	387	321 (82,9)	2,58 [1,63; 4,10]; <0,0001 1,12 [1,06; 1,18]; <0,0001 0,10 [0,05; 0,14]; <0,0001
Menopausenstatus (Interaktionstest: p=0,2936)					
Postmenopausal	346	323 (93,4)	356	310 (87,1)	2,08 [1,23; 3,52]; 0,0060 1,07 [1,02; 1,13]; 0,0053 0,06 [0,02; 0,11]; 0,0048
Prämenopausal	563	511 (90,8)	544	444 (81,6)	2,21 [1,55; 3,17]; <0,0001 1,11 [1,06; 1,17]; <0,0001 0,09 [0,05; 0,13]; <0,0001
Region (Interaktionstest: p=0,0069)					
Asien-Pazifik und Südafrika	301	288 (95,7)	317	273 (86,1)	3,57 [1,88; 6,77]; <0,0001 1,11 [1,06; 1,17]; <0,0001 0,10 [0,05; 0,14]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	423 (89,4)	444	356 (80,2)	2,09 [1,44; 3,04]; 0,0001 1,12 [1,05; 1,18]; 0,0001 0,09 [0,05; 0,14]; <0,0001
Nordamerika	121	115 (95,0)	131	125 (95,4)	0,92 [0,29; 2,93]; 0,8879 1,00 [0,94; 1,05]; 0,8881 0,00 [-0,06; 0,05]; 0,8881
Südamerika	16	10 (62,5)	12	4 (33,3)	3,33 [0,69; 16,02]; 0,1328 1,88 [0,77; 4,55]; 0,1642 0,29 [-0,07; 0,65]; 0,1093
Art der vorherigen Chemotherapie (Interaktionstest: p=0,1635)					
Adjuvant	457	426 (93,2)	450	374 (83,1)	2,79 [1,80; 4,34]; <0,0001 1,12 [1,07; 1,18]; <0,0001 0,10 [0,06; 0,14]; <0,0001
Neoadjuvant	454	410 (90,3)	454	384 (84,6)	1,70 [1,14; 2,54]; 0,0098 1,07 [1,02; 1,12]; 0,0095 0,06 [0,01; 0,10]; 0,0090
Sponsor (Interaktionstest: p=0,0005)					
AZ	801	732 (91,4)	796	654 (82,2)	2,30 [1,70; 3,13]; <0,0001 1,11 [1,07; 1,16]; <0,0001 0,09 [0,06; 0,13]; <0,0001
NRG Oncology	110	104 (94,5)	108	104 (96,3)	0,67 [0,18; 2,43]; 0,5391 0,98 [0,93; 1,04]; 0,5364 -0,02 [-0,07; 0,04]; 0,5357
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,2735)					
Ja	243	228 (93,8)	236	196 (83,1)	3,10 [1,66; 5,79]; 0,0004 1,13 [1,06; 1,21]; 0,0003 0,11 [0,05; 0,16]; 0,0002
Nein	668	608 (91,0)	668	562 (84,1)	1,91 [1,36; 2,68]; 0,0002 1,08 [1,04; 1,13]; 0,0001 0,07 [0,03; 0,10]; 0,0001
Nicht schwere UE					
Alter (Interaktionstest: p=0,0827)					
<50	690	516 (74,8)	663	500 (75,4)	0,97 [0,76; 1,24]; 0,7881 0,99 [0,93; 1,05]; 0,7880 -0,01 [-0,05; 0,04]; 0,7881
50-64	192	134 (69,8)	209	149 (71,3)	0,93 [0,61; 1,43]; 0,7419 0,98 [0,86; 1,11]; 0,7422 -0,02 [-0,10; 0,07]; 0,7420
≥65	29	16 (55,2)	32	27 (84,4)	0,23 [0,07; 0,76]; 0,0159 0,65 [0,46; 0,94]; 0,0209 -0,29 [-0,51; -0,07]; 0,0094

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,8561)					
Anthrazyklin	7	5 (71,4)	13	9 (69,2)	1,11 [0,15; 8,37]; 0,9185 1,03 [0,57; 1,87]; 0,9176 0,02 [-0,40; 0,44]; 0,9180
Anthrazyklin und Taxan	861	628 (72,9)	840	630 (75,0)	0,90 [0,72; 1,12]; 0,3328 0,97 [0,92; 1,03]; 0,3327 -0,02 [-0,06; 0,02]; 0,3325
Taxan	43	33 (76,7)	50	37 (74,0)	1,16 [0,45; 2,99]; 0,7598 1,04 [0,82; 1,31]; 0,7589 0,03 [-0,15; 0,20]; 0,7590
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,3898)					
Brusterhaltend	220	157 (71,4)	235	177 (75,3)	0,82 [0,54; 1,24]; 0,3403 0,95 [0,85; 1,06]; 0,3416 -0,04 [-0,12; 0,04]; 0,3402
Einseitige Mastektomie	355	261 (73,5)	352	252 (71,6)	1,10 [0,79; 1,53]; 0,5653 1,03 [0,94; 1,12]; 0,5654 0,02 [-0,05; 0,09]; 0,5652
Beidseitige Mastektomie	336	248 (73,8)	315	245 (77,8)	0,81 [0,56; 1,15]; 0,2383 0,95 [0,87; 1,04]; 0,2372 -0,04 [-0,11; 0,03]; 0,2366
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,9254)					
Ja	41	34 (82,9)	35	30 (85,7)	0,81 [0,23; 2,82]; 0,7400 0,97 [0,80; 1,17]; 0,7382 -0,03 [-0,19; 0,14]; 0,7381
Nein	870	632 (72,6)	866	644 (74,4)	0,92 [0,74; 1,13]; 0,4166 0,98 [0,92; 1,03]; 0,4166 -0,02 [-0,06; 0,02]; 0,4164
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,6672)					
Positiv	173	125 (72,3)	176	130 (73,9)	0,92 [0,57; 1,48]; 0,7348 0,98 [0,86; 1,11]; 0,7348 -0,02 [-0,11; 0,08]; 0,7347
Negativ	200	145 (72,5)	191	147 (77,0)	0,79 [0,50; 1,25]; 0,3108 0,94 [0,84; 1,06]; 0,3100 -0,04 [-0,13; 0,04]; 0,3090
Bilaterale Oophorektomie (Interaktionstest: p=0,1954)					
Ja	189	135 (71,4)	176	138 (78,4)	0,69 [0,43; 1,11]; 0,1258 0,91 [0,81; 1,03]; 0,1243 -0,07 [-0,16; 0,02]; 0,1224
Nein	722	531 (73,6)	728	538 (73,9)	0,98 [0,78; 1,24]; 0,8778 1,00 [0,94; 1,06]; 0,8778 0,00 [-0,05; 0,04]; 0,8778

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,3331)					
BRCA1	574	416 (72,5)	580	439 (75,7)	0,85 [0,65; 1,10]; 0,2128 0,96 [0,89; 1,03]; 0,2130 -0,03 [-0,08; 0,02]; 0,2123
BRCA2	232	176 (75,9)	215	160 (74,4)	1,08 [0,70; 1,66]; 0,7242 1,02 [0,92; 1,13]; 0,7245 0,01 [-0,07; 0,09]; 0,7243
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,2055)					
2, 3 oder 4	392	286 (73,0)	383	288 (75,2)	0,89 [0,65; 1,23]; 0,4776 0,97 [0,89; 1,05]; 0,4775 -0,02 [-0,08; 0,04]; 0,4772
5 oder 6	22	17 (77,3)	14	8 (57,1)	2,55 [0,60; 10,92]; 0,2071 1,35 [0,81; 2,25]; 0,2434 0,20 [-0,11; 0,51]; 0,2072
Ethnie (Interaktionstest: p=0,5499)					
Andere	16	13 (81,3)	15	11 (73,3)	1,58 [0,29; 8,61]; 0,5998 1,11 [0,75; 1,63]; 0,6021 0,08 [-0,22; 0,37]; 0,5981
Asiatisch	259	197 (76,1)	271	211 (77,9)	0,90 [0,60; 1,35]; 0,6231 0,98 [0,89; 1,07]; 0,6234 -0,02 [-0,09; 0,05]; 0,6232
Kaukasisch	617	447 (72,5)	589	434 (73,7)	0,94 [0,73; 1,21]; 0,6285 0,98 [0,92; 1,05]; 0,6283 -0,01 [-0,06; 0,04]; 0,6283
Schwarz oder afroamerikanisch	19	9 (47,4)	29	20 (69,0)	0,41 [0,12; 1,34]; 0,1385 0,69 [0,40; 1,17]; 0,1673 -0,22 [-0,50; 0,06]; 0,1315
Ethnische Abstammung (Interaktionstest: p=0,9811)					
Hispanisch	34	20 (58,8)	24	14 (58,3)	1,02 [0,35; 2,95]; 0,9702 1,01 [0,65; 1,57]; 0,9703 0,00 [-0,25; 0,26]; 0,9702
Nicht-hispanisch	798	585 (73,3)	803	602 (75,0)	0,92 [0,73; 1,15]; 0,4481 0,98 [0,92; 1,04]; 0,4481 -0,02 [-0,06; 0,03]; 0,4480
Unbekannt, nicht erfasst, verweigert	79	61 (77,2)	77	60 (77,9)	0,96 [0,45; 2,04]; 0,9157 0,99 [0,84; 1,17]; 0,9157 -0,01 [-0,14; 0,12]; 0,9157
Hormonrezeptorstatus (Interaktionstest: p=0,9855)					
ER- und/oder PgR-positiv, HER2-positiv	168	126 (75,0)	155	119 (76,8)	0,91 [0,54; 1,51]; 0,7098 0,98 [0,86; 1,10]; 0,7094 -0,02 [-0,11; 0,08]; 0,7094

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	539 (72,7)	749	557 (74,4)	0,92 [0,73; 1,16]; 0,4767 0,98 [0,92; 1,04]; 0,4768 -0,02 [-0,06; 0,03]; 0,4766
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,5669)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	76 (73,1)	92	73 (79,4)	0,71 [0,36; 1,37]; 0,3059 0,92 [0,79; 1,08]; 0,3024 -0,06 [-0,18; 0,06]; 0,3008
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	50 (78,1)	63	46 (73,0)	1,32 [0,59; 2,98]; 0,5034 1,07 [0,88; 1,30]; 0,5039 0,05 [-0,10; 0,20]; 0,5022
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	254 (73,0)	362	263 (72,7)	1,02 [0,73; 1,42]; 0,9197 1,00 [0,92; 1,10]; 0,9197 0,00 [-0,06; 0,07]; 0,9197
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	285 (72,5)	387	294 (76,0)	0,83 [0,61; 1,15]; 0,2710 0,95 [0,88; 1,04]; 0,2709 -0,03 [-0,10; 0,03]; 0,2702
Menopausenstatus (Interaktionstest: p=0,2043)					
Postmenopausal	346	244 (70,5)	356	269 (75,6)	0,77 [0,55; 1,08]; 0,1326 0,93 [0,85; 1,02]; 0,1334 -0,05 [-0,12; 0,02]; 0,1319
Prämenopausal	563	420 (74,6)	544	404 (74,3)	1,02 [0,78; 1,33]; 0,8982 1,00 [0,94; 1,08]; 0,8982 0,00 [-0,05; 0,05]; 0,8982
Region (Interaktionstest: p=0,0966)					
Asien-Pazifik und Südafrika	301	230 (76,4)	317	250 (78,9)	0,87 [0,59; 1,27]; 0,4645 0,97 [0,89; 1,05]; 0,4652 -0,02 [-0,09; 0,04]; 0,4646
Europa	473	345 (72,9)	444	319 (71,9)	1,06 [0,79; 1,41]; 0,7116 1,02 [0,94; 1,10]; 0,7118 0,01 [-0,05; 0,07]; 0,7117
Nordamerika	121	82 (67,8)	131	104 (79,4)	0,55 [0,31; 0,96]; 0,0373 0,85 [0,73; 0,99]; 0,0396 -0,12 [-0,22; -0,01]; 0,0355
Südamerika	16	9 (56,3)	12	3 (25,0)	3,86 [0,75; 19,84]; 0,1062 2,25 [0,77; 6,57]; 0,1378 0,31 [-0,03; 0,66]; 0,0759
Art der vorherigen Chemotherapie (Interaktionstest: p=0,7843)					
Adjuvant	457	335 (73,3)	450	340 (75,6)	0,89 [0,66; 1,20]; 0,4373 0,97 [0,90; 1,05]; 0,4372 -0,02 [-0,08; 0,03]; 0,4369
Neoadjuvant	454	331 (72,9)	454	336 (74,0)	0,95 [0,70; 1,27]; 0,7071 0,99 [0,91; 1,07]; 0,7071 -0,01 [-0,07; 0,05]; 0,7071

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,0270)					
AZ	801	593 (74,0)	796	589 (74,0)	1,00 [0,80; 1,25]; 0,9864 1,00 [0,94; 1,06]; 0,9864 0,00 [-0,04; 0,04]; 0,9864
NRG Oncology	110	73 (66,4)	108	87 (80,6)	0,48 [0,26; 0,88]; 0,0189 0,82 [0,70; 0,97]; 0,0191 -0,14 [-0,26; -0,03]; 0,0161
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,2279)					
Ja	243	186 (76,5)	236	175 (74,2)	1,14 [0,75; 1,72]; 0,5439 1,03 [0,93; 1,14]; 0,5442 0,02 [-0,05; 0,10]; 0,5438
Nein	668	480 (71,9)	668	501 (75,0)	0,85 [0,67; 1,09]; 0,1936 0,96 [0,90; 1,02]; 0,1937 -0,03 [-0,08; 0,02]; 0,1931
Schwere UE					
Alter (Interaktionstest: p=0,2997)					
<50	690	114 (16,5)	663	53 (8,0)	2,28 [1,61; 3,22]; <0,0001 2,07 [1,52; 2,81]; <0,0001 0,09 [0,05; 0,12]; <0,0001
50-64	192	43 (22,4)	209	26 (12,4)	2,03 [1,19; 3,46]; 0,0091 1,80 [1,15; 2,81]; 0,0097 0,10 [0,03; 0,17]; 0,0084
≥65	29	13 (44,8)	32	3 (9,4)	7,85 [1,94; 31,72]; 0,0038 4,78 [1,51; 15,11]; 0,0077 0,35 [0,15; 0,56]; 0,0008
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,2956)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	163 (18,9)	840	74 (8,8)	2,42 [1,80; 3,24]; <0,0001 2,15 [1,66; 2,78]; <0,0001 0,10 [0,07; 0,13]; <0,0001
Taxan	43	6 (14,0)	50	7 (14,0)	1,00 [0,31; 3,23]; 0,9949 1,00 [0,36; 2,74]; 0,9949 0,00 [-0,14; 0,14]; 0,9949
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0454)					
Brusterhaltend	220	40 (18,2)	235	12 (5,1)	4,13 [2,10; 8,11]; <0,0001 3,56 [1,92; 6,61]; <0,0001 0,13 [0,07; 0,19]; <0,0001
Einseitige Mastektomie	355	63 (17,8)	352	28 (8,0)	2,50 [1,56; 4,00]; 0,0001 2,23 [1,47; 3,40]; 0,0002 0,10 [0,05; 0,15]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	67 (19,9)	315	42 (13,3)	1,62 [1,06; 2,47]; 0,0249 1,50 [1,05; 2,13]; 0,0258 0,07 [0,01; 0,12]; 0,0228
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,5647)					
Ja	41	7 (17,1)	35	4 (11,4)	1,60 [0,43; 5,98]; 0,4883 1,49 [0,48; 4,68]; 0,4911 0,06 [-0,10; 0,21]; 0,4786
Nein	870	163 (18,7)	866	77 (8,9)	2,36 [1,77; 3,16]; <0,0001 2,11 [1,63; 2,72]; <0,0001 0,10 [0,07; 0,13]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,0345)					
Positiv	173	35 (20,2)	176	18 (10,2)	2,23 [1,21; 4,11]; 0,0105 1,98 [1,17; 3,36]; 0,0114 0,10 [0,03; 0,17]; 0,0087
Negativ	200	40 (20,0)	191	7 (3,7)	6,57 [2,86; 15,08]; <0,0001 5,46 [2,51; 11,88]; <0,0001 0,16 [0,10; 0,22]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,6558)					
Ja	189	42 (22,2)	176	21 (11,9)	2,11 [1,19; 3,73]; 0,0103 1,86 [1,15; 3,02]; 0,0114 0,10 [0,03; 0,18]; 0,0081
Nein	722	128 (17,7)	728	61 (8,4)	2,36 [1,70; 3,26]; <0,0001 2,12 [1,59; 2,82]; <0,0001 0,09 [0,06; 0,13]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,2771)					
BRCA1	574	111 (19,3)	580	52 (9,0)	2,43 [1,71; 3,46]; <0,0001 2,16 [1,58; 2,94]; <0,0001 0,10 [0,06; 0,14]; <0,0001
BRCA2	232	39 (16,8)	215	23 (10,7)	1,69 [0,97; 2,93]; 0,0637 1,57 [0,97; 2,54]; 0,0654 0,06 [0,00; 0,12]; 0,0589
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,0845)					
2, 3 oder 4	392	68 (17,4)	383	35 (9,1)	2,09 [1,35; 3,22]; 0,0009 1,90 [1,29; 2,78]; 0,0010 0,08 [0,03; 0,13]; 0,0007
5 oder 6	22	2 (9,1)	14	3 (21,4)	0,37 [0,05; 2,54]; 0,3094 0,42 [0,08; 2,23]; 0,3111 -0,12 [-0,37; 0,12]; 0,3261

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,2059)					
Andere	16	1 (6,3)	15	2 (13,3)	0,43 [0,04; 5,35]; 0,5142 0,47 [0,05; 4,65]; 0,5175 -0,07 [-0,28; 0,14]; 0,5064
Asiatisch	259	48 (18,5)	271	17 (6,3)	3,40 [1,90; 6,09]; <0,0001 2,95 [1,75; 5,00]; <0,0001 0,12 [0,07; 0,18]; <0,0001
Kaukasisch	617	113 (18,3)	589	59 (10,0)	2,01 [1,44; 2,82]; <0,0001 1,83 [1,36; 2,45]; <0,0001 0,08 [0,04; 0,12]; <0,0001
Schwarz oder afroamerikanisch	19	8 (42,1)	29	4 (13,8)	4,55 [1,13; 18,32]; 0,0333 3,05 [1,07; 8,74]; 0,0375 0,28 [0,03; 0,54]; 0,0296
Ethnische Abstammung (Interaktionstest: p=0,7803)					
Hispanisch	34	6 (17,7)	24	1 (4,2)	4,93 [0,55; 43,94]; 0,1530 4,24 [0,54; 32,95]; 0,1679 0,13 [-0,02; 0,29]; 0,0802
Nicht-hispanisch	798	153 (19,2)	803	76 (9,5)	2,27 [1,69; 3,05]; <0,0001 2,03 [1,57; 2,62]; <0,0001 0,10 [0,06; 0,13]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	11 (13,9)	77	5 (6,5)	2,33 [0,77; 7,05]; 0,1347 2,14 [0,78; 5,88]; 0,1386 0,07 [-0,02; 0,17]; 0,1218
Hormonrezeptorstatus (Interaktionstest: p=0,8247)					
ER- und/oder PgR-positiv, HER2-positiv	168	33 (19,6)	155	14 (9,0)	2,46 [1,26; 4,80]; 0,0082 2,17 [1,21; 3,91]; 0,0093 0,11 [0,03; 0,18]; 0,0056
TNBC	741	136 (18,4)	749	68 (9,1)	2,25 [1,65; 3,07]; <0,0001 2,02 [1,54; 2,66]; <0,0001 0,09 [0,06; 0,13]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,0894)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	21 (20,2)	92	7 (7,6)	3,07 [1,24; 7,61]; 0,0153 2,65 [1,18; 5,95]; 0,0179 0,13 [0,03; 0,22]; 0,0089
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	12 (18,8)	63	7 (11,1)	1,85 [0,68; 5,05]; 0,2321 1,69 [0,71; 4,01]; 0,2357 0,08 [-0,05; 0,20]; 0,2241
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	57 (16,4)	362	41 (11,3)	1,53 [1,00; 2,36]; 0,0521 1,45 [1,00; 2,10]; 0,0528 0,05 [0,00; 0,10]; 0,0511
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	79 (20,1)	387	27 (7,0)	3,35 [2,11; 5,33]; <0,0001 2,88 [1,90; 4,36]; <0,0001 0,13 [0,08; 0,18]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,6824)					
Postmenopausal	346	79 (22,8)	356	41 (11,5)	2,27 [1,51; 3,43]; <0,0001 1,98 [1,40; 2,80]; 0,0001 0,11 [0,06; 0,17]; <0,0001
Prämenopausal	563	91 (16,2)	544	40 (7,4)	2,43 [1,64; 3,60]; <0,0001 2,20 [1,54; 3,13]; <0,0001 0,09 [0,05; 0,13]; <0,0001
Region (Interaktionstest: p=0,4981)					
Asien-Pazifik und Südafrika	301	58 (19,3)	317	23 (7,3)	3,05 [1,83; 5,09]; <0,0001 2,66 [1,68; 4,19]; <0,0001 0,12 [0,07; 0,17]; <0,0001
Europa	473	78 (16,5)	444	37 (8,3)	2,17 [1,43; 3,29]; 0,0002 1,98 [1,37; 2,86]; 0,0003 0,08 [0,04; 0,12]; 0,0002
Nordamerika	121	33 (27,3)	131	21 (16,0)	1,96 [1,06; 3,63]; 0,0314 1,70 [1,04; 2,77]; 0,0329 0,11 [0,01; 0,21]; 0,0295
Südamerika	16	1 (6,3)	12	1 (8,3)	0,73 [0,04; 13,05]; 0,8328 0,75 [0,05; 10,82]; 0,8327 -0,02 [-0,22; 0,18]; 0,8352
Art der vorherigen Chemotherapie (Interaktionstest: p=0,0649)					
Adjuvant	457	91 (19,9)	450	34 (7,6)	3,04 [2,00; 4,62]; <0,0001 2,64 [1,82; 3,82]; <0,0001 0,12 [0,08; 0,17]; <0,0001
Neoadjuvant	454	79 (17,4)	454	48 (10,6)	1,78 [1,21; 2,62]; 0,0033 1,65 [1,18; 2,30]; 0,0035 0,07 [0,02; 0,11]; 0,0029
Sponsor (Interaktionstest: p=0,5737)					
AZ	801	139 (17,4)	796	65 (8,2)	2,36 [1,73; 3,23]; <0,0001 2,13 [1,61; 2,81]; <0,0001 0,09 [0,06; 0,12]; <0,0001
NRG Oncology	110	31 (28,2)	108	17 (15,7)	2,10 [1,08; 4,08]; 0,0284 1,79 [1,06; 3,04]; 0,0308 0,12 [0,02; 0,23]; 0,0247
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7902)					
Ja	243	42 (17,3)	236	21 (8,9)	2,14 [1,22; 3,74]; 0,0076 1,94 [1,19; 3,18]; 0,0082 0,08 [0,02; 0,14]; 0,0060
Nein	668	128 (19,2)	668	61 (9,1)	2,36 [1,70; 3,27]; <0,0001 2,10 [1,58; 2,79]; <0,0001 0,10 [0,06; 0,14]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
SUE					
Alter (Interaktionstest: p=0,7941)					
<50	690	57 (8,3)	663	53 (8,0)	1,04 [0,70; 1,53]; 0,8575 1,03 [0,72; 1,48]; 0,8575 0,00 [-0,03; 0,03]; 0,8574
50-64	192	17 (8,9)	209	21 (10,1)	0,87 [0,44; 1,70]; 0,6837 0,88 [0,48; 1,62]; 0,6838 -0,01 [-0,07; 0,05]; 0,6827
≥65	29	5 (17,2)	32	4 (12,5)	1,46 [0,35; 6,05]; 0,6034 1,38 [0,41; 4,65]; 0,6039 0,05 [-0,13; 0,23]; 0,6036
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,3652)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	76 (8,8)	840	73 (8,7)	1,02 [0,73; 1,42]; 0,9207 1,02 [0,75; 1,38]; 0,9207 0,00 [-0,03; 0,03]; 0,9207
Taxan	43	2 (4,7)	50	5 (10,0)	0,44 [0,08; 2,39]; 0,3407 0,47 [0,10; 2,28]; 0,3449 -0,05 [-0,16; 0,05]; 0,3148
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0261)					
Brusterhaltend	220	19 (8,6)	235	9 (3,8)	2,37 [1,05; 5,37]; 0,0378 2,26 [1,04; 4,88]; 0,0388 0,05 [0,00; 0,09]; 0,0342
Einseitige Mastektomie	355	35 (9,9)	352	33 (9,4)	1,06 [0,64; 1,74]; 0,8272 1,05 [0,67; 1,65]; 0,8272 0,00 [-0,04; 0,05]; 0,8272
Beidseitige Mastektomie	336	25 (7,4)	315	36 (11,4)	0,62 [0,36; 1,06]; 0,0831 0,65 [0,40; 1,06]; 0,0838 -0,04 [-0,08; 0,01]; 0,0821
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,5139)					
Ja	41	2 (4,9)	35	3 (8,6)	0,55 [0,09; 3,48]; 0,5226 0,57 [0,10; 3,21]; 0,5234 -0,04 [-0,15; 0,08]; 0,5247
Nein	870	77 (8,9)	866	75 (8,7)	1,02 [0,73; 1,43]; 0,8886 1,02 [0,75; 1,38]; 0,8886 0,00 [-0,02; 0,03]; 0,8886

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,1155)					
Positiv	173	16 (9,3)	176	20 (11,4)	0,79 [0,40; 1,59]; 0,5167 0,81 [0,44; 1,52]; 0,5170 -0,02 [-0,08; 0,04]; 0,5154
Negativ	200	20 (10,0)	191	11 (5,8)	1,82 [0,85; 3,90]; 0,1252 1,74 [0,85; 3,53]; 0,1269 0,04 [-0,01; 0,10]; 0,1175
Bilaterale Oophorektomie (Interaktionstest: p=0,4858)					
Ja	189	14 (7,4)	176	10 (5,7)	1,33 [0,57; 3,07]; 0,5074 1,30 [0,59; 2,86]; 0,5079 0,02 [-0,03; 0,07]; 0,5042
Nein	722	65 (9,0)	728	68 (9,3)	0,96 [0,67; 1,37]; 0,8236 0,96 [0,70; 1,33]; 0,8236 0,00 [-0,03; 0,03]; 0,8236
BRCA-Mutationsstatus (Interaktionstest: p=0,8737)					
BRCA1	574	46 (8,0)	580	50 (8,6)	0,92 [0,61; 1,40]; 0,7091 0,93 [0,63; 1,36]; 0,7091 -0,01 [-0,04; 0,03]; 0,7090
BRCA2	232	17 (7,3)	215	18 (8,4)	0,87 [0,43; 1,73]; 0,6815 0,88 [0,46; 1,65]; 0,6815 -0,01 [-0,06; 0,04]; 0,6819
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,1563)					
2, 3 oder 4	392	34 (8,7)	383	29 (7,6)	1,16 [0,69; 1,94]; 0,5750 1,15 [0,71; 1,84]; 0,5751 0,01 [-0,03; 0,05]; 0,5744
5 oder 6	22	0 (0,0)	14	2 (14,3)	0,11 [0,00; 2,50]; 0,1667 0,13 [0,01; 2,53]; 0,1783 -0,14 [-0,34; 0,05]; 0,1569
Ethnie (Interaktionstest: p=0,1523)					
Andere	16	0 (0,0)	15	3 (20,0)	0,11 [0,01; 2,29]; 0,1534 0,13 [0,01; 2,40]; 0,1726 -0,20 [-0,42; 0,02]; 0,0720
Asiatisch	259	25 (9,7)	271	21 (7,8)	1,27 [0,69; 2,33]; 0,4374 1,25 [0,72; 2,17]; 0,4376 0,02 [-0,03; 0,07]; 0,4373
Kaukasisch	617	51 (8,3)	589	54 (9,2)	0,89 [0,60; 1,33]; 0,5787 0,90 [0,63; 1,30]; 0,5787 -0,01 [-0,04; 0,02]; 0,5789
Schwarz oder afroamerikanisch	19	3 (15,8)	29	0 (0,0)	12,52 [0,61; 257,43]; 0,1014 10,50 [0,57; 192,49]; 0,1131 0,16 [-0,01; 0,33]; 0,0732

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,4949)					
Hispanisch	34	2 (5,9)	24	3 (12,5)	0,44 [0,07; 2,84]; 0,3867 0,47 [0,09; 2,60]; 0,3879 -0,07 [-0,22; 0,09]; 0,4001
Nicht-hispanisch	798	69 (8,7)	803	70 (8,7)	0,99 [0,70; 1,40]; 0,9599 0,99 [0,72; 1,36]; 0,9599 0,00 [-0,03; 0,03]; 0,9599
Unbekannt, nicht erfasst, verweigert	79	8 (10,1)	77	5 (6,5)	1,62 [0,51; 5,20]; 0,4153 1,56 [0,53; 4,56]; 0,4167 0,04 [-0,05; 0,12]; 0,4095
Hormonrezeptorstatus (Interaktionstest: p=0,2807)					
ER- und/oder PgR-positiv, HER2-positiv	168	16 (9,5)	155	10 (6,5)	1,53 [0,67; 3,47]; 0,3134 1,48 [0,69; 3,15]; 0,3148 0,03 [-0,03; 0,09]; 0,3064
TNBC	741	63 (8,5)	749	68 (9,1)	0,93 [0,65; 1,33]; 0,6943 0,94 [0,68; 1,30]; 0,6943 -0,01 [-0,03; 0,02]; 0,6942
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,1909)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	11 (10,6)	92	4 (4,4)	2,60 [0,80; 8,48]; 0,1125 2,43 [0,80; 7,38]; 0,1163 0,06 [-0,01; 0,13]; 0,0914
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	5 (7,8)	63	6 (9,5)	0,81 [0,23; 2,79]; 0,7321 0,82 [0,26; 2,55]; 0,7323 -0,02 [-0,11; 0,08]; 0,7318
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	25 (7,2)	362	36 (9,9)	0,70 [0,41; 1,19]; 0,1912 0,72 [0,44; 1,18]; 0,1920 -0,03 [-0,07; 0,01]; 0,1876
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	38 (9,7)	387	32 (8,3)	1,19 [0,73; 1,94]; 0,4942 1,17 [0,75; 1,83]; 0,4944 0,01 [-0,03; 0,05]; 0,4935
Menopausenstatus (Interaktionstest: p=0,7817)					
Postmenopausal	346	29 (8,4)	356	31 (8,7)	0,96 [0,56; 1,63]; 0,8771 0,96 [0,59; 1,56]; 0,8771 0,00 [-0,04; 0,04]; 0,8771
Prämenopausal	563	50 (8,9)	544	46 (8,5)	1,06 [0,69; 1,60]; 0,8016 1,05 [0,72; 1,54]; 0,8016 0,00 [-0,03; 0,04]; 0,8015
Region (Interaktionstest: p=0,6038)					
Asien-Pazifik und Südafrika	301	32 (10,6)	317	27 (8,5)	1,28 [0,75; 2,19]; 0,3723 1,25 [0,77; 2,03]; 0,3726 0,02 [-0,03; 0,07]; 0,3723

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	38 (8,0)	444	38 (8,6)	0,93 [0,58; 1,49]; 0,7734 0,94 [0,61; 1,44]; 0,7733 -0,01 [-0,04; 0,03]; 0,7735
Nordamerika	121	9 (7,4)	131	12 (9,2)	0,80 [0,32; 1,96]; 0,6217 0,81 [0,35; 1,86]; 0,6221 -0,02 [-0,09; 0,05]; 0,6197
Südamerika	16	0 (0,0)	12	1 (8,3)	0,23 [0,01; 6,22]; 0,3843 0,25 [0,01; 5,76]; 0,3902 -0,08 [-0,27; 0,11]; 0,3933
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4850)					
Adjuvant	457	43 (9,4)	450	38 (8,4)	1,13 [0,71; 1,78]; 0,6106 1,11 [0,73; 1,69]; 0,6107 0,01 [-0,03; 0,05]; 0,6103
Neoadjuvant	454	36 (7,9)	454	40 (8,8)	0,89 [0,56; 1,43]; 0,6318 0,90 [0,58; 1,39]; 0,6319 -0,01 [-0,04; 0,03]; 0,6317
Sponsor (Interaktionstest: p=0,5640)					
AZ	801	71 (8,9)	796	68 (8,5)	1,04 [0,74; 1,47]; 0,8199 1,04 [0,76; 1,43]; 0,8199 0,00 [-0,02; 0,03]; 0,8199
NRG Oncology	110	8 (7,3)	108	10 (9,3)	0,77 [0,29; 2,03]; 0,5950 0,79 [0,32; 1,91]; 0,5953 -0,02 [-0,09; 0,05]; 0,5943
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,8207)					
Ja	243	24 (9,9)	236	22 (9,3)	1,07 [0,58; 1,96]; 0,8369 1,06 [0,61; 1,84]; 0,8369 0,01 [-0,05; 0,06]; 0,8368
Nein	668	55 (8,2)	668	56 (8,4)	0,98 [0,66; 1,45]; 0,9210 0,98 [0,69; 1,40]; 0,9210 0,00 [-0,03; 0,03]; 0,9210
Abbruch wegen UE					
Alter (Interaktionstest: p=0,6979)					
<50	690	56 (8,1)	663	25 (3,8)	2,25 [1,39; 3,66]; 0,0010 2,15 [1,36; 3,41]; 0,0011 0,04 [0,02; 0,07]; 0,0007
50-64	192	39 (20,3)	209	15 (7,2)	3,30 [1,75; 6,20]; 0,0002 2,83 [1,61; 4,97]; 0,0003 0,13 [0,06; 0,20]; 0,0001
≥65	29	3 (10,3)	32	2 (6,3)	1,73 [0,27; 11,17]; 0,5642 1,66 [0,30; 9,22]; 0,5652 0,04 [-0,10; 0,18]; 0,5637

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,5620)					
Anthrazyklin	7	2 (28,6)	13	0 (0,0)	12,27 [0,50; 299,32]; 0,1239 8,75 [0,48; 160,53]; 0,1440 0,29 [-0,05; 0,62]; 0,0952
Anthrazyklin und Taxan	861	90 (10,5)	840	40 (4,8)	2,33 [1,59; 3,43]; <0,0001 2,20 [1,53; 3,15]; <0,0001 0,06 [0,03; 0,08]; <0,0001
Taxan	43	6 (14,0)	50	2 (4,0)	3,89 [0,74; 20,40]; 0,1079 3,49 [0,74; 16,39]; 0,1135 0,10 [-0,02; 0,22]; 0,0953
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,1224)					
Brusterhaltend	220	27 (12,3)	235	7 (3,0)	4,56 [1,94; 10,69]; 0,0005 4,12 [1,83; 9,27]; 0,0006 0,09 [0,04; 0,14]; 0,0002
Einseitige Mastektomie	355	36 (10,1)	352	14 (4,0)	2,72 [1,44; 5,15]; 0,0020 2,55 [1,40; 4,64]; 0,0022 0,06 [0,02; 0,10]; 0,0013
Beidseitige Mastektomie	336	35 (10,4)	315	21 (6,7)	1,63 [0,93; 2,86]; 0,0906 1,56 [0,93; 2,62]; 0,0917 0,04 [-0,01; 0,08]; 0,0854
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,0709)					
Ja	41	3 (7,3)	35	4 (11,4)	0,61 [0,13; 2,94]; 0,5398 0,64 [0,15; 2,67]; 0,5403 -0,04 [-0,17; 0,09]; 0,5420
Nein	870	95 (10,9)	866	38 (4,4)	2,67 [1,81; 3,94]; <0,0001 2,49 [1,73; 3,58]; <0,0001 0,07 [0,04; 0,09]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,9115)					
Positiv	173	21 (12,1)	176	8 (4,6)	2,90 [1,25; 6,74]; 0,0133 2,67 [1,22; 5,87]; 0,0144 0,08 [0,02; 0,13]; 0,0097
Negativ	200	21 (10,5)	191	8 (4,2)	2,68 [1,16; 6,22]; 0,0213 2,51 [1,14; 5,52]; 0,0226 0,06 [0,01; 0,11]; 0,0155
Bilaterale Oophorektomie (Interaktionstest: p=0,5803)					
Ja	189	23 (12,2)	176	11 (6,3)	2,08 [0,98; 4,40]; 0,0559 1,95 [0,98; 3,88]; 0,0579 0,06 [0,00; 0,12]; 0,0483
Nein	722	75 (10,4)	728	31 (4,3)	2,61 [1,69; 4,01]; <0,0001 2,44 [1,63; 3,66]; <0,0001 0,06 [0,03; 0,09]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,1671)					
BRCA1	574	59 (10,3)	580	25 (4,3)	2,54 [1,57; 4,12]; 0,0002 2,38 [1,52; 3,75]; 0,0002 0,06 [0,03; 0,09]; <0,0001
BRCA2	232	26 (11,2)	215	17 (7,9)	1,47 [0,77; 2,79]; 0,2393 1,42 [0,79; 2,54]; 0,2406 0,03 [-0,02; 0,09]; 0,2336
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,5011)					
2, 3 oder 4	392	41 (10,5)	383	24 (6,3)	1,75 [1,03; 2,95]; 0,0371 1,67 [1,03; 2,71]; 0,0379 0,04 [0,00; 0,08]; 0,0343
5 oder 6	22	3 (13,6)	14	0 (0,0)	5,21 [0,25; 108,83]; 0,2875 4,57 [0,25; 82,22]; 0,3033 0,14 [-0,04; 0,31]; 0,1216
Ethnie (Interaktionstest: p=0,0565)					
Andere	16	2 (12,5)	15	2 (13,3)	0,93 [0,11; 7,59]; 0,9449 0,94 [0,15; 5,84]; 0,9449 -0,01 [-0,24; 0,23]; 0,9449
Asiatisch	259	27 (10,4)	271	3 (1,1)	10,40 [3,11; 34,71]; 0,0001 9,42 [2,89; 30,66]; 0,0002 0,09 [0,05; 0,13]; <0,0001
Kaukasisch	617	66 (10,7)	589	35 (5,9)	1,90 [1,24; 2,90]; 0,0033 1,80 [1,21; 2,67]; 0,0034 0,05 [0,02; 0,08]; 0,0026
Schwarz oder afroamerikanisch	19	3 (15,8)	29	2 (6,9)	2,53 [0,38; 16,81]; 0,3363 2,29 [0,42; 12,45]; 0,3376 0,09 [-0,10; 0,28]; 0,3542
Ethnische Abstammung (Interaktionstest: p=0,2049)					
Hispanisch	34	1 (2,9)	24	2 (8,3)	0,33 [0,03; 3,90]; 0,3815 0,35 [0,03; 3,67]; 0,3836 -0,05 [-0,18; 0,07]; 0,3952
Nicht-hispanisch	798	85 (10,7)	803	37 (4,6)	2,47 [1,66; 3,68]; <0,0001 2,31 [1,59; 3,36]; <0,0001 0,06 [0,03; 0,09]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	12 (15,2)	77	3 (3,9)	4,42 [1,19; 16,33]; 0,0260 3,90 [1,14; 13,28]; 0,0296 0,11 [0,02; 0,20]; 0,0141
Hormonrezeptorstatus (Interaktionstest: p=0,5200)					
ER- und/oder PgR-positiv, HER2-positiv	168	18 (10,7)	155	9 (5,8)	1,95 [0,85; 4,47]; 0,1166 1,85 [0,85; 3,98]; 0,1188 0,05 [-0,01; 0,11]; 0,1061

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
TNBC	741	80 (10,8)	749	33 (4,4)	2,63 [1,73; 3,99]; <0,0001 2,45 [1,65; 3,63]; <0,0001 0,06 [0,04; 0,09]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7557)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	12 (11,5)	92	7 (7,6)	1,58 [0,60; 4,21]; 0,3566 1,52 [0,62; 3,69]; 0,3586 0,04 [-0,04; 0,12]; 0,3469
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	6 (9,4)	63	2 (3,2)	3,16 [0,61; 16,27]; 0,1697 2,95 [0,62; 14,08]; 0,1742 0,06 [-0,02; 0,15]; 0,1456
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	37 (10,6)	362	17 (4,7)	2,41 [1,33; 4,37]; 0,0037 2,26 [1,30; 3,94]; 0,0039 0,06 [0,02; 0,10]; 0,0029
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	43 (10,9)	387	16 (4,1)	2,85 [1,58; 5,15]; 0,0005 2,65 [1,52; 4,62]; 0,0006 0,07 [0,03; 0,10]; 0,0003
Menopausenstatus (Interaktionstest: p=0,8646)					
Postmenopausal	346	53 (15,3)	356	24 (6,7)	2,50 [1,51; 4,16]; 0,0004 2,27 [1,44; 3,60]; 0,0005 0,09 [0,04; 0,13]; 0,0003
Prämenopausal	563	45 (8,0)	544	18 (3,3)	2,54 [1,45; 4,44]; 0,0011 2,42 [1,42; 4,12]; 0,0012 0,05 [0,02; 0,07]; 0,0007
Region (Interaktionstest: p=0,0170)					
Asien-Pazifik und Südafrika	301	30 (10,0)	317	6 (1,9)	5,74 [2,35; 13,99]; 0,0001 5,27 [2,22; 12,47]; 0,0002 0,08 [0,04; 0,12]; <0,0001
Europa	473	56 (11,8)	444	22 (5,0)	2,58 [1,54; 4,30]; 0,0003 2,39 [1,48; 3,85]; 0,0003 0,07 [0,03; 0,10]; 0,0001
Nordamerika	121	12 (9,9)	131	13 (9,9)	1,00 [0,44; 2,28]; 0,9987 1,00 [0,47; 2,10]; 0,9987 0,00 [-0,07; 0,07]; 0,9987
Südamerika	16	0 (0,0)	12	1 (8,3)	0,23 [0,01; 6,22]; 0,3843 0,25 [0,01; 5,76]; 0,3902 -0,08 [-0,27; 0,11]; 0,3933
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4488)					
Adjuvant	457	49 (10,7)	450	18 (4,0)	2,88 [1,65; 5,03]; 0,0002 2,68 [1,59; 4,53]; 0,0002 0,07 [0,03; 0,10]; <0,0001
Neoadjuvant	454	49 (10,8)	454	24 (5,3)	2,17 [1,31; 3,60]; 0,0028 2,04 [1,28; 3,27]; 0,0030 0,06 [0,02; 0,09]; 0,0022

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Sponsor (Interaktionstest: p=0,0297)					
AZ	801	88 (11,0)	796	32 (4,0)	2,95 [1,94; 4,47]; <0,0001 2,73 [1,85; 4,05]; <0,0001 0,07 [0,04; 0,10]; <0,0001
NRG Oncology	110	10 (9,1)	108	10 (9,3)	0,98 [0,39; 2,46]; 0,9657 0,98 [0,43; 2,26]; 0,9657 0,00 [-0,08; 0,07]; 0,9657
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7657)					
Ja	243	31 (12,8)	236	12 (5,1)	2,73 [1,37; 5,45]; 0,0045 2,51 [1,32; 4,77]; 0,0050 0,08 [0,03; 0,13]; 0,0029
Nein	668	67 (10,0)	668	30 (4,5)	2,37 [1,52; 3,70]; 0,0001 2,23 [1,47; 3,39]; 0,0002 0,06 [0,03; 0,08]; <0,0001

Datenschnitt: 12.07.2021: Analyse-Set: Safety-Analysis-Set
a: Die Berechnung von OR, RR und RD erfolgte auf Basis der Vierfeldertafel.

Anhang 4-G8: Subgruppenanalysen: UE unabhängig vom Schweregrad nach SOC und PT

Tabelle 6.2.1: Subgruppenergebnisse für Unerwünschte Ereignisse unabhängig vom Schweregrad nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort					
Alter (Interaktionstest: p=0,3999)					
<50	690	380 (55,1)	663	287 (43,3)	1,61 [1,30; 1,99]; <0,0001 1,27 [1,14; 1,42]; <0,0001 0,12 [0,06; 0,17]; <0,0001
50-64	192	107 (55,7)	209	84 (40,2)	1,87 [1,26; 2,79]; 0,0019 1,39 [1,13; 1,71]; 0,0021 0,16 [0,06; 0,25]; 0,0016
≥65	29	18 (62,1)	32	11 (34,4)	3,12 [1,10; 8,89]; 0,0329 1,81 [1,03; 3,15]; 0,0376 0,28 [0,04; 0,52]; 0,0245
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,4174)					
Anthrazyklin	7	5 (71,4)	13	4 (30,8)	5,62 [0,75; 42,36]; 0,0936 2,32 [0,91; 5,95]; 0,0792 0,41 [-0,01; 0,82]; 0,0567
Anthrazyklin und Taxan	861	477 (55,4)	840	355 (42,3)	1,70 [1,40; 2,06]; <0,0001 1,31 [1,19; 1,45]; <0,0001 0,13 [0,08; 0,18]; <0,0001
Taxan	43	23 (53,5)	50	23 (46,0)	1,35 [0,60; 3,06]; 0,4719 1,16 [0,77; 1,75]; 0,4706 0,07 [-0,13; 0,28]; 0,4702
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,5677)					
Brusterhaltend	220	117 (53,2)	235	102 (43,4)	1,48 [1,02; 2,14]; 0,0373 1,23 [1,01; 1,48]; 0,0376 0,10 [0,01; 0,19]; 0,0361
Einseitige Mastektomie	355	170 (47,9)	352	120 (34,1)	1,78 [1,31; 2,41]; 0,0002 1,40 [1,17; 1,68]; 0,0002 0,14 [0,07; 0,21]; 0,0002
Beidseitige Mastektomie	336	218 (64,9)	315	160 (50,8)	1,79 [1,31; 2,45]; 0,0003 1,28 [1,12; 1,46]; 0,0003 0,14 [0,07; 0,22]; 0,0002
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,0515)					
Ja	41	27 (65,9)	35	24 (68,6)	0,88 [0,34; 2,31]; 0,8016 0,96 [0,70; 1,32]; 0,8010 -0,03 [-0,24; 0,18]; 0,8011
Nein	870	478 (54,9)	866	357 (41,2)	1,74 [1,44; 2,10]; <0,0001 1,33 [1,21; 1,47]; <0,0001 0,14 [0,09; 0,18]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,4367)					
Positiv	173	88 (50,9)	176	71 (40,3)	1,53 [1,00; 2,34]; 0,0488 1,26 [1,00; 1,59]; 0,0499 0,11 [0,00; 0,21]; 0,0471
Negativ	200	108 (54,0)	191	72 (37,7)	1,94 [1,30; 2,91]; 0,0013 1,43 [1,15; 1,79]; 0,0016 0,16 [0,07; 0,26]; 0,0010
Bilaterale Oophorektomie (Interaktionstest: p=0,3531)					
Ja	189	117 (61,9)	176	90 (51,1)	1,55 [1,02; 2,36]; 0,0384 1,21 [1,01; 1,45]; 0,0403 0,11 [0,01; 0,21]; 0,0371
Nein	722	388 (53,7)	728	292 (40,1)	1,73 [1,41; 2,14]; <0,0001 1,34 [1,20; 1,50]; <0,0001 0,14 [0,09; 0,19]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,5920)					
BRCA1	574	318 (55,4)	580	253 (43,6)	1,61 [1,27; 2,03]; <0,0001 1,27 [1,13; 1,43]; <0,0001 0,12 [0,06; 0,18]; <0,0001
BRCA2	232	141 (60,8)	215	97 (45,1)	1,88 [1,29; 2,75]; 0,0010 1,35 [1,13; 1,61]; 0,0012 0,16 [0,07; 0,25]; 0,0008
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,2033)					
2, 3 oder 4	392	220 (56,1)	383	173 (45,2)	1,55 [1,17; 2,06]; 0,0023 1,24 [1,08; 1,43]; 0,0025 0,11 [0,04; 0,18]; 0,0022
5 oder 6	22	16 (72,7)	14	5 (35,7)	4,80 [1,14; 20,27]; 0,0328 2,04 [0,96; 4,30]; 0,0624 0,37 [0,06; 0,68]; 0,0202
Ethnie (Interaktionstest: p=0,0493)					
Andere	16	11 (68,8)	15	11 (73,3)	0,80 [0,17; 3,80]; 0,7789 0,94 [0,60; 1,47]; 0,7785 -0,05 [-0,36; 0,27]; 0,7781
Asiatisch	259	122 (47,1)	271	79 (29,2)	2,16 [1,51; 3,10]; <0,0001 1,62 [1,29; 2,03]; <0,0001 0,18 [0,10; 0,26]; <0,0001
Kaukasisch	617	356 (57,7)	589	277 (47,0)	1,54 [1,22; 1,93]; 0,0002 1,23 [1,10; 1,37]; 0,0002 0,11 [0,05; 0,16]; 0,0002
Schwarz oder afroamerikanisch	19	16 (84,2)	29	15 (51,7)	4,98 [1,19; 20,85]; 0,0281 1,63 [1,09; 2,43]; 0,0175 0,32 [0,08; 0,57]; 0,0093

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,1872)					
Hispanisch	34	12 (35,3)	24	11 (45,8)	0,64 [0,22; 1,87]; 0,4201 0,77 [0,41; 1,45]; 0,4159 -0,11 [-0,36; 0,15]; 0,4197
Nicht-hispanisch	798	442 (55,4)	803	330 (41,1)	1,78 [1,46; 2,17]; <0,0001 1,35 [1,22; 1,49]; <0,0001 0,14 [0,09; 0,19]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	51 (64,6)	77	41 (53,3)	1,60 [0,84; 3,04]; 0,1521 1,21 [0,93; 1,58]; 0,1551 0,11 [-0,04; 0,27]; 0,1486
Hormonrezeptorstatus (Interaktionstest: p=0,5993)					
ER- und/oder PgR-positiv, HER2-positiv	168	99 (58,9)	155	66 (42,6)	1,93 [1,24; 3,01]; 0,0035 1,38 [1,11; 1,73]; 0,0041 0,16 [0,06; 0,27]; 0,0029
TNBC	741	405 (54,7)	749	316 (42,2)	1,65 [1,35; 2,03]; <0,0001 1,30 [1,16; 1,44]; <0,0001 0,12 [0,07; 0,18]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8279)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	59 (56,7)	92	40 (43,5)	1,70 [0,97; 3,00]; 0,0648 1,30 [0,98; 1,74]; 0,0694 0,13 [-0,01; 0,27]; 0,0617
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	40 (62,5)	63	26 (41,3)	2,37 [1,16; 4,84]; 0,0175 1,51 [1,07; 2,15]; 0,0203 0,21 [0,04; 0,38]; 0,0143
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	196 (56,3)	362	161 (44,5)	1,61 [1,20; 2,17]; 0,0016 1,27 [1,09; 1,47]; 0,0017 0,12 [0,05; 0,19]; 0,0015
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	209 (53,2)	387	155 (40,1)	1,70 [1,28; 2,26]; 0,0002 1,33 [1,14; 1,55]; 0,0003 0,13 [0,06; 0,20]; 0,0002
Menopausenstatus (Interaktionstest: p=0,2010)					
Postmenopausal	346	198 (57,2)	356	167 (46,9)	1,51 [1,12; 2,04]; 0,0063 1,22 [1,06; 1,41]; 0,0065 0,10 [0,03; 0,18]; 0,0060
Prämenopausal	563	305 (54,2)	544	213 (39,2)	1,84 [1,45; 2,33]; <0,0001 1,38 [1,22; 1,57]; <0,0001 0,15 [0,09; 0,21]; <0,0001
Region (Interaktionstest: p=0,5935)					
Asien-Pazifik und Südafrika	301	147 (48,8)	317	110 (34,7)	1,80 [1,30; 2,48]; 0,0004 1,41 [1,16; 1,70]; 0,0004 0,14 [0,06; 0,22]; 0,0003

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	256 (54,1)	444	188 (42,3)	1,61 [1,24; 2,09]; 0,0004 1,28 [1,11; 1,47]; 0,0004 0,12 [0,05; 0,18]; 0,0003
Nordamerika	121	97 (80,2)	131	83 (63,4)	2,34 [1,32; 4,14]; 0,0036 1,27 [1,08; 1,48]; 0,0034 0,17 [0,06; 0,28]; 0,0025
Südamerika	16	5 (31,3)	12	1 (8,3)	5,00 [0,50; 50,07]; 0,1710 3,75 [0,50; 28,05]; 0,1980 0,23 [-0,05; 0,50]; 0,1033
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5294)					
Adjuvant	457	249 (54,5)	450	181 (40,2)	1,78 [1,37; 2,32]; <0,0001 1,35 [1,18; 1,56]; <0,0001 0,14 [0,08; 0,21]; <0,0001
Neoadjuvant	454	256 (56,4)	454	201 (44,3)	1,63 [1,25; 2,12]; 0,0003 1,27 [1,12; 1,45]; 0,0003 0,12 [0,06; 0,19]; 0,0002
Sponsor (Interaktionstest: p=0,9522)					
AZ	801	416 (51,9)	796	315 (39,6)	1,65 [1,35; 2,01]; <0,0001 1,31 [1,18; 1,46]; <0,0001 0,12 [0,08; 0,17]; <0,0001
NRG Oncology	110	89 (80,9)	108	67 (62,0)	2,59 [1,40; 4,79]; 0,0024 1,30 [1,10; 1,55]; 0,0027 0,19 [0,07; 0,31]; 0,0016
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4591)					
Ja	243	135 (55,6)	236	106 (44,9)	1,53 [1,07; 2,20]; 0,0201 1,24 [1,03; 1,48]; 0,0210 0,11 [0,02; 0,20]; 0,0192
Nein	668	370 (55,4)	668	276 (41,3)	1,76 [1,42; 2,19]; <0,0001 1,34 [1,20; 1,50]; <0,0001 0,14 [0,09; 0,19]; <0,0001
Ermüdung					
Alter (Interaktionstest: p=0,3020)					
<50	690	282 (40,9)	663	182 (27,5)	1,83 [1,45; 2,30]; <0,0001 1,49 [1,28; 1,73]; <0,0001 0,13 [0,08; 0,18]; <0,0001
50-64	192	78 (40,6)	209	55 (26,3)	1,92 [1,26; 2,92]; 0,0025 1,54 [1,16; 2,05]; 0,0027 0,14 [0,05; 0,23]; 0,0022
≥65	29	6 (20,7)	32	9 (28,1)	0,67 [0,20; 2,18]; 0,5020 0,74 [0,30; 1,81]; 0,5049 -0,07 [-0,29; 0,14]; 0,4969

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,7476)					
Anthrazyklin	7	2 (28,6)	13	2 (15,4)	2,20 [0,24; 20,40]; 0,4877 1,86 [0,33; 10,49]; 0,4834 0,13 [-0,26; 0,52]; 0,5052
Anthrazyklin und Taxan	861	351 (40,8)	840	231 (27,5)	1,81 [1,48; 2,22]; <0,0001 1,48 [1,29; 1,70]; <0,0001 0,13 [0,09; 0,18]; <0,0001
Taxan	43	13 (30,2)	50	13 (26,0)	1,23 [0,50; 3,06]; 0,6505 1,16 [0,61; 2,23]; 0,6502 0,04 [-0,14; 0,23]; 0,6510
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,3450)					
Brusterhaltend	220	85 (38,6)	235	71 (30,2)	1,45 [0,99; 2,15]; 0,0590 1,28 [0,99; 1,65]; 0,0596 0,08 [0,00; 0,17]; 0,0580
Einseitige Mastektomie	355	110 (31,0)	352	76 (21,6)	1,63 [1,16; 2,29]; 0,0047 1,44 [1,11; 1,85]; 0,0050 0,09 [0,03; 0,16]; 0,0043
Beidseitige Mastektomie	336	171 (50,9)	315	99 (31,4)	2,26 [1,64; 3,11]; <0,0001 1,62 [1,33; 1,97]; <0,0001 0,19 [0,12; 0,27]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,0390)					
Ja	41	21 (51,2)	35	19 (54,3)	0,88 [0,36; 2,18]; 0,7896 0,94 [0,62; 1,44]; 0,7892 -0,03 [-0,26; 0,19]; 0,7894
Nein	870	345 (39,7)	866	227 (26,2)	1,85 [1,51; 2,27]; <0,0001 1,51 [1,32; 1,74]; <0,0001 0,13 [0,09; 0,18]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,1167)					
Positiv	173	63 (36,4)	176	49 (27,8)	1,48 [0,94; 2,33]; 0,0869 1,31 [0,96; 1,78]; 0,0883 0,09 [-0,01; 0,18]; 0,0851
Negativ	200	75 (37,5)	191	38 (19,9)	2,42 [1,53; 3,81]; 0,0002 1,88 [1,35; 2,64]; 0,0002 0,18 [0,09; 0,26]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,7155)					
Ja	189	94 (49,7)	176	62 (35,2)	1,82 [1,19; 2,77]; 0,0053 1,41 [1,10; 1,81]; 0,0061 0,15 [0,04; 0,25]; 0,0046
Nein	722	272 (37,7)	728	184 (25,3)	1,79 [1,43; 2,24]; <0,0001 1,49 [1,27; 1,74]; <0,0001 0,12 [0,08; 0,17]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
BRCA-Mutationsstatus (Interaktionstest: p=0,6052)					
BRCA1	574	242 (42,2)	580	161 (27,8)	1,90 [1,48; 2,43]; <0,0001 1,52 [1,29; 1,79]; <0,0001 0,14 [0,09; 0,20]; <0,0001
BRCA2	232	100 (43,1)	215	66 (30,7)	1,71 [1,16; 2,52]; 0,0069 1,40 [1,09; 1,80]; 0,0076 0,12 [0,04; 0,21]; 0,0061
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,1761)					
2, 3 oder 4	392	169 (43,1)	383	110 (28,7)	1,88 [1,40; 2,53]; <0,0001 1,50 [1,24; 1,82]; <0,0001 0,14 [0,08; 0,21]; <0,0001
5 oder 6	22	12 (54,6)	14	2 (14,3)	7,20 [1,29; 40,05]; 0,0242 3,82 [1,00; 14,56]; 0,0498 0,40 [0,13; 0,68]; 0,0044
Ethnie (Interaktionstest: p=0,0039)					
Andere	16	7 (43,8)	15	10 (66,7)	0,39 [0,09; 1,67]; 0,2045 0,66 [0,34; 1,27]; 0,2116 -0,23 [-0,57; 0,11]; 0,1872
Asiatisch	259	69 (26,6)	271	33 (12,2)	2,62 [1,66; 4,13]; <0,0001 2,19 [1,50; 3,19]; <0,0001 0,14 [0,08; 0,21]; <0,0001
Kaukasisch	617	277 (44,9)	589	195 (33,1)	1,65 [1,30; 2,08]; <0,0001 1,36 [1,17; 1,57]; <0,0001 0,12 [0,06; 0,17]; <0,0001
Schwarz oder afroamerikanisch	19	13 (68,4)	29	8 (27,6)	5,69 [1,61; 20,14]; 0,0071 2,48 [1,28; 4,82]; 0,0073 0,41 [0,14; 0,67]; 0,0025
Ethnische Abstammung (Interaktionstest: p=0,2700)					
Hispanisch	34	7 (20,6)	24	7 (29,2)	0,63 [0,19; 2,11]; 0,4539 0,71 [0,28; 1,75]; 0,4522 -0,09 [-0,31; 0,14]; 0,4589
Nicht-hispanisch	798	314 (39,4)	803	210 (26,2)	1,83 [1,48; 2,26]; <0,0001 1,50 [1,30; 1,74]; <0,0001 0,13 [0,09; 0,18]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	45 (57,0)	77	29 (37,7)	2,19 [1,15; 4,16]; 0,0165 1,51 [1,07; 2,14]; 0,0189 0,19 [0,04; 0,35]; 0,0139
Hormonrezeptorstatus (Interaktionstest: p=0,8931)					
ER- und/oder PgR-positiv, HER2-positiv	168	69 (41,1)	155	44 (28,4)	1,76 [1,10; 2,80]; 0,0174 1,45 [1,06; 1,97]; 0,0190 0,13 [0,02; 0,23]; 0,0156

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
TNBC	741	296 (40,0)	749	202 (27,0)	1,80 [1,45; 2,24]; <0,0001 1,48 [1,28; 1,72]; <0,0001 0,13 [0,08; 0,18]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7085)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	44 (42,3)	92	23 (25,0)	2,20 [1,19; 4,06]; 0,0115 1,69 [1,11; 2,57]; 0,0139 0,17 [0,04; 0,30]; 0,0090
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	25 (39,1)	63	21 (33,3)	1,28 [0,62; 2,65]; 0,5022 1,17 [0,74; 1,86]; 0,5032 0,06 [-0,11; 0,22]; 0,5009
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	151 (43,4)	362	107 (29,6)	1,83 [1,34; 2,49]; 0,0001 1,47 [1,20; 1,79]; 0,0002 0,14 [0,07; 0,21]; 0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	145 (36,9)	387	95 (24,6)	1,80 [1,32; 2,45]; 0,0002 1,50 [1,21; 1,87]; 0,0002 0,12 [0,06; 0,19]; 0,0002
Menopausenstatus (Interaktionstest: p=0,0684)					
Postmenopausal	346	145 (41,9)	356	116 (32,6)	1,49 [1,10; 2,03]; 0,0108 1,29 [1,06; 1,56]; 0,0111 0,09 [0,02; 0,16]; 0,0103
Prämenopausal	563	220 (39,1)	544	129 (23,7)	2,06 [1,59; 2,68]; <0,0001 1,65 [1,37; 1,98]; <0,0001 0,15 [0,10; 0,21]; <0,0001
Region (Interaktionstest: p=0,5675)					
Asien-Pazifik und Südafrika	301	89 (29,6)	317	54 (17,0)	2,04 [1,39; 3,00]; 0,0003 1,74 [1,29; 2,34]; 0,0003 0,13 [0,06; 0,19]; 0,0002
Europa	473	206 (43,6)	444	134 (30,2)	1,78 [1,36; 2,34]; <0,0001 1,44 [1,21; 1,72]; <0,0001 0,13 [0,07; 0,20]; <0,0001
Nordamerika	121	69 (57,0)	131	57 (43,5)	1,72 [1,05; 2,84]; 0,0326 1,31 [1,02; 1,68]; 0,0333 0,14 [0,01; 0,26]; 0,0305
Südamerika	16	2 (12,5)	12	1 (8,3)	1,57 [0,13; 19,67]; 0,7259 1,50 [0,15; 14,68]; 0,7275 0,04 [-0,18; 0,27]; 0,7169
Art der vorherigen Chemotherapie (Interaktionstest: p=0,7473)					
Adjuvant	457	170 (37,2)	450	116 (25,8)	1,71 [1,28; 2,27]; 0,0002 1,44 [1,19; 1,76]; 0,0003 0,11 [0,05; 0,17]; 0,0002
Neoadjuvant	454	196 (43,2)	454	130 (28,6)	1,89 [1,44; 2,49]; <0,0001 1,51 [1,26; 1,80]; <0,0001 0,15 [0,08; 0,21]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,5116)					
AZ	801	304 (38,0)	796	201 (25,3)	1,81 [1,46; 2,24]; <0,0001 1,50 [1,30; 1,74]; <0,0001 0,13 [0,08; 0,17]; <0,0001
NRG Oncology	110	62 (56,4)	108	45 (41,7)	1,81 [1,06; 3,09]; 0,0306 1,35 [1,03; 1,78]; 0,0327 0,15 [0,02; 0,28]; 0,0282
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4316)					
Ja	243	103 (42,4)	236	62 (26,3)	2,06 [1,40; 3,04]; 0,0002 1,61 [1,25; 2,09]; 0,0003 0,16 [0,08; 0,24]; 0,0002
Nein	668	263 (39,4)	668	184 (27,5)	1,71 [1,36; 2,15]; <0,0001 1,43 [1,22; 1,67]; <0,0001 0,12 [0,07; 0,17]; <0,0001
Unwohlsein					
Alter (Interaktionstest: p=0,6395)					
<50	690	14 (2,0)	663	8 (1,2)	1,70 [0,71; 4,07]; 0,2370 1,68 [0,71; 3,98]; 0,2374 0,01 [-0,01; 0,02]; 0,2293
50-64	192	7 (3,7)	209	2 (1,0)	3,92 [0,80; 19,09]; 0,0912 3,81 [0,80; 18,12]; 0,0927 0,03 [0,00; 0,06]; 0,0752
≥65	29	1 (3,5)	32	0 (0,0)	3,42 [0,13; 87,34]; 0,4568 3,30 [0,14; 77,95]; 0,4593 0,03 [-0,05; 0,12]; 0,4447
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,4563)					
Anthrazyklin	7	2 (28,6)	13	0 (0,0)	12,27 [0,50; 299,32]; 0,1239 8,75 [0,48; 160,53]; 0,1440 0,29 [-0,05; 0,62]; 0,0952
Anthrazyklin und Taxan	861	18 (2,1)	840	10 (1,2)	1,77 [0,81; 3,86]; 0,1499 1,76 [0,82; 3,78]; 0,1503 0,01 [0,00; 0,02]; 0,1431
Taxan	43	2 (4,7)	50	0 (0,0)	6,08 [0,28; 130,28]; 0,2481 5,80 [0,29; 117,51]; 0,2525 0,05 [-0,03; 0,12]; 0,2152
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,4957)					
Brusterhaltend	220	6 (2,7)	235	5 (2,1)	1,29 [0,39; 4,29]; 0,6781 1,28 [0,40; 4,14]; 0,6781 0,01 [-0,02; 0,03]; 0,6785
Einseitige Mastektomie	355	13 (3,7)	352	5 (1,4)	2,64 [0,93; 7,48]; 0,0681 2,58 [0,93; 7,16]; 0,0690 0,02 [0,00; 0,05]; 0,0574

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	3 (0,9)	315	0 (0,0)	6,62 [0,34; 128,72]; 0,2118 6,56 [0,34; 126,57]; 0,2127 0,01 [0,00; 0,02]; 0,1340
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	22 (2,5)	866	10 (1,2)	2,22 [1,05; 4,72]; 0,0380 2,19 [1,04; 4,60]; 0,0383 0,01 [0,00; 0,03]; 0,0330
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,1588)					
Positiv	173	8 (4,6)	176	1 (0,6)	8,48 [1,05; 68,58]; 0,0449 8,14 [1,03; 64,38]; 0,0469 0,04 [0,01; 0,07]; 0,0167
Negativ	200	6 (3,0)	191	4 (2,1)	1,45 [0,40; 5,21]; 0,5727 1,43 [0,41; 5,00]; 0,5729 0,01 [-0,02; 0,04]; 0,5689
Bilaterale Oophorektomie (Interaktionstest: p=0,8683)					
Ja	189	1 (0,5)	176	0 (0,0)	2,81 [0,11; 69,41]; 0,5279 2,79 [0,11; 68,16]; 0,5283 0,01 [-0,01; 0,02]; 0,4839
Nein	722	21 (2,9)	728	10 (1,4)	2,15 [1,01; 4,60]; 0,0483 2,12 [1,00; 4,46]; 0,0487 0,02 [0,00; 0,03]; 0,0433
BRCA-Mutationsstatus (Interaktionstest: p=0,6799)					
BRCA1	574	9 (1,6)	580	7 (1,2)	1,30 [0,48; 3,53]; 0,6010 1,30 [0,49; 3,46]; 0,6010 0,00 [-0,01; 0,02]; 0,6002
BRCA2	232	6 (2,6)	215	3 (1,4)	1,88 [0,46; 7,60]; 0,3779 1,85 [0,47; 7,32]; 0,3786 0,01 [-0,01; 0,04]; 0,3647
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	5 (1,3)	383	5 (1,3)	0,98 [0,28; 3,40]; 0,9705 0,98 [0,29; 3,35]; 0,9705 0,00 [-0,02; 0,02]; 0,9705
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,3838)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	16 (6,2)	271	10 (3,7)	1,72 [0,77; 3,86]; 0,1897 1,67 [0,77; 3,62]; 0,1905 0,02 [-0,01; 0,06]; 0,1867
Kaukasisch	617	4 (0,7)	589	0 (0,0)	8,65 [0,46; 160,97]; 0,1482 8,59 [0,46; 159,24]; 0,1488 0,01 [0,00; 0,01]; 0,0736
Schwarz oder afroamerikanisch	19	2 (10,5)	29	0 (0,0)	8,43 [0,38; 185,87]; 0,1768 7,50 [0,38; 148,13]; 0,1856 0,11 [-0,05; 0,26]; 0,1747
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	22 (2,8)	803	10 (1,2)	2,25 [1,06; 4,78]; 0,0352 2,21 [1,06; 4,64]; 0,0356 0,02 [0,00; 0,03]; 0,0307
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Hormonrezeptorstatus (Interaktionstest: p=0,8782)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	1 (0,7)	1,86 [0,17; 20,67]; 0,6153 1,85 [0,17; 20,15]; 0,6155 0,01 [-0,02; 0,03]; 0,6053
TNBC	741	20 (2,7)	749	9 (1,2)	2,28 [1,03; 5,04]; 0,0417 2,25 [1,03; 4,90]; 0,0420 0,01 [0,00; 0,03]; 0,0365
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,4369)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	1 (1,1)	0,29 [0,01; 7,25]; 0,4525 0,30 [0,01; 7,16]; 0,4533 -0,01 [-0,04; 0,02]; 0,4593
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	0 (0,0)	5,08 [0,24; 107,95]; 0,2973 4,92 [0,24; 100,55]; 0,3004 0,03 [-0,02; 0,08]; 0,2342
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	5 (1,4)	362	4 (1,1)	1,30 [0,35; 4,90]; 0,6936 1,30 [0,35; 4,80]; 0,6936 0,00 [-0,01; 0,02]; 0,6935
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	15 (3,8)	387	5 (1,3)	3,03 [1,09; 8,42]; 0,0334 2,95 [1,08; 8,05]; 0,0342 0,03 [0,00; 0,05]; 0,0247

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Menopausenstatus (Interaktionstest: p=0,2277)					
Postmenopausal	346	9 (2,6)	356	2 (0,6)	4,73 [1,01; 22,04]; 0,0480 4,63 [1,01; 21,28]; 0,0489 0,02 [0,00; 0,04]; 0,0306
Prämenopausal	563	13 (2,3)	544	8 (1,5)	1,58 [0,65; 3,85]; 0,3106 1,57 [0,66; 3,76]; 0,3110 0,01 [-0,01; 0,02]; 0,3046
Region (Interaktionstest: p=0,4631)					
Asien-Pazifik und Südafrika	301	16 (5,3)	317	10 (3,2)	1,72 [0,77; 3,86]; 0,1858 1,69 [0,78; 3,65]; 0,1865 0,02 [-0,01; 0,05]; 0,1832
Europa	473	4 (0,9)	444	0 (0,0)	8,52 [0,46; 158,72]; 0,1511 8,45 [0,46; 156,49]; 0,1519 0,01 [0,00; 0,02]; 0,0737
Nordamerika	121	2 (1,7)	131	0 (0,0)	5,50 [0,26; 115,77]; 0,2726 5,41 [0,26; 111,56]; 0,2742 0,02 [-0,01; 0,04]; 0,2343
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,1339)					
Adjuvant	457	17 (3,7)	450	5 (1,1)	3,44 [1,26; 9,40]; 0,0161 3,35 [1,25; 9,00]; 0,0166 0,03 [0,01; 0,05]; 0,0101
Neoadjuvant	454	5 (1,1)	454	5 (1,1)	1,00 [0,29; 3,48]; 1,0000 1,00 [0,29; 3,43]; 1,0000 0,00 [-0,01; 0,01]; 1,0000
Sponsor (Interaktionstest: p=0,5696)					
AZ	801	20 (2,5)	796	10 (1,3)	2,01 [0,94; 4,33]; 0,0733 1,99 [0,94; 4,22]; 0,0737 0,01 [0,00; 0,03]; 0,0673
NRG Oncology	110	2 (1,8)	108	0 (0,0)	5,00 [0,24; 105,37]; 0,3007 4,91 [0,24; 101,10]; 0,3025 0,02 [-0,01; 0,05]; 0,2408
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7915)					
Ja	243	3 (1,2)	236	1 (0,4)	2,94 [0,30; 28,44]; 0,3522 2,91 [0,31; 27,81]; 0,3529 0,01 [-0,01; 0,02]; 0,3257
Nein	668	19 (2,8)	668	9 (1,4)	2,14 [0,96; 4,77]; 0,0619 2,11 [0,96; 4,63]; 0,0624 0,01 [0,00; 0,03]; 0,0558

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
SOC: Erkrankungen des Blutes und des Lymphsystems					
Alter (Interaktionstest: p=0,1732)					
<50	690	161 (23,3)	663	35 (5,3)	5,46 [3,72; 8,01]; <0,0001 4,42 [3,12; 6,27]; <0,0001 0,18 [0,14; 0,22]; <0,0001
50-64	192	54 (28,1)	209	7 (3,4)	11,29 [4,99; 25,55]; <0,0001 8,40 [3,92; 18,00]; <0,0001 0,25 [0,18; 0,32]; <0,0001
≥65	29	14 (48,3)	32	1 (3,1)	28,93 [3,47; 241,13]; 0,0019 15,45 [2,16; 110,28]; 0,0063 0,45 [0,26; 0,64]; <0,0001
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,1828)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	216 (25,1)	840	37 (4,4)	7,27 [5,05; 10,46]; <0,0001 5,70 [4,07; 7,97]; <0,0001 0,21 [0,17; 0,24]; <0,0001
Taxan	43	12 (27,9)	50	6 (12,0)	2,84 [0,96; 8,38]; 0,0589 2,33 [0,95; 5,67]; 0,0634 0,16 [0,00; 0,32]; 0,0536
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2438)					
Brusterhaltend	220	62 (28,2)	235	8 (3,4)	11,13 [5,19; 23,90]; <0,0001 8,28 [4,06; 16,89]; <0,0001 0,25 [0,18; 0,31]; <0,0001
Einseitige Mastektomie	355	91 (25,6)	352	17 (4,8)	6,79 [3,95; 11,68]; <0,0001 5,31 [3,23; 8,72]; <0,0001 0,21 [0,16; 0,26]; <0,0001
Beidseitige Mastektomie	336	76 (22,6)	315	18 (5,7)	4,82 [2,81; 8,28]; <0,0001 3,96 [2,42; 6,46]; <0,0001 0,17 [0,12; 0,22]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,8404)					
Ja	41	5 (12,2)	35	1 (2,9)	4,72 [0,52; 42,52]; 0,1662 4,27 [0,52; 34,82]; 0,1754 0,09 [-0,02; 0,21]; 0,1095
Nein	870	224 (25,8)	866	42 (4,9)	6,80 [4,82; 9,61]; <0,0001 5,31 [3,87; 7,28]; <0,0001 0,21 [0,18; 0,24]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,4420)					
Positiv	173	59 (34,1)	176	13 (7,4)	6,49 [3,40; 12,39]; <0,0001 4,62 [2,63; 8,10]; <0,0001 0,27 [0,19; 0,35]; <0,0001
Negativ	200	43 (21,5)	191	6 (3,1)	8,44 [3,50; 20,36]; <0,0001 6,84 [2,98; 15,71]; <0,0001 0,18 [0,12; 0,25]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,4822)					
Ja	189	46 (24,3)	176	10 (5,7)	5,34 [2,60; 10,96]; <0,0001 4,28 [2,23; 8,22]; <0,0001 0,19 [0,12; 0,26]; <0,0001
Nein	722	183 (25,4)	728	33 (4,5)	7,15 [4,85; 10,53]; <0,0001 5,59 [3,92; 7,98]; <0,0001 0,21 [0,17; 0,24]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,3881)					
BRCA1	574	142 (24,7)	580	26 (4,5)	7,00 [4,53; 10,84]; <0,0001 5,52 [3,69; 8,25]; <0,0001 0,20 [0,16; 0,24]; <0,0001
BRCA2	232	52 (22,4)	215	12 (5,6)	4,89 [2,53; 9,45]; <0,0001 4,02 [2,20; 7,31]; <0,0001 0,17 [0,11; 0,23]; <0,0001
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9267)					
2, 3 oder 4	392	86 (21,9)	383	15 (3,9)	6,89 [3,90; 12,18]; <0,0001 5,60 [3,30; 9,52]; <0,0001 0,18 [0,13; 0,23]; <0,0001
5 oder 6	22	8 (36,4)	14	1 (7,1)	7,43 [0,81; 67,83]; 0,0756 5,09 [0,71; 36,43]; 0,1050 0,29 [0,05; 0,53]; 0,0180
Ethnie (Interaktionstest: p=0,0561)					
Andere	16	0 (0,0)	15	1 (6,7)	0,29 [0,01; 7,76]; 0,4628 0,31 [0,01; 7,15]; 0,4675 -0,07 [-0,23; 0,10]; 0,4252
Asiatisch	259	93 (35,9)	271	13 (4,8)	11,12 [6,03; 20,51]; <0,0001 7,49 [4,30; 13,04]; <0,0001 0,31 [0,25; 0,37]; <0,0001
Kaukasisch	617	131 (21,2)	589	25 (4,2)	6,08 [3,90; 9,49]; <0,0001 5,00 [3,31; 7,56]; <0,0001 0,17 [0,13; 0,21]; <0,0001
Schwarz oder afroamerikanisch	19	5 (26,3)	29	4 (13,8)	2,23 [0,51; 9,69]; 0,2839 1,91 [0,59; 6,21]; 0,2836 0,13 [-0,11; 0,36]; 0,2951

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,8359)					
Hispanisch	34	8 (23,5)	24	0 (0,0)	15,72 [0,86; 286,96]; 0,0630 12,14 [0,73; 200,81]; 0,0811 0,24 [0,08; 0,39]; 0,0025
Nicht-hispanisch	798	211 (26,4)	803	41 (5,1)	6,68 [4,70; 9,49]; <0,0001 5,18 [3,76; 7,13]; <0,0001 0,21 [0,18; 0,25]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	10 (12,7)	77	2 (2,6)	5,43 [1,15; 25,68]; 0,0326 4,87 [1,10; 21,52]; 0,0366 0,10 [0,02; 0,18]; 0,0155
Hormonrezeptorstatus (Interaktionstest: p=0,7018)					
ER- und/oder PgR-positiv, HER2-positiv	168	40 (23,8)	155	6 (3,9)	7,76 [3,19; 18,90]; <0,0001 6,15 [2,68; 14,10]; <0,0001 0,20 [0,13; 0,27]; <0,0001
TNBC	741	189 (25,5)	749	37 (4,9)	6,59 [4,55; 9,53]; <0,0001 5,16 [3,68; 7,24]; <0,0001 0,21 [0,17; 0,24]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,9043)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	23 (22,1)	92	4 (4,4)	6,25 [2,07; 18,84]; 0,0011 5,09 [1,83; 14,16]; 0,0019 0,18 [0,09; 0,27]; 0,0001
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	17 (26,6)	63	2 (3,2)	11,03 [2,43; 50,13]; 0,0019 8,37 [2,02; 34,73]; 0,0034 0,23 [0,12; 0,35]; <0,0001
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	80 (23,0)	362	15 (4,1)	6,91 [3,89; 12,26]; <0,0001 5,55 [3,26; 9,44]; <0,0001 0,19 [0,14; 0,24]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	109 (27,7)	387	22 (5,7)	6,37 [3,93; 10,33]; <0,0001 4,88 [3,15; 7,55]; <0,0001 0,22 [0,17; 0,27]; <0,0001
Menopausenstatus (Interaktionstest: p=0,6993)					
Postmenopausal	346	96 (27,8)	356	20 (5,6)	6,45 [3,88; 10,73]; <0,0001 4,94 [3,12; 7,81]; <0,0001 0,22 [0,17; 0,27]; <0,0001
Prämenopausal	563	133 (23,6)	544	23 (4,2)	7,01 [4,42; 11,11]; <0,0001 5,59 [3,65; 8,56]; <0,0001 0,19 [0,16; 0,23]; <0,0001
Region (Interaktionstest: p=0,2450)					
Asien-Pazifik und Südafrika	301	101 (33,6)	317	13 (4,1)	11,81 [6,45; 21,61]; <0,0001 8,18 [4,69; 14,26]; <0,0001 0,29 [0,24; 0,35]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	91 (19,2)	444	20 (4,5)	5,05 [3,05; 8,35]; <0,0001 4,27 [2,68; 6,81]; <0,0001 0,15 [0,11; 0,19]; <0,0001
Nordamerika	121	35 (28,9)	131	10 (7,6)	4,92 [2,31; 10,48]; <0,0001 3,79 [1,96; 7,32]; <0,0001 0,21 [0,12; 0,31]; <0,0001
Südamerika	16	2 (12,5)	12	0 (0,0)	4,31 [0,19; 98,51]; 0,3601 3,82 [0,20; 73,00]; 0,3728 0,12 [-0,07; 0,32]; 0,2164
Art der vorherigen Chemotherapie (Interaktionstest: p=0,8824)					
Adjuvant	457	126 (27,6)	450	24 (5,3)	6,76 [4,27; 10,70]; <0,0001 5,17 [3,41; 7,84]; <0,0001 0,22 [0,18; 0,27]; <0,0001
Neoadjuvant	454	103 (22,7)	454	19 (4,2)	6,72 [4,04; 11,18]; <0,0001 5,42 [3,38; 8,69]; <0,0001 0,19 [0,14; 0,23]; <0,0001
Sponsor (Interaktionstest: p=0,1366)					
AZ	801	195 (24,3)	796	33 (4,2)	7,44 [5,07; 10,92]; <0,0001 5,87 [4,11; 8,38]; <0,0001 0,20 [0,17; 0,23]; <0,0001
NRG Oncology	110	34 (30,9)	108	10 (9,3)	4,38 [2,04; 9,43]; 0,0002 3,34 [1,74; 6,41]; 0,0003 0,22 [0,11; 0,32]; <0,0001
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,8739)					
Ja	243	52 (21,4)	236	10 (4,2)	6,15 [3,04; 12,44]; <0,0001 5,05 [2,63; 9,70]; <0,0001 0,17 [0,11; 0,23]; <0,0001
Nein	668	177 (26,5)	668	33 (4,9)	6,94 [4,70; 10,24]; <0,0001 5,36 [3,76; 7,66]; <0,0001 0,22 [0,18; 0,25]; <0,0001
Anämie					
Alter (Interaktionstest: p=0,2806)					
<50	690	150 (21,7)	663	28 (4,2)	6,30 [4,14; 9,58]; <0,0001 5,15 [3,49; 7,60]; <0,0001 0,18 [0,14; 0,21]; <0,0001
50-64	192	51 (26,6)	209	6 (2,9)	12,24 [5,11; 29,29]; <0,0001 9,25 [4,06; 21,07]; <0,0001 0,24 [0,17; 0,30]; <0,0001
≥65	29	14 (48,3)	32	1 (3,1)	28,93 [3,47; 241,13]; 0,0019 15,45 [2,16; 110,28]; 0,0063 0,45 [0,26; 0,64]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,2045)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	203 (23,6)	840	30 (3,6)	8,33 [5,60; 12,39]; <0,0001 6,60 [4,55; 9,57]; <0,0001 0,20 [0,17; 0,23]; <0,0001
Taxan	43	11 (25,6)	50	5 (10,0)	3,09 [0,98; 9,77]; 0,0543 2,56 [0,96; 6,78]; 0,0591 0,16 [0,00; 0,31]; 0,0483
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,1739)					
Brusterhaltend	220	58 (26,4)	235	5 (2,1)	16,47 [6,46; 41,97]; <0,0001 12,39 [5,06; 30,32]; <0,0001 0,24 [0,18; 0,30]; <0,0001
Einseitige Mastektomie	355	83 (23,4)	352	15 (4,3)	6,86 [3,87; 12,15]; <0,0001 5,49 [3,23; 9,32]; <0,0001 0,19 [0,14; 0,24]; <0,0001
Beidseitige Mastektomie	336	74 (22,0)	315	15 (4,8)	5,65 [3,17; 10,08]; <0,0001 4,62 [2,71; 7,88]; <0,0001 0,17 [0,12; 0,22]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,5928)					
Ja	41	4 (9,8)	35	1 (2,9)	3,68 [0,39; 34,53]; 0,2548 3,41 [0,40; 29,15]; 0,2617 0,07 [-0,04; 0,18]; 0,2033
Nein	870	211 (24,3)	866	34 (3,9)	7,84 [5,38; 11,42]; <0,0001 6,18 [4,35; 8,76]; <0,0001 0,20 [0,17; 0,23]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,4038)					
Positiv	173	55 (31,8)	176	10 (5,7)	7,74 [3,79; 15,80]; <0,0001 5,60 [2,95; 10,61]; <0,0001 0,26 [0,18; 0,34]; <0,0001
Negativ	200	39 (19,5)	191	4 (2,1)	11,32 [3,96; 32,37]; <0,0001 9,31 [3,39; 25,56]; <0,0001 0,17 [0,12; 0,23]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,5087)					
Ja	189	42 (22,2)	176	8 (4,5)	6,00 [2,73; 13,19]; <0,0001 4,89 [2,36; 10,12]; <0,0001 0,18 [0,11; 0,24]; <0,0001
Nein	722	173 (24,0)	728	27 (3,7)	8,18 [5,37; 12,46]; <0,0001 6,46 [4,36; 9,56]; <0,0001 0,20 [0,17; 0,24]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
BRCA-Mutationsstatus (Interaktionstest: p=0,3853)					
BRCA1	574	134 (23,3)	580	21 (3,6)	8,11 [5,03; 13,06]; <0,0001 6,45 [4,13; 10,06]; <0,0001 0,20 [0,16; 0,24]; <0,0001
BRCA2	232	49 (21,1)	215	10 (4,7)	5,49 [2,70; 11,15]; <0,0001 4,54 [2,36; 8,74]; <0,0001 0,16 [0,11; 0,22]; <0,0001
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9295)					
2, 3 oder 4	392	80 (20,4)	383	14 (3,7)	6,76 [3,76; 12,16]; <0,0001 5,58 [3,22; 9,68]; <0,0001 0,17 [0,12; 0,21]; <0,0001
5 oder 6	22	8 (36,4)	14	1 (7,1)	7,43 [0,81; 67,83]; 0,0756 5,09 [0,71; 36,43]; 0,1050 0,29 [0,05; 0,53]; 0,0180
Ethnie (Interaktionstest: p=0,0760)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	85 (32,8)	271	10 (3,7)	12,75 [6,44; 25,24]; <0,0001 8,89 [4,72; 16,74]; <0,0001 0,29 [0,23; 0,35]; <0,0001
Kaukasisch	617	125 (20,3)	589	21 (3,6)	6,87 [4,26; 11,08]; <0,0001 5,68 [3,63; 8,90]; <0,0001 0,17 [0,13; 0,20]; <0,0001
Schwarz oder afroamerikanisch	19	5 (26,3)	29	4 (13,8)	2,23 [0,51; 9,69]; 0,2839 1,91 [0,59; 6,21]; 0,2836 0,13 [-0,11; 0,36]; 0,2951
Ethnische Abstammung (Interaktionstest: p=0,8141)					
Hispanisch	34	8 (23,5)	24	0 (0,0)	15,72 [0,86; 286,96]; 0,0630 12,14 [0,73; 200,81]; 0,0811 0,24 [0,08; 0,39]; 0,0025
Nicht-hispanisch	798	198 (24,8)	803	33 (4,1)	7,70 [5,25; 11,30]; <0,0001 6,04 [4,23; 8,61]; <0,0001 0,21 [0,17; 0,24]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	9 (11,4)	77	2 (2,6)	4,82 [1,01; 23,09]; 0,0490 4,39 [0,98; 19,65]; 0,0533 0,09 [0,01; 0,17]; 0,0282
Hormonrezeptorstatus (Interaktionstest: p=0,8531)					
ER- und/oder PgR-positiv, HER2-positiv	168	37 (22,0)	155	6 (3,9)	7,01 [2,87; 17,15]; <0,0001 5,69 [2,47; 13,11]; <0,0001 0,18 [0,11; 0,25]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	178 (24,0)	749	29 (3,9)	7,85 [5,22; 11,80]; <0,0001 6,20 [4,25; 9,06]; <0,0001 0,20 [0,17; 0,24]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8792)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	20 (19,2)	92	4 (4,4)	5,24 [1,72; 15,96]; 0,0036 4,42 [1,57; 12,47]; 0,0049 0,15 [0,06; 0,24]; 0,0007
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	17 (26,6)	63	2 (3,2)	11,03 [2,43; 50,13]; 0,0019 8,37 [2,02; 34,73]; 0,0034 0,23 [0,12; 0,35]; <0,0001
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	77 (22,1)	362	12 (3,3)	8,29 [4,42; 15,54]; <0,0001 6,67 [3,70; 12,04]; <0,0001 0,19 [0,14; 0,24]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	101 (25,7)	387	17 (4,4)	7,53 [4,40; 12,87]; <0,0001 5,85 [3,57; 9,59]; <0,0001 0,21 [0,17; 0,26]; <0,0001
Menopausenstatus (Interaktionstest: p=0,6285)					
Postmenopausal	346	92 (26,6)	356	17 (4,8)	7,22 [4,20; 12,42]; <0,0001 5,57 [3,39; 9,14]; <0,0001 0,22 [0,17; 0,27]; <0,0001
Prämenopausal	563	123 (21,9)	544	18 (3,3)	8,17 [4,90; 13,61]; <0,0001 6,60 [4,08; 10,67]; <0,0001 0,19 [0,15; 0,22]; <0,0001
Region (Interaktionstest: p=0,2146)					
Asien-Pazifik und Südafrika	301	92 (30,6)	317	10 (3,2)	13,51 [6,87; 26,56]; <0,0001 9,69 [5,14; 18,25]; <0,0001 0,27 [0,22; 0,33]; <0,0001
Europa	473	87 (18,4)	444	15 (3,4)	6,45 [3,66; 11,34]; <0,0001 5,44 [3,20; 9,27]; <0,0001 0,15 [0,11; 0,19]; <0,0001
Nordamerika	121	34 (28,1)	131	10 (7,6)	4,73 [2,22; 10,08]; <0,0001 3,68 [1,90; 7,12]; 0,0001 0,20 [0,11; 0,30]; <0,0001
Südamerika	16	2 (12,5)	12	0 (0,0)	4,31 [0,19; 98,51]; 0,3601 3,82 [0,20; 73,00]; 0,3728 0,12 [-0,07; 0,32]; 0,2164
Art der vorherigen Chemotherapie (Interaktionstest: p=0,9804)					
Adjuvant	457	118 (25,8)	450	19 (4,2)	7,90 [4,77; 13,08]; <0,0001 6,12 [3,83; 9,75]; <0,0001 0,22 [0,17; 0,26]; <0,0001
Neoadjuvant	454	97 (21,4)	454	16 (3,5)	7,44 [4,30; 12,85]; <0,0001 6,06 [3,63; 10,12]; <0,0001 0,18 [0,14; 0,22]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,0413)					
AZ	801	182 (22,7)	796	25 (3,1)	9,07 [5,89; 13,96]; <0,0001 7,23 [4,82; 10,86]; <0,0001 0,20 [0,16; 0,23]; <0,0001
NRG Oncology	110	33 (30,0)	108	10 (9,3)	4,20 [1,95; 9,05]; 0,0002 3,24 [1,68; 6,24]; 0,0004 0,21 [0,11; 0,31]; <0,0001
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,3616)					
Ja	243	48 (19,8)	236	10 (4,2)	5,56 [2,74; 11,29]; <0,0001 4,66 [2,42; 9,00]; <0,0001 0,16 [0,10; 0,21]; <0,0001
Nein	668	167 (25,0)	668	25 (3,7)	8,57 [5,54; 13,26]; <0,0001 6,68 [4,45; 10,03]; <0,0001 0,21 [0,18; 0,25]; <0,0001
Leukopenie					
Alter (Interaktionstest: p=0,2390)					
<50	690	9 (1,3)	663	1 (0,2)	8,75 [1,11; 69,25]; 0,0399 8,65 [1,10; 68,07]; 0,0404 0,01 [0,00; 0,02]; 0,0117
50-64	192	1 (0,5)	209	1 (0,5)	1,09 [0,07; 17,53]; 0,9520 1,09 [0,07; 17,28]; 0,9520 0,00 [-0,01; 0,01]; 0,9521
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	10 (1,2)	840	2 (0,2)	4,92 [1,08; 22,54]; 0,0400 4,88 [1,07; 22,20]; 0,0404 0,01 [0,00; 0,02]; 0,0216
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,4734)					
Brusterhaltend	220	4 (1,8)	235	1 (0,4)	4,33 [0,48; 39,07]; 0,1913 4,27 [0,48; 37,93]; 0,1924 0,01 [-0,01; 0,03]; 0,1620
Einseitige Mastektomie	355	5 (1,4)	352	0 (0,0)	11,06 [0,61; 200,82]; 0,1041 10,91 [0,61; 196,52]; 0,1053 0,01 [0,00; 0,03]; 0,0394

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	1 (0,3)	315	1 (0,3)	0,94 [0,06; 15,05]; 0,9635 0,94 [0,06; 14,92]; 0,9635 0,00 [-0,01; 0,01]; 0,9636
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	10 (1,2)	866	2 (0,2)	5,02 [1,10; 22,99]; 0,0375 4,98 [1,09; 22,65]; 0,0379 0,01 [0,00; 0,02]; 0,0205
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,9708)					
Positiv	173	2 (1,2)	176	1 (0,6)	2,05 [0,18; 22,78]; 0,5602 2,03 [0,19; 22,23]; 0,5604 0,01 [-0,01; 0,03]; 0,5529
Negativ	200	2 (1,0)	191	1 (0,5)	1,92 [0,17; 21,34]; 0,5958 1,91 [0,17; 20,89]; 0,5960 0,00 [-0,01; 0,02]; 0,5866
Bilaterale Oophorektomie (Interaktionstest: p=0,3643)					
Ja	189	2 (1,1)	176	1 (0,6)	1,87 [0,17; 20,82]; 0,6101 1,86 [0,17; 20,36]; 0,6103 0,00 [-0,01; 0,02]; 0,6004
Nein	722	8 (1,1)	728	1 (0,1)	8,15 [1,02; 65,29]; 0,0483 8,07 [1,01; 64,33]; 0,0488 0,01 [0,00; 0,02]; 0,0188
BRCA-Mutationsstatus (Interaktionstest: p=0,0814)					
BRCA1	574	9 (1,6)	580	1 (0,2)	9,22 [1,16; 73,03]; 0,0353 9,09 [1,16; 71,55]; 0,0359 0,01 [0,00; 0,02]; 0,0106
BRCA2	232	0 (0,0)	215	1 (0,5)	0,31 [0,01; 7,59]; 0,4710 0,31 [0,01; 7,54]; 0,4713 0,00 [-0,02; 0,01]; 0,4682
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	6 (1,5)	383	0 (0,0)	12,90 [0,72; 229,77]; 0,0818 12,70 [0,72; 224,70]; 0,0829 0,02 [0,00; 0,03]; 0,0222
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,2308)					
Andere	16	0 (0,0)	15	1 (6,7)	0,29 [0,01; 7,76]; 0,4628 0,31 [0,01; 7,15]; 0,4675 -0,07 [-0,23; 0,10]; 0,4252
Asiatisch	259	4 (1,5)	271	0 (0,0)	9,56 [0,51; 178,52]; 0,1305 9,42 [0,51; 174,01]; 0,1319 0,02 [0,00; 0,03]; 0,0691
Kaukasisch	617	6 (1,0)	589	1 (0,2)	5,77 [0,69; 48,11]; 0,1050 5,73 [0,69; 47,43]; 0,1056 0,01 [0,00; 0,02]; 0,0619
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,8085)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	9 (1,1)	803	2 (0,3)	4,57 [0,98; 21,21]; 0,0525 4,53 [0,98; 20,89]; 0,0529 0,01 [0,00; 0,02]; 0,0334
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	0 (0,0)	2,96 [0,12; 73,83]; 0,5081 2,92 [0,12; 70,72]; 0,5090 0,01 [-0,02; 0,05]; 0,4733
Hormonrezeptorstatus (Interaktionstest: p=0,9392)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	0 (0,0)	4,67 [0,22; 98,03]; 0,3211 4,62 [0,22; 95,39]; 0,3223 0,01 [-0,01; 0,03]; 0,2492
TNBC	741	8 (1,1)	749	2 (0,3)	4,08 [0,86; 19,26]; 0,0761 4,04 [0,86; 18,98]; 0,0766 0,01 [0,00; 0,02]; 0,0552
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6440)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	2 (1,9)	92	0 (0,0)	4,51 [0,21; 95,21]; 0,3328 4,43 [0,22; 91,07]; 0,3347 0,02 [-0,01; 0,05]; 0,2495
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	4 (1,2)	362	0 (0,0)	9,47 [0,51; 176,55]; 0,1320 9,36 [0,51; 173,23]; 0,1330 0,01 [0,00; 0,02]; 0,0701
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	4 (1,0)	387	2 (0,5)	1,98 [0,36; 10,87]; 0,4320 1,97 [0,36; 10,69]; 0,4323 0,01 [-0,01; 0,02]; 0,4219

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Menopausenstatus (Interaktionstest: p=0,1161)					
Postmenopausal	346	2 (0,6)	356	2 (0,6)	1,03 [0,14; 7,35]; 0,9772 1,03 [0,15; 7,26]; 0,9772 0,00 [-0,01; 0,01]; 0,9772
Prämenopausal	563	8 (1,4)	544	0 (0,0)	16,66 [0,96; 289,41]; 0,0534 16,43 [0,95; 283,92]; 0,0542 0,01 [0,00; 0,02]; 0,0072
Region (Interaktionstest: p=0,3461)					
Asien-Pazifik und Südafrika	301	5 (1,7)	317	0 (0,0)	11,78 [0,65; 213,94]; 0,0955 11,58 [0,64; 208,57]; 0,0968 0,02 [0,00; 0,03]; 0,0381
Europa	473	5 (1,1)	444	2 (0,5)	2,36 [0,46; 12,23]; 0,3060 2,35 [0,46; 12,03]; 0,3064 0,01 [-0,01; 0,02]; 0,2851
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,2674)					
Adjuvant	457	4 (0,9)	450	2 (0,4)	1,98 [0,36; 10,85]; 0,4323 1,97 [0,36; 10,70]; 0,4325 0,00 [-0,01; 0,01]; 0,4222
Neoadjuvant	454	6 (1,3)	454	0 (0,0)	13,17 [0,74; 234,54]; 0,0793 13,00 [0,73; 230,09]; 0,0802 0,01 [0,00; 0,02]; 0,0221
Sponsor (Interaktionstest: p=NC)					
AZ	801	10 (1,2)	796	2 (0,3)	5,02 [1,10; 22,98]; 0,0377 4,97 [1,09; 22,61]; 0,0381 0,01 [0,00; 0,02]; 0,0206
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,6974)					
Ja	243	3 (1,2)	236	0 (0,0)	6,88 [0,35; 133,99]; 0,2028 6,80 [0,35; 130,92]; 0,2040 0,01 [0,00; 0,03]; 0,1310
Nein	668	7 (1,1)	668	2 (0,3)	3,53 [0,73; 17,04]; 0,1168 3,50 [0,73; 16,79]; 0,1173 0,01 [0,00; 0,02]; 0,0941

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
SOC: Erkrankungen des Gastrointestinaltrakts					
Alter (Interaktionstest: p=0,8035)					
<50	690	506 (73,3)	663	318 (48,0)	2,98 [2,38; 3,75]; <0,0001 1,53 [1,40; 1,67]; <0,0001 0,25 [0,20; 0,30]; <0,0001
50-64	192	126 (65,6)	209	96 (45,9)	2,25 [1,50; 3,36]; <0,0001 1,43 [1,19; 1,71]; <0,0001 0,20 [0,10; 0,29]; <0,0001
≥65	29	22 (75,9)	32	16 (50,0)	3,14 [1,05; 9,41]; 0,0408 1,52 [1,01; 2,27]; 0,0425 0,26 [0,03; 0,49]; 0,0296
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,9883)					
Anthrazyklin	7	5 (71,4)	13	6 (46,2)	2,92 [0,41; 20,90]; 0,2867 1,55 [0,73; 3,28]; 0,2545 0,25 [-0,18; 0,68]; 0,2500
Anthrazyklin und Taxan	861	621 (72,1)	840	402 (47,9)	2,82 [2,31; 3,45]; <0,0001 1,51 [1,39; 1,64]; <0,0001 0,24 [0,20; 0,29]; <0,0001
Taxan	43	28 (65,1)	50	21 (42,0)	2,58 [1,11; 5,98]; 0,0275 1,55 [1,05; 2,30]; 0,0285 0,23 [0,03; 0,43]; 0,0218
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,1118)					
Brusterhaltend	220	150 (68,2)	235	111 (47,2)	2,39 [1,63; 3,51]; <0,0001 1,44 [1,23; 1,70]; <0,0001 0,21 [0,12; 0,30]; <0,0001
Einseitige Mastektomie	355	250 (70,4)	352	147 (41,8)	3,32 [2,43; 4,53]; <0,0001 1,69 [1,47; 1,94]; <0,0001 0,29 [0,22; 0,36]; <0,0001
Beidseitige Mastektomie	336	254 (75,6)	315	171 (54,3)	2,61 [1,87; 3,64]; <0,0001 1,39 [1,24; 1,57]; <0,0001 0,21 [0,14; 0,28]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7329)					
Ja	41	37 (90,2)	35	22 (62,9)	5,47 [1,58; 18,86]; 0,0072 1,44 [1,09; 1,89]; 0,0096 0,27 [0,09; 0,46]; 0,0035
Nein	870	617 (70,9)	866	407 (47,0)	2,75 [2,26; 3,35]; <0,0001 1,51 [1,39; 1,64]; <0,0001 0,24 [0,19; 0,28]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,7364)					
Positiv	173	119 (68,8)	176	74 (42,1)	3,04 [1,96; 4,71]; <0,0001 1,64 [1,34; 2,00]; <0,0001 0,27 [0,17; 0,37]; <0,0001
Negativ	200	144 (72,0)	191	88 (46,1)	3,01 [1,98; 4,58]; <0,0001 1,56 [1,31; 1,86]; <0,0001 0,26 [0,17; 0,35]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,1833)					
Ja	189	141 (74,6)	176	96 (54,6)	2,45 [1,57; 3,81]; <0,0001 1,37 [1,17; 1,60]; 0,0001 0,20 [0,10; 0,30]; <0,0001
Nein	722	513 (71,1)	728	334 (45,9)	2,90 [2,33; 3,60]; <0,0001 1,55 [1,41; 1,70]; <0,0001 0,25 [0,20; 0,30]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,1487)					
BRCA1	574	419 (73,0)	580	297 (51,2)	2,58 [2,01; 3,29]; <0,0001 1,43 [1,30; 1,57]; <0,0001 0,22 [0,16; 0,27]; <0,0001
BRCA2	232	167 (72,0)	215	94 (43,7)	3,31 [2,23; 4,90]; <0,0001 1,65 [1,39; 1,95]; <0,0001 0,28 [0,19; 0,37]; <0,0001
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,7262)					
2, 3 oder 4	392	281 (71,7)	383	193 (50,4)	2,49 [1,85; 3,36]; <0,0001 1,42 [1,27; 1,60]; <0,0001 0,21 [0,15; 0,28]; <0,0001
5 oder 6	22	14 (63,6)	14	7 (50,0)	1,75 [0,45; 6,82]; 0,4203 1,27 [0,69; 2,35]; 0,4397 0,14 [-0,19; 0,47]; 0,4182
Ethnie (Interaktionstest: p=0,2107)					
Andere	16	11 (68,8)	15	8 (53,3)	1,93 [0,44; 8,33]; 0,3809 1,29 [0,72; 2,30]; 0,3886 0,15 [-0,19; 0,49]; 0,3736
Asiatisch	259	190 (73,4)	271	115 (42,4)	3,74 [2,59; 5,39]; <0,0001 1,73 [1,48; 2,02]; <0,0001 0,31 [0,23; 0,39]; <0,0001
Kaukasisch	617	442 (71,6)	589	294 (49,9)	2,53 [2,00; 3,22]; <0,0001 1,44 [1,31; 1,58]; <0,0001 0,22 [0,16; 0,27]; <0,0001
Schwarz oder afroamerikanisch	19	11 (57,9)	29	13 (44,8)	1,69 [0,53; 5,44]; 0,3775 1,29 [0,74; 2,25]; 0,3679 0,13 [-0,16; 0,42]; 0,3713

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,6308)					
Hispanisch	34	19 (55,9)	24	11 (45,8)	1,50 [0,52; 4,28]; 0,4515 1,22 [0,72; 2,07]; 0,4615 0,10 [-0,16; 0,36]; 0,4487
Nicht-hispanisch	798	578 (72,4)	803	380 (47,3)	2,92 [2,38; 3,60]; <0,0001 1,53 [1,41; 1,67]; <0,0001 0,25 [0,20; 0,30]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	57 (72,2)	77	39 (50,7)	2,52 [1,30; 4,91]; 0,0063 1,42 [1,10; 1,85]; 0,0075 0,22 [0,07; 0,36]; 0,0047
Hormonrezeptorstatus (Interaktionstest: p=0,4464)					
ER- und/oder PgR-positiv, HER2-positiv	168	121 (72,0)	155	69 (44,5)	3,21 [2,02; 5,10]; <0,0001 1,62 [1,33; 1,98]; <0,0001 0,28 [0,17; 0,38]; <0,0001
TNBC	741	531 (71,7)	749	361 (48,2)	2,72 [2,19; 3,37]; <0,0001 1,49 [1,36; 1,62]; <0,0001 0,23 [0,19; 0,28]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,2895)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	74 (71,2)	92	38 (41,3)	3,51 [1,94; 6,35]; <0,0001 1,72 [1,31; 2,26]; <0,0001 0,30 [0,17; 0,43]; <0,0001
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	47 (73,4)	63	31 (49,2)	2,85 [1,36; 6,00]; 0,0057 1,49 [1,12; 2,00]; 0,0070 0,24 [0,08; 0,41]; 0,0038
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	250 (71,8)	362	188 (51,9)	2,36 [1,73; 3,22]; <0,0001 1,38 [1,23; 1,56]; <0,0001 0,20 [0,13; 0,27]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	281 (71,5)	387	173 (44,7)	3,10 [2,31; 4,18]; <0,0001 1,60 [1,41; 1,82]; <0,0001 0,27 [0,20; 0,33]; <0,0001
Menopausenstatus (Interaktionstest: p=0,3040)					
Postmenopausal	346	249 (72,0)	356	179 (50,3)	2,54 [1,86; 3,47]; <0,0001 1,43 [1,27; 1,62]; <0,0001 0,22 [0,15; 0,29]; <0,0001
Prämenopausal	563	403 (71,6)	544	250 (46,0)	2,96 [2,31; 3,80]; <0,0001 1,56 [1,40; 1,73]; <0,0001 0,26 [0,20; 0,31]; <0,0001
Region (Interaktionstest: p=0,2819)					
Asien-Pazifik und Südafrika	301	224 (74,4)	317	153 (48,3)	3,12 [2,22; 4,38]; <0,0001 1,54 [1,35; 1,76]; <0,0001 0,26 [0,19; 0,34]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	321 (67,9)	444	197 (44,4)	2,65 [2,02; 3,46]; <0,0001 1,53 [1,35; 1,73]; <0,0001 0,23 [0,17; 0,30]; <0,0001
Nordamerika	121	100 (82,6)	131	79 (60,3)	3,13 [1,74; 5,63]; 0,0001 1,37 [1,17; 1,61]; 0,0001 0,22 [0,12; 0,33]; <0,0001
Südamerika	16	9 (56,3)	12	1 (8,3)	14,14 [1,46; 137,30]; 0,0223 6,75 [0,98; 46,30]; 0,0519 0,48 [0,19; 0,77]; 0,0012
Art der vorherigen Chemotherapie (Interaktionstest: p=0,2528)					
Adjuvant	457	328 (71,8)	450	204 (45,3)	3,07 [2,33; 4,04]; <0,0001 1,58 [1,41; 1,78]; <0,0001 0,26 [0,20; 0,33]; <0,0001
Neoadjuvant	454	326 (71,8)	454	226 (49,8)	2,57 [1,95; 3,38]; <0,0001 1,44 [1,29; 1,61]; <0,0001 0,22 [0,16; 0,28]; <0,0001
Sponsor (Interaktionstest: p=0,3095)					
AZ	801	564 (70,4)	796	366 (46,0)	2,80 [2,28; 3,44]; <0,0001 1,53 [1,40; 1,67]; <0,0001 0,24 [0,20; 0,29]; <0,0001
NRG Oncology	110	90 (81,8)	108	64 (59,3)	3,09 [1,67; 5,74]; 0,0003 1,38 [1,15; 1,65]; 0,0004 0,23 [0,11; 0,34]; 0,0002
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,3172)					
Ja	243	184 (75,7)	236	126 (53,4)	2,72 [1,85; 4,02]; <0,0001 1,42 [1,23; 1,63]; <0,0001 0,22 [0,14; 0,31]; <0,0001
Nein	668	470 (70,4)	668	304 (45,5)	2,84 [2,27; 3,56]; <0,0001 1,55 [1,40; 1,70]; <0,0001 0,25 [0,20; 0,30]; <0,0001
Abdominale Beschwerden					
Alter (Interaktionstest: p=0,1967)					
<50	690	14 (2,0)	663	4 (0,6)	3,41 [1,12; 10,42]; 0,0312 3,36 [1,11; 10,16]; 0,0316 0,01 [0,00; 0,03]; 0,0205
50-64	192	0 (0,0)	209	1 (0,5)	0,36 [0,01; 8,92]; 0,5335 0,36 [0,01; 8,85]; 0,5338 0,00 [-0,02; 0,01]; 0,4860
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,8530)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	13 (1,5)	840	5 (0,6)	2,56 [0,91; 7,21]; 0,0753 2,54 [0,91; 7,08]; 0,0757 0,01 [0,00; 0,02]; 0,0636
Taxan	43	1 (2,3)	50	0 (0,0)	3,56 [0,14; 89,80]; 0,4400 3,48 [0,15; 83,21]; 0,4417 0,02 [-0,04; 0,08]; 0,4478
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,7093)					
Brusterhaltend	220	1 (0,5)	235	1 (0,4)	1,07 [0,07; 17,19]; 0,9627 1,07 [0,07; 16,97]; 0,9627 0,00 [-0,01; 0,01]; 0,9628
Einseitige Mastektomie	355	8 (2,3)	352	3 (0,9)	2,68 [0,71; 10,19]; 0,1476 2,64 [0,71; 9,89]; 0,1484 0,01 [0,00; 0,03]; 0,1309
Beidseitige Mastektomie	336	5 (1,5)	315	1 (0,3)	4,74 [0,55; 40,82]; 0,1564 4,69 [0,55; 39,90]; 0,1574 0,01 [0,00; 0,03]; 0,1101
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,9970)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	13 (1,5)	866	5 (0,6)	2,61 [0,93; 7,36]; 0,0692 2,59 [0,93; 7,23]; 0,0696 0,01 [0,00; 0,02]; 0,0588
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,2571)					
Positiv	173	5 (2,9)	176	1 (0,6)	5,21 [0,60; 45,05]; 0,1338 5,09 [0,60; 43,09]; 0,1357 0,02 [0,00; 0,05]; 0,0958
Negativ	200	2 (1,0)	191	2 (1,1)	0,95 [0,13; 6,85]; 0,9631 0,96 [0,14; 6,71]; 0,9631 0,00 [-0,02; 0,02]; 0,9631
Bilaterale Oophorektomie (Interaktionstest: p=0,9702)					
Ja	189	1 (0,5)	176	0 (0,0)	2,81 [0,11; 69,41]; 0,5279 2,79 [0,11; 68,16]; 0,5283 0,01 [-0,01; 0,02]; 0,4839
Nein	722	13 (1,8)	728	5 (0,7)	2,65 [0,94; 7,48]; 0,0652 2,62 [0,94; 7,32]; 0,0657 0,01 [0,00; 0,02]; 0,0556

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
BRCA-Mutationsstatus (Interaktionstest: p=0,6328)					
BRCA1	574	8 (1,4)	580	4 (0,7)	2,04 [0,61; 6,80]; 0,2480 2,02 [0,61; 6,67]; 0,2484 0,01 [0,00; 0,02]; 0,2390
BRCA2	232	4 (1,7)	215	1 (0,5)	3,75 [0,42; 33,86]; 0,2384 3,71 [0,42; 32,91]; 0,2396 0,01 [-0,01; 0,03]; 0,1954
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	6 (1,5)	383	1 (0,3)	5,94 [0,71; 49,55]; 0,0999 5,86 [0,71; 48,47]; 0,1008 0,01 [0,00; 0,03]; 0,0591
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,9885)					
Andere	16	1 (6,3)	15	0 (0,0)	3,00 [0,11; 79,50]; 0,5111 2,82 [0,12; 64,39]; 0,5153 0,06 [-0,10; 0,22]; 0,4425
Asiatisch	259	8 (3,1)	271	3 (1,1)	2,85 [0,75; 10,85]; 0,1253 2,79 [0,75; 10,40]; 0,1264 0,02 [0,00; 0,04]; 0,1125
Kaukasisch	617	5 (0,8)	589	2 (0,3)	2,40 [0,46; 12,41]; 0,2970 2,39 [0,46; 12,25]; 0,2973 0,00 [0,00; 0,01]; 0,2772
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,9479)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	13 (1,6)	803	5 (0,6)	2,64 [0,94; 7,45]; 0,0660 2,62 [0,94; 7,30]; 0,0664 0,01 [0,00; 0,02]; 0,0562
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	0 (0,0)	2,96 [0,12; 73,83]; 0,5081 2,92 [0,12; 70,72]; 0,5090 0,01 [-0,02; 0,05]; 0,4733
Hormonrezeptorstatus (Interaktionstest: p=0,7126)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	1 (0,7)	1,86 [0,17; 20,67]; 0,6153 1,85 [0,17; 20,15]; 0,6155 0,01 [-0,02; 0,03]; 0,6053

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	12 (1,6)	749	4 (0,5)	3,07 [0,98; 9,55]; 0,0533 3,03 [0,98; 9,36]; 0,0537 0,01 [0,00; 0,02]; 0,0424
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8237)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	0 (0,0)	2,68 [0,11; 66,63]; 0,5474 2,66 [0,11; 64,44]; 0,5480 0,01 [-0,02; 0,04]; 0,4873
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	1 (1,6)	0,98 [0,06; 16,09]; 0,9910 0,98 [0,06; 15,40]; 0,9910 0,00 [-0,04; 0,04]; 0,9910
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	5 (1,4)	362	1 (0,3)	5,26 [0,61; 45,27]; 0,1305 5,20 [0,61; 44,29]; 0,1314 0,01 [0,00; 0,03]; 0,0950
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	7 (1,8)	387	3 (0,8)	2,32 [0,60; 9,04]; 0,2249 2,30 [0,60; 8,82]; 0,2255 0,01 [-0,01; 0,03]; 0,2100
Menopausenstatus (Interaktionstest: p=0,9076)					
Postmenopausal	346	3 (0,9)	356	1 (0,3)	3,10 [0,32; 30,00]; 0,3275 3,09 [0,32; 29,53]; 0,3280 0,01 [-0,01; 0,02]; 0,3054
Prämenopausal	563	11 (2,0)	544	4 (0,7)	2,69 [0,85; 8,50]; 0,0918 2,66 [0,85; 8,29]; 0,0924 0,01 [0,00; 0,03]; 0,0769
Region (Interaktionstest: p=0,5633)					
Asien-Pazifik und Südafrika	301	10 (3,3)	317	3 (1,0)	3,60 [0,98; 13,20]; 0,0536 3,51 [0,98; 12,63]; 0,0546 0,02 [0,00; 0,05]; 0,0418
Europa	473	4 (0,9)	444	2 (0,5)	1,88 [0,34; 10,34]; 0,4655 1,88 [0,35; 10,20]; 0,4657 0,00 [-0,01; 0,01]; 0,4537
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,3682)					
Adjuvant	457	8 (1,8)	450	4 (0,9)	1,99 [0,59; 6,64]; 0,2651 1,97 [0,60; 6,49]; 0,2656 0,01 [-0,01; 0,02]; 0,2546
Neoadjuvant	454	6 (1,3)	454	1 (0,2)	6,07 [0,73; 50,60]; 0,0957 6,00 [0,73; 49,64]; 0,0965 0,01 [0,00; 0,02]; 0,0573

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=NC)					
AZ	801	14 (1,8)	796	5 (0,6)	2,81 [1,01; 7,85]; 0,0481 2,78 [1,01; 7,69]; 0,0485 0,01 [0,00; 0,02]; 0,0385
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,8425)					
Ja	243	5 (2,1)	236	2 (0,9)	2,46 [0,47; 12,80]; 0,2853 2,43 [0,48; 12,39]; 0,2861 0,01 [-0,01; 0,03]; 0,2664
Nein	668	9 (1,4)	668	3 (0,5)	3,03 [0,82; 11,23]; 0,0977 3,00 [0,82; 11,03]; 0,0982 0,01 [0,00; 0,02]; 0,0815
Bauch aufgetrieben					
Alter (Interaktionstest: p=0,2117)					
<50	690	18 (2,6)	663	11 (1,7)	1,59 [0,74; 3,39]; 0,2319 1,57 [0,75; 3,30]; 0,2322 0,01 [-0,01; 0,02]; 0,2257
50-64	192	6 (3,1)	209	1 (0,5)	6,71 [0,80; 56,25]; 0,0793 6,53 [0,79; 53,76]; 0,0810 0,03 [0,00; 0,05]; 0,0488
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,4019)					
Anthrazyklin	7	0 (0,0)	13	1 (7,7)	0,56 [0,02; 15,46]; 0,7291 0,58 [0,03; 12,70]; 0,7316 -0,08 [-0,31; 0,16]; 0,5180
Anthrazyklin und Taxan	861	24 (2,8)	840	10 (1,2)	2,38 [1,13; 5,01]; 0,0223 2,34 [1,13; 4,87]; 0,0226 0,02 [0,00; 0,03]; 0,0179
Taxan	43	0 (0,0)	50	1 (2,0)	0,38 [0,02; 9,55]; 0,5559 0,39 [0,02; 9,25]; 0,5572 -0,02 [-0,08; 0,04]; 0,4836
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,5195)					
Brusterhaltend	220	5 (2,3)	235	3 (1,3)	1,80 [0,42; 7,62]; 0,4254 1,78 [0,43; 7,36]; 0,4258 0,01 [-0,01; 0,03]; 0,4230
Einseitige Mastektomie	355	6 (1,7)	352	5 (1,4)	1,19 [0,36; 3,95]; 0,7723 1,19 [0,37; 3,86]; 0,7723 0,00 [-0,02; 0,02]; 0,7719

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	13 (3,9)	315	4 (1,3)	3,13 [1,01; 9,70]; 0,0481 3,05 [1,00; 9,25]; 0,0492 0,03 [0,00; 0,05]; 0,0341
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,5365)					
Ja	41	1 (2,4)	35	1 (2,9)	0,85 [0,05; 14,11]; 0,9097 0,85 [0,06; 13,15]; 0,9097 0,00 [-0,08; 0,07]; 0,9102
Nein	870	23 (2,6)	866	11 (1,3)	2,11 [1,02; 4,36]; 0,0434 2,08 [1,02; 4,24]; 0,0437 0,01 [0,00; 0,03]; 0,0385
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,7663)					
Positiv	173	5 (2,9)	176	4 (2,3)	1,28 [0,34; 4,85]; 0,7166 1,27 [0,35; 4,66]; 0,7167 0,01 [-0,03; 0,04]; 0,7162
Negativ	200	4 (2,0)	191	4 (2,1)	0,95 [0,24; 3,87]; 0,9475 0,96 [0,24; 3,76]; 0,9475 0,00 [-0,03; 0,03]; 0,9476
Bilaterale Oophorektomie (Interaktionstest: p=0,7578)					
Ja	189	3 (1,6)	176	1 (0,6)	2,82 [0,29; 27,39]; 0,3708 2,79 [0,29; 26,61]; 0,3716 0,01 [-0,01; 0,03]; 0,3414
Nein	722	21 (2,9)	728	11 (1,5)	1,95 [0,93; 4,08]; 0,0751 1,92 [0,93; 3,96]; 0,0755 0,01 [0,00; 0,03]; 0,0701
BRCA-Mutationsstatus (Interaktionstest: p=0,9996)					
BRCA1	574	22 (3,8)	580	8 (1,4)	2,85 [1,26; 6,45]; 0,0121 2,78 [1,25; 6,19]; 0,0124 0,02 [0,01; 0,04]; 0,0088
BRCA2	232	1 (0,4)	215	0 (0,0)	2,79 [0,11; 68,92]; 0,5301 2,78 [0,11; 67,90]; 0,5304 0,00 [-0,01; 0,02]; 0,4852
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	12 (3,1)	383	3 (0,8)	4,00 [1,12; 14,29]; 0,0328 3,91 [1,11; 13,74]; 0,0336 0,02 [0,00; 0,04]; 0,0201
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,4836)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	5 (1,9)	271	4 (1,5)	1,31 [0,35; 4,95]; 0,6865 1,31 [0,36; 4,82]; 0,6865 0,00 [-0,02; 0,03]; 0,6865
Kaukasisch	617	19 (3,1)	589	8 (1,4)	2,31 [1,00; 5,31]; 0,0494 2,27 [1,00; 5,14]; 0,0499 0,02 [0,00; 0,03]; 0,0413
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,6480)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	20 (2,5)	803	9 (1,1)	2,27 [1,03; 5,01]; 0,0430 2,24 [1,02; 4,88]; 0,0433 0,01 [0,00; 0,03]; 0,0376
Unbekannt, nicht erfasst, verweigert	79	3 (3,8)	77	3 (3,9)	0,97 [0,19; 4,98]; 0,9745 0,97 [0,20; 4,68]; 0,9745 0,00 [-0,06; 0,06]; 0,9745
Hormonrezeptorstatus (Interaktionstest: p=0,5649)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	0 (0,0)	4,67 [0,22; 98,03]; 0,3211 4,62 [0,22; 95,39]; 0,3223 0,01 [-0,01; 0,03]; 0,2492
TNBC	741	22 (3,0)	749	12 (1,6)	1,88 [0,92; 3,83]; 0,0820 1,85 [0,92; 3,72]; 0,0824 0,01 [0,00; 0,03]; 0,0775
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6322)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	0 (0,0)	2,68 [0,11; 66,63]; 0,5474 2,66 [0,11; 64,44]; 0,5480 0,01 [-0,02; 0,04]; 0,4873
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	0 (0,0)	3,00 [0,12; 75,04]; 0,5036 2,95 [0,12; 71,17]; 0,5047 0,02 [-0,03; 0,06]; 0,4701
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	12 (3,5)	362	4 (1,1)	3,20 [1,02; 10,01]; 0,0460 3,12 [1,02; 9,58]; 0,0468 0,02 [0,00; 0,05]; 0,0367
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	10 (2,5)	387	8 (2,1)	1,24 [0,48; 3,17]; 0,6577 1,23 [0,49; 3,09]; 0,6577 0,00 [-0,02; 0,03]; 0,6568

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Menopausenstatus (Interaktionstest: p=0,5047)					
Postmenopausal	346	7 (2,0)	356	5 (1,4)	1,45 [0,46; 4,61]; 0,5295 1,44 [0,46; 4,50]; 0,5296 0,01 [-0,01; 0,03]; 0,5282
Prämenopausal	563	17 (3,0)	544	7 (1,3)	2,39 [0,98; 5,81]; 0,0547 2,35 [0,98; 5,61]; 0,0553 0,02 [0,00; 0,03]; 0,0459
Region (Interaktionstest: p=0,1985)					
Asien-Pazifik und Südafrika	301	5 (1,7)	317	6 (1,9)	0,88 [0,26; 2,90]; 0,8278 0,88 [0,27; 2,85]; 0,8278 0,00 [-0,02; 0,02]; 0,8274
Europa	473	14 (3,0)	444	6 (1,4)	2,23 [0,85; 5,85]; 0,1041 2,19 [0,85; 5,65]; 0,1049 0,02 [0,00; 0,03]; 0,0913
Nordamerika	121	5 (4,1)	131	0 (0,0)	12,42 [0,68; 226,96]; 0,0893 11,90 [0,67; 212,99]; 0,0924 0,04 [0,00; 0,08]; 0,0344
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,2308)					
Adjuvant	457	11 (2,4)	450	8 (1,8)	1,36 [0,54; 3,42]; 0,5098 1,35 [0,55; 3,33]; 0,5100 0,01 [-0,01; 0,02]; 0,5076
Neoadjuvant	454	13 (2,9)	454	4 (0,9)	3,32 [1,07; 10,25]; 0,0373 3,25 [1,07; 9,89]; 0,0379 0,02 [0,00; 0,04]; 0,0271
Sponsor (Interaktionstest: p=0,2731)					
AZ	801	20 (2,5)	796	12 (1,5)	1,67 [0,81; 3,45]; 0,1627 1,66 [0,82; 3,37]; 0,1630 0,01 [0,00; 0,02]; 0,1578
NRG Oncology	110	4 (3,6)	108	0 (0,0)	9,17 [0,49; 172,39]; 0,1388 8,84 [0,48; 162,20]; 0,1422 0,04 [0,00; 0,08]; 0,0664
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,3459)					
Ja	243	10 (4,1)	236	3 (1,3)	3,33 [0,91; 12,27]; 0,0701 3,24 [0,90; 11,62]; 0,0715 0,03 [0,00; 0,06]; 0,0527
Nein	668	14 (2,1)	668	9 (1,4)	1,57 [0,67; 3,65]; 0,2968 1,56 [0,68; 3,57]; 0,2971 0,01 [-0,01; 0,02]; 0,2928

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Diarrhoe					
Alter (Interaktionstest: p=0,9554)					
<50	690	124 (18,0)	663	94 (14,2)	1,33 [0,99; 1,78]; 0,0583 1,27 [0,99; 1,62]; 0,0589 0,04 [0,00; 0,08]; 0,0570
50-64	192	32 (16,7)	209	26 (12,4)	1,41 [0,80; 2,46]; 0,2308 1,34 [0,83; 2,16]; 0,2314 0,04 [-0,03; 0,11]; 0,2309
≥65	29	4 (13,8)	32	4 (12,5)	1,12 [0,25; 4,96]; 0,8813 1,10 [0,30; 4,01]; 0,8813 0,01 [-0,16; 0,18]; 0,8814
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,3064)					
Anthrazyklin	7	0 (0,0)	13	5 (38,5)	0,10 [0,00; 2,19]; 0,1451 0,16 [0,01; 2,52]; 0,1920 -0,38 [-0,69; -0,08]; 0,0137
Anthrazyklin und Taxan	861	152 (17,7)	840	110 (13,1)	1,42 [1,09; 1,86]; 0,0094 1,35 [1,08; 1,69]; 0,0096 0,05 [0,01; 0,08]; 0,0090
Taxan	43	8 (18,6)	50	8 (16,0)	1,20 [0,41; 3,53]; 0,7402 1,16 [0,48; 2,83]; 0,7401 0,03 [-0,13; 0,18]; 0,7410
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,4481)					
Brusterhaltend	220	36 (16,4)	235	25 (10,6)	1,64 [0,95; 2,84]; 0,0752 1,54 [0,96; 2,48]; 0,0762 0,06 [-0,01; 0,12]; 0,0740
Einseitige Mastektomie	355	55 (15,5)	352	40 (11,4)	1,43 [0,92; 2,21]; 0,1087 1,36 [0,93; 1,99]; 0,1096 0,04 [-0,01; 0,09]; 0,1066
Beidseitige Mastektomie	336	69 (20,5)	315	59 (18,7)	1,12 [0,76; 1,65]; 0,5625 1,10 [0,80; 1,50]; 0,5628 0,02 [-0,04; 0,08]; 0,5619
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,1826)					
Ja	41	10 (24,4)	35	3 (8,6)	3,44 [0,86; 13,70]; 0,0796 2,85 [0,85; 9,53]; 0,0900 0,16 [0,00; 0,32]; 0,0539
Nein	870	150 (17,2)	866	121 (14,0)	1,28 [0,99; 1,66]; 0,0610 1,23 [0,99; 1,54]; 0,0614 0,03 [0,00; 0,07]; 0,0603

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,5385)					
Positiv	173	21 (12,1)	176	16 (9,1)	1,38 [0,69; 2,75]; 0,3566 1,34 [0,72; 2,47]; 0,3573 0,03 [-0,03; 0,10]; 0,3551
Negativ	200	33 (16,5)	191	30 (15,7)	1,06 [0,62; 1,82]; 0,8311 1,05 [0,67; 1,65]; 0,8312 0,01 [-0,06; 0,08]; 0,8310
Bilaterale Oophorektomie (Interaktionstest: p=0,4880)					
Ja	189	32 (16,9)	176	27 (15,3)	1,12 [0,64; 1,97]; 0,6801 1,10 [0,69; 1,76]; 0,6803 0,02 [-0,06; 0,09]; 0,6795
Nein	722	128 (17,7)	728	97 (13,3)	1,40 [1,05; 1,87]; 0,0209 1,33 [1,04; 1,70]; 0,0212 0,04 [0,01; 0,08]; 0,0204
BRCA-Mutationsstatus (Interaktionstest: p=0,8828)					
BRCA1	574	101 (17,6)	580	85 (14,7)	1,24 [0,91; 1,70]; 0,1749 1,20 [0,92; 1,56]; 0,1752 0,03 [-0,01; 0,07]; 0,1742
BRCA2	232	47 (20,3)	215	35 (16,3)	1,31 [0,81; 2,12]; 0,2782 1,24 [0,84; 1,85]; 0,2794 0,04 [-0,03; 0,11]; 0,2752
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,6563)					
2, 3 oder 4	392	76 (19,4)	383	53 (13,8)	1,50 [1,02; 2,20]; 0,0389 1,40 [1,02; 1,93]; 0,0396 0,06 [0,00; 0,11]; 0,0373
5 oder 6	22	3 (13,6)	14	2 (14,3)	0,95 [0,14; 6,52]; 0,9562 0,95 [0,18; 5,02]; 0,9562 -0,01 [-0,24; 0,23]; 0,9564
Ethnie (Interaktionstest: p=0,8899)					
Andere	16	3 (18,8)	15	1 (6,7)	3,23 [0,30; 35,11]; 0,3353 2,81 [0,33; 24,16]; 0,3460 0,12 [-0,11; 0,35]; 0,3014
Asiatisch	259	30 (11,6)	271	26 (9,6)	1,23 [0,71; 2,15]; 0,4571 1,21 [0,73; 1,98]; 0,4573 0,02 [-0,03; 0,07]; 0,4571
Kaukasisch	617	125 (20,3)	589	94 (16,0)	1,34 [1,00; 1,80]; 0,0533 1,27 [1,00; 1,62]; 0,0539 0,04 [0,00; 0,09]; 0,0520
Schwarz oder afroamerikanisch	19	2 (10,5)	29	3 (10,3)	1,02 [0,15; 6,75]; 0,9839 1,02 [0,19; 5,53]; 0,9839 0,00 [-0,18; 0,18]; 0,9840

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,4363)					
Hispanisch	34	6 (17,7)	24	2 (8,3)	2,36 [0,43; 12,84]; 0,3214 2,12 [0,47; 9,61]; 0,3309 0,09 [-0,08; 0,26]; 0,2808
Nicht-hispanisch	798	138 (17,3)	803	105 (13,1)	1,39 [1,06; 1,83]; 0,0190 1,32 [1,05; 1,67]; 0,0193 0,04 [0,01; 0,08]; 0,0185
Unbekannt, nicht erfasst, verweigert	79	16 (20,3)	77	17 (22,1)	0,90 [0,42; 1,93]; 0,7803 0,92 [0,50; 1,68]; 0,7803 -0,02 [-0,15; 0,11]; 0,7803
Hormonrezeptorstatus (Interaktionstest: p=0,6509)					
ER- und/oder PgR-positiv, HER2-positiv	168	31 (18,5)	155	20 (12,9)	1,53 [0,83; 2,81]; 0,1738 1,43 [0,85; 2,40]; 0,1759 0,06 [-0,02; 0,13]; 0,1681
TNBC	741	129 (17,4)	749	104 (13,9)	1,31 [0,99; 1,73]; 0,0616 1,25 [0,99; 1,59]; 0,0620 0,04 [0,00; 0,07]; 0,0610
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,9014)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	19 (18,3)	92	11 (12,0)	1,65 [0,74; 3,67]; 0,2236 1,53 [0,77; 3,04]; 0,2268 0,06 [-0,04; 0,16]; 0,2139
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	12 (18,8)	63	9 (14,3)	1,38 [0,54; 3,56]; 0,4995 1,31 [0,59; 2,90]; 0,5005 0,04 [-0,08; 0,17]; 0,4972
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	67 (19,3)	362	52 (14,4)	1,42 [0,96; 2,11]; 0,0822 1,34 [0,96; 1,87]; 0,0829 0,05 [-0,01; 0,10]; 0,0813
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	62 (15,8)	387	52 (13,4)	1,21 [0,81; 1,80]; 0,3556 1,17 [0,84; 1,65]; 0,3559 0,02 [-0,03; 0,07]; 0,3546
Menopausenstatus (Interaktionstest: p=0,7143)					
Postmenopausal	346	59 (17,1)	356	50 (14,0)	1,26 [0,84; 1,90]; 0,2720 1,21 [0,86; 1,72]; 0,2724 0,03 [-0,02; 0,08]; 0,2715
Prämenopausal	563	101 (17,9)	544	74 (13,6)	1,39 [1,00; 1,92]; 0,0486 1,32 [1,00; 1,74]; 0,0492 0,04 [0,00; 0,09]; 0,0472
Region (Interaktionstest: p=0,6556)					
Asien-Pazifik und Südafrika	301	37 (12,3)	317	36 (11,4)	1,09 [0,67; 1,78]; 0,7187 1,08 [0,70; 1,67]; 0,7187 0,01 [-0,04; 0,06]; 0,7188

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	91 (19,2)	444	64 (14,4)	1,41 [1,00; 2,01]; 0,0521 1,33 [1,00; 1,79]; 0,0529 0,05 [0,00; 0,10]; 0,0501
Nordamerika	121	29 (24,0)	131	24 (18,3)	1,41 [0,76; 2,58]; 0,2730 1,31 [0,81; 2,12]; 0,2738 0,06 [-0,04; 0,16]; 0,2726
Südamerika	16	3 (18,8)	12	0 (0,0)	6,48 [0,30; 138,43]; 0,2315 5,35 [0,30; 94,77]; 0,2526 0,19 [-0,03; 0,41]; 0,0930
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5449)					
Adjuvant	457	74 (16,2)	450	61 (13,6)	1,23 [0,85; 1,78]; 0,2651 1,19 [0,87; 1,63]; 0,2656 0,03 [-0,02; 0,07]; 0,2640
Neoadjuvant	454	86 (18,9)	454	63 (13,9)	1,45 [1,02; 2,07]; 0,0400 1,37 [1,01; 1,84]; 0,0406 0,05 [0,00; 0,10]; 0,0389
Sponsor (Interaktionstest: p=0,6137)					
AZ	801	132 (16,5)	796	105 (13,2)	1,30 [0,98; 1,71]; 0,0650 1,25 [0,99; 1,58]; 0,0654 0,03 [0,00; 0,07]; 0,0642
NRG Oncology	110	28 (25,5)	108	19 (17,6)	1,60 [0,83; 3,08]; 0,1601 1,45 [0,86; 2,43]; 0,1626 0,08 [-0,03; 0,19]; 0,1557
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4656)					
Ja	243	48 (19,8)	236	32 (13,6)	1,57 [0,96; 2,56]; 0,0706 1,46 [0,97; 2,19]; 0,0720 0,06 [0,00; 0,13]; 0,0677
Nein	668	112 (16,8)	668	92 (13,8)	1,26 [0,93; 1,70]; 0,1287 1,22 [0,94; 1,57]; 0,1291 0,03 [-0,01; 0,07]; 0,1279
Dyspepsie					
Alter (Interaktionstest: p=0,0355)					
<50	690	46 (6,7)	663	21 (3,2)	2,18 [1,29; 3,70]; 0,0037 2,10 [1,27; 3,49]; 0,0039 0,03 [0,01; 0,06]; 0,0027
50-64	192	9 (4,7)	209	13 (6,2)	0,74 [0,31; 1,78]; 0,5021 0,75 [0,33; 1,72]; 0,5026 -0,02 [-0,06; 0,03]; 0,4981
≥65	29	0 (0,0)	32	3 (9,4)	0,14 [0,01; 2,89]; 0,2046 0,16 [0,01; 2,92]; 0,2144 -0,09 [-0,21; 0,02]; 0,1089

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6571)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	52 (6,0)	840	36 (4,3)	1,44 [0,93; 2,22]; 0,1041 1,41 [0,93; 2,13]; 0,1045 0,02 [0,00; 0,04]; 0,1016
Taxan	43	2 (4,7)	50	1 (2,0)	2,39 [0,21; 27,31]; 0,4832 2,33 [0,22; 24,77]; 0,4844 0,03 [-0,05; 0,10]; 0,4822
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,1122)					
Brusterhaltend	220	12 (5,5)	235	15 (6,4)	0,85 [0,39; 1,85]; 0,6756 0,85 [0,41; 1,78]; 0,6757 -0,01 [-0,05; 0,03]; 0,6745
Einseitige Mastektomie	355	20 (5,6)	352	7 (2,0)	2,94 [1,23; 7,05]; 0,0155 2,83 [1,21; 6,62]; 0,0161 0,04 [0,01; 0,06]; 0,0109
Beidseitige Mastektomie	336	23 (6,9)	315	15 (4,8)	1,47 [0,75; 2,87]; 0,2597 1,44 [0,76; 2,70]; 0,2604 0,02 [-0,01; 0,06]; 0,2541
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,2699)					
Ja	41	2 (4,9)	35	3 (8,6)	0,55 [0,09; 3,48]; 0,5226 0,57 [0,10; 3,21]; 0,5234 -0,04 [-0,15; 0,08]; 0,5247
Nein	870	53 (6,1)	866	34 (3,9)	1,59 [1,02; 2,47]; 0,0401 1,55 [1,02; 2,36]; 0,0405 0,02 [0,00; 0,04]; 0,0383
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,9122)					
Positiv	173	13 (7,5)	176	5 (2,8)	2,78 [0,97; 7,97]; 0,0573 2,65 [0,96; 7,26]; 0,0590 0,05 [0,00; 0,09]; 0,0480
Negativ	200	18 (9,0)	191	7 (3,7)	2,60 [1,06; 6,37]; 0,0368 2,46 [1,05; 5,75]; 0,0384 0,05 [0,01; 0,10]; 0,0286
Bilaterale Oophorektomie (Interaktionstest: p=0,4495)					
Ja	189	12 (6,4)	176	10 (5,7)	1,13 [0,47; 2,67]; 0,7890 1,12 [0,50; 2,52]; 0,7891 0,01 [-0,04; 0,06]; 0,7885
Nein	722	43 (6,0)	728	27 (3,7)	1,64 [1,00; 2,69]; 0,0479 1,61 [1,00; 2,57]; 0,0483 0,02 [0,00; 0,04]; 0,0459

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,2248)					
BRCA1	574	36 (6,3)	580	22 (3,8)	1,70 [0,99; 2,92]; 0,0564 1,65 [0,99; 2,77]; 0,0569 0,02 [0,00; 0,05]; 0,0539
BRCA2	232	12 (5,2)	215	12 (5,6)	0,92 [0,41; 2,10]; 0,8480 0,93 [0,43; 2,02]; 0,8480 0,00 [-0,05; 0,04]; 0,8482
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,7624)					
2, 3 oder 4	392	15 (3,8)	383	15 (3,9)	0,98 [0,47; 2,03]; 0,9483 0,98 [0,48; 1,97]; 0,9483 0,00 [-0,03; 0,03]; 0,9483
5 oder 6	22	1 (4,6)	14	1 (7,1)	0,62 [0,04; 10,78]; 0,7421 0,64 [0,04; 9,37]; 0,7419 -0,03 [-0,19; 0,13]; 0,7512
Ethnie (Interaktionstest: p=0,3517)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	17 (6,6)	271	11 (4,1)	1,66 [0,76; 3,62]; 0,2017 1,62 [0,77; 3,39]; 0,2025 0,03 [-0,01; 0,06]; 0,1991
Kaukasisch	617	35 (5,7)	589	26 (4,4)	1,30 [0,77; 2,19]; 0,3201 1,29 [0,78; 2,11]; 0,3204 0,01 [-0,01; 0,04]; 0,3173
Schwarz oder afroamerikanisch	19	3 (15,8)	29	0 (0,0)	12,52 [0,61; 257,43]; 0,1014 10,50 [0,57; 192,49]; 0,1131 0,16 [-0,01; 0,33]; 0,0732
Ethnische Abstammung (Interaktionstest: p=0,4698)					
Hispanisch	34	1 (2,9)	24	2 (8,3)	0,33 [0,03; 3,90]; 0,3815 0,35 [0,03; 3,67]; 0,3836 -0,05 [-0,18; 0,07]; 0,3952
Nicht-hispanisch	798	47 (5,9)	803	31 (3,9)	1,56 [0,98; 2,48]; 0,0611 1,53 [0,98; 2,38]; 0,0615 0,02 [0,00; 0,04]; 0,0592
Unbekannt, nicht erfasst, verweigert	79	7 (8,9)	77	4 (5,2)	1,77 [0,50; 6,32]; 0,3765 1,71 [0,52; 5,59]; 0,3782 0,04 [-0,04; 0,12]; 0,3685
Hormonrezeptorstatus (Interaktionstest: p=0,7948)					
ER- und/oder PgR-positiv, HER2-positiv	168	7 (4,2)	155	5 (3,2)	1,30 [0,41; 4,20]; 0,6560 1,29 [0,42; 3,99]; 0,6562 0,01 [-0,03; 0,05]; 0,6534

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
TNBC	741	48 (6,5)	749	32 (4,3)	1,55 [0,98; 2,46]; 0,0607 1,52 [0,98; 2,34]; 0,0611 0,02 [0,00; 0,04]; 0,0589
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,1398)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	3 (2,9)	92	1 (1,1)	2,70 [0,28; 26,45]; 0,3928 2,65 [0,28; 25,07]; 0,3943 0,02 [-0,02; 0,06]; 0,3603
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	4 (6,3)	63	4 (6,4)	0,98 [0,23; 4,12]; 0,9816 0,98 [0,26; 3,77]; 0,9816 0,00 [-0,09; 0,08]; 0,9816
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	16 (4,6)	362	19 (5,3)	0,87 [0,44; 1,72]; 0,6890 0,88 [0,46; 1,68]; 0,6890 -0,01 [-0,04; 0,03]; 0,6884
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	32 (8,1)	387	13 (3,4)	2,55 [1,32; 4,94]; 0,0055 2,42 [1,29; 4,55]; 0,0058 0,05 [0,02; 0,08]; 0,0039
Menopausenstatus (Interaktionstest: p=0,0354)					
Postmenopausal	346	17 (4,9)	356	20 (5,6)	0,87 [0,45; 1,69]; 0,6763 0,87 [0,47; 1,64]; 0,6764 -0,01 [-0,04; 0,03]; 0,6758
Prämenopausal	563	38 (6,7)	544	17 (3,1)	2,24 [1,25; 4,03]; 0,0067 2,16 [1,23; 3,78]; 0,0070 0,04 [0,01; 0,06]; 0,0051
Region (Interaktionstest: p=0,9841)					
Asien-Pazifik und Südafrika	301	19 (6,3)	317	13 (4,1)	1,58 [0,76; 3,25]; 0,2183 1,54 [0,77; 3,06]; 0,2189 0,02 [-0,01; 0,06]; 0,2168
Europa	473	24 (5,1)	444	15 (3,4)	1,53 [0,79; 2,95]; 0,2065 1,50 [0,80; 2,83]; 0,2072 0,02 [-0,01; 0,04]; 0,2004
Nordamerika	121	11 (9,1)	131	9 (6,9)	1,36 [0,54; 3,39]; 0,5159 1,32 [0,57; 3,08]; 0,5162 0,02 [-0,04; 0,09]; 0,5165
Südamerika	16	1 (6,3)	12	0 (0,0)	2,42 [0,09; 64,70]; 0,5982 2,29 [0,10; 51,85]; 0,6017 0,06 [-0,11; 0,23]; 0,4728
Art der vorherigen Chemotherapie (Interaktionstest: p=0,0642)					
Adjuvant	457	36 (7,9)	450	17 (3,8)	2,18 [1,20; 3,94]; 0,0100 2,09 [1,19; 3,66]; 0,0104 0,04 [0,01; 0,07]; 0,0081
Neoadjuvant	454	19 (4,2)	454	20 (4,4)	0,95 [0,50; 1,80]; 0,8700 0,95 [0,51; 1,76]; 0,8700 0,00 [-0,03; 0,02]; 0,8700

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,9982)					
AZ	801	46 (5,7)	796	31 (3,9)	1,50 [0,94; 2,40]; 0,0866 1,47 [0,95; 2,30]; 0,0870 0,02 [0,00; 0,04]; 0,0842
NRG Oncology	110	9 (8,2)	108	6 (5,6)	1,51 [0,52; 4,41]; 0,4464 1,47 [0,54; 4,00]; 0,4472 0,03 [-0,04; 0,09]; 0,4424
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,5984)					
Ja	243	14 (5,8)	236	11 (4,7)	1,25 [0,56; 2,81]; 0,5890 1,24 [0,57; 2,67]; 0,5891 0,01 [-0,03; 0,05]; 0,5876
Nein	668	41 (6,1)	668	26 (3,9)	1,61 [0,98; 2,67]; 0,0622 1,58 [0,98; 2,55]; 0,0626 0,02 [0,00; 0,05]; 0,0597
Erbrechen					
Alter (Interaktionstest: p=0,4116)					
<50	690	168 (24,4)	663	54 (8,1)	3,63 [2,61; 5,04]; <0,0001 2,99 [2,24; 3,99]; <0,0001 0,16 [0,12; 0,20]; <0,0001
50-64	192	34 (17,7)	209	17 (8,1)	2,43 [1,31; 4,51]; 0,0049 2,18 [1,26; 3,77]; 0,0054 0,10 [0,03; 0,16]; 0,0042
≥65	29	4 (13,8)	32	3 (9,4)	1,55 [0,32; 7,58]; 0,5908 1,47 [0,36; 6,03]; 0,5915 0,04 [-0,12; 0,21]; 0,5909
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,8738)					
Anthrazyklin	7	2 (28,6)	13	2 (15,4)	2,20 [0,24; 20,40]; 0,4877 1,86 [0,33; 10,49]; 0,4834 0,13 [-0,26; 0,52]; 0,5052
Anthrazyklin und Taxan	861	191 (22,2)	840	66 (7,9)	3,34 [2,48; 4,51]; <0,0001 2,82 [2,17; 3,67]; <0,0001 0,14 [0,11; 0,18]; <0,0001
Taxan	43	13 (30,2)	50	6 (12,0)	3,18 [1,09; 9,29]; 0,0347 2,52 [1,05; 6,06]; 0,0390 0,18 [0,02; 0,35]; 0,0295
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0097)					
Brusterhaltend	220	52 (23,6)	235	16 (6,8)	4,24 [2,34; 7,68]; <0,0001 3,47 [2,04; 5,89]; <0,0001 0,17 [0,10; 0,23]; <0,0001
Einseitige Mastektomie	355	88 (24,8)	352	22 (6,3)	4,94 [3,02; 8,10]; <0,0001 3,97 [2,55; 6,18]; <0,0001 0,19 [0,13; 0,24]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	66 (19,6)	315	36 (11,4)	1,89 [1,22; 2,94]; 0,0044 1,72 [1,18; 2,50]; 0,0047 0,08 [0,03; 0,14]; 0,0035
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3107)					
Ja	41	9 (22,0)	35	1 (2,9)	9,56 [1,15; 79,80]; 0,0370 7,68 [1,02; 57,69]; 0,0475 0,19 [0,05; 0,33]; 0,0068
Nein	870	197 (22,6)	866	73 (8,4)	3,18 [2,39; 4,24]; <0,0001 2,69 [2,09; 3,45]; <0,0001 0,14 [0,11; 0,18]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,9709)					
Positiv	173	26 (15,0)	176	10 (5,7)	2,94 [1,37; 6,29]; 0,0056 2,65 [1,32; 5,32]; 0,0063 0,09 [0,03; 0,16]; 0,0038
Negativ	200	60 (30,0)	191	22 (11,5)	3,29 [1,92; 5,63]; <0,0001 2,60 [1,67; 4,07]; <0,0001 0,18 [0,11; 0,26]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,0017)					
Ja	189	27 (14,3)	176	20 (11,4)	1,30 [0,70; 2,41]; 0,4058 1,26 [0,73; 2,16]; 0,4067 0,03 [-0,04; 0,10]; 0,4029
Nein	722	179 (24,8)	728	54 (7,4)	4,11 [2,97; 5,69]; <0,0001 3,34 [2,51; 4,45]; <0,0001 0,17 [0,14; 0,21]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,5492)					
BRCA1	574	122 (21,3)	580	53 (9,1)	2,68 [1,90; 3,79]; <0,0001 2,33 [1,72; 3,14]; <0,0001 0,12 [0,08; 0,16]; <0,0001
BRCA2	232	54 (23,3)	215	18 (8,4)	3,32 [1,88; 5,87]; <0,0001 2,78 [1,69; 4,58]; <0,0001 0,15 [0,08; 0,21]; <0,0001
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,2961)					
2, 3 oder 4	392	86 (21,9)	383	23 (6,0)	4,40 [2,71; 7,14]; <0,0001 3,65 [2,36; 5,66]; <0,0001 0,16 [0,11; 0,21]; <0,0001
5 oder 6	22	5 (22,7)	14	2 (14,3)	1,76 [0,29; 10,66]; 0,5360 1,59 [0,36; 7,11]; 0,5432 0,08 [-0,17; 0,34]; 0,5140

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,2695)					
Andere	16	2 (12,5)	15	0 (0,0)	5,34 [0,24; 121,00]; 0,2923 4,71 [0,24; 90,69]; 0,3049 0,12 [-0,06; 0,31]; 0,1942
Asiatisch	259	72 (27,8)	271	19 (7,0)	5,11 [2,98; 8,76]; <0,0001 3,97 [2,46; 6,38]; <0,0001 0,21 [0,15; 0,27]; <0,0001
Kaukasisch	617	129 (20,9)	589	52 (8,8)	2,73 [1,93; 3,85]; <0,0001 2,37 [1,75; 3,20]; <0,0001 0,12 [0,08; 0,16]; <0,0001
Schwarz oder afroamerikanisch	19	3 (15,8)	29	3 (10,3)	1,62 [0,29; 9,05]; 0,5795 1,53 [0,34; 6,79]; 0,5786 0,05 [-0,14; 0,25]; 0,5897
Ethnische Abstammung (Interaktionstest: p=0,9354)					
Hispanisch	34	10 (29,4)	24	2 (8,3)	4,58 [0,90; 23,27]; 0,0663 3,53 [0,85; 14,68]; 0,0829 0,21 [0,02; 0,40]; 0,0287
Nicht-hispanisch	798	180 (22,6)	803	66 (8,2)	3,25 [2,41; 4,40]; <0,0001 2,74 [2,11; 3,58]; <0,0001 0,14 [0,11; 0,18]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	16 (20,3)	77	6 (7,8)	3,01 [1,11; 8,15]; 0,0306 2,60 [1,07; 6,29]; 0,0342 0,12 [0,02; 0,23]; 0,0224
Hormonrezeptorstatus (Interaktionstest: p=0,7577)					
ER- und/oder PgR-positiv, HER2-positiv	168	33 (19,6)	155	10 (6,5)	3,54 [1,68; 7,47]; 0,0009 3,04 [1,55; 5,97]; 0,0012 0,13 [0,06; 0,20]; 0,0003
TNBC	741	172 (23,2)	749	64 (8,5)	3,24 [2,38; 4,40]; <0,0001 2,72 [2,08; 3,55]; <0,0001 0,15 [0,11; 0,18]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8912)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	21 (20,2)	92	5 (5,4)	4,40 [1,59; 12,22]; 0,0044 3,72 [1,46; 9,46]; 0,0059 0,15 [0,06; 0,24]; 0,0013
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	12 (18,8)	63	5 (7,9)	2,68 [0,88; 8,11]; 0,0816 2,36 [0,88; 6,32]; 0,0867 0,11 [-0,01; 0,22]; 0,0692
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	77 (22,1)	362	28 (7,7)	3,39 [2,14; 5,38]; <0,0001 2,86 [1,90; 4,30]; <0,0001 0,14 [0,09; 0,20]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	95 (24,2)	387	36 (9,3)	3,11 [2,06; 4,70]; <0,0001 2,60 [1,82; 3,71]; <0,0001 0,15 [0,10; 0,20]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,0475)					
Postmenopausal	346	64 (18,5)	356	33 (9,3)	2,22 [1,42; 3,48]; 0,0005 2,00 [1,35; 2,96]; 0,0006 0,09 [0,04; 0,14]; 0,0004
Prämenopausal	563	142 (25,2)	544	41 (7,5)	4,14 [2,86; 6,00]; <0,0001 3,35 [2,41; 4,64]; <0,0001 0,18 [0,13; 0,22]; <0,0001
Region (Interaktionstest: p=0,1540)					
Asien-Pazifik und Südafrika	301	82 (27,2)	317	25 (7,9)	4,37 [2,70; 7,07]; <0,0001 3,45 [2,27; 5,25]; <0,0001 0,19 [0,14; 0,25]; <0,0001
Europa	473	86 (18,2)	444	27 (6,1)	3,43 [2,18; 5,40]; <0,0001 2,99 [1,98; 4,52]; <0,0001 0,12 [0,08; 0,16]; <0,0001
Nordamerika	121	35 (28,9)	131	22 (16,8)	2,02 [1,10; 3,69]; 0,0228 1,72 [1,07; 2,76]; 0,0241 0,12 [0,02; 0,22]; 0,0211
Südamerika	16	3 (18,8)	12	0 (0,0)	6,48 [0,30; 138,43]; 0,2315 5,35 [0,30; 94,77]; 0,2526 0,19 [-0,03; 0,41]; 0,0930
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5448)					
Adjuvant	457	107 (23,4)	450	41 (9,1)	3,05 [2,07; 4,49]; <0,0001 2,57 [1,84; 3,59]; <0,0001 0,14 [0,10; 0,19]; <0,0001
Neoadjuvant	454	99 (21,8)	454	33 (7,3)	3,56 [2,34; 5,41]; <0,0001 3,00 [2,07; 4,35]; <0,0001 0,15 [0,10; 0,19]; <0,0001
Sponsor (Interaktionstest: p=0,1967)					
AZ	801	176 (22,0)	796	59 (7,4)	3,52 [2,57; 4,81]; <0,0001 2,96 [2,24; 3,91]; <0,0001 0,15 [0,11; 0,18]; <0,0001
NRG Oncology	110	30 (27,3)	108	15 (13,9)	2,33 [1,17; 4,63]; 0,0162 1,96 [1,12; 3,44]; 0,0182 0,13 [0,03; 0,24]; 0,0131
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7222)					
Ja	243	50 (20,6)	236	19 (8,1)	2,96 [1,69; 5,19]; 0,0002 2,56 [1,55; 4,20]; 0,0002 0,13 [0,06; 0,19]; <0,0001
Nein	668	156 (23,4)	668	55 (8,2)	3,40 [2,44; 4,72]; <0,0001 2,84 [2,13; 3,78]; <0,0001 0,15 [0,11; 0,19]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Gastritis					
Alter (Interaktionstest: p=0,7842)					
<50	690	12 (1,7)	663	5 (0,8)	2,33 [0,82; 6,65]; 0,1141 2,31 [0,82; 6,51]; 0,1146 0,01 [0,00; 0,02]; 0,1009
50-64	192	4 (2,1)	209	1 (0,5)	4,43 [0,49; 39,95]; 0,1852 4,35 [0,49; 38,62]; 0,1865 0,02 [-0,01; 0,04]; 0,1577
≥65	29	2 (6,9)	32	0 (0,0)	5,91 [0,27; 128,38]; 0,2581 5,50 [0,27; 110,01]; 0,2647 0,07 [-0,04; 0,18]; 0,2079
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,5702)					
Anthrazyklin	7	0 (0,0)	13	1 (7,7)	0,56 [0,02; 15,46]; 0,7291 0,58 [0,03; 12,70]; 0,7316 -0,08 [-0,31; 0,16]; 0,5180
Anthrazyklin und Taxan	861	17 (2,0)	840	5 (0,6)	3,36 [1,24; 9,16]; 0,0176 3,32 [1,23; 8,95]; 0,0179 0,01 [0,00; 0,02]; 0,0111
Taxan	43	1 (2,3)	50	0 (0,0)	3,56 [0,14; 89,80]; 0,4400 3,48 [0,15; 83,21]; 0,4417 0,02 [-0,04; 0,08]; 0,4478
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,3997)					
Brusterhaltend	220	5 (2,3)	235	1 (0,4)	5,44 [0,63; 46,95]; 0,1234 5,34 [0,63; 45,36]; 0,1248 0,02 [0,00; 0,04]; 0,0904
Einseitige Mastektomie	355	9 (2,5)	352	2 (0,6)	4,55 [0,98; 21,22]; 0,0536 4,46 [0,97; 20,50]; 0,0546 0,02 [0,00; 0,04]; 0,0336
Beidseitige Mastektomie	336	4 (1,2)	315	3 (1,0)	1,25 [0,28; 5,64]; 0,7689 1,25 [0,28; 5,54]; 0,7690 0,00 [-0,01; 0,02]; 0,7677
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	18 (2,1)	866	6 (0,7)	3,03 [1,20; 7,67]; 0,0194 2,99 [1,19; 7,49]; 0,0197 0,01 [0,00; 0,02]; 0,0138

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8625)					
Positiv	173	3 (1,7)	176	1 (0,6)	3,09 [0,32; 29,98]; 0,3309 3,05 [0,32; 29,06]; 0,3318 0,01 [-0,01; 0,03]; 0,3076
Negativ	200	5 (2,5)	191	2 (1,1)	2,42 [0,46; 12,64]; 0,2937 2,39 [0,47; 12,16]; 0,2947 0,01 [-0,01; 0,04]; 0,2736
Bilaterale Oophorektomie (Interaktionstest: p=0,8214)					
Ja	189	4 (2,1)	176	1 (0,6)	3,78 [0,42; 34,18]; 0,2360 3,72 [0,42; 33,01]; 0,2374 0,02 [-0,01; 0,04]; 0,1934
Nein	722	14 (1,9)	728	5 (0,7)	2,86 [1,02; 7,98]; 0,0448 2,82 [1,02; 7,80]; 0,0452 0,01 [0,00; 0,02]; 0,0361
BRCA-Mutationsstatus (Interaktionstest: p=0,1246)					
BRCA1	574	8 (1,4)	580	5 (0,9)	1,63 [0,53; 5,00]; 0,3967 1,62 [0,53; 4,91]; 0,3969 0,01 [-0,01; 0,02]; 0,3926
BRCA2	232	9 (3,9)	215	0 (0,0)	18,32 [1,06; 316,70]; 0,0455 17,61 [1,03; 300,80]; 0,0476 0,04 [0,01; 0,06]; 0,0037
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	7 (1,8)	383	1 (0,3)	6,95 [0,85; 56,72]; 0,0705 6,84 [0,85; 55,33]; 0,0715 0,02 [0,00; 0,03]; 0,0337
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,8292)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	6 (2,3)	271	3 (1,1)	2,12 [0,52; 8,56]; 0,2920 2,09 [0,53; 8,28]; 0,2927 0,01 [-0,01; 0,03]; 0,2846
Kaukasisch	617	11 (1,8)	589	3 (0,5)	3,55 [0,98; 12,77]; 0,0529 3,50 [0,98; 12,48]; 0,0535 0,01 [0,00; 0,02]; 0,0363
Schwarz oder afroamerikanisch	19	1 (5,3)	29	0 (0,0)	4,78 [0,18; 123,74]; 0,3456 4,50 [0,19; 105,03]; 0,3494 0,05 [-0,07; 0,18]; 0,4062

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,7113)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	16 (2,0)	803	6 (0,8)	2,72 [1,06; 6,98]; 0,0378 2,68 [1,06; 6,82]; 0,0381 0,01 [0,00; 0,02]; 0,0306
Unbekannt, nicht erfasst, verweigert	79	2 (2,5)	77	0 (0,0)	5,00 [0,24; 105,86]; 0,3014 4,88 [0,24; 99,93]; 0,3040 0,03 [-0,02; 0,07]; 0,2379
Hormonrezeptorstatus (Interaktionstest: p=0,6417)					
ER- und/oder PgR-positiv, HER2-positiv	168	5 (3,0)	155	1 (0,7)	4,72 [0,55; 40,89]; 0,1586 4,61 [0,54; 39,05]; 0,1606 0,02 [-0,01; 0,05]; 0,1104
TNBC	741	13 (1,8)	749	5 (0,7)	2,66 [0,94; 7,49]; 0,0646 2,63 [0,94; 7,33]; 0,0650 0,01 [0,00; 0,02]; 0,0551
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,9451)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	3 (2,9)	92	0 (0,0)	6,38 [0,33; 125,16]; 0,2224 6,20 [0,32; 118,46]; 0,2254 0,03 [-0,01; 0,07]; 0,1307
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	1 (1,6)	2,00 [0,18; 22,63]; 0,5755 1,97 [0,18; 21,17]; 0,5762 0,02 [-0,04; 0,07]; 0,5669
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	5 (1,4)	362	2 (0,6)	2,62 [0,51; 13,61]; 0,2508 2,60 [0,51; 13,32]; 0,2514 0,01 [-0,01; 0,02]; 0,2368
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	8 (2,0)	387	3 (0,8)	2,66 [0,70; 10,10]; 0,1508 2,63 [0,70; 9,82]; 0,1515 0,01 [0,00; 0,03]; 0,1336
Menopausenstatus (Interaktionstest: p=0,2233)					
Postmenopausal	346	8 (2,3)	356	1 (0,3)	8,40 [1,05; 67,54]; 0,0453 8,23 [1,03; 65,47]; 0,0463 0,02 [0,00; 0,04]; 0,0175
Prämenopausal	563	10 (1,8)	544	5 (0,9)	1,95 [0,66; 5,74]; 0,2258 1,93 [0,66; 5,62]; 0,2262 0,01 [0,00; 0,02]; 0,2148
Region (Interaktionstest: p=0,2743)					
Asien-Pazifik und Südafrika	301	6 (2,0)	317	3 (1,0)	2,13 [0,53; 8,59]; 0,2884 2,11 [0,53; 8,35]; 0,2890 0,01 [-0,01; 0,03]; 0,2814

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	12 (2,5)	444	2 (0,5)	5,75 [1,28; 25,85]; 0,0225 5,63 [1,27; 25,02]; 0,0231 0,02 [0,01; 0,04]; 0,0082
Nordamerika	121	0 (0,0)	131	1 (0,8)	0,36 [0,01; 8,87]; 0,5306 0,36 [0,01; 8,77]; 0,5311 -0,01 [-0,03; 0,01]; 0,4833
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,6214)					
Adjuvant	457	10 (2,2)	450	4 (0,9)	2,49 [0,78; 8,01]; 0,1247 2,46 [0,78; 7,79]; 0,1254 0,01 [0,00; 0,03]; 0,1109
Neoadjuvant	454	8 (1,8)	454	2 (0,4)	4,05 [0,86; 19,20]; 0,0777 4,00 [0,85; 18,73]; 0,0784 0,01 [0,00; 0,03]; 0,0559
Sponsor (Interaktionstest: p=0,1603)					
AZ	801	18 (2,3)	796	5 (0,6)	3,64 [1,34; 9,84]; 0,0110 3,58 [1,33; 9,59]; 0,0113 0,02 [0,00; 0,03]; 0,0064
NRG Oncology	110	0 (0,0)	108	1 (0,9)	0,32 [0,01; 8,05]; 0,4919 0,33 [0,01; 7,95]; 0,4926 -0,01 [-0,03; 0,02]; 0,4709
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,0560)					
Ja	243	2 (0,8)	236	3 (1,3)	0,64 [0,11; 3,89]; 0,6321 0,65 [0,11; 3,84]; 0,6322 0,00 [-0,02; 0,01]; 0,6305
Nein	668	16 (2,4)	668	3 (0,5)	5,44 [1,58; 18,76]; 0,0073 5,33 [1,56; 18,22]; 0,0076 0,02 [0,01; 0,03]; 0,0026
Gastroösophageale Refluxerkrankung					
Alter (Interaktionstest: p=0,1430)					
<50	690	19 (2,8)	663	9 (1,4)	2,06 [0,92; 4,58]; 0,0772 2,03 [0,92; 4,45]; 0,0777 0,01 [0,00; 0,03]; 0,0691
50-64	192	13 (6,8)	209	2 (1,0)	7,52 [1,67; 33,76]; 0,0085 7,08 [1,62; 30,95]; 0,0094 0,06 [0,02; 0,10]; 0,0026
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6210)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	30 (3,5)	840	11 (1,3)	2,72 [1,35; 5,47]; 0,0049 2,66 [1,34; 5,27]; 0,0051 0,02 [0,01; 0,04]; 0,0032
Taxan	43	2 (4,7)	50	0 (0,0)	6,08 [0,28; 130,28]; 0,2481 5,80 [0,29; 117,51]; 0,2525 0,05 [-0,03; 0,12]; 0,2152
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,5000)					
Brusterhaltend	220	5 (2,3)	235	3 (1,3)	1,80 [0,42; 7,62]; 0,4254 1,78 [0,43; 7,36]; 0,4258 0,01 [-0,01; 0,03]; 0,4230
Einseitige Mastektomie	355	15 (4,2)	352	3 (0,9)	5,13 [1,47; 17,89]; 0,0102 4,96 [1,45; 16,98]; 0,0108 0,03 [0,01; 0,06]; 0,0041
Beidseitige Mastektomie	336	12 (3,6)	315	5 (1,6)	2,30 [0,80; 6,59]; 0,1224 2,25 [0,80; 6,31]; 0,1235 0,02 [0,00; 0,04]; 0,1076
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,9580)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	31 (3,6)	866	11 (1,3)	2,87 [1,43; 5,75]; 0,0029 2,81 [1,42; 5,54]; 0,0030 0,02 [0,01; 0,04]; 0,0018
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,9590)					
Positiv	173	7 (4,1)	176	2 (1,1)	3,67 [0,75; 17,91]; 0,1082 3,56 [0,75; 16,90]; 0,1100 0,03 [0,00; 0,06]; 0,0865
Negativ	200	4 (2,0)	191	1 (0,5)	3,88 [0,43; 35,01]; 0,2274 3,82 [0,43; 33,87]; 0,2287 0,01 [-0,01; 0,04]; 0,1871
Bilaterale Oophorektomie (Interaktionstest: p=0,2488)					
Ja	189	9 (4,8)	176	1 (0,6)	8,75 [1,10; 69,79]; 0,0406 8,38 [1,07; 65,48]; 0,0427 0,04 [0,01; 0,07]; 0,0110
Nein	722	23 (3,2)	728	10 (1,4)	2,36 [1,12; 5,00]; 0,0246 2,32 [1,11; 4,84]; 0,0249 0,02 [0,00; 0,03]; 0,0207

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,4813)					
BRCA1	574	21 (3,7)	580	6 (1,0)	3,63 [1,46; 9,07]; 0,0057 3,54 [1,44; 8,70]; 0,0059 0,03 [0,01; 0,04]; 0,0032
BRCA2	232	9 (3,9)	215	4 (1,9)	2,13 [0,65; 7,02]; 0,2144 2,09 [0,65; 6,67]; 0,2156 0,02 [-0,01; 0,05]; 0,1977
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	14 (3,6)	383	6 (1,6)	2,33 [0,88; 6,12]; 0,0869 2,28 [0,89; 5,87]; 0,0877 0,02 [0,00; 0,04]; 0,0765
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,7872)					
Andere	16	1 (6,3)	15	0 (0,0)	3,00 [0,11; 79,50]; 0,5111 2,82 [0,12; 64,39]; 0,5153 0,06 [-0,10; 0,22]; 0,4425
Asiatisch	259	1 (0,4)	271	1 (0,4)	1,05 [0,07; 16,82]; 0,9744 1,05 [0,07; 16,64]; 0,9744 0,00 [-0,01; 0,01]; 0,9744
Kaukasisch	617	30 (4,9)	589	10 (1,7)	2,96 [1,43; 6,11]; 0,0034 2,86 [1,41; 5,81]; 0,0035 0,03 [0,01; 0,05]; 0,0018
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,5938)					
Hispanisch	34	2 (5,9)	24	1 (4,2)	1,44 [0,12; 16,82]; 0,7724 1,41 [0,14; 14,70]; 0,7730 0,02 [-0,10; 0,13]; 0,7649
Nicht-hispanisch	798	29 (3,6)	803	9 (1,1)	3,33 [1,56; 7,07]; 0,0018 3,24 [1,54; 6,81]; 0,0019 0,03 [0,01; 0,04]; 0,0009
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	1 (1,3)	0,97 [0,06; 15,86]; 0,9854 0,97 [0,06; 15,31]; 0,9854 0,00 [-0,04; 0,03]; 0,9854
Hormonrezeptorstatus (Interaktionstest: p=0,5971)					
ER- und/oder PgR-positiv, HER2-positiv	168	4 (2,4)	155	2 (1,3)	1,87 [0,34; 10,33]; 0,4751 1,85 [0,34; 9,93]; 0,4757 0,01 [-0,02; 0,04]; 0,4627

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	27 (3,6)	749	9 (1,2)	3,11 [1,45; 6,66]; 0,0035 3,03 [1,44; 6,40]; 0,0036 0,02 [0,01; 0,04]; 0,0021
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3409)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	4 (3,9)	92	1 (1,1)	3,64 [0,40; 33,17]; 0,2518 3,54 [0,40; 31,09]; 0,2544 0,03 [-0,02; 0,07]; 0,2043
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	1 (1,6)	0,32 [0,01; 8,08]; 0,4915 0,33 [0,01; 7,91]; 0,4926 -0,02 [-0,06; 0,03]; 0,4665
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	11 (3,2)	362	6 (1,7)	1,94 [0,71; 5,30]; 0,1977 1,91 [0,71; 5,10]; 0,1984 0,02 [-0,01; 0,04]; 0,1923
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	16 (4,1)	387	3 (0,8)	5,43 [1,57; 18,80]; 0,0075 5,25 [1,54; 17,88]; 0,0080 0,03 [0,01; 0,05]; 0,0025
Menopausenstatus (Interaktionstest: p=0,0880)					
Postmenopausal	346	18 (5,2)	356	3 (0,8)	6,46 [1,88; 22,12]; 0,0030 6,17 [1,83; 20,77]; 0,0033 0,04 [0,02; 0,07]; 0,0007
Prämenopausal	563	14 (2,5)	544	8 (1,5)	1,71 [0,71; 4,11]; 0,2311 1,69 [0,72; 4,00]; 0,2316 0,01 [-0,01; 0,03]; 0,2236
Region (Interaktionstest: p=0,2904)					
Asien-Pazifik und Südafrika	301	4 (1,3)	317	3 (1,0)	1,41 [0,31; 6,35]; 0,6548 1,40 [0,32; 6,22]; 0,6549 0,00 [-0,01; 0,02]; 0,6547
Europa	473	20 (4,2)	444	8 (1,8)	2,41 [1,05; 5,52]; 0,0382 2,35 [1,04; 5,27]; 0,0389 0,02 [0,00; 0,05]; 0,0303
Nordamerika	121	8 (6,6)	131	0 (0,0)	19,70 [1,12; 345,03]; 0,0413 18,39 [1,07; 315,30]; 0,0446 0,07 [0,02; 0,11]; 0,0052
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4456)					
Adjuvant	457	16 (3,5)	450	4 (0,9)	4,05 [1,34; 12,20]; 0,0131 3,94 [1,33; 11,69]; 0,0135 0,03 [0,01; 0,05]; 0,0069
Neoadjuvant	454	16 (3,5)	454	7 (1,5)	2,33 [0,95; 5,73]; 0,0645 2,29 [0,95; 5,50]; 0,0652 0,02 [0,00; 0,04]; 0,0568

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,2106)					
AZ	801	25 (3,1)	796	11 (1,4)	2,30 [1,12; 4,70]; 0,0227 2,26 [1,12; 4,56]; 0,0230 0,02 [0,00; 0,03]; 0,0189
NRG Oncology	110	7 (6,4)	108	0 (0,0)	15,72 [0,89; 278,82]; 0,0604 14,73 [0,85; 254,77]; 0,0644 0,06 [0,02; 0,11]; 0,0099
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,3229)					
Ja	243	7 (2,9)	236	4 (1,7)	1,72 [0,50; 5,96]; 0,3918 1,70 [0,50; 5,73]; 0,3924 0,01 [-0,01; 0,04]; 0,3843
Nein	668	25 (3,7)	668	7 (1,1)	3,67 [1,58; 8,55]; 0,0026 3,57 [1,56; 8,20]; 0,0027 0,03 [0,01; 0,04]; 0,0012
Stomatitis					
Alter (Interaktionstest: p=0,9383)					
<50	690	60 (8,7)	663	26 (3,9)	2,33 [1,45; 3,75]; 0,0004 2,22 [1,42; 3,47]; 0,0005 0,05 [0,02; 0,07]; 0,0003
50-64	192	18 (9,4)	209	9 (4,3)	2,30 [1,01; 5,25]; 0,0481 2,18 [1,00; 4,73]; 0,0494 0,05 [0,00; 0,10]; 0,0451
≥65	29	3 (10,3)	32	1 (3,1)	3,58 [0,35; 36,49]; 0,2821 3,31 [0,36; 30,08]; 0,2877 0,07 [-0,05; 0,20]; 0,2621
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6914)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	78 (9,1)	840	34 (4,1)	2,36 [1,56; 3,57]; <0,0001 2,24 [1,51; 3,31]; <0,0001 0,05 [0,03; 0,07]; <0,0001
Taxan	43	2 (4,7)	50	2 (4,0)	1,17 [0,16; 8,68]; 0,8775 1,16 [0,17; 7,91]; 0,8775 0,01 [-0,08; 0,09]; 0,8780
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2265)					
Brusterhaltend	220	17 (7,7)	235	10 (4,3)	1,88 [0,84; 4,21]; 0,1224 1,82 [0,85; 3,88]; 0,1235 0,03 [-0,01; 0,08]; 0,1196
Einseitige Mastektomie	355	29 (8,2)	352	7 (2,0)	4,38 [1,89; 10,15]; 0,0006 4,11 [1,82; 9,25]; 0,0006 0,06 [0,03; 0,09]; 0,0002

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	35 (10,4)	315	18 (5,7)	1,92 [1,06; 3,46]; 0,0306 1,82 [1,05; 3,15]; 0,0315 0,05 [0,01; 0,09]; 0,0264
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,0926)					
Ja	41	5 (12,2)	35	5 (14,3)	0,83 [0,22; 3,15]; 0,7883 0,85 [0,27; 2,71]; 0,7882 -0,02 [-0,17; 0,13]; 0,7891
Nein	870	76 (8,7)	866	31 (3,6)	2,58 [1,68; 3,96]; <0,0001 2,44 [1,62; 3,67]; <0,0001 0,05 [0,03; 0,07]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,6099)					
Positiv	173	16 (9,3)	176	10 (5,7)	1,69 [0,75; 3,84]; 0,2087 1,63 [0,76; 3,49]; 0,2100 0,04 [-0,02; 0,09]; 0,2043
Negativ	200	14 (7,0)	191	6 (3,1)	2,32 [0,87; 6,17]; 0,0915 2,23 [0,87; 5,68]; 0,0932 0,04 [0,00; 0,08]; 0,0797
Bilaterale Oophorektomie (Interaktionstest: p=0,0037)					
Ja	189	13 (6,9)	176	14 (8,0)	0,85 [0,39; 1,87]; 0,6949 0,86 [0,42; 1,79]; 0,6949 -0,01 [-0,06; 0,04]; 0,6953
Nein	722	68 (9,4)	728	22 (3,0)	3,34 [2,04; 5,46]; <0,0001 3,12 [1,95; 4,98]; <0,0001 0,06 [0,04; 0,09]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,6753)					
BRCA1	574	54 (9,4)	580	26 (4,5)	2,21 [1,37; 3,59]; 0,0013 2,10 [1,33; 3,30]; 0,0014 0,05 [0,02; 0,08]; 0,0010
BRCA2	232	22 (9,5)	215	8 (3,7)	2,71 [1,18; 6,23]; 0,0188 2,55 [1,16; 5,60]; 0,0199 0,06 [0,01; 0,10]; 0,0129
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,1243)					
2, 3 oder 4	392	38 (9,7)	383	14 (3,7)	2,83 [1,51; 5,31]; 0,0012 2,65 [1,46; 4,81]; 0,0013 0,06 [0,03; 0,10]; 0,0007
5 oder 6	22	0 (0,0)	14	1 (7,1)	0,20 [0,01; 5,27]; 0,3349 0,22 [0,01; 4,99]; 0,3399 -0,07 [-0,23; 0,09]; 0,3907

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,1060)					
Andere	16	0 (0,0)	15	2 (13,3)	0,16 [0,01; 3,71]; 0,2556 0,19 [0,01; 3,63]; 0,2686 -0,13 [-0,33; 0,06]; 0,1806
Asiatisch	259	27 (10,4)	271	6 (2,2)	5,14 [2,09; 12,67]; 0,0004 4,71 [1,98; 11,22]; 0,0005 0,08 [0,04; 0,12]; <0,0001
Kaukasisch	617	52 (8,4)	589	26 (4,4)	1,99 [1,23; 3,24]; 0,0053 1,91 [1,21; 3,02]; 0,0055 0,04 [0,01; 0,07]; 0,0042
Schwarz oder afroamerikanisch	19	2 (10,5)	29	2 (6,9)	1,59 [0,20; 12,36]; 0,6585 1,53 [0,23; 9,93]; 0,6581 0,04 [-0,13; 0,20]; 0,6682
Ethnische Abstammung (Interaktionstest: p=0,3339)					
Hispanisch	34	5 (14,7)	24	1 (4,2)	3,97 [0,43; 36,35]; 0,2230 3,53 [0,44; 28,32]; 0,2353 0,11 [-0,04; 0,25]; 0,1497
Nicht-hispanisch	798	67 (8,4)	803	34 (4,2)	2,07 [1,36; 3,17]; 0,0008 1,98 [1,33; 2,96]; 0,0008 0,04 [0,02; 0,07]; 0,0006
Unbekannt, nicht erfasst, verweigert	79	9 (11,4)	77	1 (1,3)	9,77 [1,21; 79,11]; 0,0327 8,77 [1,14; 67,60]; 0,0371 0,10 [0,03; 0,18]; 0,0079
Hormonrezeptorstatus (Interaktionstest: p=0,2056)					
ER- und/oder PgR-positiv, HER2-positiv	168	18 (10,7)	155	4 (2,6)	4,53 [1,50; 13,70]; 0,0075 4,15 [1,44; 12,00]; 0,0086 0,08 [0,03; 0,13]; 0,0026
TNBC	741	63 (8,5)	749	32 (4,3)	2,08 [1,34; 3,23]; 0,0010 1,99 [1,32; 3,01]; 0,0011 0,04 [0,02; 0,07]; 0,0008
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6112)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	11 (10,6)	92	3 (3,3)	3,51 [0,95; 13,00]; 0,0602 3,24 [0,93; 11,27]; 0,0641 0,07 [0,00; 0,14]; 0,0387
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	7 (10,9)	63	1 (1,6)	7,61 [0,91; 63,81]; 0,0613 6,89 [0,87; 54,40]; 0,0671 0,09 [0,01; 0,18]; 0,0263
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	28 (8,1)	362	14 (3,9)	2,17 [1,12; 4,21]; 0,0209 2,08 [1,11; 3,88]; 0,0215 0,04 [0,01; 0,08]; 0,0186
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	35 (8,9)	387	18 (4,7)	2,00 [1,11; 3,60]; 0,0202 1,91 [1,10; 3,32]; 0,0208 0,04 [0,01; 0,08]; 0,0176

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,0731)					
Postmenopausal	346	34 (9,8)	356	22 (6,2)	1,65 [0,95; 2,89]; 0,0770 1,59 [0,95; 2,66]; 0,0778 0,04 [0,00; 0,08]; 0,0748
Prämenopausal	563	47 (8,4)	544	14 (2,6)	3,45 [1,88; 6,34]; <0,0001 3,24 [1,81; 5,82]; <0,0001 0,06 [0,03; 0,08]; <0,0001
Region (Interaktionstest: p=0,2746)					
Asien-Pazifik und Südafrika	301	29 (9,6)	317	13 (4,1)	2,49 [1,27; 4,89]; 0,0079 2,35 [1,25; 4,43]; 0,0084 0,06 [0,02; 0,10]; 0,0065
Europa	473	38 (8,0)	444	13 (2,9)	2,90 [1,52; 5,51]; 0,0012 2,74 [1,48; 5,08]; 0,0013 0,05 [0,02; 0,08]; 0,0006
Nordamerika	121	10 (8,3)	131	10 (7,6)	1,09 [0,44; 2,72]; 0,8532 1,08 [0,47; 2,51]; 0,8532 0,01 [-0,06; 0,07]; 0,8533
Südamerika	16	4 (25,0)	12	0 (0,0)	9,00 [0,44; 185,36]; 0,1546 6,88 [0,41; 116,75]; 0,1817 0,25 [0,02; 0,48]; 0,0365
Art der vorherigen Chemotherapie (Interaktionstest: p=0,8928)					
Adjuvant	457	42 (9,2)	450	19 (4,2)	2,30 [1,31; 4,01]; 0,0035 2,18 [1,29; 3,68]; 0,0038 0,05 [0,02; 0,08]; 0,0026
Neoadjuvant	454	39 (8,6)	454	17 (3,7)	2,42 [1,35; 4,34]; 0,0031 2,29 [1,32; 3,99]; 0,0033 0,05 [0,02; 0,08]; 0,0023
Sponsor (Interaktionstest: p=0,0754)					
AZ	801	71 (8,9)	796	27 (3,4)	2,77 [1,76; 4,36]; <0,0001 2,61 [1,70; 4,03]; <0,0001 0,05 [0,03; 0,08]; <0,0001
NRG Oncology	110	10 (9,1)	108	9 (8,3)	1,10 [0,43; 2,82]; 0,8429 1,09 [0,46; 2,58]; 0,8429 0,01 [-0,07; 0,08]; 0,8428
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,0671)					
Ja	243	17 (7,0)	236	13 (5,5)	1,29 [0,61; 2,72]; 0,5027 1,27 [0,63; 2,56]; 0,5030 0,01 [-0,03; 0,06]; 0,5009
Nein	668	64 (9,6)	668	23 (3,4)	2,97 [1,82; 4,85]; <0,0001 2,78 [1,75; 4,43]; <0,0001 0,06 [0,04; 0,09]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Übelkeit					
Alter (Interaktionstest: p=0,8799)					
<50	690	409 (59,3)	663	164 (24,7)	4,43 [3,51; 5,59]; <0,0001 2,40 [2,07; 2,77]; <0,0001 0,35 [0,30; 0,39]; <0,0001
50-64	192	94 (49,0)	209	43 (20,6)	3,70 [2,39; 5,74]; <0,0001 2,38 [1,76; 3,22]; <0,0001 0,28 [0,19; 0,37]; <0,0001
≥65	29	16 (55,2)	32	6 (18,8)	5,33 [1,69; 16,85]; 0,0043 2,94 [1,33; 6,50]; 0,0076 0,36 [0,14; 0,59]; 0,0016
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,5205)					
Anthrazyklin	7	4 (57,1)	13	1 (7,7)	16,00 [1,27; 200,92]; 0,0317 7,43 [1,02; 54,31]; 0,0482 0,49 [0,10; 0,89]; 0,0139
Anthrazyklin und Taxan	861	490 (56,9)	840	198 (23,6)	4,28 [3,48; 5,28]; <0,0001 2,41 [2,11; 2,76]; <0,0001 0,33 [0,29; 0,38]; <0,0001
Taxan	43	25 (58,1)	50	13 (26,0)	3,95 [1,65; 9,49]; 0,0021 2,24 [1,31; 3,81]; 0,0030 0,32 [0,13; 0,51]; 0,0010
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2378)					
Brusterhaltend	220	116 (52,7)	235	55 (23,4)	3,65 [2,44; 5,45]; <0,0001 2,25 [1,73; 2,93]; <0,0001 0,29 [0,21; 0,38]; <0,0001
Einseitige Mastektomie	355	193 (54,4)	352	68 (19,3)	4,98 [3,55; 6,97]; <0,0001 2,81 [2,23; 3,56]; <0,0001 0,35 [0,28; 0,42]; <0,0001
Beidseitige Mastektomie	336	210 (62,5)	315	90 (28,6)	4,17 [3,00; 5,79]; <0,0001 2,19 [1,80; 2,65]; <0,0001 0,34 [0,27; 0,41]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3850)					
Ja	41	30 (73,2)	35	13 (37,1)	4,62 [1,74; 12,22]; 0,0021 1,97 [1,23; 3,15]; 0,0046 0,36 [0,15; 0,57]; 0,0008
Nein	870	489 (56,2)	866	199 (23,0)	4,30 [3,50; 5,29]; <0,0001 2,45 [2,14; 2,80]; <0,0001 0,33 [0,29; 0,38]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,0834)					
Positiv	173	87 (50,3)	176	23 (13,1)	6,73 [3,96; 11,43]; <0,0001 3,85 [2,56; 5,79]; <0,0001 0,37 [0,28; 0,46]; <0,0001
Negativ	200	117 (58,5)	191	45 (23,6)	4,57 [2,95; 7,08]; <0,0001 2,48 [1,88; 3,29]; <0,0001 0,35 [0,26; 0,44]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,1964)					
Ja	189	111 (58,7)	176	50 (28,4)	3,59 [2,32; 5,55]; <0,0001 2,07 [1,59; 2,69]; <0,0001 0,30 [0,21; 0,40]; <0,0001
Nein	722	408 (56,5)	728	163 (22,4)	4,50 [3,59; 5,66]; <0,0001 2,52 [2,17; 2,93]; <0,0001 0,34 [0,29; 0,39]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,6807)					
BRCA1	574	337 (58,7)	580	152 (26,2)	4,00 [3,12; 5,13]; <0,0001 2,24 [1,92; 2,61]; <0,0001 0,33 [0,27; 0,38]; <0,0001
BRCA2	232	124 (53,5)	215	48 (22,3)	3,99 [2,65; 6,03]; <0,0001 2,39 [1,82; 3,16]; <0,0001 0,31 [0,23; 0,40]; <0,0001
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9560)					
2, 3 oder 4	392	233 (59,4)	383	104 (27,2)	3,93 [2,91; 5,32]; <0,0001 2,19 [1,82; 2,63]; <0,0001 0,32 [0,26; 0,39]; <0,0001
5 oder 6	22	10 (45,5)	14	3 (21,4)	3,06 [0,66; 14,08]; 0,1519 2,12 [0,70; 6,39]; 0,1813 0,24 [-0,06; 0,54]; 0,1155
Ethnie (Interaktionstest: p=0,0021)					
Andere	16	7 (43,8)	15	5 (33,3)	1,56 [0,36; 6,69]; 0,5528 1,31 [0,53; 3,25]; 0,5564 0,10 [-0,24; 0,44]; 0,5489
Asiatisch	259	153 (59,1)	271	43 (15,9)	7,65 [5,08; 11,52]; <0,0001 3,72 [2,78; 4,99]; <0,0001 0,43 [0,36; 0,51]; <0,0001
Kaukasisch	617	350 (56,7)	589	155 (26,3)	3,67 [2,88; 4,68]; <0,0001 2,16 [1,85; 2,51]; <0,0001 0,30 [0,25; 0,36]; <0,0001
Schwarz oder afroamerikanisch	19	9 (47,4)	29	10 (34,5)	1,71 [0,52; 5,58]; 0,3737 1,37 [0,69; 2,74]; 0,3672 0,13 [-0,15; 0,41]; 0,3729

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,0326)					
Hispanisch	34	11 (32,4)	24	8 (33,3)	0,96 [0,31; 2,91]; 0,9375 0,97 [0,46; 2,05]; 0,9375 -0,01 [-0,26; 0,24]; 0,9376
Nicht-hispanisch	798	464 (58,2)	803	184 (22,9)	4,67 [3,76; 5,80]; <0,0001 2,54 [2,21; 2,92]; <0,0001 0,35 [0,31; 0,40]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	44 (55,7)	77	21 (27,3)	3,35 [1,72; 6,55]; 0,0004 2,04 [1,35; 3,09]; 0,0007 0,28 [0,14; 0,43]; 0,0002
Hormonrezeptorstatus (Interaktionstest: p=0,5775)					
ER- und/oder PgR-positiv, HER2-positiv	168	92 (54,8)	155	38 (24,5)	3,73 [2,32; 6,00]; <0,0001 2,23 [1,64; 3,04]; <0,0001 0,30 [0,20; 0,40]; <0,0001
TNBC	741	426 (57,5)	749	175 (23,4)	4,44 [3,55; 5,55]; <0,0001 2,46 [2,13; 2,84]; <0,0001 0,34 [0,29; 0,39]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3186)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	57 (54,8)	92	22 (23,9)	3,86 [2,09; 7,14]; <0,0001 2,29 [1,53; 3,43]; <0,0001 0,31 [0,18; 0,44]; <0,0001
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	35 (54,7)	63	16 (25,4)	3,55 [1,67; 7,51]; 0,0010 2,15 [1,33; 3,47]; 0,0017 0,29 [0,13; 0,46]; 0,0004
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	207 (59,5)	362	99 (27,4)	3,90 [2,85; 5,34]; <0,0001 2,18 [1,80; 2,63]; <0,0001 0,32 [0,25; 0,39]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	219 (55,7)	387	76 (19,6)	5,15 [3,74; 7,09]; <0,0001 2,84 [2,28; 3,54]; <0,0001 0,36 [0,30; 0,42]; <0,0001
Menopausenstatus (Interaktionstest: p=0,5471)					
Postmenopausal	346	189 (54,6)	356	85 (23,9)	3,84 [2,78; 5,30]; <0,0001 2,29 [1,86; 2,82]; <0,0001 0,31 [0,24; 0,38]; <0,0001
Prämenopausal	563	329 (58,4)	544	128 (23,5)	4,57 [3,53; 5,92]; <0,0001 2,48 [2,10; 2,93]; <0,0001 0,35 [0,29; 0,40]; <0,0001
Region (Interaktionstest: p=0,1892)					
Asien-Pazifik und Südafrika	301	182 (60,5)	317	72 (22,7)	5,20 [3,67; 7,38]; <0,0001 2,66 [2,13; 3,33]; <0,0001 0,38 [0,31; 0,45]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	248 (52,4)	444	92 (20,7)	4,22 [3,15; 5,65]; <0,0001 2,53 [2,07; 3,09]; <0,0001 0,32 [0,26; 0,38]; <0,0001
Nordamerika	121	86 (71,1)	131	49 (37,4)	4,11 [2,42; 6,98]; <0,0001 1,90 [1,48; 2,44]; <0,0001 0,34 [0,22; 0,45]; <0,0001
Südamerika	16	3 (18,8)	12	0 (0,0)	6,48 [0,30; 138,43]; 0,2315 5,35 [0,30; 94,77]; 0,2526 0,19 [-0,03; 0,41]; 0,0930
Art der vorherigen Chemotherapie (Interaktionstest: p=0,1074)					
Adjuvant	457	254 (55,6)	450	92 (20,4)	4,87 [3,63; 6,53]; <0,0001 2,72 [2,23; 3,32]; <0,0001 0,35 [0,29; 0,41]; <0,0001
Neoadjuvant	454	265 (58,4)	454	121 (26,7)	3,86 [2,92; 5,10]; <0,0001 2,19 [1,85; 2,60]; <0,0001 0,32 [0,26; 0,38]; <0,0001
Sponsor (Interaktionstest: p=0,0628)					
AZ	801	442 (55,2)	796	173 (21,7)	4,43 [3,56; 5,52]; <0,0001 2,54 [2,19; 2,94]; <0,0001 0,33 [0,29; 0,38]; <0,0001
NRG Oncology	110	77 (70,0)	108	40 (37,0)	3,97 [2,26; 6,98]; <0,0001 1,89 [1,44; 2,49]; <0,0001 0,33 [0,20; 0,45]; <0,0001
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,0808)					
Ja	243	147 (60,5)	236	70 (29,7)	3,63 [2,48; 5,31]; <0,0001 2,04 [1,63; 2,54]; <0,0001 0,31 [0,22; 0,39]; <0,0001
Nein	668	372 (55,7)	668	143 (21,4)	4,61 [3,63; 5,86]; <0,0001 2,60 [2,22; 3,05]; <0,0001 0,34 [0,29; 0,39]; <0,0001
SOC: Erkrankungen des Nervensystems					
Alter (Interaktionstest: p=0,6518)					
<50	690	269 (39,0)	663	211 (31,8)	1,37 [1,09; 1,71]; 0,0060 1,22 [1,06; 1,42]; 0,0062 0,07 [0,02; 0,12]; 0,0057
50-64	192	86 (44,8)	209	76 (36,4)	1,42 [0,95; 2,12]; 0,0862 1,23 [0,97; 1,56]; 0,0865 0,08 [-0,01; 0,18]; 0,0851
≥65	29	15 (51,7)	32	10 (31,3)	2,36 [0,83; 6,69]; 0,1073 1,66 [0,89; 3,09]; 0,1127 0,20 [-0,04; 0,45]; 0,0981

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,5360)					
Anthrazyklin	7	3 (42,9)	13	3 (23,1)	2,50 [0,35; 18,04]; 0,3635 1,86 [0,50; 6,88]; 0,3544 0,20 [-0,23; 0,63]; 0,3698
Anthrazyklin und Taxan	861	349 (40,5)	840	281 (33,5)	1,36 [1,11; 1,65]; 0,0025 1,21 [1,07; 1,37]; 0,0026 0,07 [0,03; 0,12]; 0,0024
Taxan	43	18 (41,9)	50	13 (26,0)	2,05 [0,85; 4,92]; 0,1082 1,61 [0,90; 2,89]; 0,1109 0,16 [-0,03; 0,35]; 0,1038
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0794)					
Brusterhaltend	220	77 (35,0)	235	77 (32,8)	1,10 [0,75; 1,63]; 0,6148 1,07 [0,83; 1,38]; 0,6147 0,02 [-0,06; 0,11]; 0,6149
Einseitige Mastektomie	355	130 (36,6)	352	85 (24,2)	1,81 [1,31; 2,51]; 0,0003 1,52 [1,20; 1,91]; 0,0004 0,12 [0,06; 0,19]; 0,0003
Beidseitige Mastektomie	336	163 (48,5)	315	134 (42,5)	1,27 [0,93; 1,73]; 0,1265 1,14 [0,96; 1,35]; 0,1279 0,06 [-0,02; 0,14]; 0,1255
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7758)					
Ja	41	23 (56,1)	35	17 (48,6)	1,35 [0,55; 3,35]; 0,5129 1,15 [0,75; 1,78]; 0,5166 0,08 [-0,15; 0,30]; 0,5115
Nein	870	347 (39,9)	866	280 (32,3)	1,39 [1,14; 1,69]; 0,0011 1,23 [1,09; 1,40]; 0,0011 0,08 [0,03; 0,12]; 0,0010
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,9710)					
Positiv	173	66 (38,2)	176	50 (28,4)	1,55 [0,99; 2,43]; 0,0541 1,34 [0,99; 1,82]; 0,0554 0,10 [0,00; 0,20]; 0,0523
Negativ	200	85 (42,5)	191	60 (31,4)	1,61 [1,07; 2,44]; 0,0237 1,35 [1,04; 1,76]; 0,0250 0,11 [0,02; 0,21]; 0,0222
Bilaterale Oophorektomie (Interaktionstest: p=0,3078)					
Ja	189	79 (41,8)	176	67 (38,1)	1,17 [0,77; 1,78]; 0,4674 1,10 [0,85; 1,41]; 0,4682 0,04 [-0,06; 0,14]; 0,4667
Nein	722	291 (40,3)	728	230 (31,6)	1,46 [1,18; 1,81]; 0,0006 1,28 [1,11; 1,47]; 0,0006 0,09 [0,04; 0,14]; 0,0005

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
BRCA-Mutationsstatus (Interaktionstest: p=0,1351)					
BRCA1	574	248 (43,2)	580	199 (34,3)	1,46 [1,15; 1,85]; 0,0020 1,26 [1,09; 1,46]; 0,0020 0,09 [0,03; 0,14]; 0,0018
BRCA2	232	89 (38,4)	215	81 (37,7)	1,03 [0,70; 1,51]; 0,8811 1,02 [0,80; 1,29]; 0,8811 0,01 [-0,08; 0,10]; 0,8810
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,3306)					
2, 3 oder 4	392	159 (40,6)	383	124 (32,4)	1,43 [1,06; 1,91]; 0,0182 1,25 [1,04; 1,51]; 0,0187 0,08 [0,01; 0,15]; 0,0175
5 oder 6	22	6 (27,3)	14	5 (35,7)	0,68 [0,16; 2,85]; 0,5928 0,76 [0,29; 2,03]; 0,5895 -0,08 [-0,40; 0,23]; 0,5965
Ethnie (Interaktionstest: p=0,0404)					
Andere	16	5 (31,3)	15	8 (53,3)	0,40 [0,09; 1,72]; 0,2174 0,59 [0,25; 1,39]; 0,2271 -0,22 [-0,56; 0,12]; 0,2025
Asiatisch	259	97 (37,5)	271	62 (22,9)	2,02 [1,38; 2,95]; 0,0003 1,64 [1,25; 2,14]; 0,0003 0,15 [0,07; 0,22]; 0,0002
Kaukasisch	617	261 (42,3)	589	216 (36,7)	1,27 [1,00; 1,60]; 0,0458 1,15 [1,00; 1,33]; 0,0464 0,06 [0,00; 0,11]; 0,0452
Schwarz oder afroamerikanisch	19	7 (36,8)	29	11 (37,9)	0,95 [0,29; 3,16]; 0,9393 0,97 [0,46; 2,06]; 0,9394 -0,01 [-0,29; 0,27]; 0,9392
Ethnische Abstammung (Interaktionstest: p=0,4025)					
Hispanisch	34	8 (23,5)	24	8 (33,3)	0,62 [0,19; 1,97]; 0,4125 0,71 [0,31; 1,62]; 0,4103 -0,10 [-0,33; 0,14]; 0,4164
Nicht-hispanisch	798	327 (41,0)	803	262 (32,6)	1,43 [1,17; 1,76]; 0,0005 1,26 [1,10; 1,43]; 0,0006 0,08 [0,04; 0,13]; 0,0005
Unbekannt, nicht erfasst, verweigert	79	35 (44,3)	77	27 (35,1)	1,47 [0,77; 2,81]; 0,2393 1,26 [0,85; 1,87]; 0,2420 0,09 [-0,06; 0,25]; 0,2361
Hormonrezeptorstatus (Interaktionstest: p=0,3154)					
ER- und/oder PgR-positiv, HER2-positiv	168	72 (42,9)	155	47 (30,3)	1,72 [1,09; 2,73]; 0,0201 1,41 [1,05; 1,90]; 0,0218 0,13 [0,02; 0,23]; 0,0183

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	296 (40,0)	749	250 (33,4)	1,33 [1,07; 1,64]; 0,0086 1,20 [1,05; 1,37]; 0,0087 0,07 [0,02; 0,11]; 0,0084
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,2522)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	47 (45,2)	92	25 (27,2)	2,21 [1,21; 4,03]; 0,0096 1,66 [1,12; 2,47]; 0,0118 0,18 [0,05; 0,31]; 0,0074
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	25 (39,1)	63	22 (34,9)	1,19 [0,58; 2,46]; 0,6290 1,12 [0,71; 1,76]; 0,6294 0,04 [-0,13; 0,21]; 0,6285
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	135 (38,8)	362	128 (35,4)	1,16 [0,85; 1,57]; 0,3437 1,10 [0,91; 1,33]; 0,3438 0,03 [-0,04; 0,11]; 0,3434
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	161 (41,0)	387	122 (31,5)	1,51 [1,12; 2,02]; 0,0062 1,30 [1,08; 1,57]; 0,0065 0,09 [0,03; 0,16]; 0,0058
Menopausenstatus (Interaktionstest: p=0,1852)					
Postmenopausal	346	147 (42,5)	356	134 (37,6)	1,22 [0,90; 1,66]; 0,1904 1,13 [0,94; 1,35]; 0,1908 0,05 [-0,02; 0,12]; 0,1898
Prämenopausal	563	222 (39,4)	544	161 (29,6)	1,55 [1,21; 1,99]; 0,0006 1,33 [1,13; 1,57]; 0,0007 0,10 [0,04; 0,15]; 0,0005
Region (Interaktionstest: p=0,1432)					
Asien-Pazifik und Südafrika	301	126 (41,9)	317	91 (28,7)	1,79 [1,28; 2,50]; 0,0007 1,46 [1,17; 1,81]; 0,0007 0,13 [0,06; 0,21]; 0,0006
Europa	473	177 (37,4)	444	137 (30,9)	1,34 [1,02; 1,76]; 0,0365 1,21 [1,01; 1,45]; 0,0373 0,07 [0,00; 0,13]; 0,0356
Nordamerika	121	65 (53,7)	131	69 (52,7)	1,04 [0,64; 1,71]; 0,8678 1,02 [0,81; 1,29]; 0,8678 0,01 [-0,11; 0,13]; 0,8678
Südamerika	16	2 (12,5)	12	0 (0,0)	4,31 [0,19; 98,51]; 0,3601 3,82 [0,20; 73,00]; 0,3728 0,12 [-0,07; 0,32]; 0,2164
Art der vorherigen Chemotherapie (Interaktionstest: p=0,6526)					
Adjuvant	457	186 (40,7)	450	144 (32,0)	1,46 [1,11; 1,91]; 0,0066 1,27 [1,07; 1,51]; 0,0069 0,09 [0,02; 0,15]; 0,0062
Neoadjuvant	454	184 (40,5)	454	153 (33,7)	1,34 [1,02; 1,76]; 0,0334 1,20 [1,01; 1,43]; 0,0339 0,07 [0,01; 0,13]; 0,0328

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Sponsor (Interaktionstest: p=0,0897)					
AZ	801	314 (39,2)	796	242 (30,4)	1,48 [1,20; 1,82]; 0,0002 1,29 [1,13; 1,48]; 0,0002 0,09 [0,04; 0,13]; 0,0002
NRG Oncology	110	56 (50,9)	108	55 (50,9)	1,00 [0,59; 1,70]; 0,9980 1,00 [0,77; 1,30]; 0,9980 0,00 [-0,13; 0,13]; 0,9980
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,0333)					
Ja	243	100 (41,2)	236	96 (40,7)	1,02 [0,71; 1,47]; 0,9159 1,01 [0,82; 1,25]; 0,9159 0,00 [-0,08; 0,09]; 0,9159
Nein	668	270 (40,4)	668	201 (30,1)	1,58 [1,26; 1,98]; <0,0001 1,34 [1,16; 1,56]; <0,0001 0,10 [0,05; 0,15]; <0,0001
Dysgeusie					
Alter (Interaktionstest: p=0,5284)					
<50	690	79 (11,5)	663	25 (3,8)	3,30 [2,08; 5,24]; <0,0001 3,04 [1,96; 4,70]; <0,0001 0,08 [0,05; 0,10]; <0,0001
50-64	192	23 (12,0)	209	12 (5,7)	2,23 [1,08; 4,62]; 0,0303 2,09 [1,07; 4,08]; 0,0314 0,06 [0,01; 0,12]; 0,0282
≥65	29	5 (17,2)	32	1 (3,1)	6,46 [0,71; 59,00]; 0,0984 5,52 [0,68; 44,49]; 0,1088 0,14 [-0,01; 0,29]; 0,0653
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,7344)					
Anthrazyklin	7	2 (28,6)	13	0 (0,0)	12,27 [0,50; 299,32]; 0,1239 8,75 [0,48; 160,53]; 0,1440 0,29 [-0,05; 0,62]; 0,0952
Anthrazyklin und Taxan	861	100 (11,6)	840	36 (4,3)	2,93 [1,98; 4,35]; <0,0001 2,71 [1,87; 3,92]; <0,0001 0,07 [0,05; 0,10]; <0,0001
Taxan	43	5 (11,6)	50	2 (4,0)	3,16 [0,58; 17,19]; 0,1834 2,91 [0,59; 14,23]; 0,1879 0,08 [-0,03; 0,19]; 0,1746
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,3912)					
Brusterhaltend	220	20 (9,1)	235	4 (1,7)	5,77 [1,94; 17,18]; 0,0016 5,34 [1,85; 15,38]; 0,0019 0,07 [0,03; 0,12]; 0,0005
Einseitige Mastektomie	355	39 (11,0)	352	15 (4,3)	2,77 [1,50; 5,13]; 0,0012 2,58 [1,45; 4,59]; 0,0013 0,07 [0,03; 0,11]; 0,0007

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	48 (14,3)	315	19 (6,0)	2,60 [1,49; 4,52]; 0,0008 2,37 [1,42; 3,94]; 0,0009 0,08 [0,04; 0,13]; 0,0004
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7357)					
Ja	41	5 (12,2)	35	2 (5,7)	2,29 [0,42; 12,63]; 0,3409 2,13 [0,44; 10,33]; 0,3460 0,06 [-0,06; 0,19]; 0,3145
Nein	870	102 (11,7)	866	36 (4,2)	3,06 [2,07; 4,53]; <0,0001 2,82 [1,95; 4,08]; <0,0001 0,08 [0,05; 0,10]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,6089)					
Positiv	173	19 (11,0)	176	4 (2,3)	5,31 [1,77; 15,94]; 0,0029 4,83 [1,68; 13,91]; 0,0035 0,09 [0,04; 0,14]; 0,0009
Negativ	200	25 (12,5)	191	7 (3,7)	3,76 [1,58; 8,90]; 0,0027 3,41 [1,51; 7,70]; 0,0031 0,09 [0,04; 0,14]; 0,0011
Bilaterale Oophorektomie (Interaktionstest: p=0,8327)					
Ja	189	28 (14,8)	176	10 (5,7)	2,89 [1,36; 6,14]; 0,0058 2,61 [1,30; 5,21]; 0,0067 0,09 [0,03; 0,15]; 0,0034
Nein	722	79 (10,9)	728	28 (3,9)	3,07 [1,97; 4,79]; <0,0001 2,84 [1,87; 4,32]; <0,0001 0,07 [0,04; 0,10]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,0976)					
BRCA1	574	77 (13,4)	580	23 (4,0)	3,75 [2,32; 6,07]; <0,0001 3,38 [2,15; 5,31]; <0,0001 0,09 [0,06; 0,13]; <0,0001
BRCA2	232	22 (9,5)	215	12 (5,6)	1,77 [0,85; 3,68]; 0,1241 1,70 [0,86; 3,35]; 0,1257 0,04 [-0,01; 0,09]; 0,1157
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,5224)					
2, 3 oder 4	392	42 (10,7)	383	18 (4,7)	2,43 [1,37; 4,31]; 0,0023 2,28 [1,34; 3,89]; 0,0025 0,06 [0,02; 0,10]; 0,0015
5 oder 6	22	4 (18,2)	14	0 (0,0)	7,05 [0,35; 141,90]; 0,2021 5,87 [0,34; 101,31]; 0,2233 0,18 [0,00; 0,37]; 0,0552

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,2060)					
Andere	16	1 (6,3)	15	2 (13,3)	0,43 [0,04; 5,35]; 0,5142 0,47 [0,05; 4,65]; 0,5175 -0,07 [-0,28; 0,14]; 0,5064
Asiatisch	259	29 (11,2)	271	6 (2,2)	5,57 [2,27; 13,65]; 0,0002 5,06 [2,13; 11,98]; 0,0002 0,09 [0,05; 0,13]; <0,0001
Kaukasisch	617	76 (12,3)	589	29 (4,9)	2,71 [1,74; 4,23]; <0,0001 2,50 [1,66; 3,78]; <0,0001 0,07 [0,04; 0,11]; <0,0001
Schwarz oder afroamerikanisch	19	1 (5,3)	29	1 (3,5)	1,56 [0,09; 26,47]; 0,7600 1,53 [0,10; 22,96]; 0,7598 0,02 [-0,10; 0,14]; 0,7676
Ethnische Abstammung (Interaktionstest: p=0,2120)					
Hispanisch	34	2 (5,9)	24	1 (4,2)	1,44 [0,12; 16,82]; 0,7724 1,41 [0,14; 14,70]; 0,7730 0,02 [-0,10; 0,13]; 0,7649
Nicht-hispanisch	798	91 (11,4)	803	37 (4,6)	2,66 [1,79; 3,96]; <0,0001 2,47 [1,71; 3,58]; <0,0001 0,07 [0,04; 0,09]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	14 (17,7)	77	0 (0,0)	34,31 [2,01; 586,31]; 0,0146 28,28 [1,72; 465,85]; 0,0194 0,18 [0,09; 0,26]; <0,0001
Hormonrezeptorstatus (Interaktionstest: p=0,8199)					
ER- und/oder PgR-positiv, HER2-positiv	168	20 (11,9)	155	6 (3,9)	3,36 [1,31; 8,59]; 0,0116 3,08 [1,27; 7,46]; 0,0129 0,08 [0,02; 0,14]; 0,0063
TNBC	741	87 (11,7)	749	32 (4,3)	2,98 [1,96; 4,53]; <0,0001 2,75 [1,86; 4,07]; <0,0001 0,07 [0,05; 0,10]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3893)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	13 (12,5)	92	2 (2,2)	6,43 [1,41; 29,30]; 0,0162 5,75 [1,33; 24,81]; 0,0190 0,10 [0,03; 0,17]; 0,0039
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	7 (10,9)	63	4 (6,4)	1,81 [0,50; 6,52]; 0,3635 1,72 [0,53; 5,60]; 0,3656 0,05 [-0,05; 0,14]; 0,3555
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	40 (11,5)	362	19 (5,3)	2,34 [1,33; 4,13]; 0,0032 2,19 [1,29; 3,71]; 0,0035 0,06 [0,02; 0,10]; 0,0026
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	47 (12,0)	387	13 (3,4)	3,91 [2,08; 7,35]; <0,0001 3,56 [1,96; 6,47]; <0,0001 0,09 [0,05; 0,12]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Menopausenstatus (Interaktionstest: p=0,5639)					
Postmenopausal	346	49 (14,2)	356	20 (5,6)	2,77 [1,61; 4,77]; 0,0002 2,52 [1,53; 4,15]; 0,0003 0,09 [0,04; 0,13]; 0,0001
Prämenopausal	563	58 (10,3)	544	18 (3,3)	3,36 [1,95; 5,78]; <0,0001 3,11 [1,86; 5,21]; <0,0001 0,07 [0,04; 0,10]; <0,0001
Region (Interaktionstest: p=0,4362)					
Asien-Pazifik und Südafrika	301	36 (12,0)	317	15 (4,7)	2,74 [1,46; 5,11]; 0,0016 2,53 [1,41; 4,52]; 0,0018 0,07 [0,03; 0,12]; 0,0011
Europa	473	49 (10,4)	444	12 (2,7)	4,16 [2,18; 7,93]; <0,0001 3,83 [2,07; 7,11]; <0,0001 0,08 [0,05; 0,11]; <0,0001
Nordamerika	121	22 (18,2)	131	11 (8,4)	2,42 [1,12; 5,24]; 0,0244 2,17 [1,10; 4,28]; 0,0260 0,10 [0,01; 0,18]; 0,0217
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5593)					
Adjuvant	457	54 (11,8)	450	17 (3,8)	3,41 [1,95; 5,99]; <0,0001 3,13 [1,84; 5,31]; <0,0001 0,08 [0,05; 0,11]; <0,0001
Neoadjuvant	454	53 (11,7)	454	21 (4,6)	2,73 [1,61; 4,60]; 0,0002 2,52 [1,55; 4,11]; 0,0002 0,07 [0,04; 0,11]; <0,0001
Sponsor (Interaktionstest: p=0,2230)					
AZ	801	88 (11,0)	796	28 (3,5)	3,39 [2,19; 5,24]; <0,0001 3,12 [2,06; 4,72]; <0,0001 0,07 [0,05; 0,10]; <0,0001
NRG Oncology	110	19 (17,3)	108	10 (9,3)	2,05 [0,90; 4,63]; 0,0859 1,87 [0,91; 3,83]; 0,0888 0,08 [-0,01; 0,17]; 0,0787
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,2931)					
Ja	243	28 (11,5)	236	13 (5,5)	2,23 [1,13; 4,43]; 0,0213 2,09 [1,11; 3,94]; 0,0223 0,06 [0,01; 0,11]; 0,0174
Nein	668	79 (11,8)	668	25 (3,7)	3,45 [2,17; 5,48]; <0,0001 3,16 [2,04; 4,89]; <0,0001 0,08 [0,05; 0,11]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Schwindelgefühl					
Alter (Interaktionstest: p=0,6155)					
<50	690	78 (11,3)	663	50 (7,5)	1,56 [1,08; 2,27]; 0,0188 1,50 [1,07; 2,10]; 0,0192 0,04 [0,01; 0,07]; 0,0174
50-64	192	22 (11,5)	209	15 (7,2)	1,67 [0,84; 3,33]; 0,1422 1,60 [0,85; 2,99]; 0,1432 0,04 [-0,01; 0,10]; 0,1413
≥65	29	4 (13,8)	32	1 (3,1)	4,96 [0,52; 47,24]; 0,1637 4,41 [0,52; 37,25]; 0,1725 0,11 [-0,03; 0,25]; 0,1332
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,5386)					
Anthrazyklin	7	2 (28,6)	13	1 (7,7)	4,80 [0,35; 65,76]; 0,2401 3,71 [0,40; 34,12]; 0,2462 0,21 [-0,16; 0,57]; 0,2618
Anthrazyklin und Taxan	861	97 (11,3)	840	63 (7,5)	1,57 [1,12; 2,18]; 0,0082 1,50 [1,11; 2,03]; 0,0084 0,04 [0,01; 0,07]; 0,0075
Taxan	43	5 (11,6)	50	2 (4,0)	3,16 [0,58; 17,19]; 0,1834 2,91 [0,59; 14,23]; 0,1879 0,08 [-0,03; 0,19]; 0,1746
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2255)					
Brusterhaltend	220	27 (12,3)	235	16 (6,8)	1,91 [1,00; 3,66]; 0,0494 1,80 [1,00; 3,25]; 0,0505 0,05 [0,00; 0,11]; 0,0474
Einseitige Mastektomie	355	39 (11,0)	352	19 (5,4)	2,16 [1,22; 3,82]; 0,0079 2,04 [1,20; 3,45]; 0,0084 0,06 [0,02; 0,10]; 0,0064
Beidseitige Mastektomie	336	38 (11,3)	315	31 (9,8)	1,17 [0,71; 1,93]; 0,5434 1,15 [0,73; 1,80]; 0,5436 0,01 [-0,03; 0,06]; 0,5422
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,8868)					
Ja	41	6 (14,6)	35	3 (8,6)	1,83 [0,42; 7,92]; 0,4199 1,71 [0,46; 6,33]; 0,4237 0,06 [-0,08; 0,20]; 0,4043
Nein	870	98 (11,3)	866	63 (7,3)	1,62 [1,16; 2,25]; 0,0044 1,55 [1,14; 2,09]; 0,0046 0,04 [0,01; 0,07]; 0,0041

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,6829)					
Positiv	173	24 (13,9)	176	9 (5,1)	2,99 [1,35; 6,63]; 0,0071 2,71 [1,30; 5,67]; 0,0079 0,09 [0,03; 0,15]; 0,0048
Negativ	200	25 (12,5)	191	7 (3,7)	3,76 [1,58; 8,90]; 0,0027 3,41 [1,51; 7,70]; 0,0031 0,09 [0,04; 0,14]; 0,0011
Bilaterale Oophorektomie (Interaktionstest: p=0,4863)					
Ja	189	16 (8,5)	176	12 (6,8)	1,26 [0,58; 2,75]; 0,5553 1,24 [0,60; 2,55]; 0,5556 0,02 [-0,04; 0,07]; 0,5530
Nein	722	88 (12,2)	728	54 (7,4)	1,73 [1,21; 2,47]; 0,0025 1,64 [1,19; 2,27]; 0,0026 0,05 [0,02; 0,08]; 0,0022
BRCA-Mutationsstatus (Interaktionstest: p=0,1079)					
BRCA1	574	60 (10,5)	580	39 (6,7)	1,62 [1,06; 2,47]; 0,0248 1,55 [1,06; 2,29]; 0,0252 0,04 [0,01; 0,07]; 0,0236
BRCA2	232	21 (9,1)	215	22 (10,2)	0,87 [0,47; 1,64]; 0,6724 0,88 [0,50; 1,56]; 0,6724 -0,01 [-0,07; 0,04]; 0,6728
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9517)					
2, 3 oder 4	392	34 (8,7)	383	33 (8,6)	1,01 [0,61; 1,66]; 0,9774 1,01 [0,64; 1,59]; 0,9774 0,00 [-0,04; 0,04]; 0,9774
5 oder 6	22	3 (13,6)	14	2 (14,3)	0,95 [0,14; 6,52]; 0,9562 0,95 [0,18; 5,02]; 0,9562 -0,01 [-0,24; 0,23]; 0,9564
Ethnie (Interaktionstest: p=0,0816)					
Andere	16	2 (12,5)	15	4 (26,7)	0,39 [0,06; 2,55]; 0,3280 0,47 [0,10; 2,20]; 0,3362 -0,14 [-0,42; 0,13]; 0,3149
Asiatisch	259	42 (16,2)	271	17 (6,3)	2,89 [1,60; 5,23]; 0,0004 2,59 [1,51; 4,42]; 0,0005 0,10 [0,05; 0,15]; 0,0003
Kaukasisch	617	58 (9,4)	589	43 (7,3)	1,32 [0,87; 1,99]; 0,1893 1,29 [0,88; 1,88]; 0,1898 0,02 [-0,01; 0,05]; 0,1867
Schwarz oder afroamerikanisch	19	2 (10,5)	29	2 (6,9)	1,59 [0,20; 12,36]; 0,6585 1,53 [0,23; 9,93]; 0,6581 0,04 [-0,13; 0,20]; 0,6682

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Ethnische Abstammung (Interaktionstest: p=0,8682)					
Hispanisch	34	3 (8,8)	24	2 (8,3)	1,06 [0,16; 6,91]; 0,9478 1,06 [0,19; 5,86]; 0,9478 0,00 [-0,14; 0,15]; 0,9475
Nicht-hispanisch	798	94 (11,8)	803	59 (7,4)	1,68 [1,20; 2,37]; 0,0028 1,60 [1,18; 2,19]; 0,0029 0,04 [0,02; 0,07]; 0,0025
Unbekannt, nicht erfasst, verweigert	79	7 (8,9)	77	5 (6,5)	1,40 [0,42; 4,62]; 0,5805 1,36 [0,45; 4,12]; 0,5810 0,02 [-0,06; 0,11]; 0,5780
Hormonrezeptorstatus (Interaktionstest: p=0,0922)					
ER- und/oder PgR-positiv, HER2-positiv	168	16 (9,5)	155	16 (10,3)	0,91 [0,44; 1,90]; 0,8103 0,92 [0,48; 1,78]; 0,8103 -0,01 [-0,07; 0,06]; 0,8105
TNBC	741	86 (11,6)	749	50 (6,7)	1,84 [1,27; 2,64]; 0,0011 1,74 [1,25; 2,43]; 0,0012 0,05 [0,02; 0,08]; 0,0009
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,0793)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	7 (6,7)	92	8 (8,7)	0,76 [0,26; 2,18]; 0,6065 0,77 [0,29; 2,05]; 0,6066 -0,02 [-0,09; 0,06]; 0,6079
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	9 (14,1)	63	8 (12,7)	1,12 [0,40; 3,13]; 0,8215 1,11 [0,46; 2,69]; 0,8215 0,01 [-0,10; 0,13]; 0,8213
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	34 (9,8)	362	29 (8,0)	1,24 [0,74; 2,09]; 0,4106 1,22 [0,76; 1,96]; 0,4108 0,02 [-0,02; 0,06]; 0,4105
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	52 (13,2)	387	21 (5,4)	2,66 [1,57; 4,51]; 0,0003 2,44 [1,50; 3,97]; 0,0003 0,08 [0,04; 0,12]; 0,0002
Menopausenstatus (Interaktionstest: p=0,6643)					
Postmenopausal	346	38 (11,0)	356	23 (6,5)	1,79 [1,04; 3,07]; 0,0354 1,70 [1,03; 2,79]; 0,0361 0,05 [0,00; 0,09]; 0,0335
Prämenopausal	563	66 (11,7)	544	43 (7,9)	1,55 [1,03; 2,32]; 0,0341 1,48 [1,03; 2,14]; 0,0346 0,04 [0,00; 0,07]; 0,0321
Region (Interaktionstest: p=0,1611)					
Asien-Pazifik und Südafrika	301	49 (16,3)	317	24 (7,6)	2,37 [1,42; 3,98]; 0,0010 2,15 [1,35; 3,41]; 0,0012 0,09 [0,04; 0,14]; 0,0008

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	32 (6,8)	444	27 (6,1)	1,12 [0,66; 1,90]; 0,6731 1,11 [0,68; 1,83]; 0,6732 0,01 [-0,02; 0,04]; 0,6725
Nordamerika	121	23 (19,0)	131	15 (11,5)	1,81 [0,90; 3,67]; 0,0970 1,66 [0,91; 3,03]; 0,0987 0,08 [-0,01; 0,16]; 0,0948
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,0572)					
Adjuvant	457	61 (13,4)	450	29 (6,4)	2,24 [1,41; 3,55]; 0,0007 2,07 [1,36; 3,16]; 0,0007 0,07 [0,03; 0,11]; 0,0004
Neoadjuvant	454	43 (9,5)	454	37 (8,2)	1,18 [0,74; 1,87]; 0,4828 1,16 [0,76; 1,77]; 0,4829 0,01 [-0,02; 0,05]; 0,4823
Sponsor (Interaktionstest: p=0,8803)					
AZ	801	84 (10,5)	796	54 (6,8)	1,61 [1,13; 2,30]; 0,0089 1,55 [1,11; 2,14]; 0,0091 0,04 [0,01; 0,06]; 0,0083
NRG Oncology	110	20 (18,2)	108	12 (11,1)	1,78 [0,82; 3,84]; 0,1437 1,64 [0,84; 3,18]; 0,1464 0,07 [-0,02; 0,16]; 0,1375
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,5481)					
Ja	243	31 (12,8)	236	22 (9,3)	1,42 [0,80; 2,54]; 0,2325 1,37 [0,82; 2,29]; 0,2336 0,03 [-0,02; 0,09]; 0,2292
Nein	668	73 (10,9)	668	44 (6,6)	1,74 [1,18; 2,57]; 0,0054 1,66 [1,16; 2,37]; 0,0056 0,04 [0,01; 0,07]; 0,0049
SOC: Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl, Zysten und Polypen)					
Alter (Interaktionstest: p=0,6162)					
<50	690	3 (0,4)	663	17 (2,6)	0,17 [0,05; 0,57]; 0,0043 0,17 [0,05; 0,58]; 0,0044 -0,02 [-0,03; -0,01]; 0,0013
50-64	192	3 (1,6)	209	8 (3,8)	0,40 [0,10; 1,53]; 0,1793 0,41 [0,11; 1,52]; 0,1809 -0,02 [-0,05; 0,01]; 0,1570
≥65	29	0 (0,0)	32	1 (3,1)	0,36 [0,01; 9,09]; 0,5320 0,37 [0,02; 8,66]; 0,5340 -0,03 [-0,12; 0,05]; 0,4688

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,4197)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	5 (0,6)	840	24 (2,9)	0,20 [0,08; 0,52]; 0,0011 0,20 [0,08; 0,53]; 0,0011 -0,02 [-0,04; -0,01]; 0,0003
Taxan	43	1 (2,3)	50	2 (4,0)	0,57 [0,05; 6,53]; 0,6525 0,58 [0,05; 6,19]; 0,6532 -0,02 [-0,09; 0,05]; 0,6419
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,3952)					
Brusterhaltend	220	1 (0,5)	235	4 (1,7)	0,26 [0,03; 2,38]; 0,2348 0,27 [0,03; 2,37]; 0,2360 -0,01 [-0,03; 0,01]; 0,1928
Einseitige Mastektomie	355	4 (1,1)	352	10 (2,8)	0,39 [0,12; 1,25]; 0,1142 0,40 [0,13; 1,25]; 0,1150 -0,02 [-0,04; 0,00]; 0,1019
Beidseitige Mastektomie	336	1 (0,3)	315	12 (3,8)	0,08 [0,01; 0,58]; 0,0133 0,08 [0,01; 0,60]; 0,0140 -0,04 [-0,06; -0,01]; 0,0017
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,6305)					
Ja	41	0 (0,0)	35	3 (8,6)	0,11 [0,01; 2,24]; 0,1522 0,12 [0,01; 2,29]; 0,1600 -0,09 [-0,19; 0,02]; 0,1002
Nein	870	6 (0,7)	866	23 (2,7)	0,25 [0,10; 0,63]; 0,0030 0,26 [0,11; 0,63]; 0,0031 -0,02 [-0,03; -0,01]; 0,0014
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,6250)					
Positiv	173	1 (0,6)	176	9 (5,1)	0,11 [0,01; 0,86]; 0,0356 0,11 [0,01; 0,88]; 0,0376 -0,05 [-0,08; -0,01]; 0,0099
Negativ	200	1 (0,5)	191	4 (2,1)	0,23 [0,03; 2,12]; 0,1970 0,24 [0,03; 2,12]; 0,1983 -0,02 [-0,04; 0,01]; 0,1656
Bilaterale Oophorektomie (Interaktionstest: p=0,8321)					
Ja	189	1 (0,5)	176	5 (2,8)	0,18 [0,02; 1,57]; 0,1215 0,19 [0,02; 1,58]; 0,1232 -0,02 [-0,05; 0,00]; 0,0889
Nein	722	5 (0,7)	728	21 (2,9)	0,23 [0,09; 0,63]; 0,0038 0,24 [0,09; 0,63]; 0,0039 -0,02 [-0,04; -0,01]; 0,0016

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,9080)					
BRCA1	574	3 (0,5)	580	17 (2,9)	0,17 [0,05; 0,60]; 0,0054 0,18 [0,05; 0,61]; 0,0057 -0,02 [-0,04; -0,01]; 0,0016
BRCA2	232	1 (0,4)	215	6 (2,8)	0,15 [0,02; 1,26]; 0,0810 0,15 [0,02; 1,27]; 0,0826 -0,02 [-0,05; 0,00]; 0,0498
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	3 (0,8)	383	8 (2,1)	0,36 [0,10; 1,37]; 0,1351 0,37 [0,10; 1,37]; 0,1358 -0,01 [-0,03; 0,00]; 0,1208
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,9732)					
Andere	16	0 (0,0)	15	1 (6,7)	0,29 [0,01; 7,76]; 0,4628 0,31 [0,01; 7,15]; 0,4675 -0,07 [-0,23; 0,10]; 0,4252
Asiatisch	259	2 (0,8)	271	8 (3,0)	0,26 [0,05; 1,22]; 0,0866 0,26 [0,06; 1,22]; 0,0879 -0,02 [-0,04; 0,00]; 0,0609
Kaukasisch	617	4 (0,7)	589	17 (2,9)	0,22 [0,07; 0,66]; 0,0067 0,22 [0,08; 0,66]; 0,0069 -0,02 [-0,04; -0,01]; 0,0033
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,9099)					
Hispanisch	34	0 (0,0)	24	1 (4,2)	0,23 [0,01; 5,82]; 0,3703 0,24 [0,01; 5,61]; 0,3733 -0,04 [-0,14; 0,06]; 0,4190
Nicht-hispanisch	798	6 (0,8)	803	22 (2,7)	0,27 [0,11; 0,67]; 0,0046 0,27 [0,11; 0,67]; 0,0047 -0,02 [-0,03; -0,01]; 0,0023
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	3 (3,9)	0,13 [0,01; 2,64]; 0,1860 0,14 [0,01; 2,65]; 0,1898 -0,04 [-0,09; 0,01]; 0,1197
Hormonrezeptorstatus (Interaktionstest: p=0,9974)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	4 (2,6)	0,23 [0,02; 2,04]; 0,1857 0,23 [0,03; 2,04]; 0,1873 -0,02 [-0,05; 0,01]; 0,1576

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	5 (0,7)	749	22 (2,9)	0,22 [0,08; 0,60]; 0,0027 0,23 [0,09; 0,60]; 0,0028 -0,02 [-0,04; -0,01]; 0,0010
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7132)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	2 (2,2)	0,17 [0,01; 3,66]; 0,2598 0,18 [0,01; 3,64]; 0,2619 -0,02 [-0,06; 0,01]; 0,2289
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	2 (3,2)	0,48 [0,04; 5,48]; 0,5579 0,49 [0,05; 5,29]; 0,5586 -0,02 [-0,07; 0,04]; 0,5502
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	3 (0,9)	362	8 (2,2)	0,38 [0,10; 1,46]; 0,1609 0,39 [0,10; 1,46]; 0,1618 -0,01 [-0,03; 0,00]; 0,1420
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	2 (0,5)	387	14 (3,6)	0,14 [0,03; 0,60]; 0,0087 0,14 [0,03; 0,61]; 0,0092 -0,03 [-0,05; -0,01]; 0,0022
Menopausenstatus (Interaktionstest: p=0,6795)					
Postmenopausal	346	3 (0,9)	356	11 (3,1)	0,27 [0,08; 0,99]; 0,0486 0,28 [0,08; 1,00]; 0,0495 -0,02 [-0,04; 0,00]; 0,0332
Prämenopausal	563	3 (0,5)	544	15 (2,8)	0,19 [0,05; 0,66]; 0,0087 0,19 [0,06; 0,66]; 0,0090 -0,02 [-0,04; -0,01]; 0,0037
Region (Interaktionstest: p=0,9841)					
Asien-Pazifik und Südafrika	301	2 (0,7)	317	11 (3,5)	0,19 [0,04; 0,85]; 0,0296 0,19 [0,04; 0,86]; 0,0306 -0,03 [-0,05; -0,01]; 0,0130
Europa	473	3 (0,6)	444	10 (2,3)	0,28 [0,08; 1,01]; 0,0524 0,28 [0,08; 1,02]; 0,0530 -0,02 [-0,03; 0,00]; 0,0414
Nordamerika	121	1 (0,8)	131	4 (3,1)	0,26 [0,03; 2,40]; 0,2374 0,27 [0,03; 2,39]; 0,2394 -0,02 [-0,06; 0,01]; 0,1938
Südamerika	16	0 (0,0)	12	1 (8,3)	0,23 [0,01; 6,22]; 0,3843 0,25 [0,01; 5,76]; 0,3902 -0,08 [-0,27; 0,11]; 0,3933
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5920)					
Adjuvant	457	3 (0,7)	450	16 (3,6)	0,18 [0,05; 0,62]; 0,0066 0,18 [0,05; 0,63]; 0,0069 -0,03 [-0,05; -0,01]; 0,0023
Neoadjuvant	454	3 (0,7)	454	10 (2,2)	0,30 [0,08; 1,08]; 0,0653 0,30 [0,08; 1,08]; 0,0660 -0,02 [-0,03; 0,00]; 0,0500

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,7391)					
AZ	801	5 (0,6)	796	23 (2,9)	0,21 [0,08; 0,56]; 0,0017 0,22 [0,08; 0,57]; 0,0018 -0,02 [-0,04; -0,01]; 0,0006
NRG Oncology	110	1 (0,9)	108	3 (2,8)	0,32 [0,03; 3,14]; 0,3286 0,33 [0,03; 3,10]; 0,3300 -0,02 [-0,05; 0,02]; 0,3051
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7139)					
Ja	243	1 (0,4)	236	6 (2,5)	0,16 [0,02; 1,33]; 0,0892 0,16 [0,02; 1,33]; 0,0907 -0,02 [-0,04; 0,00]; 0,0536
Nein	668	5 (0,8)	668	20 (3,0)	0,24 [0,09; 0,65]; 0,0051 0,25 [0,09; 0,66]; 0,0053 -0,02 [-0,04; -0,01]; 0,0024
SOC: Herzerkrankungen					
Alter (Interaktionstest: p=0,5498)					
<50	690	29 (4,2)	663	18 (2,7)	1,57 [0,86; 2,86]; 0,1381 1,55 [0,87; 2,76]; 0,1386 0,01 [0,00; 0,03]; 0,1332
50-64	192	12 (6,3)	209	6 (2,9)	2,26 [0,83; 6,13]; 0,1110 2,18 [0,83; 5,69]; 0,1123 0,03 [-0,01; 0,07]; 0,1066
≥65	29	1 (3,5)	32	2 (6,3)	0,54 [0,05; 6,24]; 0,6183 0,55 [0,05; 5,77]; 0,6195 -0,03 [-0,13; 0,08]; 0,6077
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6713)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	39 (4,5)	840	23 (2,7)	1,69 [1,00; 2,85]; 0,0510 1,65 [1,00; 2,75]; 0,0514 0,02 [0,00; 0,04]; 0,0478
Taxan	43	3 (7,0)	50	3 (6,0)	1,18 [0,22; 6,15]; 0,8485 1,16 [0,25; 5,46]; 0,8485 0,01 [-0,09; 0,11]; 0,8492
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0050)					
Brusterhaltend	220	3 (1,4)	235	10 (4,3)	0,31 [0,08; 1,15]; 0,0791 0,32 [0,09; 1,15]; 0,0807 -0,03 [-0,06; 0,00]; 0,0590
Einseitige Mastektomie	355	16 (4,5)	352	2 (0,6)	8,26 [1,88; 36,19]; 0,0051 7,93 [1,84; 34,24]; 0,0055 0,04 [0,02; 0,06]; 0,0008

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	23 (6,9)	315	14 (4,4)	1,58 [0,80; 3,13]; 0,1894 1,54 [0,81; 2,94]; 0,1903 0,02 [-0,01; 0,06]; 0,1827
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3586)					
Ja	41	3 (7,3)	35	0 (0,0)	6,45 [0,32; 129,39]; 0,2228 6,00 [0,32; 112,32]; 0,2306 0,07 [-0,02; 0,17]; 0,1187
Nein	870	39 (4,5)	866	26 (3,0)	1,52 [0,91; 2,51]; 0,1065 1,49 [0,92; 2,43]; 0,1069 0,01 [0,00; 0,03]; 0,1038
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,2234)					
Positiv	173	2 (1,2)	176	6 (3,4)	0,33 [0,07; 1,67]; 0,1799 0,34 [0,07; 1,66]; 0,1815 -0,02 [-0,05; 0,01]; 0,1568
Negativ	200	7 (3,5)	191	6 (3,1)	1,12 [0,37; 3,39]; 0,8433 1,11 [0,38; 3,26]; 0,8434 0,00 [-0,03; 0,04]; 0,8431
Bilaterale Oophorektomie (Interaktionstest: p=0,1791)					
Ja	189	12 (6,4)	176	11 (6,3)	1,02 [0,44; 2,37]; 0,9689 1,02 [0,46; 2,24]; 0,9689 0,00 [-0,05; 0,05]; 0,9689
Nein	722	30 (4,2)	728	15 (2,1)	2,06 [1,10; 3,86]; 0,0242 2,02 [1,09; 3,72]; 0,0245 0,02 [0,00; 0,04]; 0,0214
BRCA-Mutationsstatus (Interaktionstest: p=0,4196)					
BRCA1	574	28 (4,9)	580	13 (2,2)	2,24 [1,15; 4,36]; 0,0182 2,18 [1,14; 4,16]; 0,0186 0,03 [0,01; 0,05]; 0,0155
BRCA2	232	12 (5,2)	215	8 (3,7)	1,41 [0,57; 3,52]; 0,4602 1,39 [0,58; 3,34]; 0,4607 0,01 [-0,02; 0,05]; 0,4554
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9263)					
2, 3 oder 4	392	26 (6,6)	383	9 (2,4)	2,95 [1,36; 6,39]; 0,0060 2,82 [1,34; 5,94]; 0,0063 0,04 [0,01; 0,07]; 0,0037
5 oder 6	22	2 (9,1)	14	0 (0,0)	3,54 [0,16; 79,29]; 0,4260 3,26 [0,17; 63,30]; 0,4347 0,09 [-0,07; 0,25]; 0,2543

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,2206)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	6 (2,3)	271	6 (2,2)	1,05 [0,33; 3,29]; 0,9368 1,05 [0,34; 3,20]; 0,9368 0,00 [-0,02; 0,03]; 0,9368
Kaukasisch	617	36 (5,8)	589	17 (2,9)	2,08 [1,16; 3,75]; 0,0144 2,02 [1,15; 3,56]; 0,0147 0,03 [0,01; 0,05]; 0,0117
Schwarz oder afroamerikanisch	19	0 (0,0)	29	3 (10,3)	0,19 [0,01; 3,98]; 0,2875 0,21 [0,01; 3,93]; 0,2993 -0,10 [-0,24; 0,03]; 0,1294
Ethnische Abstammung (Interaktionstest: p=0,8641)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	39 (4,9)	803	24 (3,0)	1,67 [0,99; 2,80]; 0,0530 1,64 [0,99; 2,69]; 0,0534 0,02 [0,00; 0,04]; 0,0507
Unbekannt, nicht erfasst, verweigert	79	2 (2,5)	77	2 (2,6)	0,97 [0,13; 7,09]; 0,9793 0,97 [0,14; 6,75]; 0,9793 0,00 [-0,05; 0,05]; 0,9793
Hormonrezeptorstatus (Interaktionstest: p=0,3634)					
ER- und/oder PgR-positiv, HER2-positiv	168	11 (6,5)	155	4 (2,6)	2,64 [0,82; 8,49]; 0,1021 2,54 [0,83; 7,80]; 0,1043 0,04 [-0,01; 0,08]; 0,0838
TNBC	741	31 (4,2)	749	22 (2,9)	1,44 [0,83; 2,52]; 0,1963 1,42 [0,83; 2,44]; 0,1966 0,01 [-0,01; 0,03]; 0,1942
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,0939)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	9 (8,7)	92	3 (3,3)	2,81 [0,74; 10,71]; 0,1302 2,65 [0,74; 9,51]; 0,1339 0,05 [-0,01; 0,12]; 0,1044
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	1 (1,6)	2,00 [0,18; 22,63]; 0,5755 1,97 [0,18; 21,17]; 0,5762 0,02 [-0,04; 0,07]; 0,5669
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	21 (6,0)	362	8 (2,2)	2,84 [1,24; 6,50]; 0,0134 2,73 [1,23; 6,08]; 0,0140 0,04 [0,01; 0,07]; 0,0104
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	10 (2,5)	387	14 (3,6)	0,70 [0,31; 1,59]; 0,3880 0,70 [0,32; 1,56]; 0,3882 -0,01 [-0,03; 0,01]; 0,3860

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,3450)					
Postmenopausal	346	22 (6,4)	356	17 (4,8)	1,35 [0,71; 2,60]; 0,3615 1,33 [0,72; 2,46]; 0,3618 0,02 [-0,02; 0,05]; 0,3606
Prämenopausal	563	20 (3,6)	544	9 (1,7)	2,19 [0,99; 4,85]; 0,0536 2,15 [0,99; 4,67]; 0,0542 0,02 [0,00; 0,04]; 0,0463
Region (Interaktionstest: p=0,6538)					
Asien-Pazifik und Südafrika	301	9 (3,0)	317	8 (2,5)	1,19 [0,45; 3,13]; 0,7234 1,18 [0,46; 3,03]; 0,7234 0,00 [-0,02; 0,03]; 0,7236
Europa	473	19 (4,0)	444	11 (2,5)	1,65 [0,77; 3,50]; 0,1945 1,62 [0,78; 3,37]; 0,1952 0,02 [-0,01; 0,04]; 0,1867
Nordamerika	121	14 (11,6)	131	7 (5,3)	2,32 [0,90; 5,95]; 0,0808 2,17 [0,90; 5,18]; 0,0828 0,06 [-0,01; 0,13]; 0,0760
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,0159)					
Adjuvant	457	12 (2,6)	450	15 (3,3)	0,78 [0,36; 1,69]; 0,5317 0,79 [0,37; 1,66]; 0,5318 -0,01 [-0,03; 0,02]; 0,5310
Neoadjuvant	454	30 (6,6)	454	11 (2,4)	2,85 [1,41; 5,76]; 0,0035 2,73 [1,38; 5,38]; 0,0038 0,04 [0,01; 0,07]; 0,0023
Sponsor (Interaktionstest: p=0,5806)					
AZ	801	28 (3,5)	796	19 (2,4)	1,48 [0,82; 2,67]; 0,1926 1,46 [0,82; 2,60]; 0,1929 0,01 [-0,01; 0,03]; 0,1894
NRG Oncology	110	14 (12,7)	108	7 (6,5)	2,10 [0,81; 5,44]; 0,1246 1,96 [0,82; 4,68]; 0,1274 0,06 [-0,02; 0,14]; 0,1151
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,0132)					
Ja	243	16 (6,6)	236	2 (0,9)	8,25 [1,87; 36,27]; 0,0052 7,77 [1,81; 33,42]; 0,0059 0,06 [0,02; 0,09]; 0,0007
Nein	668	26 (3,9)	668	24 (3,6)	1,09 [0,62; 1,91]; 0,7732 1,08 [0,63; 1,87]; 0,7732 0,00 [-0,02; 0,02]; 0,7731

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Palpitationen					
Alter (Interaktionstest: p=0,5615)					
<50	690	18 (2,6)	663	8 (1,2)	2,19 [0,95; 5,08]; 0,0668 2,16 [0,95; 4,94]; 0,0673 0,01 [0,00; 0,03]; 0,0582
50-64	192	6 (3,1)	209	3 (1,4)	2,22 [0,55; 8,98]; 0,2656 2,18 [0,55; 8,58]; 0,2664 0,02 [-0,01; 0,05]; 0,2604
≥65	29	0 (0,0)	32	1 (3,1)	0,36 [0,01; 9,09]; 0,5320 0,37 [0,02; 8,66]; 0,5340 -0,03 [-0,12; 0,05]; 0,4688
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6973)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	23 (2,7)	840	11 (1,3)	2,07 [1,00; 4,27]; 0,0494 2,04 [1,00; 4,16]; 0,0498 0,01 [0,00; 0,03]; 0,0437
Taxan	43	1 (2,3)	50	1 (2,0)	1,17 [0,07; 19,23]; 0,9141 1,16 [0,07; 18,04]; 0,9141 0,00 [-0,06; 0,06]; 0,9145
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0978)					
Brusterhaltend	220	3 (1,4)	235	5 (2,1)	0,64 [0,15; 2,69]; 0,5388 0,64 [0,15; 2,65]; 0,5391 -0,01 [-0,03; 0,02]; 0,5324
Einseitige Mastektomie	355	10 (2,8)	352	1 (0,3)	10,17 [1,30; 79,90]; 0,0274 9,92 [1,28; 77,05]; 0,0283 0,03 [0,01; 0,04]; 0,0061
Beidseitige Mastektomie	336	11 (3,3)	315	6 (1,9)	1,74 [0,64; 4,77]; 0,2794 1,72 [0,64; 4,59]; 0,2801 0,01 [-0,01; 0,04]; 0,2693
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,5873)					
Ja	41	2 (4,9)	35	0 (0,0)	4,49 [0,21; 96,80]; 0,3374 4,29 [0,21; 86,39]; 0,3423 0,05 [-0,03; 0,13]; 0,2386
Nein	870	22 (2,5)	866	12 (1,4)	1,85 [0,91; 3,75]; 0,0904 1,82 [0,91; 3,66]; 0,0908 0,01 [0,00; 0,02]; 0,0852

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,1517)					
Positiv	173	1 (0,6)	176	4 (2,3)	0,25 [0,03; 2,26]; 0,2171 0,25 [0,03; 2,25]; 0,2186 -0,02 [-0,04; 0,01]; 0,1795
Negativ	200	4 (2,0)	191	2 (1,1)	1,93 [0,35; 10,65]; 0,4513 1,91 [0,35; 10,31]; 0,4518 0,01 [-0,01; 0,03]; 0,4400
Bilaterale Oophorektomie (Interaktionstest: p=0,3572)					
Ja	189	5 (2,7)	176	4 (2,3)	1,17 [0,31; 4,42]; 0,8187 1,16 [0,32; 4,27]; 0,8187 0,00 [-0,03; 0,04]; 0,8180
Nein	722	19 (2,6)	728	8 (1,1)	2,43 [1,06; 5,59]; 0,0364 2,39 [1,06; 5,44]; 0,0368 0,02 [0,00; 0,03]; 0,0309
BRCA-Mutationsstatus (Interaktionstest: p=0,7353)					
BRCA1	574	17 (3,0)	580	7 (1,2)	2,50 [1,03; 6,07]; 0,0433 2,45 [1,03; 5,87]; 0,0438 0,02 [0,00; 0,03]; 0,0368
BRCA2	232	6 (2,6)	215	3 (1,4)	1,88 [0,46; 7,60]; 0,3779 1,85 [0,47; 7,32]; 0,3786 0,01 [-0,01; 0,04]; 0,3647
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9869)					
2, 3 oder 4	392	13 (3,3)	383	4 (1,0)	3,25 [1,05; 10,06]; 0,0409 3,18 [1,04; 9,65]; 0,0417 0,02 [0,00; 0,04]; 0,0294
5 oder 6	22	2 (9,1)	14	0 (0,0)	3,54 [0,16; 79,29]; 0,4260 3,26 [0,17; 63,30]; 0,4347 0,09 [-0,07; 0,25]; 0,2543
Ethnie (Interaktionstest: p=0,6246)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	4 (1,5)	271	3 (1,1)	1,40 [0,31; 6,32]; 0,6607 1,40 [0,32; 6,17]; 0,6608 0,00 [-0,02; 0,02]; 0,6604
Kaukasisch	617	20 (3,2)	589	9 (1,5)	2,16 [0,97; 4,78]; 0,0578 2,12 [0,97; 4,62]; 0,0583 0,02 [0,00; 0,03]; 0,0499
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,8023)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	23 (2,9)	803	12 (1,5)	1,96 [0,97; 3,96]; 0,0621 1,93 [0,97; 3,85]; 0,0625 0,01 [0,00; 0,03]; 0,0576
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	0 (0,0)	2,96 [0,12; 73,83]; 0,5081 2,92 [0,12; 70,72]; 0,5090 0,01 [-0,02; 0,05]; 0,4733
Hormonrezeptorstatus (Interaktionstest: p=0,4769)					
ER- und/oder PgR-positiv, HER2-positiv	168	7 (4,2)	155	2 (1,3)	3,33 [0,68; 16,26]; 0,1377 3,23 [0,68; 15,31]; 0,1399 0,03 [-0,01; 0,06]; 0,1078
TNBC	741	17 (2,3)	749	10 (1,3)	1,74 [0,79; 3,81]; 0,1703 1,72 [0,79; 3,73]; 0,1707 0,01 [0,00; 0,02]; 0,1655
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3467)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	5 (4,8)	92	1 (1,1)	4,60 [0,53; 40,08]; 0,1675 4,42 [0,53; 37,17]; 0,1710 0,04 [-0,01; 0,08]; 0,1149
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	1 (1,6)	2,00 [0,18; 22,63]; 0,5755 1,97 [0,18; 21,17]; 0,5762 0,02 [-0,04; 0,07]; 0,5669
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	12 (3,5)	362	4 (1,1)	3,20 [1,02; 10,01]; 0,0460 3,12 [1,02; 9,58]; 0,0468 0,02 [0,00; 0,05]; 0,0367
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	5 (1,3)	387	6 (1,6)	0,82 [0,25; 2,70]; 0,7423 0,82 [0,25; 2,67]; 0,7423 0,00 [-0,02; 0,01]; 0,7420
Menopausenstatus (Interaktionstest: p=0,5337)					
Postmenopausal	346	11 (3,2)	356	7 (2,0)	1,64 [0,63; 4,27]; 0,3139 1,62 [0,63; 4,12]; 0,3144 0,01 [-0,01; 0,04]; 0,3106
Prämenopausal	563	13 (2,3)	544	5 (0,9)	2,55 [0,90; 7,20]; 0,0774 2,51 [0,90; 7,00]; 0,0781 0,01 [0,00; 0,03]; 0,0652
Region (Interaktionstest: p=0,3635)					
Asien-Pazifik und Südafrika	301	7 (2,3)	317	5 (1,6)	1,49 [0,47; 4,73]; 0,5030 1,47 [0,47; 4,60]; 0,5032 0,01 [-0,01; 0,03]; 0,5023

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	10 (2,1)	444	6 (1,4)	1,58 [0,57; 4,37]; 0,3819 1,56 [0,57; 4,27]; 0,3822 0,01 [-0,01; 0,02]; 0,3745
Nordamerika	121	7 (5,8)	131	1 (0,8)	7,98 [0,97; 65,86]; 0,0537 7,58 [0,95; 60,70]; 0,0564 0,05 [0,01; 0,09]; 0,0259
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,0904)					
Adjuvant	457	7 (1,5)	450	7 (1,6)	0,98 [0,34; 2,83]; 0,9768 0,98 [0,35; 2,78]; 0,9768 0,00 [-0,02; 0,02]; 0,9768
Neoadjuvant	454	17 (3,7)	454	5 (1,1)	3,49 [1,28; 9,55]; 0,0148 3,40 [1,27; 9,14]; 0,0153 0,03 [0,01; 0,05]; 0,0093
Sponsor (Interaktionstest: p=0,1839)					
AZ	801	17 (2,1)	796	11 (1,4)	1,55 [0,72; 3,32]; 0,2632 1,54 [0,72; 3,26]; 0,2635 0,01 [-0,01; 0,02]; 0,2591
NRG Oncology	110	7 (6,4)	108	1 (0,9)	7,27 [0,88; 60,14]; 0,0657 6,87 [0,86; 54,92]; 0,0691 0,05 [0,01; 0,10]; 0,0298
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,1366)					
Ja	243	8 (3,3)	236	1 (0,4)	8,00 [0,99; 64,47]; 0,0508 7,77 [0,98; 61,64]; 0,0524 0,03 [0,00; 0,05]; 0,0187
Nein	668	16 (2,4)	668	11 (1,7)	1,47 [0,68; 3,18]; 0,3338 1,45 [0,68; 3,11]; 0,3340 0,01 [-0,01; 0,02]; 0,3308
Nasopharyngitis					
Alter (Interaktionstest: p=0,4752)					
<50	690	27 (3,9)	663	38 (5,7)	0,67 [0,40; 1,11]; 0,1200 0,68 [0,42; 1,11]; 0,1204 -0,02 [-0,04; 0,00]; 0,1189
50-64	192	4 (2,1)	209	12 (5,7)	0,35 [0,11; 1,10]; 0,0728 0,36 [0,12; 1,11]; 0,0746 -0,04 [-0,07; 0,00]; 0,0556
≥65	29	0 (0,0)	32	2 (6,3)	0,21 [0,01; 4,49]; 0,3156 0,22 [0,01; 4,40]; 0,3219 -0,06 [-0,16; 0,04]; 0,2263

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,7843)					
Anthrazyklin	7	0 (0,0)	13	1 (7,7)	0,56 [0,02; 15,46]; 0,7291 0,58 [0,03; 12,70]; 0,7316 -0,08 [-0,31; 0,16]; 0,5180
Anthrazyklin und Taxan	861	29 (3,4)	840	49 (5,8)	0,56 [0,35; 0,90]; 0,0163 0,58 [0,37; 0,90]; 0,0166 -0,02 [-0,04; 0,00]; 0,0152
Taxan	43	2 (4,7)	50	2 (4,0)	1,17 [0,16; 8,68]; 0,8775 1,16 [0,17; 7,91]; 0,8775 0,01 [-0,08; 0,09]; 0,8780
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,4131)					
Brusterhaltend	220	8 (3,6)	235	12 (5,1)	0,70 [0,28; 1,75]; 0,4467 0,71 [0,30; 1,71]; 0,4472 -0,01 [-0,05; 0,02]; 0,4419
Einseitige Mastektomie	355	16 (4,5)	352	22 (6,3)	0,71 [0,37; 1,37]; 0,3062 0,72 [0,39; 1,35]; 0,3067 -0,02 [-0,05; 0,02]; 0,3041
Beidseitige Mastektomie	336	7 (2,1)	315	18 (5,7)	0,35 [0,14; 0,85]; 0,0207 0,36 [0,15; 0,86]; 0,0214 -0,04 [-0,07; -0,01]; 0,0171
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7897)					
Ja	41	1 (2,4)	35	1 (2,9)	0,85 [0,05; 14,11]; 0,9097 0,85 [0,06; 13,15]; 0,9097 0,00 [-0,08; 0,07]; 0,9102
Nein	870	30 (3,5)	866	51 (5,9)	0,57 [0,36; 0,91]; 0,0171 0,59 [0,38; 0,91]; 0,0174 -0,02 [-0,04; 0,00]; 0,0158
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,1585)					
Positiv	173	9 (5,2)	176	6 (3,4)	1,55 [0,54; 4,47]; 0,4122 1,53 [0,55; 4,20]; 0,4128 0,02 [-0,02; 0,06]; 0,4092
Negativ	200	8 (4,0)	191	13 (6,8)	0,57 [0,23; 1,41]; 0,2237 0,59 [0,25; 1,39]; 0,2247 -0,03 [-0,07; 0,02]; 0,2203
Bilaterale Oophorektomie (Interaktionstest: p=0,3793)					
Ja	189	4 (2,1)	176	10 (5,7)	0,36 [0,11; 1,17]; 0,0883 0,37 [0,12; 1,17]; 0,0899 -0,04 [-0,08; 0,00]; 0,0798
Nein	722	27 (3,7)	728	42 (5,8)	0,63 [0,39; 1,04]; 0,0716 0,65 [0,40; 1,04]; 0,0720 -0,02 [-0,04; 0,00]; 0,0690

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,2570)					
BRCA1	574	21 (3,7)	580	33 (5,7)	0,63 [0,36; 1,10]; 0,1050 0,64 [0,38; 1,10]; 0,1056 -0,02 [-0,04; 0,00]; 0,1016
BRCA2	232	6 (2,6)	215	16 (7,4)	0,33 [0,13; 0,86]; 0,0233 0,35 [0,14; 0,87]; 0,0243 -0,05 [-0,09; -0,01]; 0,0191
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,8755)					
2, 3 oder 4	392	12 (3,1)	383	23 (6,0)	0,49 [0,24; 1,01]; 0,0526 0,51 [0,26; 1,01]; 0,0534 -0,03 [-0,06; 0,00]; 0,0487
5 oder 6	22	1 (4,6)	14	1 (7,1)	0,62 [0,04; 10,78]; 0,7421 0,64 [0,04; 9,37]; 0,7419 -0,03 [-0,19; 0,13]; 0,7512
Ethnie (Interaktionstest: p=0,5188)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	17 (6,6)	271	26 (9,6)	0,66 [0,35; 1,25]; 0,2040 0,68 [0,38; 1,23]; 0,2051 -0,03 [-0,08; 0,02]; 0,1991
Kaukasisch	617	14 (2,3)	589	26 (4,4)	0,50 [0,26; 0,97]; 0,0411 0,51 [0,27; 0,97]; 0,0415 -0,02 [-0,04; 0,00]; 0,0386
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,4231)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	29 (3,6)	803	47 (5,9)	0,61 [0,38; 0,97]; 0,0386 0,62 [0,39; 0,98]; 0,0389 -0,02 [-0,04; 0,00]; 0,0364
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	5 (6,5)	0,18 [0,02; 1,62]; 0,1272 0,19 [0,02; 1,63]; 0,1313 -0,05 [-0,11; 0,01]; 0,0893
Hormonrezeptorstatus (Interaktionstest: p=0,2742)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	7 (4,5)	0,25 [0,05; 1,25]; 0,0912 0,26 [0,06; 1,25]; 0,0931 -0,03 [-0,07; 0,00]; 0,0747

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	29 (3,9)	749	45 (6,0)	0,64 [0,39; 1,03]; 0,0647 0,65 [0,41; 1,03]; 0,0652 -0,02 [-0,04; 0,00]; 0,0622
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,4164)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	3 (3,3)	0,29 [0,03; 2,82]; 0,2848 0,29 [0,03; 2,79]; 0,2865 -0,02 [-0,06; 0,02]; 0,2700
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	4 (6,4)	0,23 [0,03; 2,16]; 0,1999 0,25 [0,03; 2,14]; 0,2040 -0,05 [-0,12; 0,02]; 0,1642
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	12 (3,5)	362	26 (7,2)	0,46 [0,23; 0,93]; 0,0305 0,48 [0,25; 0,94]; 0,0313 -0,04 [-0,07; 0,00]; 0,0256
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	17 (4,3)	387	19 (4,9)	0,88 [0,45; 1,71]; 0,6978 0,88 [0,47; 1,67]; 0,6978 -0,01 [-0,04; 0,02]; 0,6977
Menopausenstatus (Interaktionstest: p=0,0902)					
Postmenopausal	346	6 (1,7)	356	20 (5,6)	0,30 [0,12; 0,75]; 0,0100 0,31 [0,13; 0,76]; 0,0105 -0,04 [-0,07; -0,01]; 0,0058
Prämenopausal	563	25 (4,4)	544	32 (5,9)	0,74 [0,43; 1,27]; 0,2793 0,75 [0,45; 1,26]; 0,2796 -0,01 [-0,04; 0,01]; 0,2787
Region (Interaktionstest: p=0,6807)					
Asien-Pazifik und Südafrika	301	19 (6,3)	317	29 (9,2)	0,67 [0,37; 1,22]; 0,1903 0,69 [0,40; 1,20]; 0,1913 -0,03 [-0,07; 0,01]; 0,1854
Europa	473	12 (2,5)	444	21 (4,7)	0,52 [0,25; 1,08]; 0,0794 0,54 [0,27; 1,08]; 0,0800 -0,02 [-0,05; 0,00]; 0,0770
Nordamerika	121	0 (0,0)	131	2 (1,5)	0,21 [0,01; 4,49]; 0,3200 0,22 [0,01; 4,46]; 0,3215 -0,02 [-0,04; 0,01]; 0,2474
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,2276)					
Adjuvant	457	18 (3,9)	450	23 (5,1)	0,76 [0,41; 1,43]; 0,3967 0,77 [0,42; 1,41]; 0,3970 -0,01 [-0,04; 0,02]; 0,3957
Neoadjuvant	454	13 (2,9)	454	29 (6,4)	0,43 [0,22; 0,84]; 0,0137 0,45 [0,24; 0,85]; 0,0142 -0,04 [-0,06; -0,01]; 0,0112

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Sponsor (Interaktionstest: p=NC)					
AZ	801	31 (3,9)	796	52 (6,5)	0,58 [0,37; 0,91]; 0,0177 0,59 [0,38; 0,91]; 0,0180 -0,03 [-0,05; 0,00]; 0,0164
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,8178)					
Ja	243	8 (3,3)	236	12 (5,1)	0,64 [0,25; 1,58]; 0,3305 0,65 [0,27; 1,56]; 0,3310 -0,02 [-0,05; 0,02]; 0,3278
Nein	668	23 (3,4)	668	40 (6,0)	0,56 [0,33; 0,95]; 0,0302 0,58 [0,35; 0,95]; 0,0306 -0,03 [-0,05; 0,00]; 0,0279
Rhinitis					
Alter (Interaktionstest: p=0,5967)					
<50	690	12 (1,7)	663	4 (0,6)	2,92 [0,94; 9,09]; 0,0650 2,88 [0,93; 8,89]; 0,0655 0,01 [0,00; 0,02]; 0,0508
50-64	192	3 (1,6)	209	2 (1,0)	1,64 [0,27; 9,94]; 0,5888 1,63 [0,28; 9,67]; 0,5890 0,01 [-0,02; 0,03]; 0,5888
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	15 (1,7)	840	5 (0,6)	2,96 [1,07; 8,18]; 0,0364 2,93 [1,07; 8,02]; 0,0367 0,01 [0,00; 0,02]; 0,0271
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,1274)					
Brusterhaltend	220	4 (1,8)	235	5 (2,1)	0,85 [0,23; 3,21]; 0,8129 0,85 [0,23; 3,14]; 0,8129 0,00 [-0,03; 0,02]; 0,8122
Einseitige Mastektomie	355	10 (2,8)	352	0 (0,0)	21,43 [1,25; 367,05]; 0,0345 20,82 [1,22; 353,99]; 0,0357 0,03 [0,01; 0,05]; 0,0022

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	1 (0,3)	315	1 (0,3)	0,94 [0,06; 15,05]; 0,9635 0,94 [0,06; 14,92]; 0,9635 0,00 [-0,01; 0,01]; 0,9636
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,1667)					
Ja	41	0 (0,0)	35	1 (2,9)	0,28 [0,01; 7,02]; 0,4365 0,29 [0,01; 6,80]; 0,4385 -0,03 [-0,10; 0,04]; 0,4433
Nein	870	15 (1,7)	866	5 (0,6)	3,02 [1,09; 8,35]; 0,0330 2,99 [1,09; 8,18]; 0,0334 0,01 [0,00; 0,02]; 0,0248
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,0645)					
Positiv	173	5 (2,9)	176	0 (0,0)	11,52 [0,63; 209,98]; 0,0989 11,19 [0,62; 200,83]; 0,1012 0,03 [0,00; 0,06]; 0,0369
Negativ	200	2 (1,0)	191	4 (2,1)	0,47 [0,09; 2,61]; 0,3895 0,48 [0,09; 2,58]; 0,3901 -0,01 [-0,04; 0,01]; 0,3823
Bilaterale Oophorektomie (Interaktionstest: p=0,2737)					
Ja	189	4 (2,1)	176	3 (1,7)	1,25 [0,28; 5,65]; 0,7748 1,24 [0,28; 5,47]; 0,7748 0,00 [-0,02; 0,03]; 0,7735
Nein	722	11 (1,5)	728	3 (0,4)	3,74 [1,04; 13,46]; 0,0436 3,70 [1,04; 13,20]; 0,0440 0,01 [0,00; 0,02]; 0,0306
BRCA-Mutationsstatus (Interaktionstest: p=0,1825)					
BRCA1	574	9 (1,6)	580	6 (1,0)	1,52 [0,54; 4,31]; 0,4270 1,52 [0,54; 4,23]; 0,4272 0,01 [-0,01; 0,02]; 0,4241
BRCA2	232	6 (2,6)	215	0 (0,0)	12,37 [0,69; 220,89]; 0,0872 12,05 [0,68; 212,65]; 0,0892 0,03 [0,00; 0,05]; 0,0218
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	8 (2,0)	383	2 (0,5)	3,97 [0,84; 18,81]; 0,0825 3,91 [0,84; 18,29]; 0,0834 0,02 [0,00; 0,03]; 0,0588
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,8645)					
Andere	16	1 (6,3)	15	0 (0,0)	3,00 [0,11; 79,50]; 0,5111 2,82 [0,12; 64,39]; 0,5153 0,06 [-0,10; 0,22]; 0,4425
Asiatisch	259	2 (0,8)	271	0 (0,0)	5,27 [0,25; 110,34]; 0,2840 5,23 [0,25; 108,44]; 0,2848 0,01 [-0,01; 0,02]; 0,2410
Kaukasisch	617	11 (1,8)	589	6 (1,0)	1,76 [0,65; 4,80]; 0,2666 1,75 [0,65; 4,70]; 0,2670 0,01 [-0,01; 0,02]; 0,2573
Schwarz oder afroamerikanisch	19	1 (5,3)	29	0 (0,0)	4,78 [0,18; 123,74]; 0,3456 4,50 [0,19; 105,03]; 0,3494 0,05 [-0,07; 0,18]; 0,4062
Ethnische Abstammung (Interaktionstest: p=0,4785)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	14 (1,8)	803	5 (0,6)	2,85 [1,02; 7,95]; 0,0454 2,82 [1,02; 7,79]; 0,0458 0,01 [0,00; 0,02]; 0,0366
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	1 (1,3)	0,97 [0,06; 15,86]; 0,9854 0,97 [0,06; 15,31]; 0,9854 0,00 [-0,04; 0,03]; 0,9854
Hormonrezeptorstatus (Interaktionstest: p=0,9248)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	0 (0,0)	2,79 [0,11; 68,88]; 0,5315 2,77 [0,11; 67,48]; 0,5318 0,01 [-0,01; 0,02]; 0,4846
TNBC	741	14 (1,9)	749	6 (0,8)	2,38 [0,91; 6,24]; 0,0766 2,36 [0,91; 6,10]; 0,0770 0,01 [0,00; 0,02]; 0,0683
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7582)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	0 (0,0)	2,68 [0,11; 66,63]; 0,5474 2,66 [0,11; 64,44]; 0,5480 0,01 [-0,02; 0,04]; 0,4873
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	7 (2,0)	362	2 (0,6)	3,70 [0,76; 17,91]; 0,1046 3,64 [0,76; 17,41]; 0,1055 0,01 [0,00; 0,03]; 0,0851
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	7 (1,8)	387	4 (1,0)	1,74 [0,50; 5,98]; 0,3818 1,72 [0,51; 5,84]; 0,3821 0,01 [-0,01; 0,02]; 0,3748

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Menopausenstatus (Interaktionstest: p=0,1945)					
Postmenopausal	346	5 (1,5)	356	4 (1,1)	1,29 [0,34; 4,85]; 0,7058 1,29 [0,35; 4,75]; 0,7058 0,00 [-0,01; 0,02]; 0,7055
Prämenopausal	563	10 (1,8)	544	2 (0,4)	4,90 [1,07; 22,47]; 0,0408 4,83 [1,06; 21,95]; 0,0414 0,01 [0,00; 0,03]; 0,0218
Region (Interaktionstest: p=0,3539)					
Asien-Pazifik und Südafrika	301	2 (0,7)	317	2 (0,6)	1,05 [0,15; 7,53]; 0,9586 1,05 [0,15; 7,43]; 0,9586 0,00 [-0,01; 0,01]; 0,9586
Europa	473	13 (2,8)	444	4 (0,9)	3,11 [1,01; 9,61]; 0,0488 3,05 [1,00; 9,29]; 0,0495 0,02 [0,00; 0,04]; 0,0348
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4018)					
Adjuvant	457	7 (1,5)	450	4 (0,9)	1,73 [0,50; 5,97]; 0,3823 1,72 [0,51; 5,85]; 0,3826 0,01 [-0,01; 0,02]; 0,3753
Neoadjuvant	454	8 (1,8)	454	2 (0,4)	4,05 [0,86; 19,20]; 0,0777 4,00 [0,85; 18,73]; 0,0784 0,01 [0,00; 0,03]; 0,0559
Sponsor (Interaktionstest: p=NC)					
AZ	801	15 (1,9)	796	6 (0,8)	2,51 [0,97; 6,51]; 0,0578 2,48 [0,97; 6,37]; 0,0582 0,01 [0,00; 0,02]; 0,0491
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,8263)					
Ja	243	2 (0,8)	236	1 (0,4)	1,95 [0,18; 21,65]; 0,5865 1,94 [0,18; 21,28]; 0,5867 0,00 [-0,01; 0,02]; 0,5778
Nein	668	13 (1,9)	668	5 (0,7)	2,63 [0,93; 7,42]; 0,0674 2,60 [0,93; 7,25]; 0,0679 0,01 [0,00; 0,02]; 0,0573

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
SOC: Stoffwechsel- und Ernährungsstörungen					
Alter (Interaktionstest: p=0,5250)					
<50	690	110 (15,9)	663	56 (8,4)	2,06 [1,46; 2,89]; <0,0001 1,89 [1,39; 2,56]; <0,0001 0,07 [0,04; 0,11]; <0,0001
50-64	192	40 (20,8)	209	30 (14,4)	1,57 [0,93; 2,64]; 0,0893 1,45 [0,94; 2,23]; 0,0902 0,06 [-0,01; 0,14]; 0,0885
≥65	29	5 (17,2)	32	2 (6,3)	3,12 [0,56; 17,55]; 0,1956 2,76 [0,58; 13,14]; 0,2026 0,11 [-0,05; 0,27]; 0,1810
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,4872)					
Anthrazyklin	7	3 (42,9)	13	1 (7,7)	9,00 [0,72; 113,02]; 0,0888 5,57 [0,70; 44,08]; 0,1036 0,35 [-0,04; 0,75]; 0,0804
Anthrazyklin und Taxan	861	141 (16,4)	840	81 (9,6)	1,84 [1,37; 2,46]; <0,0001 1,70 [1,31; 2,19]; <0,0001 0,07 [0,04; 0,10]; <0,0001
Taxan	43	11 (25,6)	50	6 (12,0)	2,52 [0,84; 7,53]; 0,0976 2,13 [0,86; 5,28]; 0,1020 0,14 [-0,02; 0,29]; 0,0931
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0052)					
Brusterhaltend	220	38 (17,3)	235	23 (9,8)	1,92 [1,11; 3,35]; 0,0206 1,76 [1,09; 2,86]; 0,0214 0,07 [0,01; 0,14]; 0,0194
Einseitige Mastektomie	355	63 (17,8)	352	20 (5,7)	3,58 [2,11; 6,07]; <0,0001 3,12 [1,93; 5,05]; <0,0001 0,12 [0,07; 0,17]; <0,0001
Beidseitige Mastektomie	336	54 (16,1)	315	44 (14,0)	1,18 [0,77; 1,82]; 0,4536 1,15 [0,80; 1,66]; 0,4540 0,02 [-0,03; 0,08]; 0,4523
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,4749)					
Ja	41	7 (17,1)	35	2 (5,7)	3,40 [0,66; 17,56]; 0,1446 2,99 [0,66; 13,46]; 0,1541 0,11 [-0,02; 0,25]; 0,1079
Nein	870	148 (17,0)	866	86 (9,9)	1,86 [1,40; 2,47]; <0,0001 1,71 [1,34; 2,20]; <0,0001 0,07 [0,04; 0,10]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8493)					
Positiv	173	29 (16,8)	176	15 (8,5)	2,16 [1,11; 4,19]; 0,0226 1,97 [1,09; 3,54]; 0,0239 0,08 [0,01; 0,15]; 0,0197
Negativ	200	40 (20,0)	191	18 (9,4)	2,40 [1,32; 4,36]; 0,0040 2,12 [1,26; 3,57]; 0,0045 0,11 [0,04; 0,17]; 0,0027
Bilaterale Oophorektomie (Interaktionstest: p=0,3518)					
Ja	189	30 (15,9)	176	20 (11,4)	1,47 [0,80; 2,70]; 0,2124 1,40 [0,82; 2,37]; 0,2141 0,05 [-0,02; 0,12]; 0,2073
Nein	722	125 (17,3)	728	68 (9,3)	2,03 [1,48; 2,79]; <0,0001 1,85 [1,41; 2,44]; <0,0001 0,08 [0,04; 0,11]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,2267)					
BRCA1	574	95 (16,6)	580	51 (8,8)	2,06 [1,43; 2,95]; <0,0001 1,88 [1,37; 2,59]; 0,0001 0,08 [0,04; 0,12]; <0,0001
BRCA2	232	34 (14,7)	215	24 (11,2)	1,37 [0,78; 2,39]; 0,2736 1,31 [0,81; 2,14]; 0,2748 0,03 [-0,03; 0,10]; 0,2695
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,4083)					
2, 3 oder 4	392	56 (14,3)	383	41 (10,7)	1,39 [0,90; 2,14]; 0,1332 1,33 [0,91; 1,95]; 0,1340 0,04 [-0,01; 0,08]; 0,1309
5 oder 6	22	3 (13,6)	14	0 (0,0)	5,21 [0,25; 108,83]; 0,2875 4,57 [0,25; 82,22]; 0,3033 0,14 [-0,04; 0,31]; 0,1216
Ethnie (Interaktionstest: p=0,4420)					
Andere	16	2 (12,5)	15	1 (6,7)	2,00 [0,16; 24,66]; 0,5887 1,88 [0,19; 18,60]; 0,5913 0,06 [-0,15; 0,26]; 0,5778
Asiatisch	259	61 (23,6)	271	28 (10,3)	2,67 [1,65; 4,34]; <0,0001 2,28 [1,51; 3,45]; <0,0001 0,13 [0,07; 0,20]; <0,0001
Kaukasisch	617	86 (13,9)	589	51 (8,7)	1,71 [1,18; 2,46]; 0,0042 1,61 [1,16; 2,23]; 0,0044 0,05 [0,02; 0,09]; 0,0036
Schwarz oder afroamerikanisch	19	6 (31,6)	29	8 (27,6)	1,21 [0,34; 4,29]; 0,7661 1,14 [0,47; 2,78]; 0,7650 0,04 [-0,22; 0,30]; 0,7676

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,3344)					
Hispanisch	34	3 (8,8)	24	3 (12,5)	0,68 [0,12; 3,68]; 0,6522 0,71 [0,16; 3,20]; 0,6518 -0,04 [-0,20; 0,13]; 0,6586
Nicht-hispanisch	798	138 (17,3)	803	80 (10,0)	1,89 [1,41; 2,54]; <0,0001 1,74 [1,34; 2,25]; <0,0001 0,07 [0,04; 0,11]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	14 (17,7)	77	5 (6,5)	3,10 [1,06; 9,09]; 0,0390 2,73 [1,03; 7,21]; 0,0429 0,11 [0,01; 0,21]; 0,0287
Hormonrezeptorstatus (Interaktionstest: p=0,3105)					
ER- und/oder PgR-positiv, HER2-positiv	168	28 (16,7)	155	19 (12,3)	1,43 [0,76; 2,68]; 0,2632 1,36 [0,79; 2,33]; 0,2649 0,04 [-0,03; 0,12]; 0,2582
TNBC	741	127 (17,1)	749	69 (9,2)	2,04 [1,49; 2,79]; <0,0001 1,86 [1,41; 2,45]; <0,0001 0,08 [0,05; 0,11]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3124)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	14 (13,5)	92	13 (14,1)	0,95 [0,42; 2,13]; 0,8921 0,95 [0,47; 1,92]; 0,8921 -0,01 [-0,10; 0,09]; 0,8923
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	14 (21,9)	63	6 (9,5)	2,66 [0,95; 7,44]; 0,0624 2,30 [0,94; 5,60]; 0,0673 0,12 [0,00; 0,25]; 0,0519
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	52 (14,9)	362	31 (8,6)	1,88 [1,17; 3,01]; 0,0089 1,74 [1,15; 2,65]; 0,0093 0,06 [0,02; 0,11]; 0,0082
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	75 (19,1)	387	38 (9,8)	2,17 [1,42; 3,29]; 0,0003 1,94 [1,35; 2,80]; 0,0003 0,09 [0,04; 0,14]; 0,0002
Menopausenstatus (Interaktionstest: p=0,2013)					
Postmenopausal	346	59 (17,1)	356	42 (11,8)	1,54 [1,00; 2,36]; 0,0484 1,45 [1,00; 2,09]; 0,0491 0,05 [0,00; 0,10]; 0,0472
Prämenopausal	563	95 (16,9)	544	46 (8,5)	2,20 [1,51; 3,19]; <0,0001 2,00 [1,43; 2,78]; <0,0001 0,08 [0,05; 0,12]; <0,0001
Region (Interaktionstest: p=0,1923)					
Asien-Pazifik und Südafrika	301	63 (20,9)	317	29 (9,2)	2,63 [1,64; 4,22]; <0,0001 2,29 [1,52; 3,45]; <0,0001 0,12 [0,06; 0,17]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	58 (12,3)	444	31 (7,0)	1,86 [1,18; 2,94]; 0,0077 1,76 [1,16; 2,66]; 0,0080 0,05 [0,01; 0,09]; 0,0063
Nordamerika	121	34 (28,1)	131	28 (21,4)	1,44 [0,81; 2,56]; 0,2167 1,31 [0,85; 2,03]; 0,2176 0,07 [-0,04; 0,17]; 0,2158
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,2587)					
Adjuvant	457	89 (19,5)	450	44 (9,8)	2,23 [1,51; 3,29]; <0,0001 1,99 [1,42; 2,79]; <0,0001 0,10 [0,05; 0,14]; <0,0001
Neoadjuvant	454	66 (14,5)	454	44 (9,7)	1,59 [1,06; 2,38]; 0,0261 1,50 [1,05; 2,15]; 0,0267 0,05 [0,01; 0,09]; 0,0249
Sponsor (Interaktionstest: p=0,1318)					
AZ	801	124 (15,5)	796	64 (8,0)	2,09 [1,52; 2,88]; <0,0001 1,93 [1,45; 2,56]; <0,0001 0,07 [0,04; 0,11]; <0,0001
NRG Oncology	110	31 (28,2)	108	24 (22,2)	1,37 [0,74; 2,54]; 0,3120 1,27 [0,80; 2,01]; 0,3135 0,06 [-0,06; 0,17]; 0,3096
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7562)					
Ja	243	37 (15,2)	236	22 (9,3)	1,75 [1,00; 3,06]; 0,0514 1,63 [0,99; 2,68]; 0,0527 0,06 [0,00; 0,12]; 0,0477
Nein	668	118 (17,7)	668	66 (9,9)	1,96 [1,42; 2,70]; <0,0001 1,79 [1,35; 2,37]; <0,0001 0,08 [0,04; 0,11]; <0,0001
Appetit vermindert					
Alter (Interaktionstest: p=0,2059)					
<50	690	83 (12,0)	663	32 (4,8)	2,70 [1,77; 4,12]; <0,0001 2,49 [1,68; 3,69]; <0,0001 0,07 [0,04; 0,10]; <0,0001
50-64	192	31 (16,2)	209	21 (10,1)	1,72 [0,95; 3,12]; 0,0717 1,61 [0,96; 2,70]; 0,0728 0,06 [-0,01; 0,13]; 0,0706
≥65	29	5 (17,2)	32	0 (0,0)	14,59 [0,77; 276,62]; 0,0742 12,10 [0,70; 209,71]; 0,0867 0,17 [0,03; 0,32]; 0,0194

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6873)					
Anthrazyklin	7	2 (28,6)	13	1 (7,7)	4,80 [0,35; 65,76]; 0,2401 3,71 [0,40; 34,12]; 0,2462 0,21 [-0,16; 0,57]; 0,2618
Anthrazyklin und Taxan	861	108 (12,5)	840	49 (5,8)	2,32 [1,63; 3,29]; <0,0001 2,15 [1,56; 2,97]; <0,0001 0,07 [0,04; 0,09]; <0,0001
Taxan	43	9 (20,9)	50	3 (6,0)	4,15 [1,04; 16,47]; 0,0432 3,49 [1,01; 12,07]; 0,0485 0,15 [0,01; 0,29]; 0,0343
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0051)					
Brusterhaltend	220	36 (16,4)	235	15 (6,4)	2,87 [1,52; 5,41]; 0,0011 2,56 [1,44; 4,55]; 0,0013 0,10 [0,04; 0,16]; 0,0007
Einseitige Mastektomie	355	47 (13,2)	352	10 (2,8)	5,22 [2,59; 10,51]; <0,0001 4,66 [2,39; 9,07]; <0,0001 0,10 [0,06; 0,14]; <0,0001
Beidseitige Mastektomie	336	36 (10,7)	315	27 (8,6)	1,28 [0,76; 2,16]; 0,3563 1,25 [0,78; 2,01]; 0,3569 0,02 [-0,02; 0,07]; 0,3535
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7477)					
Ja	41	4 (9,8)	35	2 (5,7)	1,78 [0,31; 10,38]; 0,5195 1,71 [0,33; 8,77]; 0,5217 0,04 [-0,08; 0,16]; 0,5056
Nein	870	115 (13,2)	866	51 (5,9)	2,43 [1,73; 3,43]; <0,0001 2,24 [1,64; 3,08]; <0,0001 0,07 [0,05; 0,10]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,9537)					
Positiv	173	22 (12,7)	176	6 (3,4)	4,13 [1,63; 10,45]; 0,0028 3,73 [1,55; 8,97]; 0,0033 0,09 [0,04; 0,15]; 0,0012
Negativ	200	34 (17,0)	191	9 (4,7)	4,14 [1,93; 8,89]; 0,0003 3,61 [1,78; 7,32]; 0,0004 0,12 [0,06; 0,18]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,7512)					
Ja	189	24 (12,7)	176	9 (5,1)	2,70 [1,22; 5,98]; 0,0145 2,48 [1,19; 5,19]; 0,0157 0,08 [0,02; 0,13]; 0,0098
Nein	722	95 (13,2)	728	44 (6,0)	2,36 [1,62; 3,42]; <0,0001 2,18 [1,55; 3,07]; <0,0001 0,07 [0,04; 0,10]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,3503)					
BRCA1	574	74 (12,9)	580	33 (5,7)	2,45 [1,60; 3,76]; <0,0001 2,27 [1,53; 3,36]; <0,0001 0,07 [0,04; 0,11]; <0,0001
BRCA2	232	24 (10,3)	215	14 (6,5)	1,66 [0,83; 3,29]; 0,1499 1,59 [0,84; 2,99]; 0,1514 0,04 [-0,01; 0,09]; 0,1424
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,4467)					
2, 3 oder 4	392	42 (10,7)	383	28 (7,3)	1,52 [0,92; 2,51]; 0,1003 1,47 [0,93; 2,31]; 0,1011 0,03 [-0,01; 0,07]; 0,0971
5 oder 6	22	3 (13,6)	14	0 (0,0)	5,21 [0,25; 108,83]; 0,2875 4,57 [0,25; 82,22]; 0,3033 0,14 [-0,04; 0,31]; 0,1216
Ethnie (Interaktionstest: p=0,2969)					
Andere	16	2 (12,5)	15	0 (0,0)	5,34 [0,24; 121,00]; 0,2923 4,71 [0,24; 90,69]; 0,3049 0,12 [-0,06; 0,31]; 0,1942
Asiatisch	259	50 (19,3)	271	16 (5,9)	3,81 [2,11; 6,89]; <0,0001 3,27 [1,91; 5,59]; <0,0001 0,13 [0,08; 0,19]; <0,0001
Kaukasisch	617	62 (10,1)	589	34 (5,8)	1,82 [1,18; 2,82]; 0,0067 1,74 [1,16; 2,60]; 0,0070 0,04 [0,01; 0,07]; 0,0057
Schwarz oder afroamerikanisch	19	5 (26,3)	29	3 (10,3)	3,10 [0,64; 14,91]; 0,1589 2,54 [0,69; 9,42]; 0,1622 0,16 [-0,07; 0,39]; 0,1677
Ethnische Abstammung (Interaktionstest: p=0,4349)					
Hispanisch	34	2 (5,9)	24	2 (8,3)	0,69 [0,09; 5,25]; 0,7180 0,71 [0,11; 4,67]; 0,7178 -0,02 [-0,16; 0,11]; 0,7238
Nicht-hispanisch	798	105 (13,2)	803	47 (5,9)	2,44 [1,70; 3,49]; <0,0001 2,25 [1,62; 3,13]; <0,0001 0,07 [0,04; 0,10]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	12 (15,2)	77	4 (5,2)	3,27 [1,01; 10,63]; 0,0490 2,92 [0,99; 8,67]; 0,0531 0,10 [0,01; 0,19]; 0,0359
Hormonrezeptorstatus (Interaktionstest: p=0,4619)					
ER- und/oder PgR-positiv, HER2-positiv	168	21 (12,5)	155	11 (7,1)	1,87 [0,87; 4,02]; 0,1087 1,76 [0,88; 3,53]; 0,1109 0,05 [-0,01; 0,12]; 0,0996

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	98 (13,2)	749	42 (5,6)	2,57 [1,76; 3,74]; <0,0001 2,36 [1,67; 3,34]; <0,0001 0,08 [0,05; 0,11]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,4292)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	10 (9,6)	92	6 (6,5)	1,52 [0,53; 4,37]; 0,4325 1,47 [0,56; 3,90]; 0,4340 0,03 [-0,04; 0,11]; 0,4242
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	11 (17,2)	63	5 (7,9)	2,41 [0,78; 7,38]; 0,1244 2,17 [0,80; 5,88]; 0,1292 0,09 [-0,02; 0,21]; 0,1118
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	40 (11,5)	362	23 (6,4)	1,91 [1,12; 3,27]; 0,0175 1,81 [1,11; 2,96]; 0,0180 0,05 [0,01; 0,09]; 0,0161
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	58 (14,8)	387	19 (4,9)	3,35 [1,96; 5,75]; <0,0001 3,01 [1,83; 4,95]; <0,0001 0,10 [0,06; 0,14]; <0,0001
Menopausenstatus (Interaktionstest: p=0,7942)					
Postmenopausal	346	50 (14,5)	356	22 (6,2)	2,56 [1,52; 4,34]; 0,0004 2,34 [1,45; 3,78]; 0,0005 0,08 [0,04; 0,13]; 0,0003
Prämenopausal	563	69 (12,3)	544	31 (5,7)	2,31 [1,49; 3,59]; 0,0002 2,15 [1,43; 3,23]; 0,0002 0,07 [0,03; 0,10]; 0,0001
Region (Interaktionstest: p=0,0489)					
Asien-Pazifik und Südafrika	301	52 (17,3)	317	15 (4,7)	4,20 [2,31; 7,65]; <0,0001 3,65 [2,10; 6,34]; <0,0001 0,13 [0,08; 0,17]; <0,0001
Europa	473	46 (9,7)	444	21 (4,7)	2,17 [1,27; 3,70]; 0,0044 2,06 [1,25; 3,39]; 0,0047 0,05 [0,02; 0,08]; 0,0032
Nordamerika	121	21 (17,4)	131	17 (13,0)	1,41 [0,70; 2,82]; 0,3333 1,34 [0,74; 2,41]; 0,3340 0,04 [-0,04; 0,13]; 0,3332
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,1202)					
Adjuvant	457	69 (15,1)	450	24 (5,3)	3,16 [1,94; 5,12]; <0,0001 2,83 [1,81; 4,42]; <0,0001 0,10 [0,06; 0,14]; <0,0001
Neoadjuvant	454	50 (11,0)	454	29 (6,4)	1,81 [1,13; 2,92]; 0,0145 1,72 [1,11; 2,67]; 0,0149 0,05 [0,01; 0,08]; 0,0131

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,1093)					
AZ	801	101 (12,6)	796	40 (5,0)	2,73 [1,86; 3,99]; <0,0001 2,51 [1,76; 3,57]; <0,0001 0,08 [0,05; 0,10]; <0,0001
NRG Oncology	110	18 (16,4)	108	13 (12,0)	1,43 [0,66; 3,08]; 0,3621 1,36 [0,70; 2,64]; 0,3634 0,04 [-0,05; 0,14]; 0,3590
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,5410)					
Ja	243	25 (10,3)	236	13 (5,5)	1,97 [0,98; 3,94]; 0,0566 1,87 [0,98; 3,56]; 0,0580 0,05 [0,00; 0,10]; 0,0511
Nein	668	94 (14,1)	668	40 (6,0)	2,57 [1,75; 3,79]; <0,0001 2,35 [1,65; 3,35]; <0,0001 0,08 [0,05; 0,11]; <0,0001
SOC: Untersuchungen					
Alter (Interaktionstest: p=0,1239)					
<50	690	216 (31,3)	663	136 (20,5)	1,77 [1,38; 2,26]; <0,0001 1,53 [1,27; 1,84]; <0,0001 0,11 [0,06; 0,15]; <0,0001
50-64	192	58 (30,2)	209	47 (22,5)	1,49 [0,95; 2,33]; 0,0798 1,34 [0,96; 1,87]; 0,0806 0,08 [-0,01; 0,16]; 0,0790
≥65	29	11 (37,9)	32	2 (6,3)	9,17 [1,82; 46,13]; 0,0072 6,07 [1,47; 25,12]; 0,0128 0,32 [0,12; 0,51]; 0,0015
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,5444)					
Anthrazyklin	7	3 (42,9)	13	2 (15,4)	4,12 [0,49; 34,50]; 0,1910 2,79 [0,60; 12,93]; 0,1909 0,27 [-0,14; 0,69]; 0,1953
Anthrazyklin und Taxan	861	270 (31,4)	840	170 (20,2)	1,80 [1,44; 2,25]; <0,0001 1,55 [1,31; 1,83]; <0,0001 0,11 [0,07; 0,15]; <0,0001
Taxan	43	12 (27,9)	50	12 (24,0)	1,23 [0,48; 3,11]; 0,6679 1,16 [0,58; 2,31]; 0,6677 0,04 [-0,14; 0,22]; 0,6685
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,5471)					
Brusterhaltend	220	68 (30,9)	235	41 (17,5)	2,12 [1,36; 3,29]; 0,0009 1,77 [1,26; 2,49]; 0,0010 0,13 [0,06; 0,21]; 0,0007
Einseitige Mastektomie	355	125 (35,2)	352	88 (25,0)	1,63 [1,18; 2,26]; 0,0032 1,41 [1,12; 1,77]; 0,0034 0,10 [0,03; 0,17]; 0,0029

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	92 (27,4)	315	56 (17,8)	1,74 [1,20; 2,54]; 0,0037 1,54 [1,15; 2,07]; 0,0040 0,10 [0,03; 0,16]; 0,0031
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7594)					
Ja	41	6 (14,6)	35	4 (11,4)	1,33 [0,34; 5,15]; 0,6810 1,28 [0,39; 4,18]; 0,6818 0,03 [-0,12; 0,18]; 0,6774
Nein	870	279 (32,1)	866	180 (20,8)	1,80 [1,45; 2,24]; <0,0001 1,54 [1,31; 1,81]; <0,0001 0,11 [0,07; 0,15]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,7114)					
Positiv	173	70 (40,5)	176	52 (29,6)	1,62 [1,04; 2,53]; 0,0330 1,37 [1,02; 1,83]; 0,0342 0,11 [0,01; 0,21]; 0,0315
Negativ	200	70 (35,0)	191	45 (23,6)	1,75 [1,12; 2,72]; 0,0135 1,49 [1,08; 2,04]; 0,0146 0,11 [0,03; 0,20]; 0,0121
Bilaterale Oophorektomie (Interaktionstest: p=0,0087)					
Ja	189	50 (26,5)	176	46 (26,1)	1,02 [0,64; 1,62]; 0,9449 1,01 [0,72; 1,43]; 0,9449 0,00 [-0,09; 0,09]; 0,9449
Nein	722	235 (32,6)	728	139 (19,1)	2,04 [1,61; 2,60]; <0,0001 1,70 [1,42; 2,05]; <0,0001 0,13 [0,09; 0,18]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,3090)					
BRCA1	574	168 (29,3)	580	101 (17,4)	1,96 [1,48; 2,60]; <0,0001 1,68 [1,35; 2,09]; <0,0001 0,12 [0,07; 0,17]; <0,0001
BRCA2	232	60 (25,9)	215	41 (19,1)	1,48 [0,94; 2,32]; 0,0872 1,36 [0,95; 1,93]; 0,0890 0,07 [-0,01; 0,14]; 0,0839
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,4318)					
2, 3 oder 4	392	100 (25,5)	383	60 (15,7)	1,84 [1,29; 2,63]; 0,0008 1,63 [1,22; 2,17]; 0,0009 0,10 [0,04; 0,15]; 0,0006
5 oder 6	22	9 (40,9)	14	2 (14,3)	4,15 [0,74; 23,23]; 0,1049 2,86 [0,72; 11,36]; 0,1345 0,27 [-0,01; 0,54]; 0,0581

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,2539)					
Andere	16	1 (6,3)	15	3 (20,0)	0,27 [0,02; 2,90]; 0,2778 0,31 [0,04; 2,68]; 0,2892 -0,14 [-0,37; 0,10]; 0,2507
Asiatisch	259	136 (52,5)	271	88 (32,5)	2,30 [1,62; 3,27]; <0,0001 1,62 [1,31; 1,99]; <0,0001 0,20 [0,12; 0,28]; <0,0001
Kaukasisch	617	144 (23,3)	589	86 (14,6)	1,78 [1,33; 2,39]; 0,0001 1,60 [1,25; 2,04]; 0,0001 0,09 [0,04; 0,13]; <0,0001
Schwarz oder afroamerikanisch	19	4 (21,1)	29	8 (27,6)	0,70 [0,18; 2,76]; 0,6101 0,76 [0,27; 2,18]; 0,6144 -0,07 [-0,31; 0,18]; 0,6013
Ethnische Abstammung (Interaktionstest: p=0,9616)					
Hispanisch	34	8 (23,5)	24	4 (16,7)	1,54 [0,41; 5,84]; 0,5269 1,41 [0,48; 4,16]; 0,5316 0,07 [-0,14; 0,27]; 0,5144
Nicht-hispanisch	798	261 (32,7)	803	170 (21,2)	1,81 [1,45; 2,27]; <0,0001 1,54 [1,31; 1,82]; <0,0001 0,12 [0,07; 0,16]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	16 (20,3)	77	11 (14,3)	1,52 [0,66; 3,54]; 0,3267 1,42 [0,70; 2,86]; 0,3288 0,06 [-0,06; 0,18]; 0,3223
Hormonrezeptorstatus (Interaktionstest: p=0,4866)					
ER- und/oder PgR-positiv, HER2-positiv	168	50 (29,8)	155	34 (21,9)	1,51 [0,91; 2,50]; 0,1102 1,36 [0,93; 1,98]; 0,1127 0,08 [-0,02; 0,17]; 0,1064
TNBC	741	235 (31,7)	749	151 (20,2)	1,84 [1,45; 2,33]; <0,0001 1,57 [1,32; 1,88]; <0,0001 0,12 [0,07; 0,16]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6408)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	31 (29,8)	92	22 (23,9)	1,35 [0,71; 2,56]; 0,3546 1,25 [0,78; 1,99]; 0,3570 0,06 [-0,06; 0,18]; 0,3507
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	19 (29,7)	63	12 (19,1)	1,79 [0,79; 4,10]; 0,1655 1,56 [0,83; 2,94]; 0,1697 0,11 [-0,04; 0,25]; 0,1591
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	88 (25,3)	362	52 (14,4)	2,02 [1,38; 2,95]; 0,0003 1,76 [1,29; 2,40]; 0,0003 0,11 [0,05; 0,17]; 0,0002
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	147 (37,4)	387	99 (25,6)	1,74 [1,28; 2,36]; 0,0004 1,46 [1,18; 1,81]; 0,0005 0,12 [0,05; 0,18]; 0,0003

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,1825)					
Postmenopausal	346	99 (28,6)	356	76 (21,4)	1,48 [1,05; 2,08]; 0,0265 1,34 [1,03; 1,74]; 0,0271 0,07 [0,01; 0,14]; 0,0258
Prämenopausal	563	186 (33,0)	544	107 (19,7)	2,01 [1,53; 2,65]; <0,0001 1,68 [1,37; 2,07]; <0,0001 0,13 [0,08; 0,18]; <0,0001
Region (Interaktionstest: p=0,7063)					
Asien-Pazifik und Südafrika	301	139 (46,2)	317	95 (30,0)	2,01 [1,44; 2,79]; <0,0001 1,54 [1,25; 1,90]; <0,0001 0,16 [0,09; 0,24]; <0,0001
Europa	473	100 (21,1)	444	56 (12,6)	1,86 [1,30; 2,65]; 0,0007 1,68 [1,24; 2,26]; 0,0008 0,09 [0,04; 0,13]; 0,0005
Nordamerika	121	43 (35,5)	131	34 (26,0)	1,57 [0,92; 2,70]; 0,1000 1,37 [0,94; 1,99]; 0,1013 0,10 [-0,02; 0,21]; 0,0983
Südamerika	16	3 (18,8)	12	0 (0,0)	6,48 [0,30; 138,43]; 0,2315 5,35 [0,30; 94,77]; 0,2526 0,19 [-0,03; 0,41]; 0,0930
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5997)					
Adjuvant	457	166 (36,3)	450	111 (24,7)	1,74 [1,31; 2,32]; 0,0001 1,47 [1,20; 1,80]; 0,0002 0,12 [0,06; 0,18]; 0,0001
Neoadjuvant	454	119 (26,2)	454	74 (16,3)	1,82 [1,32; 2,53]; 0,0003 1,61 [1,24; 2,08]; 0,0003 0,10 [0,05; 0,15]; 0,0002
Sponsor (Interaktionstest: p=0,3383)					
AZ	801	243 (30,3)	796	153 (19,2)	1,83 [1,45; 2,31]; <0,0001 1,58 [1,32; 1,88]; <0,0001 0,11 [0,07; 0,15]; <0,0001
NRG Oncology	110	42 (38,2)	108	32 (29,6)	1,47 [0,83; 2,58]; 0,1833 1,29 [0,89; 1,88]; 0,1857 0,09 [-0,04; 0,21]; 0,1804
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4057)					
Ja	243	58 (23,9)	236	42 (17,8)	1,45 [0,93; 2,26]; 0,1031 1,34 [0,94; 1,91]; 0,1045 0,06 [-0,01; 0,13]; 0,1006
Nein	668	227 (34,0)	668	143 (21,4)	1,89 [1,48; 2,41]; <0,0001 1,59 [1,33; 1,90]; <0,0001 0,13 [0,08; 0,17]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Alaninaminotransferase erhöht					
Alter (Interaktionstest: p=0,5466)					
<50	690	17 (2,5)	663	30 (4,5)	0,53 [0,29; 0,98]; 0,0414 0,54 [0,30; 0,98]; 0,0418 -0,02 [-0,04; 0,00]; 0,0393
50-64	192	6 (3,1)	209	11 (5,3)	0,58 [0,21; 1,60]; 0,2937 0,59 [0,22; 1,57]; 0,2948 -0,02 [-0,06; 0,02]; 0,2828
≥65	29	1 (3,5)	32	0 (0,0)	3,42 [0,13; 87,34]; 0,4568 3,30 [0,14; 77,95]; 0,4593 0,03 [-0,05; 0,12]; 0,4447
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6574)					
Anthrazyklin	7	0 (0,0)	13	1 (7,7)	0,56 [0,02; 15,46]; 0,7291 0,58 [0,03; 12,70]; 0,7316 -0,08 [-0,31; 0,16]; 0,5180
Anthrazyklin und Taxan	861	23 (2,7)	840	35 (4,2)	0,63 [0,37; 1,08]; 0,0919 0,64 [0,38; 1,08]; 0,0922 -0,01 [-0,03; 0,00]; 0,0899
Taxan	43	1 (2,3)	50	5 (10,0)	0,21 [0,02; 1,91]; 0,1676 0,23 [0,03; 1,91]; 0,1750 -0,08 [-0,17; 0,02]; 0,1117
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,9359)					
Brusterhaltend	220	7 (3,2)	235	13 (5,5)	0,56 [0,22; 1,43]; 0,2274 0,58 [0,23; 1,42]; 0,2285 -0,02 [-0,06; 0,01]; 0,2170
Einseitige Mastektomie	355	11 (3,1)	352	17 (4,8)	0,63 [0,29; 1,37]; 0,2417 0,64 [0,30; 1,35]; 0,2423 -0,02 [-0,05; 0,01]; 0,2380
Beidseitige Mastektomie	336	6 (1,8)	315	11 (3,5)	0,50 [0,18; 1,38]; 0,1804 0,51 [0,19; 1,37]; 0,1810 -0,02 [-0,04; 0,01]; 0,1762
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,6524)					
Ja	41	0 (0,0)	35	1 (2,9)	0,28 [0,01; 7,02]; 0,4365 0,29 [0,01; 6,80]; 0,4385 -0,03 [-0,10; 0,04]; 0,4433
Nein	870	24 (2,8)	866	40 (4,6)	0,59 [0,35; 0,98]; 0,0419 0,60 [0,36; 0,98]; 0,0422 -0,02 [-0,04; 0,00]; 0,0396

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,3345)					
Positiv	173	6 (3,5)	176	8 (4,6)	0,75 [0,26; 2,22]; 0,6092 0,76 [0,27; 2,15]; 0,6094 -0,01 [-0,05; 0,03]; 0,6076
Negativ	200	7 (3,5)	191	17 (8,9)	0,37 [0,15; 0,92]; 0,0316 0,39 [0,17; 0,93]; 0,0329 -0,05 [-0,10; -0,01]; 0,0266
Bilaterale Oophorektomie (Interaktionstest: p=0,4950)					
Ja	189	5 (2,7)	176	11 (6,3)	0,41 [0,14; 1,20]; 0,1027 0,42 [0,15; 1,19]; 0,1042 -0,04 [-0,08; 0,01]; 0,0961
Nein	722	19 (2,6)	728	30 (4,1)	0,63 [0,35; 1,13]; 0,1196 0,64 [0,36; 1,12]; 0,1200 -0,01 [-0,03; 0,00]; 0,1160
BRCA-Mutationsstatus (Interaktionstest: p=0,7301)					
BRCA1	574	11 (1,9)	580	20 (3,5)	0,55 [0,26; 1,15]; 0,1125 0,56 [0,27; 1,15]; 0,1131 -0,02 [-0,03; 0,00]; 0,1067
BRCA2	232	6 (2,6)	215	8 (3,7)	0,69 [0,23; 2,01]; 0,4937 0,70 [0,25; 1,97]; 0,4939 -0,01 [-0,04; 0,02]; 0,4940
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	7 (1,8)	383	11 (2,9)	0,61 [0,24; 1,60]; 0,3199 0,62 [0,24; 1,59]; 0,3203 -0,01 [-0,03; 0,01]; 0,3164
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,4552)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	14 (5,4)	271	21 (7,8)	0,68 [0,34; 1,37]; 0,2799 0,70 [0,36; 1,34]; 0,2807 -0,02 [-0,07; 0,02]; 0,2751
Kaukasisch	617	10 (1,6)	589	20 (3,4)	0,47 [0,22; 1,01]; 0,0530 0,48 [0,23; 1,01]; 0,0535 -0,02 [-0,04; 0,00]; 0,0493
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,7491)					
Hispanisch	34	0 (0,0)	24	1 (4,2)	0,23 [0,01; 5,82]; 0,3703 0,24 [0,01; 5,61]; 0,3733 -0,04 [-0,14; 0,06]; 0,4190
Nicht-hispanisch	798	22 (2,8)	803	38 (4,7)	0,57 [0,33; 0,97]; 0,0397 0,58 [0,35; 0,98]; 0,0401 -0,02 [-0,04; 0,00]; 0,0370
Unbekannt, nicht erfasst, verweigert	79	2 (2,5)	77	2 (2,6)	0,97 [0,13; 7,09]; 0,9793 0,97 [0,14; 6,75]; 0,9793 0,00 [-0,05; 0,05]; 0,9793
Hormonrezeptorstatus (Interaktionstest: p=0,2344)					
ER- und/oder PgR-positiv, HER2-positiv	168	6 (3,6)	155	5 (3,2)	1,11 [0,33; 3,72]; 0,8642 1,11 [0,34; 3,55]; 0,8642 0,00 [-0,04; 0,04]; 0,8639
TNBC	741	18 (2,4)	749	36 (4,8)	0,49 [0,28; 0,88]; 0,0160 0,51 [0,29; 0,88]; 0,0163 -0,02 [-0,04; 0,00]; 0,0137
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,5813)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	4 (3,9)	92	4 (4,4)	0,88 [0,21; 3,62]; 0,8595 0,88 [0,23; 3,44]; 0,8595 -0,01 [-0,06; 0,05]; 0,8599
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	1 (1,6)	2,00 [0,18; 22,63]; 0,5755 1,97 [0,18; 21,17]; 0,5762 0,02 [-0,04; 0,07]; 0,5669
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	4 (1,2)	362	11 (3,0)	0,37 [0,12; 1,18]; 0,0922 0,38 [0,12; 1,18]; 0,0932 -0,02 [-0,04; 0,00]; 0,0769
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	14 (3,6)	387	25 (6,5)	0,53 [0,27; 1,05]; 0,0672 0,55 [0,29; 1,04]; 0,0679 -0,03 [-0,06; 0,00]; 0,0634
Menopausenstatus (Interaktionstest: p=0,8033)					
Postmenopausal	346	10 (2,9)	356	19 (5,3)	0,53 [0,24; 1,15]; 0,1086 0,54 [0,26; 1,15]; 0,1096 -0,02 [-0,05; 0,00]; 0,1013
Prämenopausal	563	14 (2,5)	544	22 (4,0)	0,61 [0,31; 1,20]; 0,1480 0,61 [0,32; 1,19]; 0,1485 -0,02 [-0,04; 0,01]; 0,1454
Region (Interaktionstest: p=0,3334)					
Asien-Pazifik und Südafrika	301	14 (4,7)	317	21 (6,6)	0,69 [0,34; 1,38]; 0,2911 0,70 [0,36; 1,36]; 0,2918 -0,02 [-0,06; 0,02]; 0,2863

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	8 (1,7)	444	10 (2,3)	0,75 [0,29; 1,91]; 0,5419 0,75 [0,30; 1,89]; 0,5420 -0,01 [-0,02; 0,01]; 0,5423
Nordamerika	121	2 (1,7)	131	10 (7,6)	0,20 [0,04; 0,95]; 0,0425 0,22 [0,05; 0,97]; 0,0453 -0,06 [-0,11; -0,01]; 0,0211
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,8106)					
Adjuvant	457	16 (3,5)	450	26 (5,8)	0,59 [0,31; 1,12]; 0,1063 0,61 [0,33; 1,11]; 0,1069 -0,02 [-0,05; 0,00]; 0,1029
Neoadjuvant	454	8 (1,8)	454	15 (3,3)	0,52 [0,22; 1,25]; 0,1457 0,53 [0,23; 1,25]; 0,1463 -0,02 [-0,04; 0,00]; 0,1388
Sponsor (Interaktionstest: p=0,1147)					
AZ	801	22 (2,8)	796	31 (3,9)	0,70 [0,40; 1,21]; 0,2026 0,71 [0,41; 1,21]; 0,2029 -0,01 [-0,03; 0,01]; 0,2004
NRG Oncology	110	2 (1,8)	108	10 (9,3)	0,18 [0,04; 0,85]; 0,0301 0,20 [0,04; 0,88]; 0,0328 -0,07 [-0,13; -0,01]; 0,0152
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,5729)					
Ja	243	4 (1,7)	236	9 (3,8)	0,42 [0,13; 1,39]; 0,1561 0,43 [0,13; 1,38]; 0,1572 -0,02 [-0,05; 0,01]; 0,1458
Nein	668	20 (3,0)	668	32 (4,8)	0,61 [0,35; 1,08]; 0,0925 0,62 [0,36; 1,08]; 0,0929 -0,02 [-0,04; 0,00]; 0,0893
Bilirubin im Blut erhöht					
Alter (Interaktionstest: p=0,5762)					
<50	690	4 (0,6)	663	10 (1,5)	0,38 [0,12; 1,22]; 0,1041 0,38 [0,12; 1,22]; 0,1046 -0,01 [-0,02; 0,00]; 0,0941
50-64	192	0 (0,0)	209	3 (1,4)	0,15 [0,01; 2,99]; 0,2157 0,16 [0,01; 2,99]; 0,2172 -0,01 [-0,03; 0,00]; 0,1333
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,9202)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	4 (0,5)	840	12 (1,4)	0,32 [0,10; 1,00]; 0,0505 0,33 [0,11; 1,00]; 0,0509 -0,01 [-0,02; 0,00]; 0,0405
Taxan	43	0 (0,0)	50	1 (2,0)	0,38 [0,02; 9,55]; 0,5559 0,39 [0,02; 9,25]; 0,5572 -0,02 [-0,08; 0,04]; 0,4836
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,6159)					
Brusterhaltend	220	2 (0,9)	235	3 (1,3)	0,71 [0,12; 4,29]; 0,7084 0,71 [0,12; 4,22]; 0,7085 0,00 [-0,02; 0,02]; 0,7055
Einseitige Mastektomie	355	2 (0,6)	352	9 (2,6)	0,22 [0,05; 1,01]; 0,0510 0,22 [0,05; 1,01]; 0,0519 -0,02 [-0,04; 0,00]; 0,0321
Beidseitige Mastektomie	336	0 (0,0)	315	1 (0,3)	0,31 [0,01; 7,68]; 0,4756 0,31 [0,01; 7,64]; 0,4759 0,00 [-0,01; 0,01]; 0,4704
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	4 (0,5)	866	13 (1,5)	0,30 [0,10; 0,93]; 0,0375 0,31 [0,10; 0,94]; 0,0378 -0,01 [-0,02; 0,00]; 0,0276
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,5745)					
Positiv	173	0 (0,0)	176	3 (1,7)	0,14 [0,01; 2,79]; 0,1992 0,15 [0,01; 2,79]; 0,2009 -0,02 [-0,04; 0,00]; 0,1288
Negativ	200	2 (1,0)	191	5 (2,6)	0,38 [0,07; 1,96]; 0,2455 0,38 [0,08; 1,95]; 0,2466 -0,02 [-0,04; 0,01]; 0,2317
Bilaterale Oophorektomie (Interaktionstest: p=0,9635)					
Ja	189	0 (0,0)	176	1 (0,6)	0,31 [0,01; 7,63]; 0,4726 0,31 [0,01; 7,57]; 0,4730 -0,01 [-0,02; 0,01]; 0,4680
Nein	722	4 (0,6)	728	12 (1,7)	0,33 [0,11; 1,04]; 0,0575 0,34 [0,11; 1,04]; 0,0579 -0,01 [-0,02; 0,00]; 0,0454

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,9511)					
BRCA1	574	3 (0,5)	580	6 (1,0)	0,50 [0,13; 2,02]; 0,3323 0,51 [0,13; 2,01]; 0,3326 -0,01 [-0,02; 0,01]; 0,3220
BRCA2	232	1 (0,4)	215	2 (0,9)	0,46 [0,04; 5,12]; 0,5285 0,46 [0,04; 5,07]; 0,5287 0,00 [-0,02; 0,01]; 0,5240
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	1 (0,3)	383	3 (0,8)	0,32 [0,03; 3,13]; 0,3299 0,33 [0,03; 3,12]; 0,3303 -0,01 [-0,02; 0,00]; 0,3074
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,9964)					
Andere	16	0 (0,0)	15	1 (6,7)	0,29 [0,01; 7,76]; 0,4628 0,31 [0,01; 7,15]; 0,4675 -0,07 [-0,23; 0,10]; 0,4252
Asiatisch	259	3 (1,2)	271	9 (3,3)	0,34 [0,09; 1,27]; 0,1097 0,35 [0,10; 1,27]; 0,1110 -0,02 [-0,05; 0,00]; 0,0900
Kaukasisch	617	1 (0,2)	589	3 (0,5)	0,32 [0,03; 3,06]; 0,3205 0,32 [0,03; 3,05]; 0,3208 0,00 [-0,01; 0,00]; 0,3000
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,9683)					
Hispanisch	34	0 (0,0)	24	1 (4,2)	0,23 [0,01; 5,82]; 0,3703 0,24 [0,01; 5,61]; 0,3733 -0,04 [-0,14; 0,06]; 0,4190
Nicht-hispanisch	798	4 (0,5)	803	11 (1,4)	0,36 [0,12; 1,14]; 0,0835 0,37 [0,12; 1,14]; 0,0839 -0,01 [-0,02; 0,00]; 0,0706
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	1 (1,3)	0,32 [0,01; 8,00]; 0,4883 0,32 [0,01; 7,86]; 0,4892 -0,01 [-0,05; 0,02]; 0,4675
Hormonrezeptorstatus (Interaktionstest: p=0,4889)					
ER- und/oder PgR-positiv, HER2-positiv	168	0 (0,0)	155	3 (1,9)	0,13 [0,01; 2,52]; 0,1772 0,13 [0,01; 2,53]; 0,1791 -0,02 [-0,04; 0,01]; 0,1237

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	4 (0,5)	749	10 (1,3)	0,40 [0,13; 1,28]; 0,1240 0,40 [0,13; 1,28]; 0,1244 -0,01 [-0,02; 0,00]; 0,1105
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6649)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	2 (2,2)	0,17 [0,01; 3,66]; 0,2598 0,18 [0,01; 3,64]; 0,2619 -0,02 [-0,06; 0,01]; 0,2289
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	1 (1,6)	0,32 [0,01; 8,08]; 0,4915 0,33 [0,01; 7,91]; 0,4926 -0,02 [-0,06; 0,03]; 0,4665
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	2 (0,6)	362	2 (0,6)	1,04 [0,15; 7,43]; 0,9684 1,04 [0,15; 7,34]; 0,9684 0,00 [-0,01; 0,01]; 0,9685
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	2 (0,5)	387	8 (2,1)	0,24 [0,05; 1,15]; 0,0742 0,25 [0,05; 1,15]; 0,0750 -0,02 [-0,03; 0,00]; 0,0536
Menopausenstatus (Interaktionstest: p=0,5508)					
Postmenopausal	346	0 (0,0)	356	3 (0,8)	0,15 [0,01; 2,83]; 0,2033 0,15 [0,01; 2,83]; 0,2041 -0,01 [-0,02; 0,00]; 0,1322
Prämenopausal	563	4 (0,7)	544	10 (1,8)	0,38 [0,12; 1,23]; 0,1057 0,39 [0,12; 1,22]; 0,1063 -0,01 [-0,02; 0,00]; 0,0953
Region (Interaktionstest: p=0,9229)					
Asien-Pazifik und Südafrika	301	3 (1,0)	317	8 (2,5)	0,39 [0,10; 1,48]; 0,1660 0,39 [0,11; 1,47]; 0,1669 -0,02 [-0,04; 0,01]; 0,1461
Europa	473	1 (0,2)	444	4 (0,9)	0,23 [0,03; 2,09]; 0,1934 0,23 [0,03; 2,09]; 0,1940 -0,01 [-0,02; 0,00]; 0,1642
Nordamerika	121	0 (0,0)	131	1 (0,8)	0,36 [0,01; 8,87]; 0,5306 0,36 [0,01; 8,77]; 0,5311 -0,01 [-0,03; 0,01]; 0,4833
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4773)					
Adjuvant	457	2 (0,4)	450	9 (2,0)	0,22 [0,05; 1,00]; 0,0504 0,22 [0,05; 1,01]; 0,0511 -0,02 [-0,03; 0,00]; 0,0320
Neoadjuvant	454	2 (0,4)	454	4 (0,9)	0,50 [0,09; 2,73]; 0,4219 0,50 [0,09; 2,72]; 0,4221 0,00 [-0,01; 0,01]; 0,4125

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,9945)					
AZ	801	4 (0,5)	796	12 (1,5)	0,33 [0,11; 1,02]; 0,0543 0,33 [0,11; 1,02]; 0,0547 -0,01 [-0,02; 0,00]; 0,0432
NRG Oncology	110	0 (0,0)	108	1 (0,9)	0,32 [0,01; 8,05]; 0,4919 0,33 [0,01; 7,95]; 0,4926 -0,01 [-0,03; 0,02]; 0,4709
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7043)					
Ja	243	0 (0,0)	236	2 (0,9)	0,19 [0,01; 4,03]; 0,2885 0,19 [0,01; 4,03]; 0,2894 -0,01 [-0,02; 0,01]; 0,2418
Nein	668	4 (0,6)	668	11 (1,7)	0,36 [0,11; 1,14]; 0,0813 0,36 [0,12; 1,14]; 0,0818 -0,01 [-0,02; 0,00]; 0,0688
Gewicht erhöht					
Alter (Interaktionstest: p=0,8636)					
<50	690	4 (0,6)	663	9 (1,4)	0,42 [0,13; 1,38]; 0,1547 0,43 [0,13; 1,38]; 0,1551 -0,01 [-0,02; 0,00]; 0,1455
50-64	192	1 (0,5)	209	5 (2,4)	0,21 [0,02; 1,85]; 0,1606 0,22 [0,03; 1,85]; 0,1622 -0,02 [-0,04; 0,00]; 0,1121
≥65	29	0 (0,0)	32	1 (3,1)	0,36 [0,01; 9,09]; 0,5320 0,37 [0,02; 8,66]; 0,5340 -0,03 [-0,12; 0,05]; 0,4688
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,7295)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	5 (0,6)	840	12 (1,4)	0,40 [0,14; 1,15]; 0,0891 0,41 [0,14; 1,15]; 0,0895 -0,01 [-0,02; 0,00]; 0,0801
Taxan	43	0 (0,0)	50	2 (4,0)	0,22 [0,01; 4,77]; 0,3371 0,23 [0,01; 4,70]; 0,3411 -0,04 [-0,11; 0,03]; 0,2421
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,9064)					
Brusterhaltend	220	1 (0,5)	235	2 (0,9)	0,53 [0,05; 5,91]; 0,6074 0,53 [0,05; 5,85]; 0,6075 0,00 [-0,02; 0,01]; 0,5977
Einseitige Mastektomie	355	2 (0,6)	352	7 (2,0)	0,28 [0,06; 1,35]; 0,1132 0,28 [0,06; 1,35]; 0,1141 -0,01 [-0,03; 0,00]; 0,0911

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	2 (0,6)	315	6 (1,9)	0,31 [0,06; 1,54]; 0,1515 0,31 [0,06; 1,54]; 0,1524 -0,01 [-0,03; 0,00]; 0,1354
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,8976)					
Ja	41	0 (0,0)	35	1 (2,9)	0,28 [0,01; 7,02]; 0,4365 0,29 [0,01; 6,80]; 0,4385 -0,03 [-0,10; 0,04]; 0,4433
Nein	870	5 (0,6)	866	14 (1,6)	0,35 [0,13; 0,98]; 0,0458 0,36 [0,13; 0,98]; 0,0462 -0,01 [-0,02; 0,00]; 0,0369
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8162)					
Positiv	173	0 (0,0)	176	2 (1,1)	0,20 [0,01; 4,22]; 0,3017 0,20 [0,01; 4,21]; 0,3029 -0,01 [-0,03; 0,01]; 0,2440
Negativ	200	1 (0,5)	191	3 (1,6)	0,31 [0,03; 3,05]; 0,3189 0,32 [0,03; 3,03]; 0,3197 -0,01 [-0,03; 0,01]; 0,2980
Bilaterale Oophorektomie (Interaktionstest: p=0,8441)					
Ja	189	2 (1,1)	176	5 (2,8)	0,37 [0,07; 1,91]; 0,2330 0,37 [0,07; 1,90]; 0,2342 -0,02 [-0,05; 0,01]; 0,2211
Nein	722	3 (0,4)	728	10 (1,4)	0,30 [0,08; 1,09]; 0,0680 0,30 [0,08; 1,09]; 0,0684 -0,01 [-0,02; 0,00]; 0,0521
BRCA-Mutationsstatus (Interaktionstest: p=0,4694)					
BRCA1	574	3 (0,5)	580	11 (1,9)	0,27 [0,08; 0,98]; 0,0464 0,28 [0,08; 0,98]; 0,0469 -0,01 [-0,03; 0,00]; 0,0322
BRCA2	232	2 (0,9)	215	3 (1,4)	0,61 [0,10; 3,71]; 0,5957 0,62 [0,10; 3,66]; 0,5958 -0,01 [-0,03; 0,01]; 0,5954
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,8217)					
2, 3 oder 4	392	2 (0,5)	383	6 (1,6)	0,32 [0,06; 1,61]; 0,1671 0,33 [0,07; 1,60]; 0,1678 -0,01 [-0,02; 0,00]; 0,1476
5 oder 6	22	0 (0,0)	14	1 (7,1)	0,20 [0,01; 5,27]; 0,3349 0,22 [0,01; 4,99]; 0,3399 -0,07 [-0,23; 0,09]; 0,3907

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,7918)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	0 (0,0)	271	3 (1,1)	0,15 [0,01; 2,88]; 0,2068 0,15 [0,01; 2,88]; 0,2079 -0,01 [-0,03; 0,00]; 0,1322
Kaukasisch	617	5 (0,8)	589	11 (1,9)	0,43 [0,15; 1,24]; 0,1190 0,43 [0,15; 1,24]; 0,1195 -0,01 [-0,02; 0,00]; 0,1116
Schwarz oder afroamerikanisch	19	0 (0,0)	29	1 (3,5)	0,49 [0,02; 12,59]; 0,6647 0,50 [0,02; 11,67]; 0,6663 -0,03 [-0,14; 0,07]; 0,5148
Ethnische Abstammung (Interaktionstest: p=0,8593)					
Hispanisch	34	0 (0,0)	24	1 (4,2)	0,23 [0,01; 5,82]; 0,3703 0,24 [0,01; 5,61]; 0,3733 -0,04 [-0,14; 0,06]; 0,4190
Nicht-hispanisch	798	5 (0,6)	803	12 (1,5)	0,42 [0,15; 1,19]; 0,1006 0,42 [0,15; 1,18]; 0,1010 -0,01 [-0,02; 0,00]; 0,0896
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	2 (2,6)	0,19 [0,01; 4,02]; 0,2862 0,20 [0,01; 4,00]; 0,2888 -0,03 [-0,07; 0,02]; 0,2335
Hormonrezeptorstatus (Interaktionstest: p=0,0642)					
ER- und/oder PgR-positiv, HER2-positiv	168	3 (1,8)	155	2 (1,3)	1,39 [0,23; 8,44]; 0,7198 1,38 [0,23; 8,17]; 0,7199 0,00 [-0,02; 0,03]; 0,7168
TNBC	741	2 (0,3)	749	13 (1,7)	0,15 [0,03; 0,68]; 0,0137 0,16 [0,04; 0,69]; 0,0141 -0,01 [-0,02; 0,00]; 0,0043
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3091)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	1 (1,1)	0,88 [0,05; 14,33]; 0,9306 0,88 [0,06; 13,94]; 0,9306 0,00 [-0,03; 0,03]; 0,9308
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	1 (1,6)	2,00 [0,18; 22,63]; 0,5755 1,97 [0,18; 21,17]; 0,5762 0,02 [-0,04; 0,07]; 0,5669
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	1 (0,3)	362	8 (2,2)	0,13 [0,02; 1,02]; 0,0528 0,13 [0,02; 1,03]; 0,0538 -0,02 [-0,04; 0,00]; 0,0197
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	1 (0,3)	387	5 (1,3)	0,19 [0,02; 1,68]; 0,1363 0,20 [0,02; 1,68]; 0,1372 -0,01 [-0,02; 0,00]; 0,0984

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Menopausenstatus (Interaktionstest: p=0,4760)					
Postmenopausal	346	2 (0,6)	356	9 (2,5)	0,22 [0,05; 1,05]; 0,0569 0,23 [0,05; 1,05]; 0,0579 -0,02 [-0,04; 0,00]; 0,0353
Prämenopausal	563	3 (0,5)	544	6 (1,1)	0,48 [0,12; 1,93]; 0,3015 0,48 [0,12; 1,92]; 0,3018 -0,01 [-0,02; 0,00]; 0,2936
Region (Interaktionstest: p=0,1128)					
Asien-Pazifik und Südafrika	301	0 (0,0)	317	6 (1,9)	0,08 [0,00; 1,42]; 0,0849 0,08 [0,00; 1,43]; 0,0863 -0,02 [-0,04; 0,00]; 0,0221
Europa	473	5 (1,1)	444	4 (0,9)	1,18 [0,31; 4,40]; 0,8107 1,17 [0,32; 4,34]; 0,8107 0,00 [-0,01; 0,01]; 0,8100
Nordamerika	121	0 (0,0)	131	5 (3,8)	0,09 [0,01; 1,73]; 0,1118 0,10 [0,01; 1,76]; 0,1151 -0,04 [-0,07; 0,00]; 0,0373
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4486)					
Adjuvant	457	3 (0,7)	450	6 (1,3)	0,49 [0,12; 1,97]; 0,3138 0,49 [0,12; 1,96]; 0,3142 -0,01 [-0,02; 0,01]; 0,3048
Neoadjuvant	454	2 (0,4)	454	9 (2,0)	0,22 [0,05; 1,02]; 0,0528 0,22 [0,05; 1,02]; 0,0535 -0,02 [-0,03; 0,00]; 0,0333
Sponsor (Interaktionstest: p=0,2738)					
AZ	801	5 (0,6)	796	10 (1,3)	0,49 [0,17; 1,45]; 0,1994 0,50 [0,17; 1,45]; 0,1997 -0,01 [-0,02; 0,00]; 0,1907
NRG Oncology	110	0 (0,0)	108	5 (4,6)	0,09 [0,00; 1,56]; 0,0968 0,09 [0,00; 1,60]; 0,1005 -0,05 [-0,09; 0,00]; 0,0346
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,2700)					
Ja	243	0 (0,0)	236	5 (2,1)	0,09 [0,00; 1,57]; 0,0980 0,09 [0,00; 1,59]; 0,0997 -0,02 [-0,04; 0,00]; 0,0378
Nein	668	5 (0,8)	668	10 (1,5)	0,50 [0,17; 1,46]; 0,2030 0,50 [0,17; 1,45]; 0,2034 -0,01 [-0,02; 0,00]; 0,1939

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Kreatinin im Blut erhöht					
Alter (Interaktionstest: p=0,2512)					
<50	690	13 (1,9)	663	1 (0,2)	12,71 [1,66; 97,45]; 0,0144 12,49 [1,64; 95,22]; 0,0148 0,02 [0,01; 0,03]; 0,0013
50-64	192	5 (2,6)	209	2 (1,0)	2,77 [0,53; 14,43]; 0,2271 2,72 [0,53; 13,86]; 0,2281 0,02 [-0,01; 0,04]; 0,2162
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,7894)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	17 (2,0)	840	3 (0,4)	5,62 [1,64; 19,25]; 0,0060 5,53 [1,63; 18,80]; 0,0062 0,02 [0,01; 0,03]; 0,0018
Taxan	43	1 (2,3)	50	0 (0,0)	3,56 [0,14; 89,80]; 0,4400 3,48 [0,15; 83,21]; 0,4417 0,02 [-0,04; 0,08]; 0,4478
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,3559)					
Brusterhaltend	220	4 (1,8)	235	1 (0,4)	4,33 [0,48; 39,07]; 0,1913 4,27 [0,48; 37,93]; 0,1924 0,01 [-0,01; 0,03]; 0,1620
Einseitige Mastektomie	355	10 (2,8)	352	0 (0,0)	21,43 [1,25; 367,05]; 0,0345 20,82 [1,22; 353,99]; 0,0357 0,03 [0,01; 0,05]; 0,0022
Beidseitige Mastektomie	336	4 (1,2)	315	2 (0,6)	1,89 [0,34; 10,37]; 0,4658 1,88 [0,35; 10,17]; 0,4661 0,01 [-0,01; 0,02]; 0,4539
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,6504)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	17 (2,0)	866	3 (0,4)	5,73 [1,67; 19,63]; 0,0054 5,64 [1,66; 19,18]; 0,0056 0,02 [0,01; 0,03]; 0,0016

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,5397)					
Positiv	173	2 (1,2)	176	1 (0,6)	2,05 [0,18; 22,78]; 0,5602 2,03 [0,19; 22,23]; 0,5604 0,01 [-0,01; 0,03]; 0,5529
Negativ	200	3 (1,5)	191	0 (0,0)	6,79 [0,35; 132,28]; 0,2063 6,69 [0,35; 128,60]; 0,2078 0,01 [0,00; 0,03]; 0,1310
Bilaterale Oophorektomie (Interaktionstest: p=0,0463)					
Ja	189	2 (1,1)	176	2 (1,1)	0,93 [0,13; 6,68]; 0,9429 0,93 [0,13; 6,54]; 0,9429 0,00 [-0,02; 0,02]; 0,9429
Nein	722	16 (2,2)	728	1 (0,1)	16,48 [2,18; 124,57]; 0,0066 16,13 [2,15; 121,33]; 0,0069 0,02 [0,01; 0,03]; 0,0002
BRCA-Mutationsstatus (Interaktionstest: p=0,1853)					
BRCA1	574	11 (1,9)	580	1 (0,2)	11,31 [1,46; 87,91]; 0,0204 11,11 [1,44; 85,81]; 0,0209 0,02 [0,01; 0,03]; 0,0035
BRCA2	232	4 (1,7)	215	2 (0,9)	1,87 [0,34; 10,31]; 0,4731 1,85 [0,34; 10,02]; 0,4735 0,01 [-0,01; 0,03]; 0,4609
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	9 (2,3)	383	1 (0,3)	8,98 [1,13; 71,20]; 0,0378 8,79 [1,12; 69,07]; 0,0387 0,02 [0,00; 0,04]; 0,0110
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,7904)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	5 (1,9)	271	0 (0,0)	11,73 [0,65; 213,29]; 0,0961 11,51 [0,64; 207,07]; 0,0976 0,02 [0,00; 0,04]; 0,0378
Kaukasisch	617	12 (1,9)	589	3 (0,5)	3,87 [1,09; 13,80]; 0,0366 3,82 [1,08; 13,46]; 0,0372 0,01 [0,00; 0,03]; 0,0224
Schwarz oder afroamerikanisch	19	1 (5,3)	29	0 (0,0)	4,78 [0,18; 123,74]; 0,3456 4,50 [0,19; 105,03]; 0,3494 0,05 [-0,07; 0,18]; 0,4062

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,8516)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	15 (1,9)	803	3 (0,4)	5,11 [1,47; 17,72]; 0,0102 5,03 [1,46; 17,31]; 0,0104 0,02 [0,00; 0,03]; 0,0042
Unbekannt, nicht erfasst, verweigert	79	3 (3,8)	77	0 (0,0)	7,09 [0,36; 139,61]; 0,1976 6,82 [0,36; 129,97]; 0,2014 0,04 [-0,01; 0,09]; 0,1225
Hormonrezeptorstatus (Interaktionstest: p=0,1618)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	1 (0,7)	0,92 [0,06; 14,87]; 0,9544 0,92 [0,06; 14,62]; 0,9544 0,00 [-0,02; 0,02]; 0,9545
TNBC	741	17 (2,3)	749	2 (0,3)	8,77 [2,02; 38,09]; 0,0038 8,59 [1,99; 37,06]; 0,0039 0,02 [0,01; 0,03]; 0,0005
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,2499)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	1 (1,1)	0,88 [0,05; 14,33]; 0,9306 0,88 [0,06; 13,94]; 0,9306 0,00 [-0,03; 0,03]; 0,9308
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	11 (3,2)	362	0 (0,0)	24,70 [1,45; 420,84]; 0,0266 23,92 [1,42; 404,41]; 0,0278 0,03 [0,01; 0,05]; 0,0012
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	6 (1,5)	387	2 (0,5)	2,98 [0,60; 14,88]; 0,1822 2,95 [0,60; 14,55]; 0,1829 0,01 [0,00; 0,02]; 0,1595
Menopausenstatus (Interaktionstest: p=0,2330)					
Postmenopausal	346	5 (1,5)	356	2 (0,6)	2,60 [0,50; 13,47]; 0,2563 2,57 [0,50; 13,17]; 0,2569 0,01 [-0,01; 0,02]; 0,2414
Prämenopausal	563	13 (2,3)	544	1 (0,2)	12,83 [1,67; 98,45]; 0,0141 12,56 [1,65; 95,69]; 0,0146 0,02 [0,01; 0,03]; 0,0013
Region (Interaktionstest: p=0,8237)					
Asien-Pazifik und Südafrika	301	5 (1,7)	317	0 (0,0)	11,78 [0,65; 213,94]; 0,0955 11,58 [0,64; 208,57]; 0,0968 0,02 [0,00; 0,03]; 0,0381

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	9 (1,9)	444	2 (0,5)	4,29 [0,92; 19,95]; 0,0636 4,22 [0,92; 19,44]; 0,0644 0,01 [0,00; 0,03]; 0,0391
Nordamerika	121	4 (3,3)	131	1 (0,8)	4,44 [0,49; 40,33]; 0,1850 4,33 [0,49; 38,21]; 0,1870 0,03 [-0,01; 0,06]; 0,1565
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,2881)					
Adjuvant	457	6 (1,3)	450	2 (0,4)	2,98 [0,60; 14,84]; 0,1826 2,95 [0,60; 14,56]; 0,1832 0,01 [0,00; 0,02]; 0,1599
Neoadjuvant	454	12 (2,6)	454	1 (0,2)	12,30 [1,59; 94,98]; 0,0161 12,00 [1,57; 91,90]; 0,0167 0,02 [0,01; 0,04]; 0,0020
Sponsor (Interaktionstest: p=0,6701)					
AZ	801	14 (1,8)	796	2 (0,3)	7,06 [1,60; 31,18]; 0,0099 6,96 [1,59; 30,51]; 0,0101 0,01 [0,01; 0,02]; 0,0025
NRG Oncology	110	4 (3,6)	108	1 (0,9)	4,04 [0,44; 36,72]; 0,2153 3,93 [0,45; 34,57]; 0,2177 0,03 [-0,01; 0,07]; 0,1772
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,5743)					
Ja	243	5 (2,1)	236	0 (0,0)	10,91 [0,60; 198,37]; 0,1064 10,68 [0,59; 192,16]; 0,1081 0,02 [0,00; 0,04]; 0,0388
Nein	668	13 (2,0)	668	3 (0,5)	4,40 [1,25; 15,51]; 0,0212 4,33 [1,24; 15,14]; 0,0216 0,01 [0,00; 0,03]; 0,0117
Leukozytenzahl erniedrigt					
Alter (Interaktionstest: p=0,2942)					
<50	690	107 (15,5)	663	42 (6,3)	2,71 [1,87; 3,95]; <0,0001 2,45 [1,74; 3,44]; <0,0001 0,09 [0,06; 0,12]; <0,0001
50-64	192	28 (14,6)	209	10 (4,8)	3,40 [1,60; 7,20]; 0,0014 3,05 [1,52; 6,11]; 0,0017 0,10 [0,04; 0,16]; 0,0009
≥65	29	9 (31,0)	32	0 (0,0)	30,12 [1,66; 545,83]; 0,0212 20,90 [1,27; 343,87]; 0,0334 0,31 [0,14; 0,48]; 0,0004

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6409)					
Anthrazyklin	7	2 (28,6)	13	1 (7,7)	4,80 [0,35; 65,76]; 0,2401 3,71 [0,40; 34,12]; 0,2462 0,21 [-0,16; 0,57]; 0,2618
Anthrazyklin und Taxan	861	136 (15,8)	840	50 (6,0)	2,96 [2,11; 4,16]; <0,0001 2,65 [1,95; 3,62]; <0,0001 0,10 [0,07; 0,13]; <0,0001
Taxan	43	6 (14,0)	50	1 (2,0)	7,95 [0,92; 68,87]; 0,0600 6,98 [0,87; 55,70]; 0,0668 0,12 [0,01; 0,23]; 0,0341
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2472)					
Brusterhaltend	220	30 (13,6)	235	12 (5,1)	2,93 [1,46; 5,89]; 0,0025 2,67 [1,40; 5,08]; 0,0028 0,09 [0,03; 0,14]; 0,0017
Einseitige Mastektomie	355	74 (20,9)	352	32 (9,1)	2,63 [1,69; 4,11]; <0,0001 2,29 [1,56; 3,38]; <0,0001 0,12 [0,07; 0,17]; <0,0001
Beidseitige Mastektomie	336	40 (11,9)	315	8 (2,5)	5,19 [2,39; 11,26]; <0,0001 4,69 [2,23; 9,86]; <0,0001 0,09 [0,05; 0,13]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3988)					
Ja	41	1 (2,4)	35	1 (2,9)	0,85 [0,05; 14,11]; 0,9097 0,85 [0,06; 13,15]; 0,9097 0,00 [-0,08; 0,07]; 0,9102
Nein	870	143 (16,4)	866	51 (5,9)	3,14 [2,25; 4,39]; <0,0001 2,79 [2,06; 3,79]; <0,0001 0,11 [0,08; 0,13]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,6329)					
Positiv	173	44 (25,4)	176	18 (10,2)	2,99 [1,65; 5,43]; 0,0003 2,49 [1,50; 4,13]; 0,0004 0,15 [0,07; 0,23]; 0,0002
Negativ	200	35 (17,5)	191	11 (5,8)	3,47 [1,71; 7,06]; 0,0006 3,04 [1,59; 5,81]; 0,0008 0,12 [0,06; 0,18]; 0,0002
Bilaterale Oophorektomie (Interaktionstest: p=0,8537)					
Ja	189	25 (13,2)	176	9 (5,1)	2,83 [1,28; 6,24]; 0,0101 2,59 [1,24; 5,39]; 0,0111 0,08 [0,02; 0,14]; 0,0063
Nein	722	119 (16,5)	728	43 (5,9)	3,14 [2,18; 4,53]; <0,0001 2,79 [2,00; 3,89]; <0,0001 0,11 [0,07; 0,14]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,7036)					
BRCA1	574	73 (12,7)	580	25 (4,3)	3,23 [2,02; 5,18]; <0,0001 2,95 [1,90; 4,58]; <0,0001 0,08 [0,05; 0,12]; <0,0001
BRCA2	232	30 (12,9)	215	11 (5,1)	2,75 [1,34; 5,65]; 0,0057 2,53 [1,30; 4,92]; 0,0063 0,08 [0,03; 0,13]; 0,0034
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,5998)					
2, 3 oder 4	392	42 (10,7)	383	16 (4,2)	2,75 [1,52; 4,99]; 0,0008 2,56 [1,47; 4,48]; 0,0009 0,07 [0,03; 0,10]; 0,0005
5 oder 6	22	7 (31,8)	14	1 (7,1)	6,07 [0,66; 56,03]; 0,1120 4,45 [0,61; 32,43]; 0,1402 0,25 [0,01; 0,48]; 0,0411
Ethnie (Interaktionstest: p=0,9632)					
Andere	16	1 (6,3)	15	0 (0,0)	3,00 [0,11; 79,50]; 0,5111 2,82 [0,12; 64,39]; 0,5153 0,06 [-0,10; 0,22]; 0,4425
Asiatisch	259	92 (35,5)	271	33 (12,2)	3,97 [2,55; 6,20]; <0,0001 2,92 [2,04; 4,18]; <0,0001 0,23 [0,16; 0,30]; <0,0001
Kaukasisch	617	50 (8,1)	589	18 (3,1)	2,80 [1,61; 4,85]; 0,0003 2,65 [1,57; 4,49]; 0,0003 0,05 [0,02; 0,08]; 0,0001
Schwarz oder afroamerikanisch	19	1 (5,3)	29	1 (3,5)	1,56 [0,09; 26,47]; 0,7600 1,53 [0,10; 22,96]; 0,7598 0,02 [-0,10; 0,14]; 0,7676
Ethnische Abstammung (Interaktionstest: p=0,7053)					
Hispanisch	34	3 (8,8)	24	0 (0,0)	5,44 [0,27; 110,44]; 0,2698 5,00 [0,27; 92,56]; 0,2798 0,09 [-0,03; 0,20]; 0,1277
Nicht-hispanisch	798	135 (16,9)	803	51 (6,4)	3,00 [2,14; 4,21]; <0,0001 2,66 [1,96; 3,62]; <0,0001 0,11 [0,07; 0,14]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	6 (7,6)	77	1 (1,3)	6,25 [0,73; 53,16]; 0,0936 5,85 [0,72; 47,45]; 0,0983 0,06 [0,00; 0,13]; 0,0526
Hormonrezeptorstatus (Interaktionstest: p=0,8307)					
ER- und/oder PgR-positiv, HER2-positiv	168	25 (14,9)	155	9 (5,8)	2,84 [1,28; 6,29]; 0,0103 2,56 [1,24; 5,32]; 0,0115 0,09 [0,03; 0,16]; 0,0064

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	119 (16,1)	749	43 (5,7)	3,14 [2,18; 4,52]; <0,0001 2,80 [2,00; 3,91]; <0,0001 0,10 [0,07; 0,13]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,9884)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	16 (15,4)	92	6 (6,5)	2,61 [0,97; 6,97]; 0,0565 2,36 [0,96; 5,78]; 0,0603 0,09 [0,00; 0,17]; 0,0428
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	9 (14,1)	63	3 (4,8)	3,27 [0,84; 12,71]; 0,0868 2,95 [0,84; 10,41]; 0,0920 0,09 [-0,01; 0,19]; 0,0686
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	37 (10,6)	362	14 (3,9)	2,96 [1,57; 5,57]; 0,0008 2,75 [1,51; 4,99]; 0,0009 0,07 [0,03; 0,11]; 0,0005
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	82 (20,9)	387	29 (7,5)	3,25 [2,08; 5,10]; <0,0001 2,78 [1,87; 4,15]; <0,0001 0,13 [0,09; 0,18]; <0,0001
Menopausenstatus (Interaktionstest: p=0,8905)					
Postmenopausal	346	52 (15,0)	356	19 (5,3)	3,14 [1,81; 5,43]; <0,0001 2,82 [1,70; 4,66]; <0,0001 0,10 [0,05; 0,14]; <0,0001
Prämenopausal	563	92 (16,3)	544	33 (6,1)	3,02 [1,99; 4,59]; <0,0001 2,69 [1,84; 3,94]; <0,0001 0,10 [0,07; 0,14]; <0,0001
Region (Interaktionstest: p=0,9572)					
Asien-Pazifik und Südafrika	301	93 (30,9)	317	34 (10,7)	3,72 [2,42; 5,73]; <0,0001 2,88 [2,01; 4,13]; <0,0001 0,20 [0,14; 0,26]; <0,0001
Europa	473	31 (6,6)	444	11 (2,5)	2,76 [1,37; 5,56]; 0,0045 2,65 [1,35; 5,20]; 0,0048 0,04 [0,01; 0,07]; 0,0026
Nordamerika	121	20 (16,5)	131	7 (5,3)	3,51 [1,43; 8,63]; 0,0063 3,09 [1,36; 7,05]; 0,0073 0,11 [0,04; 0,19]; 0,0042
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,8631)					
Adjuvant	457	91 (19,9)	450	32 (7,1)	3,25 [2,12; 4,98]; <0,0001 2,80 [1,91; 4,10]; <0,0001 0,13 [0,08; 0,17]; <0,0001
Neoadjuvant	454	53 (11,7)	454	20 (4,4)	2,87 [1,68; 4,88]; 0,0001 2,65 [1,61; 4,36]; 0,0001 0,07 [0,04; 0,11]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,9572)					
AZ	801	124 (15,5)	796	45 (5,7)	3,06 [2,14; 4,37]; <0,0001 2,74 [1,98; 3,80]; <0,0001 0,10 [0,07; 0,13]; <0,0001
NRG Oncology	110	20 (18,2)	108	7 (6,5)	3,21 [1,30; 7,94]; 0,0118 2,81 [1,24; 6,36]; 0,0135 0,12 [0,03; 0,20]; 0,0075
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7035)					
Ja	243	26 (10,7)	236	8 (3,4)	3,41 [1,51; 7,71]; 0,0031 3,16 [1,46; 6,83]; 0,0035 0,07 [0,03; 0,12]; 0,0015
Nein	668	118 (17,7)	668	44 (6,6)	3,04 [2,11; 4,38]; <0,0001 2,68 [1,93; 3,73]; <0,0001 0,11 [0,08; 0,15]; <0,0001
Lymphozytenzahl erniedrigt					
Alter (Interaktionstest: p=0,7663)					
<50	690	49 (7,1)	663	13 (2,0)	3,82 [2,05; 7,11]; <0,0001 3,62 [1,98; 6,61]; <0,0001 0,05 [0,03; 0,07]; <0,0001
50-64	192	12 (6,3)	209	2 (1,0)	6,90 [1,52; 31,24]; 0,0122 6,53 [1,48; 28,81]; 0,0132 0,05 [0,02; 0,09]; 0,0047
≥65	29	1 (3,5)	32	0 (0,0)	3,42 [0,13; 87,34]; 0,4568 3,30 [0,14; 77,95]; 0,4593 0,03 [-0,05; 0,12]; 0,4447
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,7745)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	57 (6,6)	840	15 (1,8)	3,90 [2,19; 6,94]; <0,0001 3,71 [2,12; 6,50]; <0,0001 0,05 [0,03; 0,07]; <0,0001
Taxan	43	4 (9,3)	50	0 (0,0)	11,51 [0,60; 220,12]; 0,1047 10,43 [0,58; 188,41]; 0,1122 0,09 [0,00; 0,19]; 0,0512
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2896)					
Brusterhaltend	220	12 (5,5)	235	4 (1,7)	3,33 [1,06; 10,49]; 0,0397 3,20 [1,05; 9,79]; 0,0409 0,04 [0,00; 0,07]; 0,0318
Einseitige Mastektomie	355	34 (9,6)	352	11 (3,1)	3,28 [1,64; 6,59]; 0,0008 3,06 [1,58; 5,95]; 0,0009 0,06 [0,03; 0,10]; 0,0004

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	16 (4,8)	315	0 (0,0)	32,49 [1,94; 543,79]; 0,0155 30,94 [1,86; 513,61]; 0,0166 0,05 [0,02; 0,07]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7791)					
Ja	41	3 (7,3)	35	0 (0,0)	6,45 [0,32; 129,39]; 0,2228 6,00 [0,32; 112,32]; 0,2306 0,07 [-0,02; 0,17]; 0,1187
Nein	870	59 (6,8)	866	15 (1,7)	4,13 [2,32; 7,33]; <0,0001 3,92 [2,24; 6,85]; <0,0001 0,05 [0,03; 0,07]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,2346)					
Positiv	173	25 (14,5)	176	9 (5,1)	3,13 [1,42; 6,93]; 0,0048 2,83 [1,36; 5,88]; 0,0054 0,09 [0,03; 0,16]; 0,0030
Negativ	200	11 (5,5)	191	1 (0,5)	11,06 [1,41; 86,50]; 0,0220 10,51 [1,37; 80,59]; 0,0237 0,05 [0,02; 0,08]; 0,0033
Bilaterale Oophorektomie (Interaktionstest: p=0,5669)					
Ja	189	13 (6,9)	176	2 (1,1)	6,43 [1,43; 28,90]; 0,0153 6,05 [1,39; 26,44]; 0,0167 0,06 [0,02; 0,10]; 0,0042
Nein	722	49 (6,8)	728	13 (1,8)	4,00 [2,15; 7,45]; <0,0001 3,80 [2,08; 6,94]; <0,0001 0,05 [0,03; 0,07]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,6051)					
BRCA1	574	32 (5,6)	580	9 (1,6)	3,75 [1,77; 7,92]; 0,0005 3,59 [1,73; 7,46]; 0,0006 0,04 [0,02; 0,06]; 0,0002
BRCA2	232	12 (5,2)	215	2 (0,9)	5,81 [1,28; 26,26]; 0,0223 5,56 [1,26; 24,56]; 0,0236 0,04 [0,01; 0,07]; 0,0078
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9869)					
2, 3 oder 4	392	13 (3,3)	383	4 (1,0)	3,25 [1,05; 10,06]; 0,0409 3,18 [1,04; 9,65]; 0,0417 0,02 [0,00; 0,04]; 0,0294
5 oder 6	22	2 (9,1)	14	0 (0,0)	3,54 [0,16; 79,29]; 0,4260 3,26 [0,17; 63,30]; 0,4347 0,09 [-0,07; 0,25]; 0,2543

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,8484)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	32 (12,4)	271	7 (2,6)	5,32 [2,30; 12,28]; <0,0001 4,78 [2,15; 10,64]; 0,0001 0,10 [0,05; 0,14]; <0,0001
Kaukasisch	617	29 (4,7)	589	8 (1,4)	3,58 [1,62; 7,90]; 0,0016 3,46 [1,60; 7,51]; 0,0017 0,03 [0,01; 0,05]; 0,0006
Schwarz oder afroamerikanisch	19	1 (5,3)	29	0 (0,0)	4,78 [0,18; 123,74]; 0,3456 4,50 [0,19; 105,03]; 0,3494 0,05 [-0,07; 0,18]; 0,4062
Ethnische Abstammung (Interaktionstest: p=0,3037)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	59 (7,4)	803	13 (1,6)	4,85 [2,64; 8,92]; <0,0001 4,57 [2,53; 8,26]; <0,0001 0,06 [0,04; 0,08]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	2 (2,5)	77	2 (2,6)	0,97 [0,13; 7,09]; 0,9793 0,97 [0,14; 6,75]; 0,9793 0,00 [-0,05; 0,05]; 0,9793
Hormonrezeptorstatus (Interaktionstest: p=0,1677)					
ER- und/oder PgR-positiv, HER2-positiv	168	13 (7,7)	155	0 (0,0)	27,00 [1,59; 458,17]; 0,0225 24,92 [1,49; 415,74]; 0,0251 0,08 [0,04; 0,12]; 0,0003
TNBC	741	49 (6,6)	749	15 (2,0)	3,46 [1,93; 6,24]; <0,0001 3,30 [1,87; 5,84]; <0,0001 0,05 [0,03; 0,07]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,5624)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	7 (6,7)	92	0 (0,0)	14,23 [0,80; 252,70]; 0,0704 13,29 [0,77; 229,47]; 0,0752 0,07 [0,02; 0,12]; 0,0104
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	6 (9,4)	63	0 (0,0)	14,11 [0,78; 256,02]; 0,0735 12,80 [0,74; 222,54]; 0,0802 0,09 [0,02; 0,17]; 0,0157
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	12 (3,5)	362	5 (1,4)	2,55 [0,89; 7,32]; 0,0817 2,50 [0,89; 7,01]; 0,0825 0,02 [0,00; 0,04]; 0,0734
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	37 (9,4)	387	10 (2,6)	3,92 [1,92; 8,00]; 0,0002 3,64 [1,84; 7,22]; 0,0002 0,07 [0,04; 0,10]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,5234)					
Postmenopausal	346	21 (6,1)	356	4 (1,1)	5,69 [1,93; 16,74]; 0,0016 5,40 [1,87; 15,58]; 0,0018 0,05 [0,02; 0,08]; 0,0004
Prämenopausal	563	41 (7,3)	544	11 (2,0)	3,81 [1,94; 7,49]; 0,0001 3,60 [1,87; 6,93]; 0,0001 0,05 [0,03; 0,08]; <0,0001
Region (Interaktionstest: p=0,0492)					
Asien-Pazifik und Südafrika	301	34 (11,3)	317	7 (2,2)	5,64 [2,46; 12,93]; <0,0001 5,12 [2,30; 11,36]; <0,0001 0,09 [0,05; 0,13]; <0,0001
Europa	473	12 (2,5)	444	7 (1,6)	1,63 [0,63; 4,17]; 0,3120 1,61 [0,64; 4,05]; 0,3125 0,01 [-0,01; 0,03]; 0,3038
Nordamerika	121	16 (13,2)	131	1 (0,8)	19,81 [2,58; 151,83]; 0,0041 17,32 [2,33; 128,65]; 0,0053 0,12 [0,06; 0,19]; <0,0001
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,8583)					
Adjuvant	457	43 (9,4)	450	10 (2,2)	4,57 [2,27; 9,21]; <0,0001 4,23 [2,15; 8,32]; <0,0001 0,07 [0,04; 0,10]; <0,0001
Neoadjuvant	454	19 (4,2)	454	5 (1,1)	3,92 [1,45; 10,60]; 0,0070 3,80 [1,43; 10,09]; 0,0074 0,03 [0,01; 0,05]; 0,0036
Sponsor (Interaktionstest: p=0,1403)					
AZ	801	46 (5,7)	796	14 (1,8)	3,40 [1,86; 6,24]; <0,0001 3,27 [1,81; 5,89]; <0,0001 0,04 [0,02; 0,06]; <0,0001
NRG Oncology	110	16 (14,6)	108	1 (0,9)	18,21 [2,37; 139,95]; 0,0053 15,71 [2,12; 116,40]; 0,0070 0,14 [0,07; 0,20]; <0,0001
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,6107)					
Ja	243	17 (7,0)	236	5 (2,1)	3,48 [1,26; 9,58]; 0,0160 3,30 [1,24; 8,81]; 0,0170 0,05 [0,01; 0,09]; 0,0097
Nein	668	45 (6,7)	668	10 (1,5)	4,75 [2,37; 9,51]; <0,0001 4,50 [2,29; 8,85]; <0,0001 0,05 [0,03; 0,07]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Neutrophilenzahl erniedrigt					
Alter (Interaktionstest: p=0,4590)					
<50	690	116 (16,8)	663	47 (7,1)	2,65 [1,85; 3,79]; <0,0001 2,37 [1,72; 3,27]; <0,0001 0,10 [0,06; 0,13]; <0,0001
50-64	192	25 (13,0)	209	12 (5,7)	2,46 [1,20; 5,04]; 0,0142 2,27 [1,17; 4,39]; 0,0150 0,07 [0,02; 0,13]; 0,0125
≥65	29	6 (20,7)	32	0 (0,0)	17,98 [0,96; 335,02]; 0,0529 14,30 [0,84; 243,20]; 0,0658 0,21 [0,05; 0,36]; 0,0081
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6553)					
Anthrazyklin	7	2 (28,6)	13	1 (7,7)	4,80 [0,35; 65,76]; 0,2401 3,71 [0,40; 34,12]; 0,2462 0,21 [-0,16; 0,57]; 0,2618
Anthrazyklin und Taxan	861	140 (16,3)	840	54 (6,4)	2,83 [2,03; 3,93]; <0,0001 2,53 [1,88; 3,41]; <0,0001 0,10 [0,07; 0,13]; <0,0001
Taxan	43	5 (11,6)	50	4 (8,0)	1,51 [0,38; 6,03]; 0,5573 1,45 [0,42; 5,07]; 0,5576 0,04 [-0,09; 0,16]; 0,5594
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,5579)					
Brusterhaltend	220	30 (13,6)	235	13 (5,5)	2,70 [1,37; 5,32]; 0,0042 2,47 [1,32; 4,60]; 0,0046 0,08 [0,03; 0,13]; 0,0032
Einseitige Mastektomie	355	67 (18,9)	352	31 (8,8)	2,41 [1,53; 3,79]; 0,0001 2,14 [1,44; 3,20]; 0,0002 0,10 [0,05; 0,15]; <0,0001
Beidseitige Mastektomie	336	50 (14,9)	315	15 (4,8)	3,50 [1,92; 6,37]; <0,0001 3,12 [1,79; 5,45]; <0,0001 0,10 [0,06; 0,15]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7559)					
Ja	41	2 (4,9)	35	1 (2,9)	1,74 [0,15; 20,09]; 0,6557 1,71 [0,16; 18,04]; 0,6565 0,02 [-0,07; 0,11]; 0,6451
Nein	870	145 (16,7)	866	58 (6,7)	2,79 [2,02; 3,84]; <0,0001 2,49 [1,86; 3,32]; <0,0001 0,10 [0,07; 0,13]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,7339)					
Positiv	173	48 (27,8)	176	18 (10,2)	3,37 [1,87; 6,08]; <0,0001 2,71 [1,65; 4,47]; <0,0001 0,18 [0,09; 0,26]; <0,0001
Negativ	200	36 (18,0)	191	11 (5,8)	3,59 [1,77; 7,29]; 0,0004 3,13 [1,64; 5,96]; 0,0005 0,12 [0,06; 0,19]; 0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,2718)					
Ja	189	25 (13,2)	176	13 (7,4)	1,91 [0,95; 3,87]; 0,0715 1,79 [0,95; 3,39]; 0,0734 0,06 [0,00; 0,12]; 0,0642
Nein	722	122 (16,9)	728	46 (6,3)	3,01 [2,11; 4,31]; <0,0001 2,67 [1,94; 3,69]; <0,0001 0,11 [0,07; 0,14]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,7467)					
BRCA1	574	92 (16,0)	580	36 (6,2)	2,88 [1,93; 4,32]; <0,0001 2,58 [1,79; 3,73]; <0,0001 0,10 [0,06; 0,13]; <0,0001
BRCA2	232	27 (11,6)	215	11 (5,1)	2,44 [1,18; 5,06]; 0,0161 2,27 [1,16; 4,47]; 0,0172 0,07 [0,01; 0,12]; 0,0117
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9926)					
2, 3 oder 4	392	49 (12,5)	383	19 (5,0)	2,74 [1,58; 4,74]; 0,0003 2,52 [1,51; 4,20]; 0,0004 0,08 [0,04; 0,11]; 0,0002
5 oder 6	22	4 (18,2)	14	1 (7,1)	2,89 [0,29; 28,94]; 0,3669 2,55 [0,32; 20,50]; 0,3801 0,11 [-0,10; 0,32]; 0,3033
Ethnie (Interaktionstest: p=0,3541)					
Andere	16	1 (6,3)	15	2 (13,3)	0,43 [0,04; 5,35]; 0,5142 0,47 [0,05; 4,65]; 0,5175 -0,07 [-0,28; 0,14]; 0,5064
Asiatisch	259	78 (30,1)	271	32 (11,8)	3,22 [2,04; 5,07]; <0,0001 2,55 [1,75; 3,71]; <0,0001 0,18 [0,12; 0,25]; <0,0001
Kaukasisch	617	67 (10,9)	589	23 (3,9)	3,00 [1,84; 4,88]; <0,0001 2,78 [1,76; 4,41]; <0,0001 0,07 [0,04; 0,10]; <0,0001
Schwarz oder afroamerikanisch	19	1 (5,3)	29	2 (6,9)	0,75 [0,06; 8,90]; 0,8197 0,76 [0,07; 7,84]; 0,8201 -0,02 [-0,15; 0,12]; 0,8143

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,7915)					
Hispanisch	34	5 (14,7)	24	1 (4,2)	3,97 [0,43; 36,35]; 0,2230 3,53 [0,44; 28,32]; 0,2353 0,11 [-0,04; 0,25]; 0,1497
Nicht-hispanisch	798	137 (17,2)	803	55 (6,8)	2,82 [2,03; 3,92]; <0,0001 2,51 [1,86; 3,37]; <0,0001 0,10 [0,07; 0,13]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	5 (6,3)	77	3 (3,9)	1,67 [0,38; 7,23]; 0,4950 1,62 [0,40; 6,56]; 0,4959 0,02 [-0,04; 0,09]; 0,4890
Hormonrezeptorstatus (Interaktionstest: p=0,0260)					
ER- und/oder PgR-positiv, HER2-positiv	168	15 (8,9)	155	12 (7,7)	1,17 [0,53; 2,58]; 0,7005 1,15 [0,56; 2,39]; 0,7007 0,01 [-0,05; 0,07]; 0,6995
TNBC	741	132 (17,8)	749	47 (6,3)	3,24 [2,28; 4,59]; <0,0001 2,84 [2,07; 3,90]; <0,0001 0,12 [0,08; 0,15]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,1392)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	11 (10,6)	92	7 (7,6)	1,44 [0,53; 3,87]; 0,4745 1,39 [0,56; 3,44]; 0,4757 0,03 [-0,05; 0,11]; 0,4681
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	4 (6,3)	63	5 (7,9)	0,77 [0,20; 3,02]; 0,7117 0,79 [0,22; 2,80]; 0,7119 -0,02 [-0,11; 0,07]; 0,7112
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	45 (12,9)	362	18 (5,0)	2,84 [1,61; 5,01]; 0,0003 2,60 [1,54; 4,40]; 0,0004 0,08 [0,04; 0,12]; 0,0002
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	87 (22,1)	387	29 (7,5)	3,51 [2,24; 5,49]; <0,0001 2,95 [1,99; 4,39]; <0,0001 0,15 [0,10; 0,20]; <0,0001
Menopausenstatus (Interaktionstest: p=0,9039)					
Postmenopausal	346	49 (14,2)	356	21 (5,9)	2,63 [1,54; 4,49]; 0,0004 2,40 [1,47; 3,92]; 0,0005 0,08 [0,04; 0,13]; 0,0002
Prämenopausal	563	98 (17,4)	544	38 (7,0)	2,81 [1,89; 4,17]; <0,0001 2,49 [1,75; 3,56]; <0,0001 0,10 [0,07; 0,14]; <0,0001
Region (Interaktionstest: p=0,7782)					
Asien-Pazifik und Südafrika	301	83 (27,6)	317	35 (11,0)	3,07 [1,99; 4,73]; <0,0001 2,50 [1,74; 3,59]; <0,0001 0,17 [0,10; 0,23]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	47 (9,9)	444	20 (4,5)	2,34 [1,36; 4,01]; 0,0021 2,21 [1,33; 3,66]; 0,0022 0,05 [0,02; 0,09]; 0,0013
Nordamerika	121	15 (12,4)	131	4 (3,1)	4,49 [1,45; 13,95]; 0,0093 4,06 [1,39; 11,89]; 0,0106 0,09 [0,03; 0,16]; 0,0053
Südamerika	16	2 (12,5)	12	0 (0,0)	4,31 [0,19; 98,51]; 0,3601 3,82 [0,20; 73,00]; 0,3728 0,12 [-0,07; 0,32]; 0,2164
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5867)					
Adjuvant	457	91 (19,9)	450	34 (7,6)	3,04 [2,00; 4,62]; <0,0001 2,64 [1,82; 3,82]; <0,0001 0,12 [0,08; 0,17]; <0,0001
Neoadjuvant	454	56 (12,3)	454	25 (5,5)	2,41 [1,48; 3,94]; 0,0004 2,24 [1,42; 3,52]; 0,0005 0,07 [0,03; 0,11]; 0,0003
Sponsor (Interaktionstest: p=0,4439)					
AZ	801	132 (16,5)	796	55 (6,9)	2,66 [1,91; 3,70]; <0,0001 2,39 [1,77; 3,22]; <0,0001 0,10 [0,06; 0,13]; <0,0001
NRG Oncology	110	15 (13,6)	108	4 (3,7)	4,11 [1,32; 12,80]; 0,0150 3,68 [1,26; 10,74]; 0,0170 0,10 [0,03; 0,17]; 0,0080
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4989)					
Ja	243	32 (13,2)	236	15 (6,4)	2,23 [1,18; 4,24]; 0,0141 2,07 [1,15; 3,72]; 0,0149 0,07 [0,02; 0,12]; 0,0113
Nein	668	115 (17,2)	668	44 (6,6)	2,95 [2,05; 4,25]; <0,0001 2,61 [1,88; 3,64]; <0,0001 0,11 [0,07; 0,14]; <0,0001
Thrombozytenzahl vermindert					
Alter (Interaktionstest: p=0,8048)					
<50	690	26 (3,8)	663	8 (1,2)	3,21 [1,44; 7,13]; 0,0043 3,12 [1,42; 6,85]; 0,0045 0,03 [0,01; 0,04]; 0,0023
50-64	192	8 (4,2)	209	4 (1,9)	2,23 [0,66; 7,52]; 0,1968 2,18 [0,67; 7,11]; 0,1978 0,02 [-0,01; 0,06]; 0,1917
≥65	29	2 (6,9)	32	0 (0,0)	5,91 [0,27; 128,38]; 0,2581 5,50 [0,27; 110,01]; 0,2647 0,07 [-0,04; 0,18]; 0,2079

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,7478)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	34 (4,0)	840	11 (1,3)	3,10 [1,56; 6,16]; 0,0012 3,02 [1,54; 5,91]; 0,0013 0,03 [0,01; 0,04]; 0,0006
Taxan	43	1 (2,3)	50	1 (2,0)	1,17 [0,07; 19,23]; 0,9141 1,16 [0,07; 18,04]; 0,9141 0,00 [-0,06; 0,06]; 0,9145
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2417)					
Brusterhaltend	220	10 (4,6)	235	0 (0,0)	23,49 [1,37; 403,38]; 0,0295 22,43 [1,32; 380,42]; 0,0313 0,05 [0,02; 0,07]; 0,0019
Einseitige Mastektomie	355	15 (4,2)	352	6 (1,7)	2,54 [0,98; 6,63]; 0,0562 2,48 [0,97; 6,32]; 0,0571 0,03 [0,00; 0,05]; 0,0474
Beidseitige Mastektomie	336	11 (3,3)	315	6 (1,9)	1,74 [0,64; 4,77]; 0,2794 1,72 [0,64; 4,59]; 0,2801 0,01 [-0,01; 0,04]; 0,2693
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7896)					
Ja	41	2 (4,9)	35	0 (0,0)	4,49 [0,21; 96,80]; 0,3374 4,29 [0,21; 86,39]; 0,3423 0,05 [-0,03; 0,13]; 0,2386
Nein	870	34 (3,9)	866	12 (1,4)	2,89 [1,49; 5,63]; 0,0017 2,82 [1,47; 5,41]; 0,0018 0,03 [0,01; 0,04]; 0,0010
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,1796)					
Positiv	173	10 (5,8)	176	5 (2,8)	2,10 [0,70; 6,27]; 0,1846 2,03 [0,71; 5,83]; 0,1860 0,03 [-0,01; 0,07]; 0,1759
Negativ	200	8 (4,0)	191	0 (0,0)	16,91 [0,97; 295,06]; 0,0526 16,24 [0,94; 279,42]; 0,0548 0,04 [0,01; 0,07]; 0,0064
Bilaterale Oophorektomie (Interaktionstest: p=0,9285)					
Ja	189	6 (3,2)	176	2 (1,1)	2,85 [0,57; 14,32]; 0,2030 2,79 [0,57; 13,66]; 0,2045 0,02 [-0,01; 0,05]; 0,1756
Nein	722	30 (4,2)	728	10 (1,4)	3,11 [1,51; 6,42]; 0,0021 3,02 [1,49; 6,14]; 0,0022 0,03 [0,01; 0,04]; 0,0012

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,4617)					
BRCA1	574	26 (4,5)	580	7 (1,2)	3,88 [1,67; 9,02]; 0,0016 3,75 [1,64; 8,58]; 0,0017 0,03 [0,01; 0,05]; 0,0007
BRCA2	232	4 (1,7)	215	2 (0,9)	1,87 [0,34; 10,31]; 0,4731 1,85 [0,34; 10,02]; 0,4735 0,01 [-0,01; 0,03]; 0,4609
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9104)					
2, 3 oder 4	392	9 (2,3)	383	4 (1,0)	2,23 [0,68; 7,29]; 0,1860 2,20 [0,68; 7,08]; 0,1867 0,01 [-0,01; 0,03]; 0,1726
5 oder 6	22	3 (13,6)	14	1 (7,1)	2,05 [0,19; 21,97]; 0,5521 1,91 [0,22; 16,58]; 0,5577 0,06 [-0,13; 0,26]; 0,5180
Ethnie (Interaktionstest: p=0,4719)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	16 (6,2)	271	6 (2,2)	2,91 [1,12; 7,55]; 0,0283 2,79 [1,11; 7,02]; 0,0293 0,04 [0,01; 0,07]; 0,0229
Kaukasisch	617	20 (3,2)	589	5 (0,9)	3,91 [1,46; 10,49]; 0,0067 3,82 [1,44; 10,11]; 0,0070 0,02 [0,01; 0,04]; 0,0030
Schwarz oder afroamerikanisch	19	0 (0,0)	29	1 (3,5)	0,49 [0,02; 12,59]; 0,6647 0,50 [0,02; 11,67]; 0,6663 -0,03 [-0,14; 0,07]; 0,5148
Ethnische Abstammung (Interaktionstest: p=0,6231)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	30 (3,8)	803	12 (1,5)	2,57 [1,31; 5,07]; 0,0062 2,52 [1,30; 4,88]; 0,0063 0,02 [0,01; 0,04]; 0,0045
Unbekannt, nicht erfasst, verweigert	79	5 (6,3)	77	0 (0,0)	11,44 [0,62; 210,58]; 0,1010 10,72 [0,60; 190,72]; 0,1062 0,06 [0,01; 0,12]; 0,0331
Hormonrezeptorstatus (Interaktionstest: p=0,1088)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	2 (1,3)	0,46 [0,04; 5,10]; 0,5256 0,46 [0,04; 5,04]; 0,5259 -0,01 [-0,03; 0,01]; 0,5212

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	35 (4,7)	749	10 (1,3)	3,66 [1,80; 7,45]; 0,0003 3,54 [1,76; 7,09]; 0,0004 0,03 [0,02; 0,05]; 0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3967)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	1 (1,1)	0,29 [0,01; 7,25]; 0,4525 0,30 [0,01; 7,16]; 0,4533 -0,01 [-0,04; 0,02]; 0,4593
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	1 (1,6)	0,98 [0,06; 16,09]; 0,9910 0,98 [0,06; 15,40]; 0,9910 0,00 [-0,04; 0,04]; 0,9910
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	15 (4,3)	362	5 (1,4)	3,22 [1,16; 8,95]; 0,0252 3,12 [1,15; 8,49]; 0,0259 0,03 [0,00; 0,05]; 0,0191
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	20 (5,1)	387	5 (1,3)	4,10 [1,52; 11,03]; 0,0053 3,94 [1,49; 10,39]; 0,0056 0,04 [0,01; 0,06]; 0,0024
Menopausenstatus (Interaktionstest: p=0,5708)					
Postmenopausal	346	16 (4,6)	356	4 (1,1)	4,27 [1,41; 12,89]; 0,0101 4,12 [1,39; 12,19]; 0,0106 0,04 [0,01; 0,06]; 0,0055
Prämenopausal	563	20 (3,6)	544	7 (1,3)	2,83 [1,19; 6,74]; 0,0191 2,76 [1,18; 6,48]; 0,0196 0,02 [0,00; 0,04]; 0,0135
Region (Interaktionstest: p=0,5336)					
Asien-Pazifik und Südafrika	301	16 (5,3)	317	7 (2,2)	2,49 [1,01; 6,13]; 0,0480 2,41 [1,00; 5,77]; 0,0489 0,03 [0,00; 0,06]; 0,0428
Europa	473	12 (2,5)	444	4 (0,9)	2,86 [0,92; 8,94]; 0,0703 2,82 [0,92; 8,67]; 0,0711 0,02 [0,00; 0,03]; 0,0545
Nordamerika	121	8 (6,6)	131	1 (0,8)	9,20 [1,13; 74,71]; 0,0378 8,66 [1,10; 68,24]; 0,0404 0,06 [0,01; 0,11]; 0,0141
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,6279)					
Adjuvant	457	21 (4,6)	450	6 (1,3)	3,56 [1,42; 8,92]; 0,0066 3,45 [1,40; 8,46]; 0,0069 0,03 [0,01; 0,05]; 0,0036
Neoadjuvant	454	15 (3,3)	454	6 (1,3)	2,55 [0,98; 6,64]; 0,0548 2,50 [0,98; 6,39]; 0,0555 0,02 [0,00; 0,04]; 0,0464

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,3071)					
AZ	801	28 (3,5)	796	11 (1,4)	2,58 [1,28; 5,23]; 0,0082 2,53 [1,27; 5,05]; 0,0084 0,02 [0,01; 0,04]; 0,0060
NRG Oncology	110	8 (7,3)	108	1 (0,9)	8,39 [1,03; 68,29]; 0,0467 7,85 [1,00; 61,74]; 0,0501 0,06 [0,01; 0,12]; 0,0163
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,2532)					
Ja	243	9 (3,7)	236	5 (2,1)	1,78 [0,59; 5,38]; 0,3093 1,75 [0,59; 5,14]; 0,3100 0,02 [-0,01; 0,05]; 0,3008
Nein	668	27 (4,0)	668	7 (1,0)	3,98 [1,72; 9,20]; 0,0012 3,86 [1,69; 8,80]; 0,0013 0,03 [0,01; 0,05]; 0,0005
SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen					
Alter (Interaktionstest: p=0,8991)					
<50	690	40 (5,8)	663	62 (9,4)	0,60 [0,39; 0,90]; 0,0141 0,62 [0,42; 0,91]; 0,0144 -0,04 [-0,06; -0,01]; 0,0135
50-64	192	8 (4,2)	209	13 (6,2)	0,66 [0,27; 1,62]; 0,3595 0,67 [0,28; 1,58]; 0,3604 -0,02 [-0,06; 0,02]; 0,3521
≥65	29	2 (6,9)	32	5 (15,6)	0,40 [0,07; 2,24]; 0,2977 0,44 [0,09; 2,10]; 0,3045 -0,09 [-0,24; 0,07]; 0,2728
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,8948)					
Anthrazyklin	7	0 (0,0)	13	1 (7,7)	0,56 [0,02; 15,46]; 0,7291 0,58 [0,03; 12,70]; 0,7316 -0,08 [-0,31; 0,16]; 0,5180
Anthrazyklin und Taxan	861	47 (5,5)	840	75 (8,9)	0,59 [0,40; 0,86]; 0,0060 0,61 [0,43; 0,87]; 0,0062 -0,03 [-0,06; -0,01]; 0,0056
Taxan	43	3 (7,0)	50	4 (8,0)	0,86 [0,18; 4,09]; 0,8522 0,87 [0,21; 3,68]; 0,8523 -0,01 [-0,12; 0,10]; 0,8513
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0880)					
Brusterhaltend	220	7 (3,2)	235	15 (6,4)	0,48 [0,19; 1,21]; 0,1187 0,50 [0,21; 1,20]; 0,1202 -0,03 [-0,07; 0,01]; 0,1069
Einseitige Mastektomie	355	24 (6,8)	352	24 (6,8)	0,99 [0,55; 1,78]; 0,9757 0,99 [0,57; 1,71]; 0,9757 0,00 [-0,04; 0,04]; 0,9757

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	19 (5,7)	315	41 (13,0)	0,40 [0,23; 0,71]; 0,0016 0,43 [0,26; 0,73]; 0,0017 -0,07 [-0,12; -0,03]; 0,0012
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7688)					
Ja	41	3 (7,3)	35	5 (14,3)	0,47 [0,10; 2,14]; 0,3319 0,51 [0,13; 1,99]; 0,3344 -0,07 [-0,21; 0,07]; 0,3316
Nein	870	47 (5,4)	866	74 (8,6)	0,61 [0,42; 0,89]; 0,0108 0,63 [0,44; 0,90]; 0,0110 -0,03 [-0,06; -0,01]; 0,0100
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,0462)					
Positiv	173	4 (2,3)	176	14 (8,0)	0,27 [0,09; 0,85]; 0,0249 0,29 [0,10; 0,87]; 0,0265 -0,06 [-0,10; -0,01]; 0,0158
Negativ	200	14 (7,0)	191	12 (6,3)	1,12 [0,51; 2,49]; 0,7761 1,11 [0,53; 2,35]; 0,7761 0,01 [-0,04; 0,06]; 0,7757
Bilaterale Oophorektomie (Interaktionstest: p=0,3037)					
Ja	189	13 (6,9)	176	26 (14,8)	0,43 [0,21; 0,86]; 0,0170 0,47 [0,25; 0,88]; 0,0180 -0,08 [-0,14; -0,02]; 0,0150
Nein	722	37 (5,1)	728	54 (7,4)	0,67 [0,44; 1,04]; 0,0734 0,69 [0,46; 1,04]; 0,0738 -0,02 [-0,05; 0,00]; 0,0713
BRCA-Mutationsstatus (Interaktionstest: p=0,6225)					
BRCA1	574	28 (4,9)	580	54 (9,3)	0,50 [0,31; 0,80]; 0,0039 0,52 [0,34; 0,81]; 0,0041 -0,04 [-0,07; -0,01]; 0,0032
BRCA2	232	17 (7,3)	215	25 (11,6)	0,60 [0,31; 1,15]; 0,1225 0,63 [0,35; 1,13]; 0,1235 -0,04 [-0,10; 0,01]; 0,1214
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,3484)					
2, 3 oder 4	392	22 (5,6)	383	35 (9,1)	0,59 [0,34; 1,03]; 0,0625 0,61 [0,37; 1,03]; 0,0632 -0,04 [-0,07; 0,00]; 0,0602
5 oder 6	22	1 (4,6)	14	3 (21,4)	0,17 [0,02; 1,88]; 0,1503 0,21 [0,02; 1,84]; 0,1598 -0,17 [-0,40; 0,06]; 0,1536

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,8153)					
Andere	16	1 (6,3)	15	2 (13,3)	0,43 [0,04; 5,35]; 0,5142 0,47 [0,05; 4,65]; 0,5175 -0,07 [-0,28; 0,14]; 0,5064
Asiatisch	259	13 (5,0)	271	20 (7,4)	0,66 [0,32; 1,36]; 0,2637 0,68 [0,35; 1,34]; 0,2645 -0,02 [-0,06; 0,02]; 0,2584
Kaukasisch	617	36 (5,8)	589	54 (9,2)	0,61 [0,40; 0,95]; 0,0289 0,64 [0,42; 0,96]; 0,0293 -0,03 [-0,06; 0,00]; 0,0281
Schwarz oder afroamerikanisch	19	0 (0,0)	29	4 (13,8)	0,15 [0,01; 2,86]; 0,2046 0,17 [0,01; 2,93]; 0,2205 -0,14 [-0,28; 0,01]; 0,0622
Ethnische Abstammung (Interaktionstest: p=0,6190)					
Hispanisch	34	0 (0,0)	24	2 (8,3)	0,13 [0,01; 2,85]; 0,1953 0,14 [0,01; 2,85]; 0,2025 -0,08 [-0,21; 0,04]; 0,1878
Nicht-hispanisch	798	46 (5,8)	803	72 (9,0)	0,62 [0,42; 0,91]; 0,0150 0,64 [0,45; 0,92]; 0,0152 -0,03 [-0,06; -0,01]; 0,0140
Unbekannt, nicht erfasst, verweigert	79	4 (5,1)	77	6 (7,8)	0,63 [0,17; 2,33]; 0,4898 0,65 [0,19; 2,21]; 0,4906 -0,03 [-0,10; 0,05]; 0,4870
Hormonrezeptorstatus (Interaktionstest: p=0,6190)					
ER- und/oder PgR-positiv, HER2-positiv	168	14 (8,3)	155	24 (15,5)	0,50 [0,25; 1,00]; 0,0495 0,54 [0,29; 1,00]; 0,0509 -0,07 [-0,14; 0,00]; 0,0473
TNBC	741	36 (4,9)	749	56 (7,5)	0,63 [0,41; 0,97]; 0,0371 0,65 [0,43; 0,98]; 0,0375 -0,03 [-0,05; 0,00]; 0,0353
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7637)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	8 (7,7)	92	16 (17,4)	0,40 [0,16; 0,97]; 0,0437 0,44 [0,20; 0,99]; 0,0459 -0,10 [-0,19; 0,00]; 0,0406
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	6 (9,4)	63	8 (12,7)	0,71 [0,23; 2,18]; 0,5513 0,74 [0,27; 2,01]; 0,5519 -0,03 [-0,14; 0,08]; 0,5497
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	17 (4,9)	362	24 (6,6)	0,72 [0,38; 1,37]; 0,3209 0,74 [0,40; 1,35]; 0,3214 -0,02 [-0,05; 0,02]; 0,3174
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	19 (4,8)	387	32 (8,3)	0,56 [0,31; 1,01]; 0,0551 0,58 [0,34; 1,01]; 0,0558 -0,03 [-0,07; 0,00]; 0,0523

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI]; p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,9360)					
Postmenopausal	346	22 (6,4)	356	37 (10,4)	0,59 [0,34; 1,01]; 0,0563 0,61 [0,37; 1,02]; 0,0572 -0,04 [-0,08; 0,00]; 0,0527
Prämenopausal	563	28 (5,0)	544	43 (7,9)	0,61 [0,37; 1,00]; 0,0485 0,63 [0,40; 1,00]; 0,0489 -0,03 [-0,06; 0,00]; 0,0470
Region (Interaktionstest: p=0,8724)					
Asien-Pazifik und Südafrika	301	16 (5,3)	317	23 (7,3)	0,72 [0,37; 1,39]; 0,3234 0,73 [0,39; 1,36]; 0,3240 -0,02 [-0,06; 0,02]; 0,3193
Europa	473	20 (4,2)	444	29 (6,5)	0,63 [0,35; 1,13]; 0,1240 0,65 [0,37; 1,13]; 0,1245 -0,02 [-0,05; 0,01]; 0,1231
Nordamerika	121	14 (11,6)	131	27 (20,6)	0,50 [0,25; 1,01]; 0,0549 0,56 [0,31; 1,02]; 0,0577 -0,09 [-0,18; 0,00]; 0,0482
Südamerika	16	0 (0,0)	12	1 (8,3)	0,23 [0,01; 6,22]; 0,3843 0,25 [0,01; 5,76]; 0,3902 -0,08 [-0,27; 0,11]; 0,3933
Art der vorherigen Chemotherapie (Interaktionstest: p=0,9646)					
Adjuvant	457	25 (5,5)	450	40 (8,9)	0,59 [0,35; 1,00]; 0,0480 0,62 [0,38; 1,00]; 0,0486 -0,03 [-0,07; 0,00]; 0,0459
Neoadjuvant	454	25 (5,5)	454	40 (8,8)	0,60 [0,36; 1,01]; 0,0556 0,62 [0,39; 1,01]; 0,0562 -0,03 [-0,07; 0,00]; 0,0530
Sponsor (Interaktionstest: p=0,8668)					
AZ	801	38 (4,7)	796	60 (7,5)	0,61 [0,40; 0,93]; 0,0211 0,63 [0,42; 0,93]; 0,0214 -0,03 [-0,05; 0,00]; 0,0199
NRG Oncology	110	12 (10,9)	108	20 (18,5)	0,54 [0,25; 1,17]; 0,1161 0,59 [0,30; 1,15]; 0,1186 -0,08 [-0,17; 0,02]; 0,1111
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,8375)					
Ja	243	12 (4,9)	236	20 (8,5)	0,56 [0,27; 1,18]; 0,1255 0,58 [0,29; 1,17]; 0,1266 -0,04 [-0,08; 0,01]; 0,1216
Nein	668	38 (5,7)	668	60 (9,0)	0,61 [0,40; 0,93]; 0,0220 0,63 [0,43; 0,94]; 0,0224 -0,03 [-0,06; -0,01]; 0,0207

Anhang 4-G9: Subgruppenanalysen: Schwere UE nach SOC und PT

Tabelle 6.3.1: Subgruppenergebnisse für schwere Unerwünschte Ereignisse nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Ermüdung					
Alter (Interaktionstest: p=0,6321)					
<50	690	7 (1,0)	663	2 (0,3)	3,39 [0,70; 16,36]; 0,1290 3,36 [0,70; 16,13]; 0,1295 0,01 [0,00; 0,02]; 0,1028
50-64	192	3 (1,6)	209	0 (0,0)	7,74 [0,40; 150,80]; 0,1769 7,62 [0,40; 146,51]; 0,1783 0,02 [0,00; 0,04]; 0,1247
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,8968)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	9 (1,1)	840	2 (0,2)	4,43 [0,95; 20,55]; 0,0575 4,39 [0,95; 20,26]; 0,0579 0,01 [0,00; 0,02]; 0,0361
Taxan	43	1 (2,3)	50	0 (0,0)	3,56 [0,14; 89,80]; 0,4400 3,48 [0,15; 83,21]; 0,4417 0,02 [-0,04; 0,08]; 0,4478
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2899)					
Brusterhaltend	220	3 (1,4)	235	0 (0,0)	7,58 [0,39; 147,57]; 0,1812 7,48 [0,39; 143,89]; 0,1825 0,01 [0,00; 0,03]; 0,1261
Einseitige Mastektomie	355	5 (1,4)	352	0 (0,0)	11,06 [0,61; 200,82]; 0,1041 10,91 [0,61; 196,52]; 0,1053 0,01 [0,00; 0,03]; 0,0394
Beidseitige Mastektomie	336	2 (0,6)	315	2 (0,6)	0,94 [0,13; 6,69]; 0,9484 0,94 [0,13; 6,62]; 0,9484 0,00 [-0,01; 0,01]; 0,9484
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7572)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	9 (1,0)	866	2 (0,2)	4,52 [0,97; 20,96]; 0,0543 4,48 [0,97; 20,67]; 0,0546 0,01 [0,00; 0,02]; 0,0344

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8533)					
Positiv	173	3 (1,7)	176	0 (0,0)	7,25 [0,37; 141,34]; 0,1913 7,12 [0,37; 136,84]; 0,1930 0,02 [0,00; 0,04]; 0,1271
Negativ	200	2 (1,0)	191	0 (0,0)	4,82 [0,23; 101,13]; 0,3108 4,78 [0,23; 98,84]; 0,3118 0,01 [-0,01; 0,03]; 0,2471
Bilaterale Oophorektomie (Interaktionstest: p=0,7544)					
Ja	189	4 (2,1)	176	1 (0,6)	3,78 [0,42; 34,18]; 0,2360 3,72 [0,42; 33,01]; 0,2374 0,02 [-0,01; 0,04]; 0,1934
Nein	722	6 (0,8)	728	1 (0,1)	6,09 [0,73; 50,73]; 0,0947 6,05 [0,73; 50,13]; 0,0952 0,01 [0,00; 0,01]; 0,0572
BRCA-Mutationsstatus (Interaktionstest: p=0,9371)					
BRCA1	574	8 (1,4)	580	2 (0,3)	4,08 [0,86; 19,32]; 0,0759 4,04 [0,86; 18,95]; 0,0765 0,01 [0,00; 0,02]; 0,0550
BRCA2	232	2 (0,9)	215	0 (0,0)	4,67 [0,22; 97,92]; 0,3204 4,64 [0,22; 96,00]; 0,3213 0,01 [-0,01; 0,02]; 0,2504
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	4 (1,0)	383	2 (0,5)	1,96 [0,36; 10,79]; 0,4374 1,95 [0,36; 10,61]; 0,4376 0,00 [-0,01; 0,02]; 0,4269
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,9793)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	0 (0,0)	271	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Kaukasisch	617	9 (1,5)	589	2 (0,3)	4,34 [0,93; 20,19]; 0,0609 4,30 [0,93; 19,80]; 0,0615 0,01 [0,00; 0,02]; 0,0378
Schwarz oder afroamerikanisch	19	1 (5,3)	29	0 (0,0)	4,78 [0,18; 123,74]; 0,3456 4,50 [0,19; 105,03]; 0,3494 0,05 [-0,07; 0,18]; 0,4062

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	10 (1,3)	803	2 (0,3)	5,08 [1,11; 23,27]; 0,0362 5,03 [1,11; 22,89]; 0,0366 0,01 [0,00; 0,02]; 0,0199
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Hormonrezeptorstatus (Interaktionstest: p=0,9392)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	0 (0,0)	4,67 [0,22; 98,03]; 0,3211 4,62 [0,22; 95,39]; 0,3223 0,01 [-0,01; 0,03]; 0,2492
TNBC	741	8 (1,1)	749	2 (0,3)	4,08 [0,86; 19,26]; 0,0761 4,04 [0,86; 18,98]; 0,0766 0,01 [0,00; 0,02]; 0,0552
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,5125)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	2 (1,9)	92	0 (0,0)	4,51 [0,21; 95,21]; 0,3328 4,43 [0,22; 91,07]; 0,3347 0,02 [-0,01; 0,05]; 0,2495
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	3 (0,9)	362	2 (0,6)	1,57 [0,26; 9,42]; 0,6248 1,56 [0,26; 9,28]; 0,6248 0,00 [-0,01; 0,02]; 0,6233
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	5 (1,3)	387	0 (0,0)	10,97 [0,60; 199,10]; 0,1053 10,83 [0,60; 195,24]; 0,1063 0,01 [0,00; 0,02]; 0,0397
Menopausenstatus (Interaktionstest: p=0,8252)					
Postmenopausal	346	4 (1,2)	356	1 (0,3)	4,15 [0,46; 37,34]; 0,2039 4,12 [0,46; 36,64]; 0,2047 0,01 [0,00; 0,02]; 0,1711
Prämenopausal	563	6 (1,1)	544	1 (0,2)	5,85 [0,70; 48,75]; 0,1025 5,80 [0,70; 48,00]; 0,1032 0,01 [0,00; 0,02]; 0,0607
Region (Interaktionstest: p=0,8331)					
Asien-Pazifik und Südafrika	301	0 (0,0)	317	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	8 (1,7)	444	2 (0,5)	3,80 [0,80; 18,00]; 0,0923 3,75 [0,80; 17,59]; 0,0931 0,01 [0,00; 0,03]; 0,0651
Nordamerika	121	2 (1,7)	131	0 (0,0)	5,50 [0,26; 115,77]; 0,2726 5,41 [0,26; 111,56]; 0,2742 0,02 [-0,01; 0,04]; 0,2343
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,3870)					
Adjuvant	457	5 (1,1)	450	0 (0,0)	10,95 [0,60; 198,63]; 0,1055 10,83 [0,60; 195,32]; 0,1064 0,01 [0,00; 0,02]; 0,0399
Neoadjuvant	454	5 (1,1)	454	2 (0,4)	2,52 [0,49; 13,04]; 0,2715 2,50 [0,49; 12,82]; 0,2719 0,01 [0,00; 0,02]; 0,2547
Sponsor (Interaktionstest: p=0,9030)					
AZ	801	8 (1,0)	796	2 (0,3)	4,01 [0,85; 18,92]; 0,0798 3,98 [0,85; 18,66]; 0,0803 0,01 [0,00; 0,02]; 0,0576
NRG Oncology	110	2 (1,8)	108	0 (0,0)	5,00 [0,24; 105,37]; 0,3007 4,91 [0,24; 101,10]; 0,3025 0,02 [-0,01; 0,05]; 0,2408
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,5284)					
Ja	243	4 (1,7)	236	0 (0,0)	8,89 [0,48; 165,98]; 0,1435 8,74 [0,47; 161,48]; 0,1451 0,02 [0,00; 0,03]; 0,0709
Nein	668	6 (0,9)	668	2 (0,3)	3,02 [0,61; 15,01]; 0,1771 3,00 [0,61; 14,81]; 0,1775 0,01 [0,00; 0,01]; 0,1557
SOC: Erkrankungen des Blutes und des Lymphsystems					
Alter (Interaktionstest: p=0,3114)					
<50	690	33 (4,8)	663	0 (0,0)	67,61 [4,13; 1105,75]; 0,0031 64,38 [3,95; 1048,61]; 0,0034 0,05 [0,03; 0,06]; <0,0001
50-64	192	10 (5,2)	209	2 (1,0)	5,69 [1,23; 26,29]; 0,0261 5,44 [1,21; 24,53]; 0,0274 0,04 [0,01; 0,08]; 0,0145
≥65	29	4 (13,8)	32	0 (0,0)	11,47 [0,59; 223,00]; 0,1071 9,90 [0,56; 176,29]; 0,1187 0,14 [0,00; 0,27]; 0,0443

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,0619)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	45 (5,2)	840	1 (0,1)	46,27 [6,36; 336,44]; 0,0002 43,90 [6,07; 317,76]; 0,0002 0,05 [0,04; 0,07]; <0,0001
Taxan	43	2 (4,7)	50	1 (2,0)	2,39 [0,21; 27,31]; 0,4832 2,33 [0,22; 24,77]; 0,4844 0,03 [-0,05; 0,10]; 0,4822
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,4565)					
Brusterhaltend	220	17 (7,7)	235	0 (0,0)	40,50 [2,42; 677,74]; 0,0100 37,38 [2,26; 617,79]; 0,0114 0,08 [0,04; 0,11]; <0,0001
Einseitige Mastektomie	355	15 (4,2)	352	0 (0,0)	32,09 [1,91; 538,46]; 0,0159 30,74 [1,85; 511,75]; 0,0170 0,04 [0,02; 0,06]; 0,0001
Beidseitige Mastektomie	336	15 (4,5)	315	2 (0,6)	7,31 [1,66; 32,24]; 0,0086 7,03 [1,62; 30,50]; 0,0092 0,04 [0,01; 0,06]; 0,0016
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3289)					
Ja	41	2 (4,9)	35	0 (0,0)	4,49 [0,21; 96,80]; 0,3374 4,29 [0,21; 86,39]; 0,3423 0,05 [-0,03; 0,13]; 0,2386
Nein	870	45 (5,2)	866	2 (0,2)	23,56 [5,70; 97,44]; <0,0001 22,40 [5,45; 92,03]; <0,0001 0,05 [0,03; 0,06]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,7042)					
Positiv	173	11 (6,4)	176	1 (0,6)	11,88 [1,52; 93,07]; 0,0184 11,19 [1,46; 85,75]; 0,0201 0,06 [0,02; 0,10]; 0,0028
Negativ	200	11 (5,5)	191	0 (0,0)	23,24 [1,36; 397,24]; 0,0298 21,97 [1,30; 370,25]; 0,0320 0,06 [0,02; 0,09]; 0,0011
Bilaterale Oophorektomie (Interaktionstest: p=0,9610)					
Ja	189	9 (4,8)	176	0 (0,0)	18,58 [1,07; 321,63]; 0,0446 17,70 [1,04; 301,87]; 0,0471 0,05 [0,02; 0,08]; 0,0035
Nein	722	38 (5,3)	728	2 (0,3)	20,17 [4,85; 83,91]; <0,0001 19,16 [4,64; 79,11]; <0,0001 0,05 [0,03; 0,07]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,4752)					
BRCA1	574	31 (5,4)	580	1 (0,2)	33,06 [4,50; 242,97]; 0,0006 31,32 [4,29; 228,69]; 0,0007 0,05 [0,03; 0,07]; <0,0001
BRCA2	232	12 (5,2)	215	1 (0,5)	11,67 [1,50; 90,55]; 0,0187 11,12 [1,46; 84,80]; 0,0201 0,05 [0,02; 0,08]; 0,0020
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,1826)					
2, 3 oder 4	392	17 (4,3)	383	0 (0,0)	35,75 [2,14; 596,54]; 0,0128 34,20 [2,06; 566,68]; 0,0137 0,04 [0,02; 0,06]; <0,0001
5 oder 6	22	1 (4,6)	14	0 (0,0)	2,02 [0,08; 53,19]; 0,6727 1,96 [0,09; 44,92]; 0,6747 0,05 [-0,09; 0,18]; 0,5117
Ethnie (Interaktionstest: p=0,7786)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	15 (5,8)	271	0 (0,0)	34,42 [2,05; 578,36]; 0,0140 32,43 [1,95; 539,22]; 0,0153 0,06 [0,03; 0,09]; 0,0001
Kaukasisch	617	30 (4,9)	589	2 (0,3)	15,00 [3,57; 63,05]; 0,0002 14,32 [3,44; 59,65]; 0,0003 0,05 [0,03; 0,06]; <0,0001
Schwarz oder afroamerikanisch	19	2 (10,5)	29	0 (0,0)	8,43 [0,38; 185,87]; 0,1768 7,50 [0,38; 148,13]; 0,1856 0,11 [-0,05; 0,26]; 0,1747
Ethnische Abstammung (Interaktionstest: p=0,0795)					
Hispanisch	34	3 (8,8)	24	0 (0,0)	5,44 [0,27; 110,44]; 0,2698 5,00 [0,27; 92,56]; 0,2798 0,09 [-0,03; 0,20]; 0,1277
Nicht-hispanisch	798	43 (5,4)	803	1 (0,1)	45,68 [6,27; 332,52]; 0,0002 43,27 [5,97; 313,45]; 0,0002 0,05 [0,04; 0,07]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	1 (1,3)	0,97 [0,06; 15,86]; 0,9854 0,97 [0,06; 15,31]; 0,9854 0,00 [-0,04; 0,03]; 0,9854
Hormonrezeptorstatus (Interaktionstest: p=0,3355)					
ER- und/oder PgR-positiv, HER2-positiv	168	10 (6,0)	155	1 (0,7)	9,75 [1,23; 77,05]; 0,0309 9,23 [1,19; 71,24]; 0,0331 0,05 [0,02; 0,09]; 0,0061

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
TNBC	741	37 (5,0)	749	1 (0,1)	39,31 [5,38; 287,29]; 0,0003 37,40 [5,14; 271,87]; 0,0003 0,05 [0,03; 0,06]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6136)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	6 (5,8)	92	0 (0,0)	12,21 [0,68; 219,75]; 0,0898 11,51 [0,66; 201,63]; 0,0943 0,06 [0,01; 0,11]; 0,0196
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	4 (6,3)	63	1 (1,6)	4,13 [0,45; 38,05]; 0,2102 3,94 [0,45; 34,26]; 0,2144 0,05 [-0,02; 0,11]; 0,1716
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	13 (3,7)	362	0 (0,0)	29,17 [1,73; 492,66]; 0,0193 28,08 [1,68; 470,60]; 0,0204 0,04 [0,02; 0,06]; 0,0004
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	24 (6,1)	387	1 (0,3)	25,11 [3,38; 186,52]; 0,0016 23,63 [3,21; 173,84]; 0,0019 0,06 [0,03; 0,08]; <0,0001
Menopausenstatus (Interaktionstest: p=0,3064)					
Postmenopausal	346	20 (5,8)	356	2 (0,6)	10,86 [2,52; 46,82]; 0,0014 10,29 [2,42; 43,69]; 0,0016 0,05 [0,03; 0,08]; <0,0001
Prämenopausal	563	27 (4,8)	544	0 (0,0)	55,82 [3,40; 917,42]; 0,0049 53,15 [3,25; 869,12]; 0,0053 0,05 [0,03; 0,07]; <0,0001
Region (Interaktionstest: p=0,5025)					
Asien-Pazifik und Südafrika	301	17 (5,7)	317	0 (0,0)	39,06 [2,34; 652,47]; 0,0107 36,85 [2,23; 610,14]; 0,0118 0,06 [0,03; 0,08]; <0,0001
Europa	473	23 (4,9)	444	1 (0,2)	22,64 [3,04; 168,38]; 0,0023 21,59 [2,93; 159,20]; 0,0026 0,05 [0,03; 0,07]; <0,0001
Nordamerika	121	6 (5,0)	131	1 (0,8)	6,78 [0,80; 57,18]; 0,0784 6,50 [0,79; 53,18]; 0,0811 0,04 [0,00; 0,08]; 0,0473
Südamerika	16	1 (6,3)	12	0 (0,0)	2,42 [0,09; 64,70]; 0,5982 2,29 [0,10; 51,85]; 0,6017 0,06 [-0,11; 0,23]; 0,4728
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5172)					
Adjuvant	457	28 (6,1)	450	2 (0,4)	14,62 [3,46; 61,75]; 0,0003 13,79 [3,30; 57,53]; 0,0003 0,06 [0,03; 0,08]; <0,0001
Neoadjuvant	454	19 (4,2)	454	0 (0,0)	40,70 [2,45; 676,18]; 0,0097 39,00 [2,36; 643,98]; 0,0104 0,04 [0,02; 0,06]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Sponsor (Interaktionstest: p=0,1893)					
AZ	801	41 (5,1)	796	1 (0,1)	42,89 [5,88; 312,56]; 0,0002 40,74 [5,62; 295,48]; 0,0002 0,05 [0,03; 0,07]; <0,0001
NRG Oncology	110	6 (5,5)	108	1 (0,9)	6,17 [0,73; 52,16]; 0,0946 5,89 [0,72; 48,12]; 0,0979 0,05 [0,00; 0,09]; 0,0543
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4937)					
Ja	243	13 (5,4)	236	1 (0,4)	13,28 [1,72; 102,36]; 0,0130 12,63 [1,66; 95,75]; 0,0142 0,05 [0,02; 0,08]; 0,0011
Nein	668	34 (5,1)	668	1 (0,2)	35,77 [4,88; 262,08]; 0,0004 34,00 [4,67; 247,66]; 0,0005 0,05 [0,03; 0,07]; <0,0001
Anämie					
Alter (Interaktionstest: p=0,3292)					
<50	690	28 (4,1)	663	0 (0,0)	57,09 [3,48; 936,97]; 0,0046 54,77 [3,35; 895,32]; 0,0050 0,04 [0,03; 0,06]; <0,0001
50-64	192	9 (4,7)	209	2 (1,0)	5,09 [1,09; 23,86]; 0,0390 4,90 [1,07; 22,39]; 0,0404 0,04 [0,00; 0,07]; 0,0253
≥65	29	4 (13,8)	32	0 (0,0)	11,47 [0,59; 223,00]; 0,1071 9,90 [0,56; 176,29]; 0,1187 0,14 [0,00; 0,27]; 0,0443
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,0759)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	39 (4,5)	840	1 (0,1)	39,81 [5,46; 290,41]; 0,0003 38,05 [5,24; 276,31]; 0,0003 0,04 [0,03; 0,06]; <0,0001
Taxan	43	2 (4,7)	50	1 (2,0)	2,39 [0,21; 27,31]; 0,4832 2,33 [0,22; 24,77]; 0,4844 0,03 [-0,05; 0,10]; 0,4822
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,5030)					
Brusterhaltend	220	14 (6,4)	235	0 (0,0)	33,07 [1,96; 557,85]; 0,0152 30,97 [1,86; 516,04]; 0,0168 0,06 [0,03; 0,10]; 0,0002
Einseitige Mastektomie	355	13 (3,7)	352	0 (0,0)	27,79 [1,65; 469,28]; 0,0211 26,77 [1,60; 448,63]; 0,0223 0,04 [0,02; 0,06]; 0,0004

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	14 (4,2)	315	2 (0,6)	6,80 [1,53; 30,18]; 0,0116 6,56 [1,50; 28,64]; 0,0123 0,04 [0,01; 0,06]; 0,0027
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,2479)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	40 (4,6)	866	2 (0,2)	20,82 [5,02; 86,42]; <0,0001 19,91 [4,83; 82,12]; <0,0001 0,04 [0,03; 0,06]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,6603)					
Positiv	173	9 (5,2)	176	1 (0,6)	9,60 [1,20; 76,64]; 0,0328 9,16 [1,17; 71,50]; 0,0347 0,05 [0,01; 0,08]; 0,0093
Negativ	200	10 (5,0)	191	0 (0,0)	21,11 [1,23; 362,81]; 0,0356 20,06 [1,18; 339,97]; 0,0378 0,05 [0,02; 0,08]; 0,0019
Bilaterale Oophorektomie (Interaktionstest: p=0,8178)					
Ja	189	6 (3,2)	176	0 (0,0)	12,50 [0,70; 223,61]; 0,0860 12,11 [0,69; 213,41]; 0,0884 0,03 [0,00; 0,06]; 0,0212
Nein	722	35 (4,8)	728	2 (0,3)	18,49 [4,43; 77,18]; <0,0001 17,65 [4,26; 73,09]; <0,0001 0,05 [0,03; 0,06]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,4588)					
BRCA1	574	27 (4,7)	580	1 (0,2)	28,58 [3,87; 211,04]; 0,0010 27,28 [3,72; 200,10]; 0,0011 0,05 [0,03; 0,06]; <0,0001
BRCA2	232	10 (4,3)	215	1 (0,5)	9,64 [1,22; 75,95]; 0,0314 9,27 [1,20; 71,79]; 0,0330 0,04 [0,01; 0,07]; 0,0065
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,2137)					
2, 3 oder 4	392	14 (3,6)	383	0 (0,0)	29,38 [1,75; 494,32]; 0,0189 28,34 [1,70; 473,34]; 0,0199 0,04 [0,02; 0,05]; 0,0002
5 oder 6	22	1 (4,6)	14	0 (0,0)	2,02 [0,08; 53,19]; 0,6727 1,96 [0,09; 44,92]; 0,6747 0,05 [-0,09; 0,18]; 0,5117

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,8336)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	12 (4,6)	271	0 (0,0)	27,42 [1,62; 465,62]; 0,0219 26,15 [1,56; 439,47]; 0,0234 0,05 [0,02; 0,07]; 0,0006
Kaukasisch	617	27 (4,4)	589	2 (0,3)	13,43 [3,18; 56,74]; 0,0004 12,89 [3,08; 53,95]; 0,0005 0,04 [0,02; 0,06]; <0,0001
Schwarz oder afroamerikanisch	19	2 (10,5)	29	0 (0,0)	8,43 [0,38; 185,87]; 0,1768 7,50 [0,38; 148,13]; 0,1856 0,11 [-0,05; 0,26]; 0,1747
Ethnische Abstammung (Interaktionstest: p=0,0989)					
Hispanisch	34	3 (8,8)	24	0 (0,0)	5,44 [0,27; 110,44]; 0,2698 5,00 [0,27; 92,56]; 0,2798 0,09 [-0,03; 0,20]; 0,1277
Nicht-hispanisch	798	37 (4,6)	803	1 (0,1)	38,99 [5,34; 284,90]; 0,0003 37,23 [5,12; 270,70]; 0,0004 0,05 [0,03; 0,06]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	1 (1,3)	0,97 [0,06; 15,86]; 0,9854 0,97 [0,06; 15,31]; 0,9854 0,00 [-0,04; 0,03]; 0,9854
Hormonrezeptorstatus (Interaktionstest: p=0,3025)					
ER- und/oder PgR-positiv, HER2-positiv	168	8 (4,8)	155	1 (0,7)	7,70 [0,95; 62,29]; 0,0557 7,38 [0,93; 58,34]; 0,0581 0,04 [0,01; 0,08]; 0,0196
TNBC	741	33 (4,5)	749	1 (0,1)	34,86 [4,76; 255,59]; 0,0005 33,36 [4,57; 243,25]; 0,0005 0,04 [0,03; 0,06]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6477)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	4 (3,9)	92	0 (0,0)	8,28 [0,44; 155,97]; 0,1580 7,97 [0,43; 146,09]; 0,1618 0,04 [0,00; 0,08]; 0,0692
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	4 (6,3)	63	1 (1,6)	4,13 [0,45; 38,05]; 0,2102 3,94 [0,45; 34,26]; 0,2144 0,05 [-0,02; 0,11]; 0,1716
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	12 (3,5)	362	0 (0,0)	26,93 [1,59; 456,64]; 0,0226 26,00 [1,55; 437,50]; 0,0237 0,03 [0,01; 0,05]; 0,0007
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	21 (5,3)	387	1 (0,3)	21,79 [2,92; 162,81]; 0,0027 20,68 [2,80; 152,98]; 0,0030 0,05 [0,03; 0,07]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Menopausenstatus (Interaktionstest: p=0,3230)					
Postmenopausal	346	18 (5,2)	356	2 (0,6)	9,71 [2,24; 42,19]; 0,0024 9,26 [2,16; 39,61]; 0,0027 0,05 [0,02; 0,07]; 0,0002
Prämenopausal	563	23 (4,1)	544	0 (0,0)	47,35 [2,87; 781,48]; 0,0070 45,42 [2,77; 745,86]; 0,0075 0,04 [0,02; 0,06]; <0,0001
Region (Interaktionstest: p=0,5312)					
Asien-Pazifik und Südafrika	301	13 (4,3)	317	0 (0,0)	29,71 [1,76; 502,09]; 0,0187 28,43 [1,70; 476,15]; 0,0199 0,04 [0,02; 0,07]; 0,0004
Europa	473	22 (4,7)	444	1 (0,2)	21,61 [2,90; 161,01]; 0,0027 20,65 [2,80; 152,57]; 0,0030 0,04 [0,02; 0,06]; <0,0001
Nordamerika	121	5 (4,1)	131	1 (0,8)	5,60 [0,65; 48,66]; 0,1181 5,41 [0,64; 45,68]; 0,1207 0,03 [0,00; 0,07]; 0,0861
Südamerika	16	1 (6,3)	12	0 (0,0)	2,42 [0,09; 64,70]; 0,5982 2,29 [0,10; 51,85]; 0,6017 0,06 [-0,11; 0,23]; 0,4728
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5401)					
Adjuvant	457	25 (5,5)	450	2 (0,4)	12,96 [3,05; 55,06]; 0,0005 12,31 [2,93; 51,66]; 0,0006 0,05 [0,03; 0,07]; <0,0001
Neoadjuvant	454	16 (3,5)	454	0 (0,0)	34,20 [2,05; 571,86]; 0,0140 33,00 [1,99; 548,40]; 0,0148 0,04 [0,02; 0,05]; <0,0001
Sponsor (Interaktionstest: p=0,1812)					
AZ	801	36 (4,5)	796	1 (0,1)	37,41 [5,12; 273,54]; 0,0004 35,78 [4,92; 260,30]; 0,0004 0,04 [0,03; 0,06]; <0,0001
NRG Oncology	110	5 (4,6)	108	1 (0,9)	5,10 [0,59; 44,35]; 0,1402 4,91 [0,58; 41,33]; 0,1433 0,04 [-0,01; 0,08]; 0,0983
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4775)					
Ja	243	11 (4,5)	236	1 (0,4)	11,14 [1,43; 87,00]; 0,0215 10,68 [1,39; 82,10]; 0,0228 0,04 [0,01; 0,07]; 0,0034
Nein	668	30 (4,5)	668	1 (0,2)	31,36 [4,26; 230,66]; 0,0007 30,00 [4,10; 219,35]; 0,0008 0,04 [0,03; 0,06]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
SOC: Untersuchungen					
Alter (Interaktionstest: p=0,8023)					
<50	690	35 (5,1)	663	8 (1,2)	4,38 [2,01; 9,50]; 0,0002 4,20 [1,96; 8,99]; 0,0002 0,04 [0,02; 0,06]; <0,0001
50-64	192	11 (5,7)	209	2 (1,0)	6,29 [1,38; 28,75]; 0,0177 5,99 [1,34; 26,67]; 0,0189 0,05 [0,01; 0,08]; 0,0083
≥65	29	4 (13,8)	32	0 (0,0)	11,47 [0,59; 223,00]; 0,1071 9,90 [0,56; 176,29]; 0,1187 0,14 [0,00; 0,27]; 0,0443
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	50 (5,8)	840	9 (1,1)	5,69 [2,78; 11,65]; <0,0001 5,42 [2,68; 10,95]; <0,0001 0,05 [0,03; 0,06]; <0,0001
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2987)					
Brusterhaltend	220	8 (3,6)	235	4 (1,7)	2,18 [0,65; 7,34]; 0,2088 2,14 [0,65; 6,99]; 0,2097 0,02 [-0,01; 0,05]; 0,2026
Einseitige Mastektomie	355	22 (6,2)	352	3 (0,9)	7,69 [2,28; 25,92]; 0,0010 7,27 [2,20; 24,08]; 0,0012 0,05 [0,03; 0,08]; <0,0001
Beidseitige Mastektomie	336	20 (6,0)	315	3 (1,0)	6,58 [1,94; 22,37]; 0,0025 6,25 [1,88; 20,83]; 0,0028 0,05 [0,02; 0,08]; 0,0004
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3663)					
Ja	41	2 (4,9)	35	1 (2,9)	1,74 [0,15; 20,09]; 0,6557 1,71 [0,16; 18,04]; 0,6565 0,02 [-0,07; 0,11]; 0,6451
Nein	870	48 (5,5)	866	9 (1,0)	5,56 [2,71; 11,40]; <0,0001 5,31 [2,62; 10,75]; <0,0001 0,04 [0,03; 0,06]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,2186)					
Positiv	173	14 (8,1)	176	1 (0,6)	15,41 [2,00; 118,51]; 0,0086 14,24 [1,89; 107,14]; 0,0099 0,08 [0,03; 0,12]; 0,0005
Negativ	200	10 (5,0)	191	3 (1,6)	3,30 [0,89; 12,17]; 0,0733 3,18 [0,89; 11,39]; 0,0750 0,03 [0,00; 0,07]; 0,0546
Bilaterale Oophorektomie (Interaktionstest: p=0,7116)					
Ja	189	13 (6,9)	176	3 (1,7)	4,26 [1,19; 15,21]; 0,0256 4,04 [1,17; 13,92]; 0,0273 0,05 [0,01; 0,09]; 0,0130
Nein	722	37 (5,1)	728	7 (1,0)	5,56 [2,46; 12,56]; <0,0001 5,33 [2,39; 11,88]; <0,0001 0,04 [0,02; 0,06]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,7350)					
BRCA1	574	35 (6,1)	580	7 (1,2)	5,32 [2,34; 12,07]; <0,0001 5,05 [2,26; 11,28]; <0,0001 0,05 [0,03; 0,07]; <0,0001
BRCA2	232	8 (3,5)	215	1 (0,5)	7,64 [0,95; 61,62]; 0,0562 7,41 [0,93; 58,79]; 0,0579 0,03 [0,00; 0,06]; 0,0202
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,3626)					
2, 3 oder 4	392	17 (4,3)	383	4 (1,0)	4,30 [1,43; 12,88]; 0,0093 4,15 [1,41; 12,23]; 0,0098 0,03 [0,01; 0,06]; 0,0043
5 oder 6	22	2 (9,1)	14	1 (7,1)	1,30 [0,11; 15,84]; 0,8370 1,27 [0,13; 12,76]; 0,8375 0,02 [-0,16; 0,20]; 0,8326
Ethnie (Interaktionstest: p=0,5169)					
Andere	16	1 (6,3)	15	0 (0,0)	3,00 [0,11; 79,50]; 0,5111 2,82 [0,12; 64,39]; 0,5153 0,06 [-0,10; 0,22]; 0,4425
Asiatisch	259	18 (7,0)	271	4 (1,5)	4,99 [1,66; 14,94]; 0,0041 4,71 [1,62; 13,73]; 0,0045 0,05 [0,02; 0,09]; 0,0017
Kaukasisch	617	31 (5,0)	589	5 (0,9)	6,18 [2,39; 16,00]; 0,0002 5,92 [2,32; 15,12]; 0,0002 0,04 [0,02; 0,06]; <0,0001
Schwarz oder afroamerikanisch	19	0 (0,0)	29	1 (3,5)	0,49 [0,02; 12,59]; 0,6647 0,50 [0,02; 11,67]; 0,6663 -0,03 [-0,14; 0,07]; 0,5148

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,8242)					
Hispanisch	34	3 (8,8)	24	0 (0,0)	5,44 [0,27; 110,44]; 0,2698 5,00 [0,27; 92,56]; 0,2798 0,09 [-0,03; 0,20]; 0,1277
Nicht-hispanisch	798	42 (5,3)	803	10 (1,3)	4,41 [2,19; 8,84]; <0,0001 4,23 [2,14; 8,36]; <0,0001 0,04 [0,02; 0,06]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	5 (6,3)	77	0 (0,0)	11,44 [0,62; 210,58]; 0,1010 10,72 [0,60; 190,72]; 0,1062 0,06 [0,01; 0,12]; 0,0331
Hormonrezeptorstatus (Interaktionstest: p=0,5092)					
ER- und/oder PgR-positiv, HER2-positiv	168	6 (3,6)	155	0 (0,0)	12,44 [0,69; 222,68]; 0,0868 12,00 [0,68; 211,26]; 0,0895 0,04 [0,01; 0,07]; 0,0210
TNBC	741	44 (5,9)	749	10 (1,3)	4,67 [2,33; 9,34]; <0,0001 4,45 [2,26; 8,77]; <0,0001 0,05 [0,03; 0,06]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7575)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	3 (2,9)	92	0 (0,0)	6,38 [0,33; 125,16]; 0,2224 6,20 [0,32; 118,46]; 0,2254 0,03 [-0,01; 0,07]; 0,1307
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	3 (4,7)	63	0 (0,0)	7,23 [0,37; 142,85]; 0,1939 6,89 [0,36; 130,77]; 0,1986 0,05 [-0,01; 0,11]; 0,1192
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	18 (5,2)	362	6 (1,7)	3,24 [1,27; 8,25]; 0,0139 3,12 [1,25; 7,77]; 0,0145 0,04 [0,01; 0,06]; 0,0100
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	26 (6,6)	387	4 (1,0)	6,78 [2,34; 19,63]; 0,0004 6,40 [2,25; 18,17]; 0,0005 0,06 [0,03; 0,08]; <0,0001
Menopausenstatus (Interaktionstest: p=0,5782)					
Postmenopausal	346	24 (6,9)	356	4 (1,1)	6,56 [2,25; 19,11]; 0,0006 6,17 [2,16; 17,61]; 0,0007 0,06 [0,03; 0,09]; <0,0001
Prämenopausal	563	26 (4,6)	544	6 (1,1)	4,34 [1,77; 10,63]; 0,0013 4,19 [1,74; 10,09]; 0,0014 0,04 [0,02; 0,05]; 0,0004
Region (Interaktionstest: p=0,8702)					
Asien-Pazifik und Südafrika	301	21 (7,0)	317	5 (1,6)	4,68 [1,74; 12,58]; 0,0022 4,42 [1,69; 11,58]; 0,0025 0,05 [0,02; 0,09]; 0,0009

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	19 (4,0)	444	4 (0,9)	4,60 [1,55; 13,64]; 0,0059 4,46 [1,53; 13,00]; 0,0062 0,03 [0,01; 0,05]; 0,0020
Nordamerika	121	9 (7,4)	131	1 (0,8)	10,45 [1,30; 83,73]; 0,0271 9,74 [1,25; 75,78]; 0,0296 0,07 [0,02; 0,12]; 0,0077
Südamerika	16	1 (6,3)	12	0 (0,0)	2,42 [0,09; 64,70]; 0,5982 2,29 [0,10; 51,85]; 0,6017 0,06 [-0,11; 0,23]; 0,4728
Art der vorherigen Chemotherapie (Interaktionstest: p=0,3085)					
Adjuvant	457	29 (6,4)	450	4 (0,9)	7,55 [2,63; 21,67]; 0,0002 7,14 [2,53; 20,14]; 0,0002 0,05 [0,03; 0,08]; <0,0001
Neoadjuvant	454	21 (4,6)	454	6 (1,3)	3,62 [1,45; 9,06]; 0,0059 3,50 [1,43; 8,59]; 0,0062 0,03 [0,01; 0,06]; 0,0032
Sponsor (Interaktionstest: p=0,5458)					
AZ	801	41 (5,1)	796	9 (1,1)	4,72 [2,28; 9,77]; <0,0001 4,53 [2,22; 9,25]; <0,0001 0,04 [0,02; 0,06]; <0,0001
NRG Oncology	110	9 (8,2)	108	1 (0,9)	9,53 [1,19; 76,61]; 0,0339 8,84 [1,14; 68,56]; 0,0371 0,07 [0,02; 0,13]; 0,0088
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,6038)					
Ja	243	7 (2,9)	236	2 (0,9)	3,47 [0,71; 16,88]; 0,1232 3,40 [0,71; 16,20]; 0,1245 0,02 [0,00; 0,04]; 0,0977
Nein	668	43 (6,4)	668	8 (1,2)	5,68 [2,65; 12,17]; <0,0001 5,38 [2,55; 11,34]; <0,0001 0,05 [0,03; 0,07]; <0,0001
Leukozytenzahl erniedrigt					
Alter (Interaktionstest: p=0,7523)					
<50	690	11 (1,6)	663	1 (0,2)	10,72 [1,38; 83,30]; 0,0233 10,57 [1,37; 81,64]; 0,0238 0,01 [0,00; 0,02]; 0,0039
50-64	192	1 (0,5)	209	0 (0,0)	3,28 [0,13; 81,05]; 0,4676 3,26 [0,13; 79,65]; 0,4680 0,01 [-0,01; 0,02]; 0,4670
≥65	29	1 (3,5)	32	0 (0,0)	3,42 [0,13; 87,34]; 0,4568 3,30 [0,14; 77,95]; 0,4593 0,03 [-0,05; 0,12]; 0,4447

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	13 (1,5)	840	1 (0,1)	12,86 [1,68; 98,54]; 0,0139 12,68 [1,66; 96,74]; 0,0143 0,01 [0,01; 0,02]; 0,0013
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,7711)					
Brusterhaltend	220	1 (0,5)	235	0 (0,0)	3,22 [0,13; 79,43]; 0,4748 3,20 [0,13; 78,23]; 0,4751 0,00 [-0,01; 0,02]; 0,4693
Einseitige Mastektomie	355	5 (1,4)	352	1 (0,3)	5,01 [0,58; 43,14]; 0,1420 4,96 [0,58; 42,22]; 0,1429 0,01 [0,00; 0,02]; 0,1016
Beidseitige Mastektomie	336	7 (2,1)	315	0 (0,0)	14,36 [0,82; 252,52]; 0,0685 14,07 [0,81; 245,26]; 0,0699 0,02 [0,00; 0,04]; 0,0125
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	13 (1,5)	866	1 (0,1)	13,12 [1,71; 100,52]; 0,0132 12,94 [1,70; 98,70]; 0,0135 0,01 [0,01; 0,02]; 0,0012
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,7698)					
Positiv	173	5 (2,9)	176	1 (0,6)	5,21 [0,60; 45,05]; 0,1338 5,09 [0,60; 43,09]; 0,1357 0,02 [0,00; 0,05]; 0,0958
Negativ	200	1 (0,5)	191	0 (0,0)	2,88 [0,12; 71,12]; 0,5180 2,87 [0,12; 69,92]; 0,5183 0,00 [-0,01; 0,02]; 0,4812
Bilaterale Oophorektomie (Interaktionstest: p=0,8124)					
Ja	189	3 (1,6)	176	0 (0,0)	6,62 [0,34; 129,17]; 0,2122 6,52 [0,34; 125,35]; 0,2138 0,02 [0,00; 0,04]; 0,1321
Nein	722	10 (1,4)	728	1 (0,1)	10,21 [1,30; 79,97]; 0,0269 10,08 [1,29; 78,56]; 0,0274 0,01 [0,00; 0,02]; 0,0062

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,5055)					
BRCA1	574	10 (1,7)	580	1 (0,2)	10,27 [1,31; 80,46]; 0,0266 10,10 [1,30; 78,68]; 0,0272 0,02 [0,00; 0,03]; 0,0061
BRCA2	232	1 (0,4)	215	0 (0,0)	2,79 [0,11; 68,92]; 0,5301 2,78 [0,11; 67,90]; 0,5304 0,00 [-0,01; 0,02]; 0,4852
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,5693)					
2, 3 oder 4	392	3 (0,8)	383	0 (0,0)	6,89 [0,35; 133,88]; 0,2022 6,84 [0,35; 131,97]; 0,2029 0,01 [0,00; 0,02]; 0,1322
5 oder 6	22	1 (4,6)	14	0 (0,0)	2,02 [0,08; 53,19]; 0,6727 1,96 [0,09; 44,92]; 0,6747 0,05 [-0,09; 0,18]; 0,5117
Ethnie (Interaktionstest: p=0,8094)					
Andere	16	1 (6,3)	15	0 (0,0)	3,00 [0,11; 79,50]; 0,5111 2,82 [0,12; 64,39]; 0,5153 0,06 [-0,10; 0,22]; 0,4425
Asiatisch	259	5 (1,9)	271	0 (0,0)	11,73 [0,65; 213,29]; 0,0961 11,51 [0,64; 207,07]; 0,0976 0,02 [0,00; 0,04]; 0,0378
Kaukasisch	617	7 (1,1)	589	1 (0,2)	6,75 [0,83; 55,01]; 0,0745 6,68 [0,82; 54,15]; 0,0752 0,01 [0,00; 0,02]; 0,0355
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,7529)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	9 (1,1)	803	1 (0,1)	9,15 [1,16; 72,38]; 0,0359 9,06 [1,15; 71,32]; 0,0364 0,01 [0,00; 0,02]; 0,0109
Unbekannt, nicht erfasst, verweigert	79	3 (3,8)	77	0 (0,0)	7,09 [0,36; 139,61]; 0,1976 6,82 [0,36; 129,97]; 0,2014 0,04 [-0,01; 0,09]; 0,1225
Hormonrezeptorstatus (Interaktionstest: p=0,4447)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	0 (0,0)	2,79 [0,11; 68,88]; 0,5315 2,77 [0,11; 67,48]; 0,5318 0,01 [-0,01; 0,02]; 0,4846

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	12 (1,6)	749	1 (0,1)	12,31 [1,60; 94,93]; 0,0160 12,13 [1,58; 93,05]; 0,0164 0,01 [0,01; 0,02]; 0,0021
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8245)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	0 (0,0)	3,00 [0,12; 75,04]; 0,5036 2,95 [0,12; 71,17]; 0,5047 0,02 [-0,03; 0,06]; 0,4701
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	5 (1,4)	362	0 (0,0)	11,61 [0,64; 210,72]; 0,0974 11,44 [0,64; 206,14]; 0,0985 0,01 [0,00; 0,03]; 0,0386
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	7 (1,8)	387	1 (0,3)	7,00 [0,86; 57,17]; 0,0694 6,89 [0,85; 55,76]; 0,0703 0,02 [0,00; 0,03]; 0,0333
Menopausenstatus (Interaktionstest: p=0,5894)					
Postmenopausal	346	7 (2,0)	356	0 (0,0)	15,75 [0,90; 276,85]; 0,0594 15,43 [0,88; 269,17]; 0,0607 0,02 [0,00; 0,04]; 0,0120
Prämenopausal	563	6 (1,1)	544	1 (0,2)	5,85 [0,70; 48,75]; 0,1025 5,80 [0,70; 48,00]; 0,1032 0,01 [0,00; 0,02]; 0,0607
Region (Interaktionstest: p=0,4861)					
Asien-Pazifik und Südafrika	301	7 (2,3)	317	0 (0,0)	16,17 [0,92; 284,39]; 0,0571 15,79 [0,91; 275,35]; 0,0585 0,02 [0,01; 0,04]; 0,0117
Europa	473	2 (0,4)	444	1 (0,2)	1,88 [0,17; 20,82]; 0,6064 1,88 [0,17; 20,63]; 0,6065 0,00 [-0,01; 0,01]; 0,5969
Nordamerika	121	4 (3,3)	131	0 (0,0)	10,07 [0,54; 189,07]; 0,1226 9,74 [0,53; 179,00]; 0,1255 0,03 [0,00; 0,07]; 0,0645
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,8541)					
Adjuvant	457	8 (1,8)	450	1 (0,2)	8,00 [1,00; 64,23]; 0,0504 7,88 [0,99; 62,73]; 0,0512 0,02 [0,00; 0,03]; 0,0191
Neoadjuvant	454	5 (1,1)	454	0 (0,0)	11,12 [0,61; 201,73]; 0,1033 11,00 [0,61; 198,35]; 0,1042 0,01 [0,00; 0,02]; 0,0397

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Sponsor (Interaktionstest: p=0,9948)					
AZ	801	9 (1,1)	796	1 (0,1)	9,03 [1,14; 71,47]; 0,0370 8,94 [1,14; 70,43]; 0,0374 0,01 [0,00; 0,02]; 0,0111
NRG Oncology	110	4 (3,6)	108	0 (0,0)	9,17 [0,49; 172,39]; 0,1388 8,84 [0,48; 162,20]; 0,1422 0,04 [0,00; 0,08]; 0,0664
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,1912)					
Ja	243	2 (0,8)	236	1 (0,4)	1,95 [0,18; 21,65]; 0,5865 1,94 [0,18; 21,28]; 0,5867 0,00 [-0,01; 0,02]; 0,5778
Nein	668	11 (1,7)	668	0 (0,0)	23,38 [1,38; 397,64]; 0,0292 23,00 [1,36; 389,51]; 0,0299 0,02 [0,01; 0,03]; 0,0013
Lymphozytenzahl erniedrigt					
Alter (Interaktionstest: p=0,3797)					
<50	690	11 (1,6)	663	0 (0,0)	22,46 [1,32; 381,88]; 0,0314 22,10 [1,31; 374,30]; 0,0320 0,02 [0,01; 0,03]; 0,0014
50-64	192	1 (0,5)	209	0 (0,0)	3,28 [0,13; 81,05]; 0,4676 3,26 [0,13; 79,65]; 0,4680 0,01 [-0,01; 0,02]; 0,4670
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	12 (1,4)	840	0 (0,0)	24,74 [1,46; 418,44]; 0,0262 24,39 [1,45; 411,30]; 0,0267 0,01 [0,01; 0,02]; 0,0008
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,7982)					
Brusterhaltend	220	1 (0,5)	235	0 (0,0)	3,22 [0,13; 79,43]; 0,4748 3,20 [0,13; 78,23]; 0,4751 0,00 [-0,01; 0,02]; 0,4693
Einseitige Mastektomie	355	6 (1,7)	352	0 (0,0)	13,11 [0,74; 233,63]; 0,0799 12,89 [0,73; 227,96]; 0,0811 0,02 [0,00; 0,03]; 0,0219

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	5 (1,5)	315	0 (0,0)	10,47 [0,58; 190,11]; 0,1124 10,31 [0,57; 185,78]; 0,1136 0,01 [0,00; 0,03]; 0,0403
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3132)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	11 (1,3)	866	0 (0,0)	23,19 [1,36; 394,10]; 0,0296 22,89 [1,35; 387,90]; 0,0301 0,01 [0,00; 0,02]; 0,0014
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,5352)					
Positiv	173	5 (2,9)	176	0 (0,0)	11,52 [0,63; 209,98]; 0,0989 11,19 [0,62; 200,83]; 0,1012 0,03 [0,00; 0,06]; 0,0369
Negativ	200	1 (0,5)	191	0 (0,0)	2,88 [0,12; 71,12]; 0,5180 2,87 [0,12; 69,92]; 0,5183 0,00 [-0,01; 0,02]; 0,4812
Bilaterale Oophorektomie (Interaktionstest: p=0,7310)					
Ja	189	4 (2,1)	176	0 (0,0)	8,56 [0,46; 160,21]; 0,1507 8,38 [0,45; 154,61]; 0,1527 0,02 [0,00; 0,04]; 0,0712
Nein	722	8 (1,1)	728	0 (0,0)	17,33 [1,00; 300,86]; 0,0501 17,14 [0,99; 296,42]; 0,0507 0,01 [0,00; 0,02]; 0,0072
BRCA-Mutationsstatus (Interaktionstest: p=0,6423)					
BRCA1	574	8 (1,4)	580	0 (0,0)	17,42 [1,00; 302,52]; 0,0498 17,18 [0,99; 296,91]; 0,0505 0,01 [0,00; 0,02]; 0,0071
BRCA2	232	3 (1,3)	215	0 (0,0)	6,57 [0,34; 127,99]; 0,2139 6,49 [0,34; 124,90]; 0,2152 0,01 [0,00; 0,03]; 0,1333
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,5693)					
2, 3 oder 4	392	3 (0,8)	383	0 (0,0)	6,89 [0,35; 133,88]; 0,2022 6,84 [0,35; 131,97]; 0,2029 0,01 [0,00; 0,02]; 0,1322
5 oder 6	22	1 (4,6)	14	0 (0,0)	2,02 [0,08; 53,19]; 0,6727 1,96 [0,09; 44,92]; 0,6747 0,05 [-0,09; 0,18]; 0,5117

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,6647)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	3 (1,2)	271	0 (0,0)	7,41 [0,38; 144,15]; 0,1860 7,32 [0,38; 141,08]; 0,1871 0,01 [0,00; 0,03]; 0,1277
Kaukasisch	617	9 (1,5)	589	0 (0,0)	18,41 [1,07; 316,96]; 0,0449 18,14 [1,06; 310,96]; 0,0456 0,01 [0,00; 0,02]; 0,0042
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	12 (1,5)	803	0 (0,0)	25,54 [1,51; 432,11]; 0,0247 25,16 [1,49; 424,16]; 0,0252 0,02 [0,01; 0,02]; 0,0008
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Hormonrezeptorstatus (Interaktionstest: p=0,4710)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	0 (0,0)	4,67 [0,22; 98,03]; 0,3211 4,62 [0,22; 95,39]; 0,3223 0,01 [-0,01; 0,03]; 0,2492
TNBC	741	10 (1,4)	749	0 (0,0)	21,52 [1,26; 367,86]; 0,0341 21,23 [1,25; 361,57]; 0,0347 0,01 [0,00; 0,02]; 0,0024
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8408)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	0 (0,0)	2,68 [0,11; 66,63]; 0,5474 2,66 [0,11; 64,44]; 0,5480 0,01 [-0,02; 0,04]; 0,4873
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	0 (0,0)	3,00 [0,12; 75,04]; 0,5036 2,95 [0,12; 71,17]; 0,5047 0,02 [-0,03; 0,06]; 0,4701
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	3 (0,9)	362	0 (0,0)	7,34 [0,38; 142,71]; 0,1878 7,28 [0,38; 140,44]; 0,1886 0,01 [0,00; 0,02]; 0,1289
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	7 (1,8)	387	0 (0,0)	15,04 [0,86; 264,23]; 0,0638 14,77 [0,85; 257,75]; 0,0649 0,02 [0,00; 0,03]; 0,0124

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,9051)					
Postmenopausal	346	5 (1,5)	356	0 (0,0)	11,48 [0,63; 208,46]; 0,0989 11,32 [0,63; 203,89]; 0,1000 0,01 [0,00; 0,03]; 0,0387
Prämenopausal	563	7 (1,2)	544	0 (0,0)	14,68 [0,84; 257,60]; 0,0661 14,49 [0,83; 253,17]; 0,0669 0,01 [0,00; 0,02]; 0,0128
Region (Interaktionstest: p=0,9606)					
Asien-Pazifik und Südafrika	301	4 (1,3)	317	0 (0,0)	9,61 [0,51; 179,16]; 0,1297 9,48 [0,51; 175,27]; 0,1308 0,01 [0,00; 0,03]; 0,0693
Europa	473	3 (0,6)	444	0 (0,0)	6,61 [0,34; 128,39]; 0,2119 6,57 [0,34; 126,87]; 0,2126 0,01 [0,00; 0,01]; 0,1348
Nordamerika	121	5 (4,1)	131	0 (0,0)	12,42 [0,68; 226,96]; 0,0893 11,90 [0,67; 212,99]; 0,0924 0,04 [0,00; 0,08]; 0,0344
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,7656)					
Adjuvant	457	8 (1,8)	450	0 (0,0)	17,04 [0,98; 296,07]; 0,0516 16,74 [0,97; 289,17]; 0,0526 0,02 [0,00; 0,03]; 0,0071
Neoadjuvant	454	4 (0,9)	454	0 (0,0)	9,08 [0,49; 169,14]; 0,1393 9,00 [0,49; 166,68]; 0,1401 0,01 [0,00; 0,02]; 0,0717
Sponsor (Interaktionstest: p=0,8765)					
AZ	801	7 (0,9)	796	0 (0,0)	15,04 [0,86; 263,74]; 0,0636 14,91 [0,85; 260,56]; 0,0642 0,01 [0,00; 0,02]; 0,0128
NRG Oncology	110	5 (4,6)	108	0 (0,0)	11,31 [0,62; 207,13]; 0,1020 10,80 [0,60; 193,00]; 0,1057 0,05 [0,00; 0,09]; 0,0353
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4893)					
Ja	243	2 (0,8)	236	0 (0,0)	4,90 [0,23; 102,53]; 0,3060 4,86 [0,23; 100,63]; 0,3068 0,01 [-0,01; 0,02]; 0,2465
Nein	668	10 (1,5)	668	0 (0,0)	21,32 [1,25; 364,55]; 0,0347 21,00 [1,23; 357,64]; 0,0353 0,01 [0,01; 0,02]; 0,0023

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Neutrophilenzahl erniedrigt					
Alter (Interaktionstest: p=0,8961)					
<50	690	21 (3,0)	663	3 (0,5)	6,91 [2,05; 23,26]; 0,0018 6,73 [2,02; 22,44]; 0,0019 0,03 [0,01; 0,04]; 0,0002
50-64	192	6 (3,1)	209	0 (0,0)	14,60 [0,82; 260,98]; 0,0684 14,15 [0,80; 249,43]; 0,0704 0,03 [0,00; 0,06]; 0,0198
≥65	29	3 (10,3)	32	0 (0,0)	8,58 [0,42; 173,69]; 0,1611 7,70 [0,41; 143,00]; 0,1709 0,10 [-0,02; 0,23]; 0,0971
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	30 (3,5)	840	3 (0,4)	10,07 [3,06; 33,13]; 0,0001 9,76 [2,99; 31,85]; 0,0002 0,03 [0,02; 0,04]; <0,0001
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,3042)					
Brusterhaltend	220	5 (2,3)	235	2 (0,9)	2,71 [0,52; 14,11]; 0,2365 2,67 [0,52; 13,62]; 0,2374 0,01 [-0,01; 0,04]; 0,2243
Einseitige Mastektomie	355	11 (3,1)	352	1 (0,3)	11,22 [1,44; 87,40]; 0,0209 10,91 [1,42; 84,03]; 0,0218 0,03 [0,01; 0,05]; 0,0035
Beidseitige Mastektomie	336	14 (4,2)	315	0 (0,0)	28,37 [1,69; 477,62]; 0,0202 27,19 [1,63; 453,94]; 0,0215 0,04 [0,02; 0,06]; 0,0002
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,4447)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	29 (3,3)	866	3 (0,4)	9,92 [3,01; 32,69]; 0,0002 9,62 [2,94; 31,47]; 0,0002 0,03 [0,02; 0,04]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8841)					
Positiv	173	9 (5,2)	176	0 (0,0)	20,39 [1,18; 353,04]; 0,0383 19,33 [1,13; 329,52]; 0,0407 0,05 [0,02; 0,09]; 0,0033
Negativ	200	7 (3,5)	191	0 (0,0)	14,84 [0,84; 261,74]; 0,0654 14,33 [0,82; 249,16]; 0,0677 0,04 [0,01; 0,06]; 0,0116
Bilaterale Oophorektomie (Interaktionstest: p=0,6288)					
Ja	189	8 (4,2)	176	0 (0,0)	16,53 [0,95; 288,58]; 0,0545 15,84 [0,92; 272,37]; 0,0570 0,04 [0,01; 0,07]; 0,0064
Nein	722	22 (3,1)	728	3 (0,4)	7,60 [2,26; 25,49]; 0,0010 7,39 [2,22; 24,60]; 0,0011 0,03 [0,01; 0,04]; 0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,8632)					
BRCA1	574	23 (4,0)	580	3 (0,5)	8,03 [2,40; 26,89]; 0,0007 7,75 [2,34; 25,66]; 0,0008 0,03 [0,02; 0,05]; <0,0001
BRCA2	232	5 (2,2)	215	0 (0,0)	10,42 [0,57; 189,57]; 0,1133 10,20 [0,57; 183,33]; 0,1152 0,02 [0,00; 0,04]; 0,0395
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,1954)					
2, 3 oder 4	392	10 (2,6)	383	2 (0,5)	4,99 [1,09; 22,91]; 0,0389 4,89 [1,08; 22,15]; 0,0397 0,02 [0,00; 0,04]; 0,0208
5 oder 6	22	1 (4,6)	14	1 (7,1)	0,62 [0,04; 10,78]; 0,7421 0,64 [0,04; 9,37]; 0,7419 -0,03 [-0,19; 0,13]; 0,7512
Ethnie (Interaktionstest: p=0,2258)					
Andere	16	1 (6,3)	15	0 (0,0)	3,00 [0,11; 79,50]; 0,5111 2,82 [0,12; 64,39]; 0,5153 0,06 [-0,10; 0,22]; 0,4425
Asiatisch	259	8 (3,1)	271	2 (0,7)	4,29 [0,90; 20,38]; 0,0673 4,19 [0,90; 19,52]; 0,0685 0,02 [0,00; 0,05]; 0,0490
Kaukasisch	617	21 (3,4)	589	0 (0,0)	42,50 [2,57; 703,14]; 0,0088 41,05 [2,49; 676,15]; 0,0094 0,03 [0,02; 0,05]; <0,0001
Schwarz oder afroamerikanisch	19	0 (0,0)	29	1 (3,5)	0,49 [0,02; 12,59]; 0,6647 0,50 [0,02; 11,67]; 0,6663 -0,03 [-0,14; 0,07]; 0,5148

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,9554)					
Hispanisch	34	3 (8,8)	24	0 (0,0)	5,44 [0,27; 110,44]; 0,2698 5,00 [0,27; 92,56]; 0,2798 0,09 [-0,03; 0,20]; 0,1277
Nicht-hispanisch	798	24 (3,0)	803	3 (0,4)	8,27 [2,48; 27,57]; 0,0006 8,05 [2,43; 26,63]; 0,0006 0,03 [0,01; 0,04]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	3 (3,8)	77	0 (0,0)	7,09 [0,36; 139,61]; 0,1976 6,82 [0,36; 129,97]; 0,2014 0,04 [-0,01; 0,09]; 0,1225
Hormonrezeptorstatus (Interaktionstest: p=0,6666)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	0 (0,0)	4,67 [0,22; 98,03]; 0,3211 4,62 [0,22; 95,39]; 0,3223 0,01 [-0,01; 0,03]; 0,2492
TNBC	741	28 (3,8)	749	3 (0,4)	9,77 [2,96; 32,26]; 0,0002 9,43 [2,88; 30,90]; 0,0002 0,03 [0,02; 0,05]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,5238)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	0 (0,0)	2,68 [0,11; 66,63]; 0,5474 2,66 [0,11; 64,44]; 0,5480 0,01 [-0,02; 0,04]; 0,4873
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	0 (0,0)	3,00 [0,12; 75,04]; 0,5036 2,95 [0,12; 71,17]; 0,5047 0,02 [-0,03; 0,06]; 0,4701
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	11 (3,2)	362	3 (0,8)	3,91 [1,08; 14,12]; 0,0377 3,81 [1,07; 13,56]; 0,0385 0,02 [0,00; 0,04]; 0,0266
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	17 (4,3)	387	0 (0,0)	36,02 [2,16; 601,15]; 0,0126 34,47 [2,08; 571,14]; 0,0135 0,04 [0,02; 0,06]; <0,0001
Menopausenstatus (Interaktionstest: p=0,2624)					
Postmenopausal	346	14 (4,1)	356	0 (0,0)	31,09 [1,85; 523,29]; 0,0170 29,84 [1,79; 498,21]; 0,0181 0,04 [0,02; 0,06]; 0,0002
Prämenopausal	563	16 (2,8)	544	3 (0,6)	5,27 [1,53; 18,21]; 0,0085 5,15 [1,51; 17,59]; 0,0088 0,02 [0,01; 0,04]; 0,0029
Region (Interaktionstest: p=0,8082)					
Asien-Pazifik und Südafrika	301	11 (3,7)	317	2 (0,6)	5,97 [1,31; 27,18]; 0,0208 5,79 [1,29; 25,92]; 0,0216 0,03 [0,01; 0,05]; 0,0097

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	13 (2,8)	444	1 (0,2)	12,52 [1,63; 96,10]; 0,0151 12,20 [1,60; 92,90]; 0,0157 0,03 [0,01; 0,04]; 0,0013
Nordamerika	121	5 (4,1)	131	0 (0,0)	12,42 [0,68; 226,96]; 0,0893 11,90 [0,67; 212,99]; 0,0924 0,04 [0,00; 0,08]; 0,0344
Südamerika	16	1 (6,3)	12	0 (0,0)	2,42 [0,09; 64,70]; 0,5982 2,29 [0,10; 51,85]; 0,6017 0,06 [-0,11; 0,23]; 0,4728
Art der vorherigen Chemotherapie (Interaktionstest: p=0,1591)					
Adjuvant	457	18 (3,9)	450	0 (0,0)	37,93 [2,28; 631,26]; 0,0113 36,43 [2,20; 602,76]; 0,0120 0,04 [0,02; 0,06]; <0,0001
Neoadjuvant	454	12 (2,6)	454	3 (0,7)	4,08 [1,14; 14,56]; 0,0302 4,00 [1,14; 14,08]; 0,0308 0,02 [0,00; 0,04]; 0,0188
Sponsor (Interaktionstest: p=0,8674)					
AZ	801	25 (3,1)	796	3 (0,4)	8,52 [2,56; 28,32]; 0,0005 8,28 [2,51; 27,32]; 0,0005 0,03 [0,01; 0,04]; <0,0001
NRG Oncology	110	5 (4,6)	108	0 (0,0)	11,31 [0,62; 207,13]; 0,1020 10,80 [0,60; 193,00]; 0,1057 0,05 [0,00; 0,09]; 0,0353
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4721)					
Ja	243	5 (2,1)	236	1 (0,4)	4,94 [0,57; 42,58]; 0,1464 4,86 [0,57; 41,25]; 0,1477 0,02 [0,00; 0,04]; 0,1037
Nein	668	25 (3,7)	668	2 (0,3)	12,95 [3,05; 54,88]; 0,0005 12,50 [2,97; 52,56]; 0,0006 0,03 [0,02; 0,05]; <0,0001

Datenschnitt: 12.07.2021; Analyse-Set: Safety-Analysis-Set
a: Die Berechnung von OR, RR und RD erfolgte auf Basis der Vierfeldertafel.

Anhang 4-G10: Subgruppenanalysen: SUE nach SOC und PT

Tabelle 6.4.1: Subgruppenergebnisse für schwerwiegende Unerwünschte Ereignisse nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
SOC: Erkrankungen des Blutes und des Lymphsystems					
Alter (Interaktionstest: p=0,9811)					
<50	690	13 (1,9)	663	1 (0,2)	12,71 [1,66; 97,45]; 0,0144 12,49 [1,64; 95,22]; 0,0148 0,02 [0,01; 0,03]; 0,0013
50-64	192	5 (2,6)	209	0 (0,0)	12,29 [0,68; 223,76]; 0,0902 11,97 [0,67; 215,03]; 0,0921 0,03 [0,00; 0,05]; 0,0363
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,4155)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	17 (2,0)	840	1 (0,1)	16,90 [2,24; 127,27]; 0,0061 16,59 [2,21; 124,35]; 0,0063 0,02 [0,01; 0,03]; 0,0001
Taxan	43	1 (2,3)	50	0 (0,0)	3,56 [0,14; 89,80]; 0,4400 3,48 [0,15; 83,21]; 0,4417 0,02 [-0,04; 0,08]; 0,4478
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,6576)					
Brusterhaltend	220	9 (4,1)	235	0 (0,0)	21,16 [1,22; 365,69]; 0,0358 20,29 [1,19; 346,54]; 0,0376 0,04 [0,01; 0,07]; 0,0034
Einseitige Mastektomie	355	4 (1,1)	352	1 (0,3)	4,00 [0,44; 35,97]; 0,2160 3,97 [0,45; 35,31]; 0,2168 0,01 [0,00; 0,02]; 0,1796
Beidseitige Mastektomie	336	5 (1,5)	315	0 (0,0)	10,47 [0,58; 190,11]; 0,1124 10,31 [0,57; 185,78]; 0,1136 0,01 [0,00; 0,03]; 0,0403
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3255)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	17 (2,0)	866	1 (0,1)	17,24 [2,29; 129,82]; 0,0057 16,92 [2,26; 126,87]; 0,0059 0,02 [0,01; 0,03]; 0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8839)					
Positiv	173	4 (2,3)	176	0 (0,0)	9,37 [0,50; 175,39]; 0,1343 9,16 [0,50; 168,77]; 0,1364 0,02 [0,00; 0,05]; 0,0682
Negativ	200	6 (3,0)	191	0 (0,0)	12,80 [0,72; 228,78]; 0,0831 12,42 [0,70; 218,93]; 0,0853 0,03 [0,00; 0,06]; 0,0211
Bilaterale Oophorektomie (Interaktionstest: p=0,7736)					
Ja	189	4 (2,1)	176	0 (0,0)	8,56 [0,46; 160,21]; 0,1507 8,38 [0,45; 154,61]; 0,1527 0,02 [0,00; 0,04]; 0,0712
Nein	722	14 (1,9)	728	1 (0,1)	14,38 [1,89; 109,61]; 0,0101 14,12 [1,86; 107,07]; 0,0104 0,02 [0,01; 0,03]; 0,0007
BRCA-Mutationsstatus (Interaktionstest: p=0,9619)					
BRCA1	574	11 (1,9)	580	1 (0,2)	11,31 [1,46; 87,91]; 0,0204 11,11 [1,44; 85,81]; 0,0209 0,02 [0,01; 0,03]; 0,0035
BRCA2	232	5 (2,2)	215	0 (0,0)	10,42 [0,57; 189,57]; 0,1133 10,20 [0,57; 183,33]; 0,1152 0,02 [0,00; 0,04]; 0,0395
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	6 (1,5)	383	1 (0,3)	5,94 [0,71; 49,55]; 0,0999 5,86 [0,71; 48,47]; 0,1008 0,01 [0,00; 0,03]; 0,0591
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,8467)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	4 (1,5)	271	0 (0,0)	9,56 [0,51; 178,52]; 0,1305 9,42 [0,51; 174,01]; 0,1319 0,02 [0,00; 0,03]; 0,0691
Kaukasisch	617	14 (2,3)	589	1 (0,2)	13,65 [1,79; 104,15]; 0,0117 13,36 [1,76; 101,31]; 0,0121 0,02 [0,01; 0,03]; 0,0008
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,4766)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	16 (2,0)	803	1 (0,1)	16,41 [2,17; 124,03]; 0,0067 16,10 [2,14; 121,12]; 0,0070 0,02 [0,01; 0,03]; 0,0002
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	0 (0,0)	2,96 [0,12; 73,83]; 0,5081 2,92 [0,12; 70,72]; 0,5090 0,01 [-0,02; 0,05]; 0,4733
Hormonrezeptorstatus (Interaktionstest: p=0,7686)					
ER- und/oder PgR-positiv, HER2-positiv	168	4 (2,4)	155	0 (0,0)	8,51 [0,45; 159,32]; 0,1521 8,31 [0,45; 153,06]; 0,1544 0,02 [0,00; 0,05]; 0,0709
TNBC	741	14 (1,9)	749	1 (0,1)	14,40 [1,89; 109,82]; 0,0101 14,15 [1,87; 107,34]; 0,0104 0,02 [0,01; 0,03]; 0,0007
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8274)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	2 (1,9)	92	0 (0,0)	4,51 [0,21; 95,21]; 0,3328 4,43 [0,22; 91,07]; 0,3347 0,02 [-0,01; 0,05]; 0,2495
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	0 (0,0)	5,08 [0,24; 107,95]; 0,2973 4,92 [0,24; 100,55]; 0,3004 0,03 [-0,02; 0,08]; 0,2342
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	4 (1,2)	362	1 (0,3)	4,20 [0,47; 37,74]; 0,2005 4,16 [0,47; 37,04]; 0,2012 0,01 [0,00; 0,02]; 0,1688
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	10 (2,5)	387	0 (0,0)	21,22 [1,24; 363,38]; 0,0350 20,68 [1,22; 351,69]; 0,0361 0,03 [0,01; 0,04]; 0,0022
Menopausenstatus (Interaktionstest: p=0,9367)					
Postmenopausal	346	6 (1,7)	356	0 (0,0)	13,61 [0,76; 242,53]; 0,0756 13,37 [0,76; 236,51]; 0,0768 0,02 [0,00; 0,03]; 0,0215
Prämenopausal	563	12 (2,1)	544	1 (0,2)	11,83 [1,53; 91,26]; 0,0178 11,60 [1,51; 88,87]; 0,0184 0,02 [0,01; 0,03]; 0,0022
Region (Interaktionstest: p=0,7830)					
Asien-Pazifik und Südafrika	301	6 (2,0)	317	0 (0,0)	13,97 [0,78; 249,03]; 0,0728 13,69 [0,77; 241,94]; 0,0742 0,02 [0,00; 0,04]; 0,0211

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	11 (2,3)	444	1 (0,2)	10,55 [1,36; 82,04]; 0,0244 10,33 [1,34; 79,65]; 0,0251 0,02 [0,01; 0,04]; 0,0039
Nordamerika	121	1 (0,8)	131	0 (0,0)	3,27 [0,13; 81,13]; 0,4690 3,25 [0,13; 78,93]; 0,4696 0,01 [-0,01; 0,03]; 0,4653
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4327)					
Adjuvant	457	12 (2,6)	450	0 (0,0)	25,28 [1,49; 428,28]; 0,0253 24,62 [1,46; 414,55]; 0,0262 0,03 [0,01; 0,04]; 0,0007
Neoadjuvant	454	6 (1,3)	454	1 (0,2)	6,07 [0,73; 50,60]; 0,0957 6,00 [0,73; 49,64]; 0,0965 0,01 [0,00; 0,02]; 0,0573
Sponsor (Interaktionstest: p=0,3642)					
AZ	801	17 (2,1)	796	1 (0,1)	17,24 [2,29; 129,85]; 0,0057 16,89 [2,25; 126,64]; 0,0059 0,02 [0,01; 0,03]; 0,0001
NRG Oncology	110	1 (0,9)	108	0 (0,0)	2,97 [0,12; 73,78]; 0,5061 2,95 [0,12; 71,53]; 0,5068 0,01 [-0,02; 0,03]; 0,4751
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7794)					
Ja	243	8 (3,3)	236	0 (0,0)	17,07 [0,98; 297,47]; 0,0517 16,51 [0,96; 284,48]; 0,0535 0,03 [0,01; 0,06]; 0,0066
Nein	668	10 (1,5)	668	1 (0,2)	10,14 [1,29; 79,41]; 0,0274 10,00 [1,28; 77,90]; 0,0279 0,01 [0,00; 0,02]; 0,0063
Anämie					
Alter (Interaktionstest: p=0,9665)					
<50	690	11 (1,6)	663	1 (0,2)	10,72 [1,38; 83,30]; 0,0233 10,57 [1,37; 81,64]; 0,0238 0,01 [0,00; 0,02]; 0,0039
50-64	192	4 (2,1)	209	0 (0,0)	10,00 [0,53; 187,02]; 0,1232 9,79 [0,53; 180,70]; 0,1250 0,02 [0,00; 0,04]; 0,0669
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,4765)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	14 (1,6)	840	1 (0,1)	13,87 [1,82; 105,70]; 0,0112 13,66 [1,80; 103,64]; 0,0115 0,02 [0,01; 0,02]; 0,0008
Taxan	43	1 (2,3)	50	0 (0,0)	3,56 [0,14; 89,80]; 0,4400 3,48 [0,15; 83,21]; 0,4417 0,02 [-0,04; 0,08]; 0,4478
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,7611)					
Brusterhaltend	220	6 (2,7)	235	0 (0,0)	14,27 [0,80; 254,86]; 0,0707 13,88 [0,79; 244,99]; 0,0725 0,03 [0,00; 0,05]; 0,0203
Einseitige Mastektomie	355	4 (1,1)	352	1 (0,3)	4,00 [0,44; 35,97]; 0,2160 3,97 [0,45; 35,31]; 0,2168 0,01 [0,00; 0,02]; 0,1796
Beidseitige Mastektomie	336	5 (1,5)	315	0 (0,0)	10,47 [0,58; 190,11]; 0,1124 10,31 [0,57; 185,78]; 0,1136 0,01 [0,00; 0,03]; 0,0403
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	15 (1,7)	866	1 (0,1)	15,18 [2,00; 115,14]; 0,0085 14,93 [1,98; 112,79]; 0,0088 0,02 [0,01; 0,03]; 0,0004
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8536)					
Positiv	173	3 (1,7)	176	0 (0,0)	7,25 [0,37; 141,34]; 0,1913 7,12 [0,37; 136,84]; 0,1930 0,02 [0,00; 0,04]; 0,1271
Negativ	200	5 (2,5)	191	0 (0,0)	10,77 [0,59; 196,20]; 0,1084 10,51 [0,58; 188,74]; 0,1105 0,03 [0,00; 0,05]; 0,0385
Bilaterale Oophorektomie (Interaktionstest: p=0,5782)					
Ja	189	2 (1,1)	176	0 (0,0)	4,71 [0,22; 98,72]; 0,3185 4,66 [0,23; 96,35]; 0,3195 0,01 [-0,01; 0,03]; 0,2490
Nein	722	13 (1,8)	728	1 (0,1)	13,33 [1,74; 102,17]; 0,0127 13,11 [1,72; 99,94]; 0,0130 0,02 [0,01; 0,03]; 0,0012

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
BRCA-Mutationsstatus (Interaktionstest: p=0,8982)					
BRCA1	574	8 (1,4)	580	1 (0,2)	8,18 [1,02; 65,64]; 0,0478 8,08 [1,01; 64,42]; 0,0485 0,01 [0,00; 0,02]; 0,0186
BRCA2	232	5 (2,2)	215	0 (0,0)	10,42 [0,57; 189,57]; 0,1133 10,20 [0,57; 183,33]; 0,1152 0,02 [0,00; 0,04]; 0,0395
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	5 (1,3)	383	1 (0,3)	4,94 [0,57; 42,44]; 0,1459 4,89 [0,57; 41,62]; 0,1467 0,01 [0,00; 0,02]; 0,1040
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,8071)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	3 (1,2)	271	0 (0,0)	7,41 [0,38; 144,15]; 0,1860 7,32 [0,38; 141,08]; 0,1871 0,01 [0,00; 0,03]; 0,1277
Kaukasisch	617	12 (1,9)	589	1 (0,2)	11,66 [1,51; 89,98]; 0,0185 11,46 [1,49; 87,82]; 0,0190 0,02 [0,01; 0,03]; 0,0023
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,5579)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	13 (1,6)	803	1 (0,1)	13,28 [1,73; 101,77]; 0,0128 13,08 [1,72; 99,76]; 0,0131 0,02 [0,01; 0,02]; 0,0012
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	0 (0,0)	2,96 [0,12; 73,83]; 0,5081 2,92 [0,12; 70,72]; 0,5090 0,01 [-0,02; 0,05]; 0,4733
Hormonrezeptorstatus (Interaktionstest: p=0,8725)					
ER- und/oder PgR-positiv, HER2-positiv	168	4 (2,4)	155	0 (0,0)	8,51 [0,45; 159,32]; 0,1521 8,31 [0,45; 153,06]; 0,1544 0,02 [0,00; 0,05]; 0,0709

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
TNBC	741	11 (1,5)	749	1 (0,1)	11,27 [1,45; 87,52]; 0,0205 11,12 [1,44; 85,90]; 0,0209 0,01 [0,00; 0,02]; 0,0036
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8368)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	2 (1,9)	92	0 (0,0)	4,51 [0,21; 95,21]; 0,3328 4,43 [0,22; 91,07]; 0,3347 0,02 [-0,01; 0,05]; 0,2495
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	0 (0,0)	5,08 [0,24; 107,95]; 0,2973 4,92 [0,24; 100,55]; 0,3004 0,03 [-0,02; 0,08]; 0,2342
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	3 (0,9)	362	1 (0,3)	3,14 [0,32; 30,32]; 0,3229 3,12 [0,33; 29,86]; 0,3233 0,01 [-0,01; 0,02]; 0,3017
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	8 (2,0)	387	0 (0,0)	17,09 [0,98; 297,09]; 0,0514 16,74 [0,97; 289,05]; 0,0525 0,02 [0,01; 0,04]; 0,0070
Menopausenstatus (Interaktionstest: p=0,9395)					
Postmenopausal	346	4 (1,2)	356	0 (0,0)	9,37 [0,50; 174,65]; 0,1339 9,26 [0,50; 171,34]; 0,1349 0,01 [0,00; 0,02]; 0,0703
Prämenopausal	563	11 (2,0)	544	1 (0,2)	10,82 [1,39; 84,10]; 0,0228 10,63 [1,38; 82,05]; 0,0234 0,02 [0,01; 0,03]; 0,0038
Region (Interaktionstest: p=0,8457)					
Asien-Pazifik und Südafrika	301	4 (1,3)	317	0 (0,0)	9,61 [0,51; 179,16]; 0,1297 9,48 [0,51; 175,27]; 0,1308 0,01 [0,00; 0,03]; 0,0693
Europa	473	10 (2,1)	444	1 (0,2)	9,57 [1,22; 75,05]; 0,0316 9,39 [1,21; 73,03]; 0,0324 0,02 [0,01; 0,03]; 0,0069
Nordamerika	121	1 (0,8)	131	0 (0,0)	3,27 [0,13; 81,13]; 0,4690 3,25 [0,13; 78,93]; 0,4696 0,01 [-0,01; 0,03]; 0,4653
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4336)					
Adjuvant	457	10 (2,2)	450	0 (0,0)	21,14 [1,24; 361,86]; 0,0352 20,68 [1,22; 351,84]; 0,0362 0,02 [0,01; 0,04]; 0,0023
Neoadjuvant	454	5 (1,1)	454	1 (0,2)	5,04 [0,59; 43,35]; 0,1403 5,00 [0,59; 42,63]; 0,1410 0,01 [0,00; 0,02]; 0,1008

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,4207)					
AZ	801	14 (1,8)	796	1 (0,1)	14,14 [1,86; 107,80]; 0,0106 13,91 [1,83; 105,55]; 0,0109 0,02 [0,01; 0,03]; 0,0007
NRG Oncology	110	1 (0,9)	108	0 (0,0)	2,97 [0,12; 73,78]; 0,5061 2,95 [0,12; 71,53]; 0,5068 0,01 [-0,02; 0,03]; 0,4751
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,8511)					
Ja	243	6 (2,5)	236	0 (0,0)	12,95 [0,73; 231,09]; 0,0816 12,63 [0,72; 222,90]; 0,0834 0,02 [0,00; 0,05]; 0,0214
Nein	668	9 (1,4)	668	1 (0,2)	9,11 [1,15; 72,10]; 0,0363 9,00 [1,14; 70,84]; 0,0369 0,01 [0,00; 0,02]; 0,0109
SOC: Gutartige, bösartige und nicht spezifizierte Neubildungen (einschl, Zysten und Polypen)					
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	2 (0,5)	383	6 (1,6)	0,32 [0,06; 1,61]; 0,1671 0,33 [0,07; 1,60]; 0,1678 -0,01 [-0,02; 0,00]; 0,1476
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Alter (Interaktionstest: p=0,4468)					
<50	690	2 (0,3)	663	13 (2,0)	0,15 [0,03; 0,65]; 0,0113 0,15 [0,03; 0,65]; 0,0116 -0,02 [-0,03; -0,01]; 0,0037
50-64	192	3 (1,6)	209	6 (2,9)	0,54 [0,13; 2,18]; 0,3841 0,54 [0,14; 2,15]; 0,3848 -0,01 [-0,04; 0,02]; 0,3706
≥65	29	0 (0,0)	32	1 (3,1)	0,36 [0,01; 9,09]; 0,5320 0,37 [0,02; 8,66]; 0,5340 -0,03 [-0,12; 0,05]; 0,4688
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,9230)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	5 (0,6)	840	18 (2,1)	0,27 [0,10; 0,72]; 0,0093 0,27 [0,10; 0,73]; 0,0095 -0,02 [-0,03; 0,00]; 0,0055
Taxan	43	0 (0,0)	50	2 (4,0)	0,22 [0,01; 4,77]; 0,3371 0,23 [0,01; 4,70]; 0,3411 -0,04 [-0,11; 0,03]; 0,2421

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,3504)					
Brusterhaltend	220	1 (0,5)	235	2 (0,9)	0,53 [0,05; 5,91]; 0,6074 0,53 [0,05; 5,85]; 0,6075 0,00 [-0,02; 0,01]; 0,5977
Einseitige Mastektomie	355	4 (1,1)	352	9 (2,6)	0,43 [0,13; 1,42]; 0,1685 0,44 [0,14; 1,42]; 0,1693 -0,01 [-0,03; 0,01]; 0,1571
Beidseitige Mastektomie	336	0 (0,0)	315	9 (2,9)	0,05 [0,00; 0,83]; 0,0366 0,05 [0,00; 0,84]; 0,0378 -0,03 [-0,05; -0,01]; 0,0037
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7669)					
Ja	41	0 (0,0)	35	2 (5,7)	0,16 [0,01; 3,48]; 0,2444 0,17 [0,01; 3,46]; 0,2498 -0,06 [-0,15; 0,03]; 0,2097
Nein	870	5 (0,6)	866	18 (2,1)	0,27 [0,10; 0,74]; 0,0104 0,28 [0,10; 0,74]; 0,0106 -0,02 [-0,03; 0,00]; 0,0061
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,7472)					
Positiv	173	1 (0,6)	176	7 (4,0)	0,14 [0,02; 1,15]; 0,0676 0,15 [0,02; 1,17]; 0,0698 -0,03 [-0,06; 0,00]; 0,0316
Negativ	200	1 (0,5)	191	4 (2,1)	0,23 [0,03; 2,12]; 0,1970 0,24 [0,03; 2,12]; 0,1983 -0,02 [-0,04; 0,01]; 0,1656
Bilaterale Oophorektomie (Interaktionstest: p=0,8332)					
Ja	189	1 (0,5)	176	3 (1,7)	0,31 [0,03; 2,98]; 0,3081 0,31 [0,03; 2,96]; 0,3090 -0,01 [-0,03; 0,01]; 0,2893
Nein	722	4 (0,6)	728	17 (2,3)	0,23 [0,08; 0,70]; 0,0091 0,24 [0,08; 0,70]; 0,0093 -0,02 [-0,03; -0,01]; 0,0043
BRCA-Mutationsstatus (Interaktionstest: p=0,3888)					
BRCA1	574	2 (0,4)	580	15 (2,6)	0,13 [0,03; 0,58]; 0,0073 0,13 [0,03; 0,59]; 0,0076 -0,02 [-0,04; -0,01]; 0,0015
BRCA2	232	1 (0,4)	215	2 (0,9)	0,46 [0,04; 5,12]; 0,5285 0,46 [0,04; 5,07]; 0,5287 0,00 [-0,02; 0,01]; 0,5240

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,9006)					
Andere	16	0 (0,0)	15	1 (6,7)	0,29 [0,01; 7,76]; 0,4628 0,31 [0,01; 7,15]; 0,4675 -0,07 [-0,23; 0,10]; 0,4252
Asiatisch	259	2 (0,8)	271	6 (2,2)	0,34 [0,07; 1,72]; 0,1934 0,35 [0,07; 1,71]; 0,1945 -0,01 [-0,03; 0,01]; 0,1682
Kaukasisch	617	3 (0,5)	589	13 (2,2)	0,22 [0,06; 0,76]; 0,0173 0,22 [0,06; 0,77]; 0,0177 -0,02 [-0,03; 0,00]; 0,0099
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,8709)					
Hispanisch	34	0 (0,0)	24	1 (4,2)	0,23 [0,01; 5,82]; 0,3703 0,24 [0,01; 5,61]; 0,3733 -0,04 [-0,14; 0,06]; 0,4190
Nicht-hispanisch	798	5 (0,6)	803	16 (2,0)	0,31 [0,11; 0,85]; 0,0230 0,31 [0,12; 0,85]; 0,0233 -0,01 [-0,02; 0,00]; 0,0159
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	3 (3,9)	0,13 [0,01; 2,64]; 0,1860 0,14 [0,01; 2,65]; 0,1898 -0,04 [-0,09; 0,01]; 0,1197
Hormonrezeptorstatus (Interaktionstest: p=0,8403)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	3 (1,9)	0,30 [0,03; 2,95]; 0,3039 0,31 [0,03; 2,93]; 0,3049 -0,01 [-0,04; 0,01]; 0,2858
TNBC	741	4 (0,5)	749	17 (2,3)	0,23 [0,08; 0,70]; 0,0092 0,24 [0,08; 0,70]; 0,0094 -0,02 [-0,03; -0,01]; 0,0044
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7288)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	2 (2,2)	0,17 [0,01; 3,66]; 0,2598 0,18 [0,01; 3,64]; 0,2619 -0,02 [-0,06; 0,01]; 0,2289
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	1 (1,6)	0,98 [0,06; 16,09]; 0,9910 0,98 [0,06; 15,40]; 0,9910 0,00 [-0,04; 0,04]; 0,9910
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	2 (0,6)	362	6 (1,7)	0,34 [0,07; 1,71]; 0,1919 0,35 [0,07; 1,71]; 0,1927 -0,01 [-0,03; 0,00]; 0,1672
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	2 (0,5)	387	11 (2,8)	0,17 [0,04; 0,79]; 0,0239 0,18 [0,04; 0,80]; 0,0246 -0,02 [-0,04; -0,01]; 0,0110

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,5090)					
Postmenopausal	346	3 (0,9)	356	9 (2,5)	0,34 [0,09; 1,26]; 0,1052 0,34 [0,09; 1,26]; 0,1062 -0,02 [-0,04; 0,00]; 0,0868
Prämenopausal	563	2 (0,4)	544	11 (2,0)	0,17 [0,04; 0,78]; 0,0228 0,18 [0,04; 0,79]; 0,0233 -0,02 [-0,03; 0,00]; 0,0108
Region (Interaktionstest: p=0,9956)					
Asien-Pazifik und Südafrika	301	2 (0,7)	317	8 (2,5)	0,26 [0,05; 1,23]; 0,0886 0,26 [0,06; 1,23]; 0,0897 -0,02 [-0,04; 0,00]; 0,0624
Europa	473	3 (0,6)	444	9 (2,0)	0,31 [0,08; 1,15]; 0,0792 0,31 [0,09; 1,15]; 0,0799 -0,01 [-0,03; 0,00]; 0,0676
Nordamerika	121	0 (0,0)	131	2 (1,5)	0,21 [0,01; 4,49]; 0,3200 0,22 [0,01; 4,46]; 0,3215 -0,02 [-0,04; 0,01]; 0,2474
Südamerika	16	0 (0,0)	12	1 (8,3)	0,23 [0,01; 6,22]; 0,3843 0,25 [0,01; 5,76]; 0,3902 -0,08 [-0,27; 0,11]; 0,3933
Art der vorherigen Chemotherapie (Interaktionstest: p=0,9879)					
Adjuvant	457	3 (0,7)	450	12 (2,7)	0,24 [0,07; 0,86]; 0,0284 0,25 [0,07; 0,87]; 0,0290 -0,02 [-0,04; 0,00]; 0,0178
Neoadjuvant	454	2 (0,4)	454	8 (1,8)	0,25 [0,05; 1,17]; 0,0777 0,25 [0,05; 1,17]; 0,0784 -0,01 [-0,03; 0,00]; 0,0559
Sponsor (Interaktionstest: p=0,8339)					
AZ	801	5 (0,6)	796	18 (2,3)	0,27 [0,10; 0,73]; 0,0103 0,28 [0,10; 0,74]; 0,0105 -0,02 [-0,03; 0,00]; 0,0060
NRG Oncology	110	0 (0,0)	108	2 (1,9)	0,19 [0,01; 4,06]; 0,2898 0,20 [0,01; 4,04]; 0,2916 -0,02 [-0,05; 0,01]; 0,2377
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4990)					
Ja	243	0 (0,0)	236	4 (1,7)	0,11 [0,01; 1,98]; 0,1331 0,11 [0,01; 1,99]; 0,1346 -0,02 [-0,04; 0,00]; 0,0692
Nein	668	5 (0,8)	668	16 (2,4)	0,31 [0,11; 0,84]; 0,0220 0,31 [0,12; 0,85]; 0,0224 -0,02 [-0,03; 0,00]; 0,0153

Anhang 4-G11: Subgruppenanalysen: UESI

Tabelle 6.5.1: Subgruppenergebnisse für UESI aus RCT mit dem zu bewertenden Arzneimittel

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Anämie					
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9295)					
2, 3 oder 4	392	80 (20,4)	383	14 (3,7)	6,76 [3,76; 12,16]; <0,0001 5,58 [3,22; 9,68]; <0,0001 0,17 [0,12; 0,21]; <0,0001
5 oder 6	22	8 (36,4)	14	1 (7,1)	7,43 [0,81; 67,83]; 0,0756 5,09 [0,71; 36,43]; 0,1050 0,29 [0,05; 0,53]; 0,0180
Alter (Interaktionstest: p=0,2936)					
<50	690	152 (22,0)	663	28 (4,2)	6,41 [4,21; 9,74]; <0,0001 5,22 [3,54; 7,69]; <0,0001 0,18 [0,14; 0,21]; <0,0001
50-64	192	51 (26,6)	209	6 (2,9)	12,24 [5,11; 29,29]; <0,0001 9,25 [4,06; 21,07]; <0,0001 0,24 [0,17; 0,30]; <0,0001
≥65	29	14 (48,3)	32	1 (3,1)	28,93 [3,47; 241,13]; 0,0019 15,45 [2,16; 110,28]; 0,0063 0,45 [0,26; 0,64]; <0,0001
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,1977)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	205 (23,8)	840	30 (3,6)	8,44 [5,67; 12,55]; <0,0001 6,67 [4,60; 9,66]; <0,0001 0,20 [0,17; 0,23]; <0,0001
Taxan	43	11 (25,6)	50	5 (10,0)	3,09 [0,98; 9,77]; 0,0543 2,56 [0,96; 6,78]; 0,0591 0,16 [0,00; 0,31]; 0,0483
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,1643)					
Brusterhaltend	220	59 (26,8)	235	5 (2,1)	16,86 [6,62; 42,93]; <0,0001 12,60 [5,15; 30,82]; <0,0001 0,25 [0,19; 0,31]; <0,0001
Einseitige Mastektomie	355	84 (23,7)	352	15 (4,3)	6,96 [3,93; 12,34]; <0,0001 5,55 [3,27; 9,43]; <0,0001 0,19 [0,15; 0,24]; <0,0001
Beidseitige Mastektomie	336	74 (22,0)	315	15 (4,8)	5,65 [3,17; 10,08]; <0,0001 4,62 [2,71; 7,88]; <0,0001 0,17 [0,12; 0,22]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,5869)					
Ja	41	4 (9,8)	35	1 (2,9)	3,68 [0,39; 34,53]; 0,2548 3,41 [0,40; 29,15]; 0,2617 0,07 [-0,04; 0,18]; 0,2033
Nein	870	213 (24,5)	866	34 (3,9)	7,93 [5,45; 11,56]; <0,0001 6,24 [4,40; 8,84]; <0,0001 0,21 [0,17; 0,24]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,3965)					
Positiv	173	56 (32,4)	176	10 (5,7)	7,95 [3,89; 16,21]; <0,0001 5,70 [3,01; 10,80]; <0,0001 0,27 [0,19; 0,34]; <0,0001
Negativ	200	40 (20,0)	191	4 (2,1)	11,69 [4,09; 33,37]; <0,0001 9,55 [3,48; 26,18]; <0,0001 0,18 [0,12; 0,24]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,4913)					
Ja	189	42 (22,2)	176	8 (4,6)	6,00 [2,73; 13,19]; <0,0001 4,89 [2,36; 10,12]; <0,0001 0,18 [0,11; 0,24]; <0,0001
Nein	722	175 (24,2)	728	27 (3,7)	8,31 [5,46; 12,65]; <0,0001 6,54 [4,42; 9,67]; <0,0001 0,21 [0,17; 0,24]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,3752)					
BRCA1	574	135 (23,5)	580	21 (3,6)	8,19 [5,08; 13,18]; <0,0001 6,50 [4,16; 10,14]; <0,0001 0,20 [0,16; 0,24]; <0,0001
BRCA2	232	49 (21,1)	215	10 (4,7)	5,49 [2,70; 11,15]; <0,0001 4,54 [2,36; 8,74]; <0,0001 0,16 [0,11; 0,22]; <0,0001
Ethnie (Interaktionstest: p=0,0691)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	87 (33,6)	271	10 (3,7)	13,20 [6,67; 26,12]; <0,0001 9,10 [4,84; 17,12]; <0,0001 0,30 [0,24; 0,36]; <0,0001
Kaukasisch	617	125 (20,3)	589	21 (3,6)	6,87 [4,26; 11,08]; <0,0001 5,68 [3,63; 8,90]; <0,0001 0,17 [0,13; 0,20]; <0,0001
Schwarz oder afroamerikanisch	19	5 (26,3)	29	4 (13,8)	2,23 [0,51; 9,69]; 0,2839 1,91 [0,59; 6,21]; 0,2836 0,13 [-0,11; 0,36]; 0,2951

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,8124)					
Hispanisch	34	8 (23,5)	24	0 (0,0)	15,72 [0,86; 286,96]; 0,0630 12,14 [0,73; 200,81]; 0,0811 0,24 [0,08; 0,39]; 0,0025
Nicht-hispanisch	798	200 (25,1)	803	33 (4,1)	7,80 [5,32; 11,45]; <0,0001 6,10 [4,28; 8,70]; <0,0001 0,21 [0,18; 0,24]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	9 (11,4)	77	2 (2,6)	4,82 [1,01; 23,09]; 0,0490 4,39 [0,98; 19,65]; 0,0533 0,09 [0,01; 0,17]; 0,0282
Hormonrezeptorstatus (Interaktionstest: p=0,8344)					
ER- und/oder PgR-positiv, HER2-positiv	168	37 (22,0)	155	6 (3,9)	7,01 [2,87; 17,15]; <0,0001 5,69 [2,47; 13,11]; <0,0001 0,18 [0,11; 0,25]; <0,0001
TNBC	741	180 (24,3)	749	29 (3,9)	7,97 [5,30; 11,97]; <0,0001 6,27 [4,30; 9,16]; <0,0001 0,20 [0,17; 0,24]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8835)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	20 (19,2)	92	4 (4,4)	5,24 [1,72; 15,96]; 0,0036 4,42 [1,57; 12,47]; 0,0049 0,15 [0,06; 0,24]; 0,0007
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	17 (26,6)	63	2 (3,2)	11,03 [2,43; 50,13]; 0,0019 8,37 [2,02; 34,73]; 0,0034 0,23 [0,12; 0,35]; <0,0001
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	77 (22,1)	362	12 (3,3)	8,29 [4,42; 15,54]; <0,0001 6,67 [3,70; 12,04]; <0,0001 0,19 [0,14; 0,24]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	103 (26,2)	387	17 (4,4)	7,73 [4,52; 13,21]; <0,0001 5,97 [3,64; 9,77]; <0,0001 0,22 [0,17; 0,27]; <0,0001
Menopausenstatus (Interaktionstest: p=0,5962)					
Postmenopausal	346	92 (26,6)	356	17 (4,8)	7,22 [4,20; 12,42]; <0,0001 5,57 [3,39; 9,14]; <0,0001 0,22 [0,17; 0,27]; <0,0001
Prämenopausal	563	125 (22,2)	544	18 (3,3)	8,34 [5,01; 13,89]; <0,0001 6,71 [4,15; 10,84]; <0,0001 0,19 [0,15; 0,23]; <0,0001
Region (Interaktionstest: p=0,1954)					
Asien-Pazifik und Südafrika	301	94 (31,2)	317	10 (3,2)	13,94 [7,10; 27,39]; <0,0001 9,90 [5,26; 18,64]; <0,0001 0,28 [0,22; 0,34]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	87 (18,4)	444	15 (3,4)	6,45 [3,66; 11,34]; <0,0001 5,44 [3,20; 9,27]; <0,0001 0,15 [0,11; 0,19]; <0,0001
Nordamerika	121	34 (28,1)	131	10 (7,6)	4,73 [2,22; 10,08]; <0,0001 3,68 [1,90; 7,12]; 0,0001 0,20 [0,11; 0,30]; <0,0001
Südamerika	16	2 (12,5)	12	0 (0,0)	4,31 [0,19; 98,51]; 0,3601 3,82 [0,20; 73,00]; 0,3728 0,12 [-0,07; 0,32]; 0,2164
Art der vorherigen Chemotherapie (Interaktionstest: p=0,9425)					
Adjuvant	457	120 (26,3)	450	19 (4,2)	8,08 [4,88; 13,38]; <0,0001 6,22 [3,90; 9,91]; <0,0001 0,22 [0,18; 0,26]; <0,0001
Neoadjuvant	454	97 (21,4)	454	16 (3,5)	7,44 [4,30; 12,85]; <0,0001 6,06 [3,63; 10,12]; <0,0001 0,18 [0,14; 0,22]; <0,0001
Sponsor (Interaktionstest: p=0,0386)					
AZ	801	184 (23,0)	796	25 (3,1)	9,20 [5,98; 14,15]; <0,0001 7,31 [4,87; 10,98]; <0,0001 0,20 [0,17; 0,23]; <0,0001
NRG Oncology	110	33 (30,0)	108	10 (9,3)	4,20 [1,95; 9,05]; 0,0002 3,24 [1,68; 6,24]; 0,0004 0,21 [0,11; 0,31]; <0,0001
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,3458)					
Ja	243	48 (19,8)	236	10 (4,2)	5,56 [2,74; 11,29]; <0,0001 4,66 [2,42; 9,00]; <0,0001 0,16 [0,10; 0,21]; <0,0001
Nein	668	169 (25,3)	668	25 (3,7)	8,71 [5,63; 13,47]; <0,0001 6,76 [4,50; 10,15]; <0,0001 0,22 [0,18; 0,25]; <0,0001
Erbrechen					
Alter (Interaktionstest: p=0,4116)					
<50	690	168 (24,4)	663	54 (8,1)	3,63 [2,61; 5,04]; <0,0001 2,99 [2,24; 3,99]; <0,0001 0,16 [0,12; 0,20]; <0,0001
50-64	192	34 (17,7)	209	17 (8,1)	2,43 [1,31; 4,51]; 0,0049 2,18 [1,26; 3,77]; 0,0054 0,10 [0,03; 0,16]; 0,0042
≥65	29	4 (13,8)	32	3 (9,4)	1,55 [0,32; 7,58]; 0,5908 1,47 [0,36; 6,03]; 0,5915 0,04 [-0,12; 0,21]; 0,5909

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,8738)					
Anthrazyklin	7	2 (28,6)	13	2 (15,4)	2,20 [0,24; 20,40]; 0,4877 1,86 [0,33; 10,49]; 0,4834 0,13 [-0,26; 0,52]; 0,5052
Anthrazyklin und Taxan	861	191 (22,2)	840	66 (7,9)	3,34 [2,48; 4,51]; <0,0001 2,82 [2,17; 3,67]; <0,0001 0,14 [0,11; 0,18]; <0,0001
Taxan	43	13 (30,2)	50	6 (12,0)	3,18 [1,09; 9,29]; 0,0347 2,52 [1,05; 6,06]; 0,0390 0,18 [0,02; 0,35]; 0,0295
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0097)					
Brusterhaltend	220	52 (23,6)	235	16 (6,8)	4,24 [2,34; 7,68]; <0,0001 3,47 [2,04; 5,89]; <0,0001 0,17 [0,10; 0,23]; <0,0001
Einseitige Mastektomie	355	88 (24,8)	352	22 (6,3)	4,94 [3,02; 8,10]; <0,0001 3,97 [2,55; 6,18]; <0,0001 0,19 [0,13; 0,24]; <0,0001
Beidseitige Mastektomie	336	66 (19,6)	315	36 (11,4)	1,89 [1,22; 2,94]; 0,0044 1,72 [1,18; 2,50]; 0,0047 0,08 [0,03; 0,14]; 0,0035
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3107)					
Ja	41	9 (22,0)	35	1 (2,9)	9,56 [1,15; 79,80]; 0,0370 7,68 [1,02; 57,69]; 0,0475 0,19 [0,05; 0,33]; 0,0068
Nein	870	197 (22,6)	866	73 (8,4)	3,18 [2,39; 4,24]; <0,0001 2,69 [2,09; 3,45]; <0,0001 0,14 [0,11; 0,18]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,9709)					
Positiv	173	26 (15,0)	176	10 (5,7)	2,94 [1,37; 6,29]; 0,0056 2,65 [1,32; 5,32]; 0,0063 0,09 [0,03; 0,16]; 0,0038
Negativ	200	60 (30,0)	191	22 (11,5)	3,29 [1,92; 5,63]; <0,0001 2,60 [1,67; 4,07]; <0,0001 0,18 [0,11; 0,26]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,0017)					
Ja	189	27 (14,3)	176	20 (11,4)	1,30 [0,70; 2,41]; 0,4058 1,26 [0,73; 2,16]; 0,4067 0,03 [-0,04; 0,10]; 0,4029
Nein	722	179 (24,8)	728	54 (7,4)	4,11 [2,97; 5,69]; <0,0001 3,34 [2,51; 4,45]; <0,0001 0,17 [0,14; 0,21]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
BRCA-Mutationsstatus (Interaktionstest: p=0,5492)					
BRCA1	574	122 (21,3)	580	53 (9,1)	2,68 [1,90; 3,79]; <0,0001 2,33 [1,72; 3,14]; <0,0001 0,12 [0,08; 0,16]; <0,0001
BRCA2	232	54 (23,3)	215	18 (8,4)	3,32 [1,88; 5,87]; <0,0001 2,78 [1,69; 4,58]; <0,0001 0,15 [0,08; 0,21]; <0,0001
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,2961)					
2, 3 oder 4	392	86 (21,9)	383	23 (6,0)	4,40 [2,71; 7,14]; <0,0001 3,65 [2,36; 5,66]; <0,0001 0,16 [0,11; 0,21]; <0,0001
5 oder 6	22	5 (22,7)	14	2 (14,3)	1,76 [0,29; 10,66]; 0,5360 1,59 [0,36; 7,11]; 0,5432 0,08 [-0,17; 0,34]; 0,5140
Ethnie (Interaktionstest: p=0,2695)					
Andere	16	2 (12,5)	15	0 (0,0)	5,34 [0,24; 121,00]; 0,2923 4,71 [0,24; 90,69]; 0,3049 0,12 [-0,06; 0,31]; 0,1942
Asiatisch	259	72 (27,8)	271	19 (7,0)	5,11 [2,98; 8,76]; <0,0001 3,97 [2,46; 6,38]; <0,0001 0,21 [0,15; 0,27]; <0,0001
Kaukasisch	617	129 (20,9)	589	52 (8,8)	2,73 [1,93; 3,85]; <0,0001 2,37 [1,75; 3,20]; <0,0001 0,12 [0,08; 0,16]; <0,0001
Schwarz oder afroamerikanisch	19	3 (15,8)	29	3 (10,3)	1,62 [0,29; 9,05]; 0,5795 1,53 [0,34; 6,79]; 0,5786 0,05 [-0,14; 0,25]; 0,5897
Ethnische Abstammung (Interaktionstest: p=0,9354)					
Hispanisch	34	10 (29,4)	24	2 (8,3)	4,58 [0,90; 23,27]; 0,0663 3,53 [0,85; 14,68]; 0,0829 0,21 [0,02; 0,40]; 0,0287
Nicht-hispanisch	798	180 (22,6)	803	66 (8,2)	3,25 [2,41; 4,40]; <0,0001 2,74 [2,11; 3,58]; <0,0001 0,14 [0,11; 0,18]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	16 (20,3)	77	6 (7,8)	3,01 [1,11; 8,15]; 0,0306 2,60 [1,07; 6,29]; 0,0342 0,12 [0,02; 0,23]; 0,0224
Hormonrezeptorstatus (Interaktionstest: p=0,7577)					
ER- und/oder PgR-positiv, HER2-positiv	168	33 (19,6)	155	10 (6,5)	3,54 [1,68; 7,47]; 0,0009 3,04 [1,55; 5,97]; 0,0012 0,13 [0,06; 0,20]; 0,0003

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	172 (23,2)	749	64 (8,5)	3,24 [2,38; 4,40]; <0,0001 2,72 [2,08; 3,55]; <0,0001 0,15 [0,11; 0,18]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8912)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	21 (20,2)	92	5 (5,4)	4,40 [1,59; 12,22]; 0,0044 3,72 [1,46; 9,46]; 0,0059 0,15 [0,06; 0,24]; 0,0013
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	12 (18,8)	63	5 (7,9)	2,68 [0,88; 8,11]; 0,0816 2,36 [0,88; 6,32]; 0,0867 0,11 [-0,01; 0,22]; 0,0692
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	77 (22,1)	362	28 (7,7)	3,39 [2,14; 5,38]; <0,0001 2,86 [1,90; 4,30]; <0,0001 0,14 [0,09; 0,20]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	95 (24,2)	387	36 (9,3)	3,11 [2,06; 4,70]; <0,0001 2,60 [1,82; 3,71]; <0,0001 0,15 [0,10; 0,20]; <0,0001
Menopausenstatus (Interaktionstest: p=0,0475)					
Postmenopausal	346	64 (18,5)	356	33 (9,3)	2,22 [1,42; 3,48]; 0,0005 2,00 [1,35; 2,96]; 0,0006 0,09 [0,04; 0,14]; 0,0004
Prämenopausal	563	142 (25,2)	544	41 (7,5)	4,14 [2,86; 6,00]; <0,0001 3,35 [2,41; 4,64]; <0,0001 0,18 [0,13; 0,22]; <0,0001
Region (Interaktionstest: p=0,1540)					
Asien-Pazifik und Südafrika	301	82 (27,2)	317	25 (7,9)	4,37 [2,70; 7,07]; <0,0001 3,45 [2,27; 5,25]; <0,0001 0,19 [0,14; 0,25]; <0,0001
Europa	473	86 (18,2)	444	27 (6,1)	3,43 [2,18; 5,40]; <0,0001 2,99 [1,98; 4,52]; <0,0001 0,12 [0,08; 0,16]; <0,0001
Nordamerika	121	35 (28,9)	131	22 (16,8)	2,02 [1,10; 3,69]; 0,0228 1,72 [1,07; 2,76]; 0,0241 0,12 [0,02; 0,22]; 0,0211
Südamerika	16	3 (18,8)	12	0 (0,0)	6,48 [0,30; 138,43]; 0,2315 5,35 [0,30; 94,77]; 0,2526 0,19 [-0,03; 0,41]; 0,0930
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5448)					
Adjuvant	457	107 (23,4)	450	41 (9,1)	3,05 [2,07; 4,49]; <0,0001 2,57 [1,84; 3,59]; <0,0001 0,14 [0,10; 0,19]; <0,0001
Neoadjuvant	454	99 (21,8)	454	33 (7,3)	3,56 [2,34; 5,41]; <0,0001 3,00 [2,07; 4,35]; <0,0001 0,15 [0,10; 0,19]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Sponsor (Interaktionstest: p=0,1967)					
AZ	801	176 (22,0)	796	59 (7,4)	3,52 [2,57; 4,81]; <0,0001 2,96 [2,24; 3,91]; <0,0001 0,15 [0,11; 0,18]; <0,0001
NRG Oncology	110	30 (27,3)	108	15 (13,9)	2,33 [1,17; 4,63]; 0,0162 1,96 [1,12; 3,44]; 0,0182 0,13 [0,03; 0,24]; 0,0131
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7222)					
Ja	243	50 (20,6)	236	19 (8,1)	2,96 [1,69; 5,19]; 0,0002 2,56 [1,55; 4,20]; 0,0002 0,13 [0,06; 0,19]; <0,0001
Nein	668	156 (23,4)	668	55 (8,2)	3,40 [2,44; 4,72]; <0,0001 2,84 [2,13; 3,78]; <0,0001 0,15 [0,11; 0,19]; <0,0001
Übelkeit					
Alter (Interaktionstest: p=0,8799)					
<50	690	409 (59,3)	663	164 (24,7)	4,43 [3,51; 5,59]; <0,0001 2,40 [2,07; 2,77]; <0,0001 0,35 [0,30; 0,39]; <0,0001
50-64	192	94 (49,0)	209	43 (20,6)	3,70 [2,39; 5,74]; <0,0001 2,38 [1,76; 3,22]; <0,0001 0,28 [0,19; 0,37]; <0,0001
≥65	29	16 (55,2)	32	6 (18,8)	5,33 [1,69; 16,85]; 0,0043 2,94 [1,33; 6,50]; 0,0076 0,36 [0,14; 0,59]; 0,0016
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,5205)					
Anthrazyklin	7	4 (57,1)	13	1 (7,7)	16,00 [1,27; 200,92]; 0,0317 7,43 [1,02; 54,31]; 0,0482 0,49 [0,10; 0,89]; 0,0139
Anthrazyklin und Taxan	861	490 (56,9)	840	198 (23,6)	4,28 [3,48; 5,28]; <0,0001 2,41 [2,11; 2,76]; <0,0001 0,33 [0,29; 0,38]; <0,0001
Taxan	43	25 (58,1)	50	13 (26,0)	3,95 [1,65; 9,49]; 0,0021 2,24 [1,31; 3,81]; 0,0030 0,32 [0,13; 0,51]; 0,0010
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2378)					
Brusterhaltend	220	116 (52,7)	235	55 (23,4)	3,65 [2,44; 5,45]; <0,0001 2,25 [1,73; 2,93]; <0,0001 0,29 [0,21; 0,38]; <0,0001
Einseitige Mastektomie	355	193 (54,4)	352	68 (19,3)	4,98 [3,55; 6,97]; <0,0001 2,81 [2,23; 3,56]; <0,0001 0,35 [0,28; 0,42]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	210 (62,5)	315	90 (28,6)	4,17 [3,00; 5,79]; <0,0001 2,19 [1,80; 2,65]; <0,0001 0,34 [0,27; 0,41]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3850)					
Ja	41	30 (73,2)	35	13 (37,1)	4,62 [1,74; 12,22]; 0,0021 1,97 [1,23; 3,15]; 0,0046 0,36 [0,15; 0,57]; 0,0008
Nein	870	489 (56,2)	866	199 (23,0)	4,30 [3,50; 5,29]; <0,0001 2,45 [2,14; 2,80]; <0,0001 0,33 [0,29; 0,38]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,0834)					
Positiv	173	87 (50,3)	176	23 (13,1)	6,73 [3,96; 11,43]; <0,0001 3,85 [2,56; 5,79]; <0,0001 0,37 [0,28; 0,46]; <0,0001
Negativ	200	117 (58,5)	191	45 (23,6)	4,57 [2,95; 7,08]; <0,0001 2,48 [1,88; 3,29]; <0,0001 0,35 [0,26; 0,44]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,1964)					
Ja	189	111 (58,7)	176	50 (28,4)	3,59 [2,32; 5,55]; <0,0001 2,07 [1,59; 2,69]; <0,0001 0,30 [0,21; 0,40]; <0,0001
Nein	722	408 (56,5)	728	163 (22,4)	4,50 [3,59; 5,66]; <0,0001 2,52 [2,17; 2,93]; <0,0001 0,34 [0,29; 0,39]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,6807)					
BRCA1	574	337 (58,7)	580	152 (26,2)	4,00 [3,12; 5,13]; <0,0001 2,24 [1,92; 2,61]; <0,0001 0,33 [0,27; 0,38]; <0,0001
BRCA2	232	124 (53,5)	215	48 (22,3)	3,99 [2,65; 6,03]; <0,0001 2,39 [1,82; 3,16]; <0,0001 0,31 [0,23; 0,40]; <0,0001
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9560)					
2, 3 oder 4	392	233 (59,4)	383	104 (27,2)	3,93 [2,91; 5,32]; <0,0001 2,19 [1,82; 2,63]; <0,0001 0,32 [0,26; 0,39]; <0,0001
5 oder 6	22	10 (45,5)	14	3 (21,4)	3,06 [0,66; 14,08]; 0,1519 2,12 [0,70; 6,39]; 0,1813 0,24 [-0,06; 0,54]; 0,1155

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,0021)					
Andere	16	7 (43,8)	15	5 (33,3)	1,56 [0,36; 6,69]; 0,5528 1,31 [0,53; 3,25]; 0,5564 0,10 [-0,24; 0,44]; 0,5489
Asiatisch	259	153 (59,1)	271	43 (15,9)	7,65 [5,08; 11,52]; <0,0001 3,72 [2,78; 4,99]; <0,0001 0,43 [0,36; 0,51]; <0,0001
Kaukasisch	617	350 (56,7)	589	155 (26,3)	3,67 [2,88; 4,68]; <0,0001 2,16 [1,85; 2,51]; <0,0001 0,30 [0,25; 0,36]; <0,0001
Schwarz oder afroamerikanisch	19	9 (47,4)	29	10 (34,5)	1,71 [0,52; 5,58]; 0,3737 1,37 [0,69; 2,74]; 0,3672 0,13 [-0,15; 0,41]; 0,3729
Ethnische Abstammung (Interaktionstest: p=0,0326)					
Hispanisch	34	11 (32,4)	24	8 (33,3)	0,96 [0,31; 2,91]; 0,9375 0,97 [0,46; 2,05]; 0,9375 -0,01 [-0,26; 0,24]; 0,9376
Nicht-hispanisch	798	464 (58,2)	803	184 (22,9)	4,67 [3,76; 5,80]; <0,0001 2,54 [2,21; 2,92]; <0,0001 0,35 [0,31; 0,40]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	44 (55,7)	77	21 (27,3)	3,35 [1,72; 6,55]; 0,0004 2,04 [1,35; 3,09]; 0,0007 0,28 [0,14; 0,43]; 0,0002
Hormonrezeptorstatus (Interaktionstest: p=0,5775)					
ER- und/oder PgR-positiv, HER2-positiv	168	92 (54,8)	155	38 (24,5)	3,73 [2,32; 6,00]; <0,0001 2,23 [1,64; 3,04]; <0,0001 0,30 [0,20; 0,40]; <0,0001
TNBC	741	426 (57,5)	749	175 (23,4)	4,44 [3,55; 5,55]; <0,0001 2,46 [2,13; 2,84]; <0,0001 0,34 [0,29; 0,39]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3186)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	57 (54,8)	92	22 (23,9)	3,86 [2,09; 7,14]; <0,0001 2,29 [1,53; 3,43]; <0,0001 0,31 [0,18; 0,44]; <0,0001
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	35 (54,7)	63	16 (25,4)	3,55 [1,67; 7,51]; 0,0010 2,15 [1,33; 3,47]; 0,0017 0,29 [0,13; 0,46]; 0,0004
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	207 (59,5)	362	99 (27,4)	3,90 [2,85; 5,34]; <0,0001 2,18 [1,80; 2,63]; <0,0001 0,32 [0,25; 0,39]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	219 (55,7)	387	76 (19,6)	5,15 [3,74; 7,09]; <0,0001 2,84 [2,28; 3,54]; <0,0001 0,36 [0,30; 0,42]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,5471)					
Postmenopausal	346	189 (54,6)	356	85 (23,9)	3,84 [2,78; 5,30]; <0,0001 2,29 [1,86; 2,82]; <0,0001 0,31 [0,24; 0,38]; <0,0001
Prämenopausal	563	329 (58,4)	544	128 (23,5)	4,57 [3,53; 5,92]; <0,0001 2,48 [2,10; 2,93]; <0,0001 0,35 [0,29; 0,40]; <0,0001
Region (Interaktionstest: p=0,1892)					
Asien-Pazifik und Südafrika	301	182 (60,5)	317	72 (22,7)	5,20 [3,67; 7,38]; <0,0001 2,66 [2,13; 3,33]; <0,0001 0,38 [0,31; 0,45]; <0,0001
Europa	473	248 (52,4)	444	92 (20,7)	4,22 [3,15; 5,65]; <0,0001 2,53 [2,07; 3,09]; <0,0001 0,32 [0,26; 0,38]; <0,0001
Nordamerika	121	86 (71,1)	131	49 (37,4)	4,11 [2,42; 6,98]; <0,0001 1,90 [1,48; 2,44]; <0,0001 0,34 [0,22; 0,45]; <0,0001
Südamerika	16	3 (18,8)	12	0 (0,0)	6,48 [0,30; 138,43]; 0,2315 5,35 [0,30; 94,77]; 0,2526 0,19 [-0,03; 0,41]; 0,0930
Art der vorherigen Chemotherapie (Interaktionstest: p=0,1074)					
Adjuvant	457	254 (55,6)	450	92 (20,4)	4,87 [3,63; 6,53]; <0,0001 2,72 [2,23; 3,32]; <0,0001 0,35 [0,29; 0,41]; <0,0001
Neoadjuvant	454	265 (58,4)	454	121 (26,7)	3,86 [2,92; 5,10]; <0,0001 2,19 [1,85; 2,60]; <0,0001 0,32 [0,26; 0,38]; <0,0001
Sponsor (Interaktionstest: p=0,0628)					
AZ	801	442 (55,2)	796	173 (21,7)	4,43 [3,56; 5,52]; <0,0001 2,54 [2,19; 2,94]; <0,0001 0,33 [0,29; 0,38]; <0,0001
NRG Oncology	110	77 (70,0)	108	40 (37,0)	3,97 [2,26; 6,98]; <0,0001 1,89 [1,44; 2,49]; <0,0001 0,33 [0,20; 0,45]; <0,0001
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,0808)					
Ja	243	147 (60,5)	236	70 (29,7)	3,63 [2,48; 5,31]; <0,0001 2,04 [1,63; 2,54]; <0,0001 0,31 [0,22; 0,39]; <0,0001
Nein	668	372 (55,7)	668	143 (21,4)	4,61 [3,63; 5,86]; <0,0001 2,60 [2,22; 3,05]; <0,0001 0,34 [0,29; 0,39]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Neutropenie					
Alter (Interaktionstest: p=0,4639)					
<50	690	118 (17,1)	663	48 (7,2)	2,64 [1,85; 3,77]; <0,0001 2,36 [1,72; 3,25]; <0,0001 0,10 [0,06; 0,13]; <0,0001
50-64	192	26 (13,5)	209	12 (5,7)	2,57 [1,26; 5,25]; 0,0096 2,36 [1,22; 4,54]; 0,0103 0,08 [0,02; 0,14]; 0,0081
≥65	29	6 (20,7)	32	0 (0,0)	17,98 [0,96; 335,02]; 0,0529 14,30 [0,84; 243,20]; 0,0658 0,21 [0,05; 0,36]; 0,0081
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,6533)					
Anthrazyklin	7	2 (28,6)	13	1 (7,7)	4,80 [0,35; 65,76]; 0,2401 3,71 [0,40; 34,12]; 0,2462 0,21 [-0,16; 0,57]; 0,2618
Anthrazyklin und Taxan	861	143 (16,6)	840	55 (6,6)	2,84 [2,05; 3,94]; <0,0001 2,54 [1,89; 3,41]; <0,0001 0,10 [0,07; 0,13]; <0,0001
Taxan	43	5 (11,6)	50	4 (8,0)	1,51 [0,38; 6,03]; 0,5573 1,45 [0,42; 5,07]; 0,5576 0,04 [-0,09; 0,16]; 0,5594
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,5557)					
Brusterhaltend	220	33 (15,0)	235	14 (6,0)	2,79 [1,45; 5,36]; 0,0022 2,52 [1,39; 4,58]; 0,0025 0,09 [0,03; 0,15]; 0,0016
Einseitige Mastektomie	355	67 (18,9)	352	31 (8,8)	2,41 [1,53; 3,79]; 0,0001 2,14 [1,44; 3,20]; 0,0002 0,10 [0,05; 0,15]; <0,0001
Beidseitige Mastektomie	336	50 (14,9)	315	15 (4,8)	3,50 [1,92; 6,37]; <0,0001 3,12 [1,79; 5,45]; <0,0001 0,10 [0,06; 0,15]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,9776)					
Ja	41	3 (7,3)	35	1 (2,9)	2,68 [0,27; 27,04]; 0,4022 2,56 [0,28; 23,53]; 0,4059 0,04 [-0,05; 0,14]; 0,3673
Nein	870	147 (16,9)	866	59 (6,8)	2,78 [2,02; 3,82]; <0,0001 2,48 [1,86; 3,30]; <0,0001 0,10 [0,07; 0,13]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,6228)					
Positiv	173	49 (28,3)	176	19 (10,8)	3,27 [1,83; 5,83]; <0,0001 2,62 [1,61; 4,27]; 0,0001 0,18 [0,09; 0,26]; <0,0001
Negativ	200	37 (18,5)	191	11 (5,8)	3,71 [1,83; 7,52]; 0,0003 3,21 [1,69; 6,11]; 0,0004 0,13 [0,06; 0,19]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,2497)					
Ja	189	27 (14,3)	176	14 (8,0)	1,93 [0,98; 3,81]; 0,0588 1,80 [0,97; 3,31]; 0,0608 0,06 [0,00; 0,13]; 0,0523
Nein	722	123 (17,0)	728	46 (6,3)	3,04 [2,13; 4,35]; <0,0001 2,70 [1,95; 3,72]; <0,0001 0,11 [0,07; 0,14]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,7368)					
BRCA1	574	95 (16,6)	580	37 (6,4)	2,91 [1,95; 4,34]; <0,0001 2,59 [1,81; 3,73]; <0,0001 0,10 [0,07; 0,14]; <0,0001
BRCA2	232	27 (11,6)	215	11 (5,1)	2,44 [1,18; 5,06]; 0,0161 2,27 [1,16; 4,47]; 0,0172 0,07 [0,01; 0,12]; 0,0117
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9927)					
2, 3 oder 4	392	50 (12,8)	383	19 (5,0)	2,80 [1,62; 4,85]; 0,0002 2,57 [1,55; 4,28]; 0,0003 0,08 [0,04; 0,12]; 0,0001
5 oder 6	22	4 (18,2)	14	1 (7,1)	2,89 [0,29; 28,94]; 0,3669 2,55 [0,32; 20,50]; 0,3801 0,11 [-0,10; 0,32]; 0,3033
Ethnie (Interaktionstest: p=0,3579)					
Andere	16	1 (6,3)	15	2 (13,3)	0,43 [0,04; 5,35]; 0,5142 0,47 [0,05; 4,65]; 0,5175 -0,07 [-0,28; 0,14]; 0,5064
Asiatisch	259	79 (30,5)	271	32 (11,8)	3,28 [2,08; 5,16]; <0,0001 2,58 [1,78; 3,75]; <0,0001 0,19 [0,12; 0,25]; <0,0001
Kaukasisch	617	69 (11,2)	589	24 (4,1)	2,96 [1,84; 4,79]; <0,0001 2,74 [1,75; 4,31]; <0,0001 0,07 [0,04; 0,10]; <0,0001
Schwarz oder afroamerikanisch	19	1 (5,3)	29	2 (6,9)	0,75 [0,06; 8,90]; 0,8197 0,76 [0,07; 7,84]; 0,8201 -0,02 [-0,15; 0,12]; 0,8143

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,7899)					
Hispanisch	34	5 (14,7)	24	1 (4,2)	3,97 [0,43; 36,35]; 0,2230 3,53 [0,44; 28,32]; 0,2353 0,11 [-0,04; 0,25]; 0,1497
Nicht-hispanisch	798	140 (17,5)	803	56 (7,0)	2,84 [2,05; 3,94]; <0,0001 2,52 [1,87; 3,38]; <0,0001 0,11 [0,07; 0,14]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	5 (6,3)	77	3 (3,9)	1,67 [0,38; 7,23]; 0,4950 1,62 [0,40; 6,56]; 0,4959 0,02 [-0,04; 0,09]; 0,4890
Hormonrezeptorstatus (Interaktionstest: p=0,0255)					
ER- und/oder PgR-positiv, HER2-positiv	168	15 (8,9)	155	12 (7,7)	1,17 [0,53; 2,58]; 0,7005 1,15 [0,56; 2,39]; 0,7007 0,01 [-0,05; 0,07]; 0,6995
TNBC	741	135 (18,2)	749	48 (6,4)	3,25 [2,30; 4,60]; <0,0001 2,84 [2,08; 3,89]; <0,0001 0,12 [0,09; 0,15]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,1410)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	11 (10,6)	92	7 (7,6)	1,44 [0,53; 3,87]; 0,4745 1,39 [0,56; 3,44]; 0,4757 0,03 [-0,05; 0,11]; 0,4681
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	4 (6,3)	63	5 (7,9)	0,77 [0,20; 3,02]; 0,7117 0,79 [0,22; 2,80]; 0,7119 -0,02 [-0,11; 0,07]; 0,7112
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	46 (13,2)	362	18 (5,0)	2,91 [1,65; 5,13]; 0,0002 2,66 [1,57; 4,49]; 0,0003 0,08 [0,04; 0,12]; 0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	89 (22,7)	387	30 (7,8)	3,48 [2,24; 5,42]; <0,0001 2,92 [1,98; 4,31]; <0,0001 0,15 [0,10; 0,20]; <0,0001
Menopausenstatus (Interaktionstest: p=0,8590)					
Postmenopausal	346	51 (14,7)	356	22 (6,2)	2,62 [1,55; 4,43]; 0,0003 2,39 [1,48; 3,85]; 0,0004 0,09 [0,04; 0,13]; 0,0002
Prämenopausal	563	99 (17,6)	544	38 (7,0)	2,84 [1,91; 4,22]; <0,0001 2,52 [1,77; 3,59]; <0,0001 0,11 [0,07; 0,14]; <0,0001
Region (Interaktionstest: p=0,7431)					
Asien-Pazifik und Südafrika	301	85 (28,2)	317	35 (11,0)	3,17 [2,06; 4,88]; <0,0001 2,56 [1,78; 3,67]; <0,0001 0,17 [0,11; 0,23]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	48 (10,2)	444	21 (4,7)	2,27 [1,34; 3,87]; 0,0024 2,15 [1,31; 3,52]; 0,0026 0,05 [0,02; 0,09]; 0,0016
Nordamerika	121	15 (12,4)	131	4 (3,1)	4,49 [1,45; 13,95]; 0,0093 4,06 [1,39; 11,89]; 0,0106 0,09 [0,03; 0,16]; 0,0053
Südamerika	16	2 (12,5)	12	0 (0,0)	4,31 [0,19; 98,51]; 0,3601 3,82 [0,20; 73,00]; 0,3728 0,12 [-0,07; 0,32]; 0,2164
Art der vorherigen Chemotherapie (Interaktionstest: p=0,6428)					
Adjuvant	457	93 (20,4)	450	35 (7,8)	3,03 [2,00; 4,58]; <0,0001 2,62 [1,81; 3,77]; <0,0001 0,13 [0,08; 0,17]; <0,0001
Neoadjuvant	454	57 (12,6)	454	25 (5,5)	2,46 [1,51; 4,02]; 0,0003 2,28 [1,45; 3,58]; 0,0003 0,07 [0,03; 0,11]; 0,0002
Sponsor (Interaktionstest: p=0,4482)					
AZ	801	135 (16,9)	796	56 (7,0)	2,68 [1,93; 3,72]; <0,0001 2,40 [1,78; 3,22]; <0,0001 0,10 [0,07; 0,13]; <0,0001
NRG Oncology	110	15 (13,6)	108	4 (3,7)	4,11 [1,32; 12,80]; 0,0150 3,68 [1,26; 10,74]; 0,0170 0,10 [0,03; 0,17]; 0,0080
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,6424)					
Ja	243	34 (14,0)	236	15 (6,4)	2,40 [1,27; 4,53]; 0,0071 2,20 [1,23; 3,93]; 0,0077 0,08 [0,02; 0,13]; 0,0052
Nein	668	116 (17,4)	668	45 (6,7)	2,91 [2,02; 4,18]; <0,0001 2,58 [1,86; 3,58]; <0,0001 0,11 [0,07; 0,14]; <0,0001
Thrombozytopenie					
Alter (Interaktionstest: p=0,8566)					
<50	690	27 (3,9)	663	8 (1,2)	3,33 [1,50; 7,39]; 0,0030 3,24 [1,48; 7,09]; 0,0032 0,03 [0,01; 0,04]; 0,0015
50-64	192	9 (4,7)	209	4 (1,9)	2,52 [0,76; 8,32]; 0,1293 2,45 [0,77; 7,82]; 0,1306 0,03 [-0,01; 0,06]; 0,1225
≥65	29	2 (6,9)	32	0 (0,0)	5,91 [0,27; 128,38]; 0,2581 5,50 [0,27; 110,01]; 0,2647 0,07 [-0,04; 0,18]; 0,2079

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,7367)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	36 (4,2)	840	11 (1,3)	3,29 [1,66; 6,50]; 0,0006 3,19 [1,64; 6,23]; 0,0007 0,03 [0,01; 0,04]; 0,0003
Taxan	43	1 (2,3)	50	1 (2,0)	1,17 [0,07; 19,23]; 0,9141 1,16 [0,07; 18,04]; 0,9141 0,00 [-0,06; 0,06]; 0,9145
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2405)					
Brusterhaltend	220	11 (5,0)	235	0 (0,0)	25,85 [1,51; 441,43]; 0,0247 24,56 [1,46; 414,32]; 0,0264 0,05 [0,02; 0,08]; 0,0010
Einseitige Mastektomie	355	15 (4,2)	352	6 (1,7)	2,54 [0,98; 6,63]; 0,0562 2,48 [0,97; 6,32]; 0,0571 0,03 [0,00; 0,05]; 0,0474
Beidseitige Mastektomie	336	12 (3,6)	315	6 (1,9)	1,91 [0,71; 5,15]; 0,2021 1,87 [0,71; 4,94]; 0,2030 0,02 [-0,01; 0,04]; 0,1901
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,8177)					
Ja	41	2 (4,9)	35	0 (0,0)	4,49 [0,21; 96,80]; 0,3374 4,29 [0,21; 86,39]; 0,3423 0,05 [-0,03; 0,13]; 0,2386
Nein	870	36 (4,1)	866	12 (1,4)	3,07 [1,59; 5,95]; 0,0009 2,99 [1,56; 5,70]; 0,0009 0,03 [0,01; 0,04]; 0,0004
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,1796)					
Positiv	173	10 (5,8)	176	5 (2,8)	2,10 [0,70; 6,27]; 0,1846 2,03 [0,71; 5,83]; 0,1860 0,03 [-0,01; 0,07]; 0,1759
Negativ	200	8 (4,0)	191	0 (0,0)	16,91 [0,97; 295,06]; 0,0526 16,24 [0,94; 279,42]; 0,0548 0,04 [0,01; 0,07]; 0,0064
Bilaterale Oophorektomie (Interaktionstest: p=0,8708)					
Ja	189	6 (3,2)	176	2 (1,1)	2,85 [0,57; 14,32]; 0,2030 2,79 [0,57; 13,66]; 0,2045 0,02 [-0,01; 0,05]; 0,1756
Nein	722	32 (4,4)	728	10 (1,4)	3,33 [1,62; 6,83]; 0,0010 3,23 [1,60; 6,51]; 0,0011 0,03 [0,01; 0,05]; 0,0005

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
BRCA-Mutationsstatus (Interaktionstest: p=0,5765)					
BRCA1	574	27 (4,7)	580	7 (1,2)	4,04 [1,75; 9,35]; 0,0011 3,90 [1,71; 8,88]; 0,0012 0,03 [0,02; 0,05]; 0,0004
BRCA2	232	5 (2,2)	215	2 (0,9)	2,35 [0,45; 12,22]; 0,3113 2,32 [0,45; 11,82]; 0,3122 0,01 [-0,01; 0,03]; 0,2895
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,7839)					
2, 3 oder 4	392	11 (2,8)	383	4 (1,0)	2,74 [0,86; 8,67]; 0,0872 2,69 [0,86; 8,36]; 0,0881 0,02 [0,00; 0,04]; 0,0730
5 oder 6	22	3 (13,6)	14	1 (7,1)	2,05 [0,19; 21,97]; 0,5521 1,91 [0,22; 16,58]; 0,5577 0,06 [-0,13; 0,26]; 0,5180
Ethnie (Interaktionstest: p=0,4569)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	17 (6,6)	271	6 (2,2)	3,10 [1,20; 8,00]; 0,0191 2,96 [1,19; 7,40]; 0,0199 0,04 [0,01; 0,08]; 0,0145
Kaukasisch	617	21 (3,4)	589	5 (0,9)	4,12 [1,54; 10,99]; 0,0047 4,01 [1,52; 10,56]; 0,0050 0,03 [0,01; 0,04]; 0,0019
Schwarz oder afroamerikanisch	19	0 (0,0)	29	1 (3,5)	0,49 [0,02; 12,59]; 0,6647 0,50 [0,02; 11,67]; 0,6663 -0,03 [-0,14; 0,07]; 0,5148
Ethnische Abstammung (Interaktionstest: p=0,6447)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	32 (4,0)	803	12 (1,5)	2,75 [1,41; 5,39]; 0,0031 2,68 [1,39; 5,17]; 0,0032 0,03 [0,01; 0,04]; 0,0020
Unbekannt, nicht erfasst, verweigert	79	5 (6,3)	77	0 (0,0)	11,44 [0,62; 210,58]; 0,1010 10,72 [0,60; 190,72]; 0,1062 0,06 [0,01; 0,12]; 0,0331
Hormonrezeptorstatus (Interaktionstest: p=0,1933)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	2 (1,3)	0,92 [0,13; 6,62]; 0,9354 0,92 [0,13; 6,47]; 0,9354 0,00 [-0,03; 0,02]; 0,9355

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	36 (4,9)	749	10 (1,3)	3,77 [1,86; 7,66]; 0,0002 3,64 [1,82; 7,28]; 0,0003 0,04 [0,02; 0,05]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6332)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	1 (1,1)	0,88 [0,05; 14,33]; 0,9306 0,88 [0,06; 13,94]; 0,9306 0,00 [-0,03; 0,03]; 0,9308
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	1 (1,6)	0,98 [0,06; 16,09]; 0,9910 0,98 [0,06; 15,40]; 0,9910 0,00 [-0,04; 0,04]; 0,9910
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	16 (4,6)	362	5 (1,4)	3,44 [1,25; 9,50]; 0,0170 3,33 [1,23; 8,99]; 0,0177 0,03 [0,01; 0,06]; 0,0119
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	20 (5,1)	387	5 (1,3)	4,10 [1,52; 11,03]; 0,0053 3,94 [1,49; 10,39]; 0,0056 0,04 [0,01; 0,06]; 0,0024
Menopausenstatus (Interaktionstest: p=0,5570)					
Postmenopausal	346	17 (4,9)	356	4 (1,1)	4,55 [1,51; 13,65]; 0,0069 4,37 [1,49; 12,86]; 0,0074 0,04 [0,01; 0,06]; 0,0033
Prämenopausal	563	21 (3,7)	544	7 (1,3)	2,97 [1,25; 7,05]; 0,0134 2,90 [1,24; 6,76]; 0,0138 0,02 [0,01; 0,04]; 0,0089
Region (Interaktionstest: p=0,5653)					
Asien-Pazifik und Südafrika	301	17 (5,7)	317	7 (2,2)	2,65 [1,08; 6,49]; 0,0327 2,56 [1,08; 6,08]; 0,0335 0,03 [0,00; 0,07]; 0,0280
Europa	473	13 (2,8)	444	4 (0,9)	3,11 [1,01; 9,61]; 0,0488 3,05 [1,00; 9,29]; 0,0495 0,02 [0,00; 0,04]; 0,0348
Nordamerika	121	8 (6,6)	131	1 (0,8)	9,20 [1,13; 74,71]; 0,0378 8,66 [1,10; 68,24]; 0,0404 0,06 [0,01; 0,11]; 0,0141
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,7654)					
Adjuvant	457	21 (4,6)	450	6 (1,3)	3,56 [1,42; 8,92]; 0,0066 3,45 [1,40; 8,46]; 0,0069 0,03 [0,01; 0,05]; 0,0036
Neoadjuvant	454	17 (3,7)	454	6 (1,3)	2,90 [1,13; 7,44]; 0,0262 2,83 [1,13; 7,12]; 0,0268 0,02 [0,00; 0,04]; 0,0198

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,3370)					
AZ	801	30 (3,8)	796	11 (1,4)	2,78 [1,38; 5,58]; 0,0041 2,71 [1,37; 5,37]; 0,0043 0,02 [0,01; 0,04]; 0,0027
NRG Oncology	110	8 (7,3)	108	1 (0,9)	8,39 [1,03; 68,29]; 0,0467 7,85 [1,00; 61,74]; 0,0501 0,06 [0,01; 0,12]; 0,0163
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,2116)					
Ja	243	9 (3,7)	236	5 (2,1)	1,78 [0,59; 5,38]; 0,3093 1,75 [0,59; 5,14]; 0,3100 0,02 [-0,01; 0,05]; 0,3008
Nein	668	29 (4,3)	668	7 (1,1)	4,29 [1,86; 9,85]; 0,0006 4,14 [1,83; 9,39]; 0,0007 0,03 [0,02; 0,05]; 0,0002
Fatigue und Asthenie					
Alter (Interaktionstest: p=0,5280)					
<50	690	297 (43,0)	663	191 (28,8)	1,87 [1,49; 2,34]; <0,0001 1,49 [1,29; 1,73]; <0,0001 0,14 [0,09; 0,19]; <0,0001
50-64	192	81 (42,2)	209	55 (26,3)	2,04 [1,34; 3,11]; 0,0009 1,60 [1,21; 2,12]; 0,0010 0,16 [0,07; 0,25]; 0,0007
≥65	29	8 (27,6)	32	9 (28,1)	0,97 [0,32; 2,99]; 0,9626 0,98 [0,44; 2,20]; 0,9626 -0,01 [-0,23; 0,22]; 0,9626
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,9142)					
Anthrazyklin	7	2 (28,6)	13	2 (15,4)	2,20 [0,24; 20,40]; 0,4877 1,86 [0,33; 10,49]; 0,4834 0,13 [-0,26; 0,52]; 0,5052
Anthrazyklin und Taxan	861	369 (42,9)	840	240 (28,6)	1,88 [1,53; 2,29]; <0,0001 1,50 [1,31; 1,71]; <0,0001 0,14 [0,10; 0,19]; <0,0001
Taxan	43	15 (34,9)	50	13 (26,0)	1,52 [0,63; 3,71]; 0,3531 1,34 [0,72; 2,50]; 0,3534 0,09 [-0,10; 0,28]; 0,3525
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,4416)					
Brusterhaltend	220	89 (40,5)	235	73 (31,1)	1,51 [1,03; 2,22]; 0,0370 1,30 [1,02; 1,67]; 0,0376 0,09 [0,01; 0,18]; 0,0360
Einseitige Mastektomie	355	119 (33,5)	352	77 (21,9)	1,80 [1,29; 2,52]; 0,0006 1,53 [1,20; 1,96]; 0,0007 0,12 [0,05; 0,18]; 0,0005

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	178 (53,0)	315	105 (33,3)	2,25 [1,64; 3,09]; <0,0001 1,59 [1,32; 1,91]; <0,0001 0,20 [0,12; 0,27]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,0037)					
Ja	41	22 (53,7)	35	22 (62,9)	0,68 [0,27; 1,72]; 0,4190 0,85 [0,58; 1,25]; 0,4167 -0,09 [-0,31; 0,13]; 0,4150
Nein	870	364 (41,8)	866	233 (26,9)	1,95 [1,60; 2,39]; <0,0001 1,56 [1,36; 1,78]; <0,0001 0,15 [0,11; 0,19]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,1390)					
Positiv	173	68 (39,3)	176	50 (28,4)	1,63 [1,04; 2,55]; 0,0320 1,38 [1,03; 1,87]; 0,0332 0,11 [0,01; 0,21]; 0,0304
Negativ	200	79 (39,5)	191	39 (20,4)	2,54 [1,62; 4,00]; <0,0001 1,93 [1,39; 2,69]; <0,0001 0,19 [0,10; 0,28]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,9543)					
Ja	189	99 (52,4)	176	62 (35,2)	2,02 [1,33; 3,08]; 0,0010 1,49 [1,17; 1,89]; 0,0013 0,17 [0,07; 0,27]; 0,0008
Nein	722	287 (39,8)	728	193 (26,5)	1,83 [1,46; 2,28]; <0,0001 1,50 [1,29; 1,74]; <0,0001 0,13 [0,08; 0,18]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,7614)					
BRCA1	574	252 (43,9)	580	167 (28,8)	1,94 [1,52; 2,47]; <0,0001 1,52 [1,30; 1,79]; <0,0001 0,15 [0,10; 0,21]; <0,0001
BRCA2	232	107 (46,1)	215	68 (31,6)	1,85 [1,26; 2,72]; 0,0018 1,46 [1,15; 1,86]; 0,0021 0,14 [0,06; 0,23]; 0,0015
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,1341)					
2, 3 oder 4	392	176 (44,9)	383	116 (30,3)	1,88 [1,40; 2,52]; <0,0001 1,48 [1,23; 1,79]; <0,0001 0,15 [0,08; 0,21]; <0,0001
5 oder 6	22	13 (59,1)	14	2 (14,3)	8,67 [1,55; 48,47]; 0,0139 4,14 [1,09; 15,63]; 0,0363 0,45 [0,17; 0,72]; 0,0014

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,0020)					
Andere	16	7 (43,8)	15	10 (66,7)	0,39 [0,09; 1,67]; 0,2045 0,66 [0,34; 1,27]; 0,2116 -0,23 [-0,57; 0,11]; 0,1872
Asiatisch	259	75 (29,0)	271	34 (12,6)	2,84 [1,81; 4,45]; <0,0001 2,31 [1,60; 3,33]; <0,0001 0,16 [0,10; 0,23]; <0,0001
Kaukasisch	617	291 (47,2)	589	203 (34,5)	1,70 [1,35; 2,14]; <0,0001 1,37 [1,19; 1,57]; <0,0001 0,13 [0,07; 0,18]; <0,0001
Schwarz oder afroamerikanisch	19	13 (68,4)	29	8 (27,6)	5,69 [1,61; 20,14]; 0,0071 2,48 [1,28; 4,82]; 0,0073 0,41 [0,14; 0,67]; 0,0025
Ethnische Abstammung (Interaktionstest: p=0,3603)					
Hispanisch	34	8 (23,5)	24	7 (29,2)	0,75 [0,23; 2,44]; 0,6297 0,81 [0,34; 1,92]; 0,6283 -0,06 [-0,29; 0,17]; 0,6326
Nicht-hispanisch	798	332 (41,6)	803	218 (27,2)	1,91 [1,55; 2,36]; <0,0001 1,53 [1,33; 1,76]; <0,0001 0,14 [0,10; 0,19]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	46 (58,2)	77	30 (39,0)	2,18 [1,15; 4,14]; 0,0168 1,49 [1,07; 2,09]; 0,0192 0,19 [0,04; 0,35]; 0,0142
Hormonrezeptorstatus (Interaktionstest: p=0,9367)					
ER- und/oder PgR-positiv, HER2-positiv	168	74 (44,1)	155	45 (29,0)	1,92 [1,21; 3,05]; 0,0054 1,52 [1,12; 2,05]; 0,0064 0,15 [0,05; 0,25]; 0,0045
TNBC	741	311 (42,0)	749	210 (28,0)	1,86 [1,50; 2,30]; <0,0001 1,50 [1,30; 1,73]; <0,0001 0,14 [0,09; 0,19]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8050)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	46 (44,2)	92	24 (26,1)	2,25 [1,23; 4,12]; 0,0087 1,70 [1,13; 2,54]; 0,0108 0,18 [0,05; 0,31]; 0,0066
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	28 (43,8)	63	21 (33,3)	1,56 [0,76; 3,20]; 0,2290 1,31 [0,84; 2,05]; 0,2323 0,10 [-0,06; 0,27]; 0,2251
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	157 (45,1)	362	113 (31,2)	1,81 [1,33; 2,46]; 0,0001 1,45 [1,19; 1,75]; 0,0002 0,14 [0,07; 0,21]; 0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	154 (39,2)	387	97 (25,1)	1,93 [1,42; 2,62]; <0,0001 1,56 [1,27; 1,93]; <0,0001 0,14 [0,08; 0,21]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,1255)					
Postmenopausal	346	152 (43,9)	356	117 (32,9)	1,60 [1,18; 2,17]; 0,0026 1,34 [1,11; 1,62]; 0,0028 0,11 [0,04; 0,18]; 0,0024
Prämenopausal	563	232 (41,2)	544	137 (25,2)	2,08 [1,61; 2,69]; <0,0001 1,64 [1,37; 1,95]; <0,0001 0,16 [0,11; 0,21]; <0,0001
Region (Interaktionstest: p=0,4497)					
Asien-Pazifik und Südafrika	301	96 (31,9)	317	58 (18,3)	2,09 [1,44; 3,04]; 0,0001 1,74 [1,31; 2,32]; 0,0001 0,14 [0,07; 0,20]; <0,0001
Europa	473	217 (45,9)	444	139 (31,3)	1,86 [1,42; 2,44]; <0,0001 1,47 [1,24; 1,74]; <0,0001 0,15 [0,08; 0,21]; <0,0001
Nordamerika	121	69 (57,0)	131	57 (43,5)	1,72 [1,05; 2,84]; 0,0326 1,31 [1,02; 1,68]; 0,0333 0,14 [0,01; 0,26]; 0,0305
Südamerika	16	4 (25,0)	12	1 (8,3)	3,67 [0,35; 38,03]; 0,2763 3,00 [0,38; 23,53]; 0,2958 0,17 [-0,10; 0,43]; 0,2152
Art der vorherigen Chemotherapie (Interaktionstest: p=0,8808)					
Adjuvant	457	182 (39,8)	450	118 (26,2)	1,86 [1,41; 2,47]; <0,0001 1,52 [1,25; 1,84]; <0,0001 0,14 [0,08; 0,20]; <0,0001
Neoadjuvant	454	204 (44,9)	454	137 (30,2)	1,89 [1,44; 2,48]; <0,0001 1,49 [1,25; 1,77]; <0,0001 0,15 [0,09; 0,21]; <0,0001
Sponsor (Interaktionstest: p=0,4314)					
AZ	801	324 (40,5)	796	210 (26,4)	1,90 [1,53; 2,34]; <0,0001 1,53 [1,33; 1,77]; <0,0001 0,14 [0,09; 0,19]; <0,0001
NRG Oncology	110	62 (56,4)	108	45 (41,7)	1,81 [1,06; 3,09]; 0,0306 1,35 [1,03; 1,78]; 0,0327 0,15 [0,02; 0,28]; 0,0282
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,8705)					
Ja	243	107 (44,0)	236	68 (28,8)	1,94 [1,33; 2,84]; 0,0006 1,53 [1,20; 1,95]; 0,0007 0,15 [0,07; 0,24]; 0,0005
Nein	668	279 (41,8)	668	187 (28,0)	1,84 [1,47; 2,32]; <0,0001 1,49 [1,28; 1,74]; <0,0001 0,14 [0,09; 0,19]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
MDS/AML					
Alter (Interaktionstest: p=NC)					
<50	690	1 (0,1)	663	1 (0,2)	0,96 [0,06; 15,39]; 0,9775 0,96 [0,06; 15,33]; 0,9775 0,00 [0,00; 0,00]; 0,9775
50-64	192	0 (0,0)	209	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	1 (0,1)	840	1 (0,1)	0,98 [0,06; 15,62]; 0,9861 0,98 [0,06; 15,57]; 0,9861 0,00 [0,00; 0,00]; 0,9861
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=NC)					
Brusterhaltend	220	0 (0,0)	235	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Einseitige Mastektomie	355	1 (0,3)	352	1 (0,3)	0,99 [0,06; 15,91]; 0,9952 0,99 [0,06; 15,79]; 0,9952 0,00 [-0,01; 0,01]; 0,9952
Beidseitige Mastektomie	336	0 (0,0)	315	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	1 (0,1)	866	1 (0,1)	1,00 [0,06; 15,94]; 0,9974 1,00 [0,06; 15,89]; 0,9974 0,00 [0,00; 0,00]; 0,9974

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	1 (0,6)	176	0 (0,0)	3,07 [0,12; 75,87]; 0,4931 3,05 [0,13; 74,40]; 0,4935 0,01 [-0,01; 0,02]; 0,4735
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Bilaterale Oophorektomie (Interaktionstest: p=NC)					
Ja	189	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Nein	722	1 (0,1)	728	1 (0,1)	1,01 [0,06; 16,15]; 0,9953 1,01 [0,06; 16,09]; 0,9953 0,00 [0,00; 0,00]; 0,9953
BRCA-Mutationsstatus (Interaktionstest: p=NC)					
BRCA1	574	0 (0,0)	580	1 (0,2)	0,34 [0,01; 8,27]; 0,5048 0,34 [0,01; 8,25]; 0,5049 0,00 [-0,01; 0,00]; 0,4794
BRCA2	232	0 (0,0)	215	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	0 (0,0)	383	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=NC)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	1 (0,4)	271	1 (0,4)	1,05 [0,07; 16,82]; 0,9744 1,05 [0,07; 16,64]; 0,9744 0,00 [-0,01; 0,01]; 0,9744
Kaukasisch	617	0 (0,0)	589	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	1 (0,1)	803	1 (0,1)	1,01 [0,06; 16,12]; 0,9965 1,01 [0,06; 16,06]; 0,9965 0,00 [0,00; 0,00]; 0,9965
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Hormonrezeptorstatus (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv, HER2-positiv	168	0 (0,0)	155	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
TNBC	741	1 (0,1)	749	1 (0,1)	1,01 [0,06; 16,19]; 0,9939 1,01 [0,06; 16,13]; 0,9939 0,00 [0,00; 0,00]; 0,9939
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3531)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	0 (0,0)	362	1 (0,3)	0,35 [0,01; 8,52]; 0,5159 0,35 [0,01; 8,48]; 0,5161 0,00 [-0,01; 0,00]; 0,4820
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	1 (0,3)	387	0 (0,0)	2,96 [0,12; 72,93]; 0,5065 2,95 [0,12; 72,30]; 0,5067 0,00 [0,00; 0,01]; 0,4794
Menopausenstatus (Interaktionstest: p=0,3549)					
Postmenopausal	346	0 (0,0)	356	1 (0,3)	0,34 [0,01; 8,42]; 0,5116 0,34 [0,01; 8,39]; 0,5118 0,00 [-0,01; 0,00]; 0,4807
Prämenopausal	563	1 (0,2)	544	0 (0,0)	2,90 [0,12; 71,44]; 0,5141 2,90 [0,12; 71,01]; 0,5143 0,00 [0,00; 0,01]; 0,4821
Region (Interaktionstest: p=NC)					
Asien-Pazifik und Südafrika	301	1 (0,3)	317	1 (0,3)	1,05 [0,07; 16,92]; 0,9707 1,05 [0,07; 16,76]; 0,9707 0,00 [-0,01; 0,01]; 0,9708

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	0 (0,0)	444	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,3444)					
Adjuvant	457	1 (0,2)	450	0 (0,0)	2,96 [0,12; 72,87]; 0,5066 2,95 [0,12; 72,33]; 0,5068 0,00 [0,00; 0,01]; 0,4797
Neoadjuvant	454	0 (0,0)	454	1 (0,2)	0,33 [0,01; 8,19]; 0,5006 0,33 [0,01; 8,16]; 0,5007 0,00 [-0,01; 0,00]; 0,4779
Sponsor (Interaktionstest: p=NC)					
AZ	801	1 (0,1)	796	1 (0,1)	0,99 [0,06; 15,92]; 0,9965 0,99 [0,06; 15,86]; 0,9965 0,00 [0,00; 0,00]; 0,9965
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=NC)					
Ja	243	0 (0,0)	236	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Nein	668	1 (0,2)	668	1 (0,2)	1,00 [0,06; 16,02]; 1,0000 1,00 [0,06; 15,95]; 1,0000 0,00 [0,00; 0,00]; 1,0000
Neue primäre Malignität (ausgenommen MDS/AML)					
Alter (Interaktionstest: p=0,7513)					
<50	690	2 (0,3)	663	9 (1,4)	0,21 [0,05; 0,98]; 0,0473 0,21 [0,05; 0,98]; 0,0477 -0,01 [-0,02; 0,00]; 0,0306
50-64	192	3 (1,6)	209	7 (3,4)	0,46 [0,12; 1,80]; 0,2629 0,47 [0,12; 1,78]; 0,2641 -0,02 [-0,05; 0,01]; 0,2438
≥65	29	0 (0,0)	32	1 (3,1)	0,36 [0,01; 9,09]; 0,5320 0,37 [0,02; 8,66]; 0,5340 -0,03 [-0,12; 0,05]; 0,4688

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,5457)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	4 (0,5)	840	15 (1,8)	0,26 [0,08; 0,78]; 0,0161 0,26 [0,09; 0,78]; 0,0163 -0,01 [-0,02; 0,00]; 0,0099
Taxan	43	1 (2,3)	50	2 (4,0)	0,57 [0,05; 6,53]; 0,6525 0,58 [0,05; 6,19]; 0,6532 -0,02 [-0,09; 0,05]; 0,6419
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,5357)					
Brusterhaltend	220	1 (0,5)	235	2 (0,9)	0,53 [0,05; 5,91]; 0,6074 0,53 [0,05; 5,85]; 0,6075 0,00 [-0,02; 0,01]; 0,5977
Einseitige Mastektomie	355	3 (0,9)	352	7 (2,0)	0,42 [0,11; 1,64]; 0,2115 0,42 [0,11; 1,63]; 0,2122 -0,01 [-0,03; 0,01]; 0,1982
Beidseitige Mastektomie	336	1 (0,3)	315	8 (2,5)	0,11 [0,01; 0,92]; 0,0416 0,12 [0,01; 0,93]; 0,0427 -0,02 [-0,04; 0,00]; 0,0165
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,6829)					
Ja	41	0 (0,0)	35	2 (5,7)	0,16 [0,01; 3,48]; 0,2444 0,17 [0,01; 3,46]; 0,2498 -0,06 [-0,15; 0,03]; 0,2097
Nein	870	5 (0,6)	866	15 (1,7)	0,33 [0,12; 0,91]; 0,0316 0,33 [0,12; 0,91]; 0,0319 -0,01 [-0,02; 0,00]; 0,0238
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,5441)					
Positiv	173	0 (0,0)	176	6 (3,4)	0,08 [0,00; 1,35]; 0,0793 0,08 [0,00; 1,38]; 0,0817 -0,03 [-0,06; -0,01]; 0,0205
Negativ	200	1 (0,5)	191	4 (2,1)	0,23 [0,03; 2,12]; 0,1970 0,24 [0,03; 2,12]; 0,1983 -0,02 [-0,04; 0,01]; 0,1656
Bilaterale Oophorektomie (Interaktionstest: p=0,8183)					
Ja	189	1 (0,5)	176	4 (2,3)	0,23 [0,03; 2,07]; 0,1890 0,23 [0,03; 2,06]; 0,1904 -0,02 [-0,04; 0,01]; 0,1601
Nein	722	4 (0,6)	728	13 (1,8)	0,31 [0,10; 0,94]; 0,0394 0,31 [0,10; 0,95]; 0,0398 -0,01 [-0,02; 0,00]; 0,0288

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
BRCA-Mutationsstatus (Interaktionstest: p=0,8307)					
BRCA1	574	3 (0,5)	580	13 (2,2)	0,23 [0,06; 0,81]; 0,0220 0,23 [0,07; 0,81]; 0,0224 -0,02 [-0,03; 0,00]; 0,0120
BRCA2	232	1 (0,4)	215	3 (1,4)	0,31 [0,03; 2,96]; 0,3066 0,31 [0,03; 2,95]; 0,3074 -0,01 [-0,03; 0,01]; 0,2884
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	3 (0,8)	383	6 (1,6)	0,48 [0,12; 1,95]; 0,3081 0,49 [0,12; 1,94]; 0,3085 -0,01 [-0,02; 0,01]; 0,2995
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,9909)					
Andere	16	0 (0,0)	15	1 (6,7)	0,29 [0,01; 7,76]; 0,4628 0,31 [0,01; 7,15]; 0,4675 -0,07 [-0,23; 0,10]; 0,4252
Asiatisch	259	1 (0,4)	271	3 (1,1)	0,35 [0,04; 3,35]; 0,3597 0,35 [0,04; 3,33]; 0,3603 -0,01 [-0,02; 0,01]; 0,3321
Kaukasisch	617	4 (0,7)	589	13 (2,2)	0,29 [0,09; 0,89]; 0,0308 0,29 [0,10; 0,90]; 0,0313 -0,02 [-0,03; 0,00]; 0,0231
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,9119)					
Hispanisch	34	0 (0,0)	24	1 (4,2)	0,23 [0,01; 5,82]; 0,3703 0,24 [0,01; 5,61]; 0,3733 -0,04 [-0,14; 0,06]; 0,4190
Nicht-hispanisch	798	5 (0,6)	803	14 (1,7)	0,36 [0,13; 0,99]; 0,0481 0,36 [0,13; 0,99]; 0,0485 -0,01 [-0,02; 0,00]; 0,0385
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	2 (2,6)	0,19 [0,01; 4,02]; 0,2862 0,20 [0,01; 4,00]; 0,2888 -0,03 [-0,07; 0,02]; 0,2335
Hormonrezeptorstatus (Interaktionstest: p=0,9608)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	3 (1,9)	0,30 [0,03; 2,95]; 0,3039 0,31 [0,03; 2,93]; 0,3049 -0,01 [-0,04; 0,01]; 0,2858

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
TNBC	741	4 (0,5)	749	14 (1,9)	0,28 [0,09; 0,87]; 0,0274 0,29 [0,10; 0,87]; 0,0278 -0,01 [-0,02; 0,00]; 0,0183
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3536)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	2 (2,2)	0,17 [0,01; 3,66]; 0,2598 0,18 [0,01; 3,64]; 0,2619 -0,02 [-0,06; 0,01]; 0,2289
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	1 (1,6)	0,98 [0,06; 16,09]; 0,9910 0,98 [0,06; 15,40]; 0,9910 0,00 [-0,04; 0,04]; 0,9910
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	3 (0,9)	362	4 (1,1)	0,78 [0,17; 3,50]; 0,7439 0,78 [0,18; 3,46]; 0,7440 0,00 [-0,02; 0,01]; 0,7427
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	1 (0,3)	387	10 (2,6)	0,10 [0,01; 0,75]; 0,0259 0,10 [0,01; 0,77]; 0,0267 -0,02 [-0,04; -0,01]; 0,0059
Menopausenstatus (Interaktionstest: p=0,7335)					
Postmenopausal	346	3 (0,9)	356	9 (2,5)	0,34 [0,09; 1,26]; 0,1052 0,34 [0,09; 1,26]; 0,1062 -0,02 [-0,04; 0,00]; 0,0868
Prämenopausal	563	2 (0,4)	544	8 (1,5)	0,24 [0,05; 1,13]; 0,0709 0,24 [0,05; 1,13]; 0,0715 -0,01 [-0,02; 0,00]; 0,0519
Region (Interaktionstest: p=0,9787)					
Asien-Pazifik und Südafrika	301	1 (0,3)	317	5 (1,6)	0,21 [0,02; 1,79]; 0,1529 0,21 [0,02; 1,79]; 0,1539 -0,01 [-0,03; 0,00]; 0,1079
Europa	473	3 (0,6)	444	8 (1,8)	0,35 [0,09; 1,32]; 0,1206 0,35 [0,09; 1,32]; 0,1212 -0,01 [-0,03; 0,00]; 0,1093
Nordamerika	121	1 (0,8)	131	3 (2,3)	0,36 [0,04; 3,47]; 0,3734 0,36 [0,04; 3,42]; 0,3746 -0,01 [-0,04; 0,02]; 0,3433
Südamerika	16	0 (0,0)	12	1 (8,3)	0,23 [0,01; 6,22]; 0,3843 0,25 [0,01; 5,76]; 0,3902 -0,08 [-0,27; 0,11]; 0,3933
Art der vorherigen Chemotherapie (Interaktionstest: p=0,3235)					
Adjuvant	457	2 (0,4)	450	11 (2,4)	0,18 [0,04; 0,80]; 0,0241 0,18 [0,04; 0,80]; 0,0247 -0,02 [-0,04; 0,00]; 0,0112
Neoadjuvant	454	3 (0,7)	454	6 (1,3)	0,50 [0,12; 2,00]; 0,3245 0,50 [0,13; 1,99]; 0,3248 -0,01 [-0,02; 0,01]; 0,3146

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=0,6455)					
AZ	801	4 (0,5)	796	15 (1,9)	0,26 [0,09; 0,79]; 0,0175 0,27 [0,09; 0,79]; 0,0178 -0,01 [-0,02; 0,00]; 0,0107
NRG Oncology	110	1 (0,9)	108	2 (1,9)	0,49 [0,04; 5,44]; 0,5585 0,49 [0,05; 5,33]; 0,5589 -0,01 [-0,04; 0,02]; 0,5512
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,6616)					
Ja	243	1 (0,4)	236	5 (2,1)	0,19 [0,02; 1,65]; 0,1320 0,19 [0,02; 1,65]; 0,1333 -0,02 [-0,04; 0,00]; 0,0953
Nein	668	4 (0,6)	668	12 (1,8)	0,33 [0,11; 1,03]; 0,0555 0,33 [0,11; 1,03]; 0,0559 -0,01 [-0,02; 0,00]; 0,0439
Pneumonitis					
Alter (Interaktionstest: p=0,1450)					
<50	690	8 (1,2)	663	6 (0,9)	1,28 [0,44; 3,72]; 0,6447 1,28 [0,45; 3,67]; 0,6447 0,00 [-0,01; 0,01]; 0,6430
50-64	192	1 (0,5)	209	5 (2,4)	0,21 [0,02; 1,85]; 0,1606 0,22 [0,03; 1,85]; 0,1622 -0,02 [-0,04; 0,00]; 0,1121
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,3454)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	8 (0,9)	840	11 (1,3)	0,71 [0,28; 1,77]; 0,4577 0,71 [0,29; 1,76]; 0,4578 0,00 [-0,01; 0,01]; 0,4563
Taxan	43	1 (2,3)	50	0 (0,0)	3,56 [0,14; 89,80]; 0,4400 3,48 [0,15; 83,21]; 0,4417 0,02 [-0,04; 0,08]; 0,4478
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,7623)					
Brusterhaltend	220	1 (0,5)	235	2 (0,9)	0,53 [0,05; 5,91]; 0,6074 0,53 [0,05; 5,85]; 0,6075 0,00 [-0,02; 0,01]; 0,5977
Einseitige Mastektomie	355	4 (1,1)	352	6 (1,7)	0,66 [0,18; 2,35]; 0,5183 0,66 [0,19; 2,32]; 0,5185 -0,01 [-0,02; 0,01]; 0,5156

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	4 (1,2)	315	3 (1,0)	1,25 [0,28; 5,64]; 0,7689 1,25 [0,28; 5,54]; 0,7690 0,00 [-0,01; 0,02]; 0,7677
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,4511)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	8 (0,9)	866	11 (1,3)	0,72 [0,29; 1,80]; 0,4845 0,72 [0,29; 1,79]; 0,4845 0,00 [-0,01; 0,01]; 0,4827
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,4397)					
Positiv	173	2 (1,2)	176	3 (1,7)	0,67 [0,11; 4,09]; 0,6683 0,68 [0,11; 4,01]; 0,6684 -0,01 [-0,03; 0,02]; 0,6658
Negativ	200	1 (0,5)	191	0 (0,0)	2,88 [0,12; 71,12]; 0,5180 2,87 [0,12; 69,92]; 0,5183 0,00 [-0,01; 0,02]; 0,4812
Bilaterale Oophorektomie (Interaktionstest: p=0,6178)					
Ja	189	1 (0,5)	176	2 (1,1)	0,46 [0,04; 5,15]; 0,5308 0,47 [0,04; 5,09]; 0,5310 -0,01 [-0,02; 0,01]; 0,5259
Nein	722	8 (1,1)	728	9 (1,2)	0,90 [0,34; 2,33]; 0,8207 0,90 [0,35; 2,31]; 0,8207 0,00 [-0,01; 0,01]; 0,8205
BRCA-Mutationsstatus (Interaktionstest: p=0,6096)					
BRCA1	574	4 (0,7)	580	5 (0,9)	0,81 [0,22; 3,02]; 0,7502 0,81 [0,22; 3,00]; 0,7502 0,00 [-0,01; 0,01]; 0,7496
BRCA2	232	2 (0,9)	215	4 (1,9)	0,46 [0,08; 2,53]; 0,3710 0,46 [0,09; 2,50]; 0,3715 -0,01 [-0,03; 0,01]; 0,3656
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,3756)					
2, 3 oder 4	392	3 (0,8)	383	7 (1,8)	0,41 [0,11; 1,61]; 0,2040 0,42 [0,11; 1,61]; 0,2047 -0,01 [-0,03; 0,01]; 0,1917
5 oder 6	22	1 (4,6)	14	0 (0,0)	2,02 [0,08; 53,19]; 0,6727 1,96 [0,09; 44,92]; 0,6747 0,05 [-0,09; 0,18]; 0,5117

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,5148)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	6 (2,3)	271	6 (2,2)	1,05 [0,33; 3,29]; 0,9368 1,05 [0,34; 3,20]; 0,9368 0,00 [-0,02; 0,03]; 0,9368
Kaukasisch	617	3 (0,5)	589	5 (0,9)	0,57 [0,14; 2,40]; 0,4439 0,57 [0,14; 2,39]; 0,4440 0,00 [-0,01; 0,01]; 0,4408
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,5485)					
Hispanisch	34	0 (0,0)	24	1 (4,2)	0,23 [0,01; 5,82]; 0,3703 0,24 [0,01; 5,61]; 0,3733 -0,04 [-0,14; 0,06]; 0,4190
Nicht-hispanisch	798	8 (1,0)	803	10 (1,3)	0,80 [0,32; 2,05]; 0,6456 0,81 [0,32; 2,03]; 0,6456 0,00 [-0,01; 0,01]; 0,6448
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	0 (0,0)	2,96 [0,12; 73,83]; 0,5081 2,92 [0,12; 70,72]; 0,5090 0,01 [-0,02; 0,05]; 0,4733
Hormonrezeptorstatus (Interaktionstest: p=0,8104)					
ER- und/oder PgR-positiv, HER2-positiv	168	3 (1,8)	155	4 (2,6)	0,69 [0,15; 3,12]; 0,6259 0,69 [0,16; 3,04]; 0,6260 -0,01 [-0,04; 0,02]; 0,6264
TNBC	741	6 (0,8)	749	7 (0,9)	0,87 [0,29; 2,59]; 0,7957 0,87 [0,29; 2,57]; 0,7957 0,00 [-0,01; 0,01]; 0,7955
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7116)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	3 (3,3)	0,29 [0,03; 2,82]; 0,2848 0,29 [0,03; 2,79]; 0,2865 -0,02 [-0,06; 0,02]; 0,2700
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	1 (1,6)	2,00 [0,18; 22,63]; 0,5755 1,97 [0,18; 21,17]; 0,5762 0,02 [-0,04; 0,07]; 0,5669
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	3 (0,9)	362	4 (1,1)	0,78 [0,17; 3,50]; 0,7439 0,78 [0,18; 3,46]; 0,7440 0,00 [-0,02; 0,01]; 0,7427
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	3 (0,8)	387	3 (0,8)	0,98 [0,20; 4,91]; 0,9849 0,98 [0,20; 4,85]; 0,9849 0,00 [-0,01; 0,01]; 0,9849

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Menopausenstatus (Interaktionstest: p=0,3137)					
Postmenopausal	346	2 (0,6)	356	5 (1,4)	0,41 [0,08; 2,12]; 0,2861 0,41 [0,08; 2,11]; 0,2867 -0,01 [-0,02; 0,01]; 0,2673
Prämenopausal	563	7 (1,2)	544	6 (1,1)	1,13 [0,38; 3,38]; 0,8285 1,13 [0,38; 3,33]; 0,8285 0,00 [-0,01; 0,01]; 0,8282
Region (Interaktionstest: p=0,7647)					
Asien-Pazifik und Südafrika	301	7 (2,3)	317	7 (2,2)	1,05 [0,37; 3,04]; 0,9219 1,05 [0,37; 2,97]; 0,9219 0,00 [-0,02; 0,02]; 0,9220
Europa	473	1 (0,2)	444	2 (0,5)	0,47 [0,04; 5,18]; 0,5361 0,47 [0,04; 5,16]; 0,5362 0,00 [-0,01; 0,01]; 0,5310
Nordamerika	121	1 (0,8)	131	2 (1,5)	0,54 [0,05; 6,00]; 0,6141 0,54 [0,05; 5,89]; 0,6144 -0,01 [-0,03; 0,02]; 0,6042
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4008)					
Adjuvant	457	5 (1,1)	450	4 (0,9)	1,23 [0,33; 4,62]; 0,7557 1,23 [0,33; 4,55]; 0,7557 0,00 [-0,01; 0,01]; 0,7550
Neoadjuvant	454	4 (0,9)	454	7 (1,5)	0,57 [0,17; 1,95]; 0,3690 0,57 [0,17; 1,94]; 0,3692 -0,01 [-0,02; 0,01]; 0,3626
Sponsor (Interaktionstest: p=0,6538)					
AZ	801	8 (1,0)	796	9 (1,1)	0,88 [0,34; 2,30]; 0,7974 0,88 [0,34; 2,28]; 0,7975 0,00 [-0,01; 0,01]; 0,7974
NRG Oncology	110	1 (0,9)	108	2 (1,9)	0,49 [0,04; 5,44]; 0,5585 0,49 [0,05; 5,33]; 0,5589 -0,01 [-0,04; 0,02]; 0,5512
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4754)					
Ja	243	2 (0,8)	236	4 (1,7)	0,48 [0,09; 2,65]; 0,4011 0,49 [0,09; 2,63]; 0,4016 -0,01 [-0,03; 0,01]; 0,3930
Nein	668	7 (1,1)	668	7 (1,1)	1,00 [0,35; 2,87]; 1,0000 1,00 [0,35; 2,84]; 1,0000 0,00 [-0,01; 0,01]; 1,0000

Anhang 4-G12: Subgruppenanalysen: Nicht schwere UESI

Tabelle 6.6.1: Subgruppenergebnisse für nicht schwere UESI aus RCT mit dem zu bewertenden Arzneimittel

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Anämie					
Alter (Interaktionstest: p=0,1260)					
<50	690	134 (19,4)	663	28 (4,2)	5,47 [3,58; 8,34]; <0,0001 4,60 [3,10; 6,81]; <0,0001 0,15 [0,12; 0,19]; <0,0001
50-64	192	45 (23,4)	209	4 (1,9)	15,69 [5,52; 44,58]; <0,0001 12,25 [4,49; 33,41]; <0,0001 0,22 [0,15; 0,28]; <0,0001
≥65	29	13 (44,8)	32	1 (3,1)	25,19 [3,02; 210,17]; 0,0029 14,34 [2,00; 102,95]; 0,0081 0,42 [0,23; 0,61]; <0,0001
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,3614)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	182 (21,1)	840	29 (3,5)	7,50 [5,00; 11,24]; <0,0001 6,12 [4,19; 8,95]; <0,0001 0,18 [0,15; 0,21]; <0,0001
Taxan	43	9 (20,9)	50	4 (8,0)	3,04 [0,86; 10,72]; 0,0830 2,62 [0,87; 7,90]; 0,0880 0,13 [-0,01; 0,27]; 0,0763
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2251)					
Brusterhaltend	220	53 (24,1)	235	5 (2,1)	14,60 [5,71; 37,31]; <0,0001 11,32 [4,61; 27,80]; <0,0001 0,22 [0,16; 0,28]; <0,0001
Einseitige Mastektomie	355	75 (21,1)	352	15 (4,3)	6,02 [3,38; 10,71]; <0,0001 4,96 [2,91; 8,46]; <0,0001 0,17 [0,12; 0,22]; <0,0001
Beidseitige Mastektomie	336	64 (19,1)	315	13 (4,1)	5,47 [2,95; 10,14]; <0,0001 4,62 [2,59; 8,21]; <0,0001 0,15 [0,10; 0,20]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,4686)					
Ja	41	3 (7,3)	35	1 (2,9)	2,68 [0,27; 27,04]; 0,4022 2,56 [0,28; 23,53]; 0,4059 0,04 [-0,05; 0,14]; 0,3673
Nein	870	189 (21,7)	866	32 (3,7)	7,23 [4,91; 10,66]; <0,0001 5,88 [4,09; 8,45]; <0,0001 0,18 [0,15; 0,21]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,5510)					
Positiv	173	51 (29,5)	176	9 (5,1)	7,76 [3,68; 16,36]; <0,0001 5,76 [2,93; 11,34]; <0,0001 0,24 [0,17; 0,32]; <0,0001
Negativ	200	35 (17,5)	191	4 (2,1)	9,92 [3,45; 28,49]; <0,0001 8,36 [3,03; 23,06]; <0,0001 0,15 [0,10; 0,21]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,4288)					
Ja	189	38 (20,1)	176	8 (4,6)	5,28 [2,39; 11,68]; <0,0001 4,42 [2,12; 9,22]; <0,0001 0,16 [0,09; 0,22]; <0,0001
Nein	722	154 (21,3)	728	25 (3,4)	7,62 [4,93; 11,80]; <0,0001 6,21 [4,12; 9,36]; <0,0001 0,18 [0,15; 0,21]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,4964)					
BRCA1	574	117 (20,4)	580	20 (3,5)	7,17 [4,39; 11,70]; <0,0001 5,91 [3,73; 9,36]; <0,0001 0,17 [0,13; 0,21]; <0,0001
BRCA2	232	43 (18,5)	215	9 (4,2)	5,21 [2,47; 10,97]; <0,0001 4,43 [2,21; 8,86]; <0,0001 0,14 [0,09; 0,20]; <0,0001
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9685)					
2, 3 oder 4	392	70 (17,9)	383	14 (3,7)	5,73 [3,17; 10,37]; <0,0001 4,89 [2,80; 8,52]; <0,0001 0,14 [0,10; 0,18]; <0,0001
5 oder 6	22	8 (36,4)	14	1 (7,1)	7,43 [0,81; 67,83]; 0,0756 5,09 [0,71; 36,43]; 0,1050 0,29 [0,05; 0,53]; 0,0180
Ethnie (Interaktionstest: p=0,0530)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	82 (31,7)	271	10 (3,7)	12,09 [6,10; 23,96]; <0,0001 8,58 [4,55; 16,17]; <0,0001 0,28 [0,22; 0,34]; <0,0001
Kaukasisch	617	106 (17,2)	589	19 (3,2)	6,22 [3,76; 10,29]; <0,0001 5,33 [3,31; 8,56]; <0,0001 0,14 [0,11; 0,17]; <0,0001
Schwarz oder afroamerikanisch	19	4 (21,1)	29	4 (13,8)	1,67 [0,36; 7,67]; 0,5119 1,53 [0,43; 5,38]; 0,5105 0,07 [-0,15; 0,29]; 0,5219

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,8989)					
Hispanisch	34	6 (17,7)	24	0 (0,0)	11,18 [0,60; 208,60]; 0,1060 9,29 [0,55; 157,40]; 0,1228 0,18 [0,04; 0,32]; 0,0135
Nicht-hispanisch	798	178 (22,3)	803	32 (4,0)	6,92 [4,68; 10,23]; <0,0001 5,60 [3,89; 8,05]; <0,0001 0,18 [0,15; 0,22]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	8 (10,1)	77	1 (1,3)	8,56 [1,04; 70,20]; 0,0454 7,80 [1,00; 60,88]; 0,0501 0,09 [0,02; 0,16]; 0,0151
Hormonrezeptorstatus (Interaktionstest: p=0,9654)					
ER- und/oder PgR-positiv, HER2-positiv	168	32 (19,1)	155	5 (3,2)	7,06 [2,67; 18,63]; <0,0001 5,90 [2,36; 14,77]; 0,0001 0,16 [0,09; 0,22]; <0,0001
TNBC	741	160 (21,6)	749	28 (3,7)	7,09 [4,68; 10,75]; <0,0001 5,78 [3,92; 8,52]; <0,0001 0,18 [0,15; 0,21]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7497)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	18 (17,3)	92	4 (4,4)	4,60 [1,50; 14,16]; 0,0077 3,98 [1,40; 11,34]; 0,0097 0,13 [0,05; 0,21]; 0,0024
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	14 (21,9)	63	1 (1,6)	17,36 [2,21; 136,57]; 0,0067 13,78 [1,87; 101,70]; 0,0101 0,20 [0,10; 0,31]; 0,0002
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	68 (19,5)	362	12 (3,3)	7,08 [3,76; 13,35]; <0,0001 5,89 [3,25; 10,70]; <0,0001 0,16 [0,12; 0,21]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	92 (23,4)	387	16 (4,1)	7,09 [4,08; 12,31]; <0,0001 5,66 [3,39; 9,45]; <0,0001 0,19 [0,15; 0,24]; <0,0001
Menopausenstatus (Interaktionstest: p=0,8944)					
Postmenopausal	346	82 (23,7)	356	15 (4,2)	7,06 [3,98; 12,53]; <0,0001 5,62 [3,31; 9,56]; <0,0001 0,19 [0,15; 0,24]; <0,0001
Prämenopausal	563	110 (19,5)	544	18 (3,3)	7,10 [4,24; 11,86]; <0,0001 5,90 [3,64; 9,58]; <0,0001 0,16 [0,13; 0,20]; <0,0001
Region (Interaktionstest: p=0,2170)					
Asien-Pazifik und Südafrika	301	88 (29,2)	317	10 (3,2)	12,68 [6,44; 24,96]; <0,0001 9,27 [4,91; 17,48]; <0,0001 0,26 [0,21; 0,32]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	73 (15,4)	444	14 (3,2)	5,61 [3,11; 10,09]; <0,0001 4,89 [2,80; 8,54]; <0,0001 0,12 [0,09; 0,16]; <0,0001
Nordamerika	121	30 (24,8)	131	9 (6,9)	4,47 [2,02; 9,87]; 0,0002 3,61 [1,79; 7,29]; 0,0003 0,18 [0,09; 0,27]; <0,0001
Südamerika	16	1 (6,3)	12	0 (0,0)	2,42 [0,09; 64,70]; 0,5982 2,29 [0,10; 51,85]; 0,6017 0,06 [-0,11; 0,23]; 0,4728
Art der vorherigen Chemotherapie (Interaktionstest: p=0,7159)					
Adjuvant	457	106 (23,2)	450	17 (3,8)	7,69 [4,52; 13,08]; <0,0001 6,14 [3,74; 10,07]; <0,0001 0,19 [0,15; 0,24]; <0,0001
Neoadjuvant	454	86 (18,9)	454	16 (3,5)	6,40 [3,69; 11,10]; <0,0001 5,38 [3,20; 9,02]; <0,0001 0,15 [0,11; 0,19]; <0,0001
Sponsor (Interaktionstest: p=0,0681)					
AZ	801	163 (20,4)	796	24 (3,0)	8,22 [5,29; 12,78]; <0,0001 6,75 [4,45; 10,24]; <0,0001 0,17 [0,14; 0,20]; <0,0001
NRG Oncology	110	29 (26,4)	108	9 (8,3)	3,94 [1,76; 8,80]; 0,0008 3,16 [1,57; 6,37]; 0,0012 0,18 [0,08; 0,28]; 0,0003
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,3567)					
Ja	243	40 (16,5)	236	9 (3,8)	4,97 [2,35; 10,49]; <0,0001 4,32 [2,14; 8,70]; <0,0001 0,13 [0,07; 0,18]; <0,0001
Nein	668	152 (22,8)	668	24 (3,6)	7,90 [5,06; 12,34]; <0,0001 6,33 [4,17; 9,61]; <0,0001 0,19 [0,16; 0,23]; <0,0001
Erbrechen					
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,9709)					
Positiv	173	26 (15,0)	176	10 (5,7)	2,94 [1,37; 6,29]; 0,0056 2,65 [1,32; 5,32]; 0,0063 0,09 [0,03; 0,16]; 0,0038
Negativ	200	60 (30,0)	191	22 (11,5)	3,29 [1,92; 5,63]; <0,0001 2,60 [1,67; 4,07]; <0,0001 0,18 [0,11; 0,26]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Alter (Interaktionstest: p=0,3975)					
<50	690	166 (24,1)	663	54 (8,1)	3,57 [2,57; 4,96]; <0,0001 2,95 [2,21; 3,94]; <0,0001 0,16 [0,12; 0,20]; <0,0001
50-64	192	33 (17,2)	209	17 (8,1)	2,34 [1,26; 4,36]; 0,0072 2,11 [1,22; 3,67]; 0,0078 0,09 [0,03; 0,16]; 0,0063
≥65	29	4 (13,8)	32	3 (9,4)	1,55 [0,32; 7,58]; 0,5908 1,47 [0,36; 6,03]; 0,5915 0,04 [-0,12; 0,21]; 0,5909
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,8870)					
Anthrazyklin	7	2 (28,6)	13	2 (15,4)	2,20 [0,24; 20,40]; 0,4877 1,86 [0,33; 10,49]; 0,4834 0,13 [-0,26; 0,52]; 0,5052
Anthrazyklin und Taxan	861	188 (21,8)	840	66 (7,9)	3,28 [2,43; 4,42]; <0,0001 2,78 [2,13; 3,62]; <0,0001 0,14 [0,11; 0,17]; <0,0001
Taxan	43	13 (30,2)	50	6 (12,0)	3,18 [1,09; 9,29]; 0,0347 2,52 [1,05; 6,06]; 0,0390 0,18 [0,02; 0,35]; 0,0295
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,0077)					
Brusterhaltend	220	52 (23,6)	235	16 (6,8)	4,24 [2,34; 7,68]; <0,0001 3,47 [2,04; 5,89]; <0,0001 0,17 [0,10; 0,23]; <0,0001
Einseitige Mastektomie	355	87 (24,5)	352	22 (6,3)	4,87 [2,97; 7,99]; <0,0001 3,92 [2,52; 6,11]; <0,0001 0,18 [0,13; 0,23]; <0,0001
Beidseitige Mastektomie	336	64 (19,1)	315	36 (11,4)	1,82 [1,17; 2,83]; 0,0076 1,67 [1,14; 2,43]; 0,0081 0,08 [0,02; 0,13]; 0,0064
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3037)					
Ja	41	9 (22,0)	35	1 (2,9)	9,56 [1,15; 79,80]; 0,0370 7,68 [1,02; 57,69]; 0,0475 0,19 [0,05; 0,33]; 0,0068
Nein	870	194 (22,3)	866	73 (8,4)	3,12 [2,34; 4,16]; <0,0001 2,65 [2,06; 3,40]; <0,0001 0,14 [0,11; 0,17]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,0014)					
Ja	189	26 (13,8)	176	20 (11,4)	1,24 [0,67; 2,32]; 0,4918 1,21 [0,70; 2,09]; 0,4924 0,02 [-0,04; 0,09]; 0,4897

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Nein	722	177 (24,5)	728	54 (7,4)	4,05 [2,93; 5,61]; <0,0001 3,31 [2,48; 4,40]; <0,0001 0,17 [0,13; 0,21]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,5552)					
BRCA1	574	120 (20,9)	580	53 (9,1)	2,63 [1,86; 3,72]; <0,0001 2,29 [1,69; 3,09]; <0,0001 0,12 [0,08; 0,16]; <0,0001
BRCA2	232	53 (22,8)	215	18 (8,4)	3,24 [1,83; 5,74]; <0,0001 2,73 [1,65; 4,51]; <0,0001 0,14 [0,08; 0,21]; <0,0001
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,3030)					
2, 3 oder 4	392	85 (21,7)	383	23 (6,0)	4,33 [2,67; 7,04]; <0,0001 3,61 [2,33; 5,60]; <0,0001 0,16 [0,11; 0,20]; <0,0001
5 oder 6	22	5 (22,7)	14	2 (14,3)	1,76 [0,29; 10,66]; 0,5360 1,59 [0,36; 7,11]; 0,5432 0,08 [-0,17; 0,34]; 0,5140
Ethnie (Interaktionstest: p=0,2411)					
Andere	16	2 (12,5)	15	0 (0,0)	5,34 [0,24; 121,00]; 0,2923 4,71 [0,24; 90,69]; 0,3049 0,12 [-0,06; 0,31]; 0,1942
Asiatisch	259	72 (27,8)	271	19 (7,0)	5,11 [2,98; 8,76]; <0,0001 3,97 [2,46; 6,38]; <0,0001 0,21 [0,15; 0,27]; <0,0001
Kaukasisch	617	126 (20,4)	589	52 (8,8)	2,65 [1,88; 3,74]; <0,0001 2,31 [1,71; 3,13]; <0,0001 0,12 [0,08; 0,16]; <0,0001
Schwarz oder afroamerikanisch	19	3 (15,8)	29	3 (10,3)	1,62 [0,29; 9,05]; 0,5795 1,53 [0,34; 6,79]; 0,5786 0,05 [-0,14; 0,25]; 0,5897
Ethnische Abstammung (Interaktionstest: p=0,9317)					
Hispanisch	34	10 (29,4)	24	2 (8,3)	4,58 [0,90; 23,27]; 0,0663 3,53 [0,85; 14,68]; 0,0829 0,21 [0,02; 0,40]; 0,0287
Nicht-hispanisch	798	177 (22,2)	803	66 (8,2)	3,18 [2,35; 4,31]; <0,0001 2,70 [2,07; 3,52]; <0,0001 0,14 [0,11; 0,17]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	16 (20,3)	77	6 (7,8)	3,01 [1,11; 8,15]; 0,0306 2,60 [1,07; 6,29]; 0,0342 0,12 [0,02; 0,23]; 0,0224

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Hormonrezeptorstatus (Interaktionstest: p=0,7980)					
ER- und/oder PgR-positiv, HER2-positiv	168	32 (19,1)	155	10 (6,5)	3,41 [1,62; 7,21]; 0,0013 2,95 [1,50; 5,80]; 0,0017 0,13 [0,06; 0,20]; 0,0005
TNBC	741	170 (22,9)	749	64 (8,5)	3,19 [2,34; 4,34]; <0,0001 2,68 [2,05; 3,51]; <0,0001 0,14 [0,11; 0,18]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8725)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	21 (20,2)	92	5 (5,4)	4,40 [1,59; 12,22]; 0,0044 3,72 [1,46; 9,46]; 0,0059 0,15 [0,06; 0,24]; 0,0013
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	11 (17,2)	63	5 (7,9)	2,41 [0,78; 7,38]; 0,1244 2,17 [0,80; 5,88]; 0,1292 0,09 [-0,02; 0,21]; 0,1118
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	75 (21,6)	362	28 (7,7)	3,28 [2,06; 5,20]; <0,0001 2,79 [1,85; 4,19]; <0,0001 0,14 [0,09; 0,19]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	95 (24,2)	387	36 (9,3)	3,11 [2,06; 4,70]; <0,0001 2,60 [1,82; 3,71]; <0,0001 0,15 [0,10; 0,20]; <0,0001
Menopausenstatus (Interaktionstest: p=0,0312)					
Postmenopausal	346	61 (17,6)	356	33 (9,3)	2,09 [1,33; 3,29]; 0,0014 1,90 [1,28; 2,83]; 0,0015 0,08 [0,03; 0,13]; 0,0011
Prämenopausal	563	142 (25,2)	544	41 (7,5)	4,14 [2,86; 6,00]; <0,0001 3,35 [2,41; 4,64]; <0,0001 0,18 [0,13; 0,22]; <0,0001
Region (Interaktionstest: p=0,1351)					
Asien-Pazifik und Südafrika	301	82 (27,2)	317	25 (7,9)	4,37 [2,70; 7,07]; <0,0001 3,45 [2,27; 5,25]; <0,0001 0,19 [0,14; 0,25]; <0,0001
Europa	473	84 (17,8)	444	27 (6,1)	3,34 [2,12; 5,26]; <0,0001 2,92 [1,93; 4,42]; <0,0001 0,12 [0,08; 0,16]; <0,0001
Nordamerika	121	34 (28,1)	131	22 (16,8)	1,94 [1,06; 3,55]; 0,0325 1,67 [1,04; 2,69]; 0,0340 0,11 [0,01; 0,22]; 0,0307
Südamerika	16	3 (18,8)	12	0 (0,0)	6,48 [0,30; 138,43]; 0,2315 5,35 [0,30; 94,77]; 0,2526 0,19 [-0,03; 0,41]; 0,0930

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5746)					
Adjuvant	457	106 (23,2)	450	41 (9,1)	3,01 [2,04; 4,44]; <0,0001 2,55 [1,82; 3,56]; <0,0001 0,14 [0,09; 0,19]; <0,0001
Neoadjuvant	454	97 (21,4)	454	33 (7,3)	3,47 [2,28; 5,27]; <0,0001 2,94 [2,02; 4,27]; <0,0001 0,14 [0,10; 0,19]; <0,0001
Sponsor (Interaktionstest: p=0,1759)					
AZ	801	174 (21,7)	796	59 (7,4)	3,47 [2,53; 4,74]; <0,0001 2,93 [2,22; 3,87]; <0,0001 0,14 [0,11; 0,18]; <0,0001
NRG Oncology	110	29 (26,4)	108	15 (13,9)	2,22 [1,11; 4,43]; 0,0237 1,90 [1,08; 3,34]; 0,0259 0,12 [0,02; 0,23]; 0,0199
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7045)					
Ja	243	49 (20,2)	236	19 (8,1)	2,88 [1,64; 5,07]; 0,0002 2,50 [1,52; 4,12]; 0,0003 0,12 [0,06; 0,18]; 0,0001
Nein	668	154 (23,1)	668	55 (8,2)	3,34 [2,40; 4,64]; <0,0001 2,80 [2,10; 3,74]; <0,0001 0,15 [0,11; 0,19]; <0,0001
Übelkeit					
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,0834)					
Positiv	173	87 (50,3)	176	23 (13,1)	6,73 [3,96; 11,43]; <0,0001 3,85 [2,56; 5,79]; <0,0001 0,37 [0,28; 0,46]; <0,0001
Negativ	200	117 (58,5)	191	45 (23,6)	4,57 [2,95; 7,08]; <0,0001 2,48 [1,88; 3,29]; <0,0001 0,35 [0,26; 0,44]; <0,0001
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,9560)					
2, 3 oder 4	392	233 (59,4)	383	104 (27,2)	3,93 [2,91; 5,32]; <0,0001 2,19 [1,82; 2,63]; <0,0001 0,32 [0,26; 0,39]; <0,0001
5 oder 6	22	10 (45,5)	14	3 (21,4)	3,06 [0,66; 14,08]; 0,1519 2,12 [0,70; 6,39]; 0,1813 0,24 [-0,06; 0,54]; 0,1155
Alter (Interaktionstest: p=0,8781)					
<50	690	408 (59,1)	663	164 (24,7)	4,40 [3,49; 5,56]; <0,0001 2,39 [2,06; 2,77]; <0,0001 0,34 [0,29; 0,39]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
50-64	192	94 (49,0)	209	43 (20,6)	3,70 [2,39; 5,74]; <0,0001 2,38 [1,76; 3,22]; <0,0001 0,28 [0,19; 0,37]; <0,0001
≥65	29	16 (55,2)	32	6 (18,8)	5,33 [1,69; 16,85]; 0,0043 2,94 [1,33; 6,50]; 0,0076 0,36 [0,14; 0,59]; 0,0016
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,5204)					
Anthrazyklin	7	4 (57,1)	13	1 (7,7)	16,00 [1,27; 200,92]; 0,0317 7,43 [1,02; 54,31]; 0,0482 0,49 [0,10; 0,89]; 0,0139
Anthrazyklin und Taxan	861	489 (56,8)	840	198 (23,6)	4,26 [3,46; 5,25]; <0,0001 2,41 [2,11; 2,76]; <0,0001 0,33 [0,29; 0,38]; <0,0001
Taxan	43	25 (58,1)	50	13 (26,0)	3,95 [1,65; 9,49]; 0,0021 2,24 [1,31; 3,81]; 0,0030 0,32 [0,13; 0,51]; 0,0010
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2313)					
Brusterhaltend	220	115 (52,3)	235	55 (23,4)	3,58 [2,40; 5,36]; <0,0001 2,23 [1,72; 2,91]; <0,0001 0,29 [0,20; 0,37]; <0,0001
Einseitige Mastektomie	355	193 (54,4)	352	68 (19,3)	4,98 [3,55; 6,97]; <0,0001 2,81 [2,23; 3,56]; <0,0001 0,35 [0,28; 0,42]; <0,0001
Beidseitige Mastektomie	336	210 (62,5)	315	90 (28,6)	4,17 [3,00; 5,79]; <0,0001 2,19 [1,80; 2,65]; <0,0001 0,34 [0,27; 0,41]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,3895)					
Ja	41	30 (73,2)	35	13 (37,1)	4,62 [1,74; 12,22]; 0,0021 1,97 [1,23; 3,15]; 0,0046 0,36 [0,15; 0,57]; 0,0008
Nein	870	488 (56,1)	866	199 (23,0)	4,28 [3,48; 5,27]; <0,0001 2,44 [2,13; 2,79]; <0,0001 0,33 [0,29; 0,37]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,2021)					
Ja	189	111 (58,7)	176	50 (28,4)	3,59 [2,32; 5,55]; <0,0001 2,07 [1,59; 2,69]; <0,0001 0,30 [0,21; 0,40]; <0,0001
Nein	722	407 (56,4)	728	163 (22,4)	4,48 [3,57; 5,63]; <0,0001 2,52 [2,17; 2,92]; <0,0001 0,34 [0,29; 0,39]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=0,6673)					
BRCA1	574	336 (58,5)	580	152 (26,2)	3,98 [3,10; 5,10]; <0,0001 2,23 [1,92; 2,60]; <0,0001 0,32 [0,27; 0,38]; <0,0001
BRCA2	232	124 (53,5)	215	48 (22,3)	3,99 [2,65; 6,03]; <0,0001 2,39 [1,82; 3,16]; <0,0001 0,31 [0,23; 0,40]; <0,0001
Ethnie (Interaktionstest: p=0,0020)					
Andere	16	7 (43,8)	15	5 (33,3)	1,56 [0,36; 6,69]; 0,5528 1,31 [0,53; 3,25]; 0,5564 0,10 [-0,24; 0,44]; 0,5489
Asiatisch	259	153 (59,1)	271	43 (15,9)	7,65 [5,08; 11,52]; <0,0001 3,72 [2,78; 4,99]; <0,0001 0,43 [0,36; 0,51]; <0,0001
Kaukasisch	617	349 (56,6)	589	155 (26,3)	3,65 [2,86; 4,65]; <0,0001 2,15 [1,85; 2,50]; <0,0001 0,30 [0,25; 0,36]; <0,0001
Schwarz oder afroamerikanisch	19	9 (47,4)	29	10 (34,5)	1,71 [0,52; 5,58]; 0,3737 1,37 [0,69; 2,74]; 0,3672 0,13 [-0,15; 0,41]; 0,3729
Ethnische Abstammung (Interaktionstest: p=0,0333)					
Hispanisch	34	11 (32,4)	24	8 (33,3)	0,96 [0,31; 2,91]; 0,9375 0,97 [0,46; 2,05]; 0,9375 -0,01 [-0,26; 0,24]; 0,9376
Nicht-hispanisch	798	463 (58,0)	803	184 (22,9)	4,65 [3,74; 5,77]; <0,0001 2,53 [2,20; 2,91]; <0,0001 0,35 [0,31; 0,40]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	44 (55,7)	77	21 (27,3)	3,35 [1,72; 6,55]; 0,0004 2,04 [1,35; 3,09]; 0,0007 0,28 [0,14; 0,43]; 0,0002
Hormonrezeptorstatus (Interaktionstest: p=0,5361)					
ER- und/oder PgR-positiv, HER2-positiv	168	91 (54,2)	155	38 (24,5)	3,64 [2,26; 5,85]; <0,0001 2,21 [1,62; 3,01]; <0,0001 0,30 [0,20; 0,40]; <0,0001
TNBC	741	426 (57,5)	749	175 (23,4)	4,44 [3,55; 5,55]; <0,0001 2,46 [2,13; 2,84]; <0,0001 0,34 [0,29; 0,39]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3131)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	56 (53,9)	92	22 (23,9)	3,71 [2,01; 6,87]; <0,0001 2,25 [1,50; 3,38]; <0,0001 0,30 [0,17; 0,43]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	35 (54,7)	63	16 (25,4)	3,55 [1,67; 7,51]; 0,0010 2,15 [1,33; 3,47]; 0,0017 0,29 [0,13; 0,46]; 0,0004
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	207 (59,5)	362	99 (27,4)	3,90 [2,85; 5,34]; <0,0001 2,18 [1,80; 2,63]; <0,0001 0,32 [0,25; 0,39]; <0,0001
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	219 (55,7)	387	76 (19,6)	5,15 [3,74; 7,09]; <0,0001 2,84 [2,28; 3,54]; <0,0001 0,36 [0,30; 0,42]; <0,0001
Menopausenstatus (Interaktionstest: p=0,5621)					
Postmenopausal	346	189 (54,6)	356	85 (23,9)	3,84 [2,78; 5,30]; <0,0001 2,29 [1,86; 2,82]; <0,0001 0,31 [0,24; 0,38]; <0,0001
Prämenopausal	563	328 (58,3)	544	128 (23,5)	4,54 [3,50; 5,88]; <0,0001 2,48 [2,10; 2,93]; <0,0001 0,35 [0,29; 0,40]; <0,0001
Region (Interaktionstest: p=0,1928)					
Asien-Pazifik und Südafrika	301	182 (60,5)	317	72 (22,7)	5,20 [3,67; 7,38]; <0,0001 2,66 [2,13; 3,33]; <0,0001 0,38 [0,31; 0,45]; <0,0001
Europa	473	247 (52,2)	444	92 (20,7)	4,18 [3,12; 5,60]; <0,0001 2,52 [2,06; 3,08]; <0,0001 0,31 [0,26; 0,37]; <0,0001
Nordamerika	121	86 (71,1)	131	49 (37,4)	4,11 [2,42; 6,98]; <0,0001 1,90 [1,48; 2,44]; <0,0001 0,34 [0,22; 0,45]; <0,0001
Südamerika	16	3 (18,8)	12	0 (0,0)	6,48 [0,30; 138,43]; 0,2315 5,35 [0,30; 94,77]; 0,2526 0,19 [-0,03; 0,41]; 0,0930
Art der vorherigen Chemotherapie (Interaktionstest: p=0,1015)					
Adjuvant	457	254 (55,6)	450	92 (20,4)	4,87 [3,63; 6,53]; <0,0001 2,72 [2,23; 3,32]; <0,0001 0,35 [0,29; 0,41]; <0,0001
Neoadjuvant	454	264 (58,2)	454	121 (26,7)	3,82 [2,89; 5,06]; <0,0001 2,18 [1,84; 2,59]; <0,0001 0,31 [0,25; 0,38]; <0,0001
Sponsor (Interaktionstest: p=0,0649)					
AZ	801	441 (55,1)	796	173 (21,7)	4,41 [3,55; 5,49]; <0,0001 2,53 [2,19; 2,93]; <0,0001 0,33 [0,29; 0,38]; <0,0001
NRG Oncology	110	77 (70,0)	108	40 (37,0)	3,97 [2,26; 6,98]; <0,0001 1,89 [1,44; 2,49]; <0,0001 0,33 [0,20; 0,45]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,0730)					
Ja	243	146 (60,1)	236	70 (29,7)	3,57 [2,44; 5,22]; <0,0001 2,03 [1,62; 2,53]; <0,0001 0,30 [0,22; 0,39]; <0,0001
Nein	668	372 (55,7)	668	143 (21,4)	4,61 [3,63; 5,86]; <0,0001 2,60 [2,22; 3,05]; <0,0001 0,34 [0,29; 0,39]; <0,0001
Neutropenie					
Alter (Interaktionstest: p=0,5507)					
<50	690	98 (14,2)	663	46 (6,9)	2,22 [1,54; 3,21]; <0,0001 2,05 [1,47; 2,86]; <0,0001 0,07 [0,04; 0,11]; <0,0001
50-64	192	21 (10,9)	209	12 (5,7)	2,02 [0,96; 4,22]; 0,0627 1,90 [0,96; 3,77]; 0,0639 0,05 [0,00; 0,11]; 0,0605
≥65	29	4 (13,8)	32	0 (0,0)	11,47 [0,59; 223,00]; 0,1071 9,90 [0,56; 176,29]; 0,1187 0,14 [0,00; 0,27]; 0,0443
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,7419)					
Anthrazyklin	7	2 (28,6)	13	1 (7,7)	4,80 [0,35; 65,76]; 0,2401 3,71 [0,40; 34,12]; 0,2462 0,21 [-0,16; 0,57]; 0,2618
Anthrazyklin und Taxan	861	116 (13,5)	840	53 (6,3)	2,31 [1,65; 3,25]; <0,0001 2,14 [1,56; 2,91]; <0,0001 0,07 [0,04; 0,10]; <0,0001
Taxan	43	5 (11,6)	50	4 (8,0)	1,51 [0,38; 6,03]; 0,5573 1,45 [0,42; 5,07]; 0,5576 0,04 [-0,09; 0,16]; 0,5594
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,7609)					
Brusterhaltend	220	27 (12,3)	235	13 (5,5)	2,39 [1,20; 4,76]; 0,0133 2,22 [1,17; 4,19]; 0,0140 0,07 [0,02; 0,12]; 0,0115
Einseitige Mastektomie	355	57 (16,1)	352	30 (8,5)	2,05 [1,28; 3,28]; 0,0027 1,88 [1,24; 2,86]; 0,0029 0,08 [0,03; 0,12]; 0,0021
Beidseitige Mastektomie	336	39 (11,6)	315	15 (4,8)	2,63 [1,42; 4,87]; 0,0022 2,44 [1,37; 4,33]; 0,0024 0,07 [0,03; 0,11]; 0,0012
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,5147)					
Ja	41	1 (2,4)	35	1 (2,9)	0,85 [0,05; 14,11]; 0,9097 0,85 [0,06; 13,15]; 0,9097 0,00 [-0,08; 0,07]; 0,9102

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Nein	870	122 (14,0)	866	57 (6,6)	2,31 [1,66; 3,22]; <0,0001 2,13 [1,58; 2,88]; <0,0001 0,07 [0,05; 0,10]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,5495)					
Positiv	173	39 (22,5)	176	19 (10,8)	2,40 [1,33; 4,36]; 0,0038 2,09 [1,26; 3,47]; 0,0044 0,12 [0,04; 0,19]; 0,0029
Negativ	200	31 (15,5)	191	11 (5,8)	3,00 [1,46; 6,16]; 0,0027 2,69 [1,39; 5,20]; 0,0032 0,10 [0,04; 0,16]; 0,0015
Bilaterale Oophorektomie (Interaktionstest: p=0,0931)					
Ja	189	19 (10,1)	176	14 (8,0)	1,29 [0,63; 2,67]; 0,4858 1,26 [0,65; 2,44]; 0,4863 0,02 [-0,04; 0,08]; 0,4829
Nein	722	104 (14,4)	728	44 (6,0)	2,62 [1,81; 3,78]; <0,0001 2,38 [1,70; 3,34]; <0,0001 0,08 [0,05; 0,11]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,8095)					
BRCA1	574	74 (12,9)	580	35 (6,0)	2,30 [1,51; 3,51]; <0,0001 2,14 [1,45; 3,14]; 0,0001 0,07 [0,04; 0,10]; <0,0001
BRCA2	232	23 (9,9)	215	11 (5,1)	2,04 [0,97; 4,29]; 0,0602 1,94 [0,97; 3,88]; 0,0618 0,05 [0,00; 0,10]; 0,0522
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,6204)					
2, 3 oder 4	392	40 (10,2)	383	18 (4,7)	2,30 [1,30; 4,10]; 0,0045 2,17 [1,27; 3,72]; 0,0047 0,06 [0,02; 0,09]; 0,0033
5 oder 6	22	3 (13,6)	14	0 (0,0)	5,21 [0,25; 108,83]; 0,2875 4,57 [0,25; 82,22]; 0,3033 0,14 [-0,04; 0,31]; 0,1216
Ethnie (Interaktionstest: p=0,2550)					
Andere	16	0 (0,0)	15	2 (13,3)	0,16 [0,01; 3,71]; 0,2556 0,19 [0,01; 3,63]; 0,2686 -0,13 [-0,33; 0,06]; 0,1806
Asiatisch	259	72 (27,8)	271	30 (11,1)	3,09 [1,94; 4,93]; <0,0001 2,51 [1,70; 3,71]; <0,0001 0,17 [0,10; 0,23]; <0,0001
Kaukasisch	617	50 (8,1)	589	24 (4,1)	2,08 [1,26; 3,42]; 0,0042 1,99 [1,24; 3,19]; 0,0044 0,04 [0,01; 0,07]; 0,0032

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Schwarz oder afroamerikanisch	19	1 (5,3)	29	2 (6,9)	0,75 [0,06; 8,90]; 0,8197 0,76 [0,07; 7,84]; 0,8201 -0,02 [-0,15; 0,12]; 0,8143
Ethnische Abstammung (Interaktionstest: p=0,6145)					
Hispanisch	34	3 (8,8)	24	1 (4,2)	2,23 [0,22; 22,80]; 0,5003 2,12 [0,23; 19,15]; 0,5042 0,05 [-0,08; 0,17]; 0,4632
Nicht-hispanisch	798	117 (14,7)	803	54 (6,7)	2,38 [1,70; 3,34]; <0,0001 2,18 [1,60; 2,96]; <0,0001 0,08 [0,05; 0,11]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	3 (3,8)	77	3 (3,9)	0,97 [0,19; 4,98]; 0,9745 0,97 [0,20; 4,68]; 0,9745 0,00 [-0,06; 0,06]; 0,9745
Hormonrezeptorstatus (Interaktionstest: p=0,0528)					
ER- und/oder PgR-positiv, HER2-positiv	168	14 (8,3)	155	12 (7,7)	1,08 [0,48; 2,42]; 0,8453 1,08 [0,51; 2,25]; 0,8453 0,01 [-0,05; 0,07]; 0,8450
TNBC	741	109 (14,7)	749	46 (6,1)	2,64 [1,84; 3,78]; <0,0001 2,40 [1,72; 3,33]; <0,0001 0,09 [0,05; 0,12]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,2602)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	10 (9,6)	92	7 (7,6)	1,29 [0,47; 3,54]; 0,6191 1,26 [0,50; 3,18]; 0,6196 0,02 [-0,06; 0,10]; 0,6159
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	4 (6,3)	63	5 (7,9)	0,77 [0,20; 3,02]; 0,7117 0,79 [0,22; 2,80]; 0,7119 -0,02 [-0,11; 0,07]; 0,7112
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	36 (10,3)	362	16 (4,4)	2,50 [1,36; 4,59]; 0,0032 2,34 [1,32; 4,14]; 0,0035 0,06 [0,02; 0,10]; 0,0025
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	73 (18,6)	387	30 (7,8)	2,71 [1,73; 4,26]; <0,0001 2,40 [1,60; 3,58]; <0,0001 0,11 [0,06; 0,16]; <0,0001
Menopausenstatus (Interaktionstest: p=0,5825)					
Postmenopausal	346	40 (11,6)	356	22 (6,2)	1,98 [1,15; 3,42]; 0,0133 1,87 [1,14; 3,08]; 0,0138 0,05 [0,01; 0,10]; 0,0120
Prämenopausal	563	83 (14,7)	544	36 (6,6)	2,44 [1,62; 3,68]; <0,0001 2,23 [1,53; 3,23]; <0,0001 0,08 [0,05; 0,12]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Region (Interaktionstest: p=0,5819)					
Asien-Pazifik und Südafrika	301	74 (24,6)	317	33 (10,4)	2,81 [1,80; 4,38]; <0,0001 2,36 [1,62; 3,45]; <0,0001 0,14 [0,08; 0,20]; <0,0001
Europa	473	36 (7,6)	444	21 (4,7)	1,66 [0,95; 2,89]; 0,0735 1,61 [0,95; 2,71]; 0,0743 0,03 [0,00; 0,06]; 0,0685
Nordamerika	121	12 (9,9)	131	4 (3,1)	3,50 [1,10; 11,15]; 0,0345 3,25 [1,08; 9,80]; 0,0365 0,07 [0,01; 0,13]; 0,0271
Südamerika	16	1 (6,3)	12	0 (0,0)	2,42 [0,09; 64,70]; 0,5982 2,29 [0,10; 51,85]; 0,6017 0,06 [-0,11; 0,23]; 0,4728
Art der vorherigen Chemotherapie (Interaktionstest: p=0,7986)					
Adjuvant	457	77 (16,9)	450	35 (7,8)	2,40 [1,57; 3,67]; <0,0001 2,17 [1,48; 3,16]; <0,0001 0,09 [0,05; 0,13]; <0,0001
Neoadjuvant	454	46 (10,1)	454	23 (5,1)	2,11 [1,26; 3,55]; 0,0047 2,00 [1,23; 3,24]; 0,0049 0,05 [0,02; 0,08]; 0,0038
Sponsor (Interaktionstest: p=0,5302)					
AZ	801	111 (13,9)	796	54 (6,8)	2,21 [1,57; 3,11]; <0,0001 2,04 [1,50; 2,79]; <0,0001 0,07 [0,04; 0,10]; <0,0001
NRG Oncology	110	12 (10,9)	108	4 (3,7)	3,18 [0,99; 10,20]; 0,0513 2,95 [0,98; 8,85]; 0,0543 0,07 [0,00; 0,14]; 0,0386
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,7684)					
Ja	243	28 (11,5)	236	14 (5,9)	2,07 [1,06; 4,03]; 0,0335 1,94 [1,05; 3,60]; 0,0347 0,06 [0,01; 0,11]; 0,0291
Nein	668	95 (14,2)	668	44 (6,6)	2,35 [1,62; 3,42]; <0,0001 2,16 [1,54; 3,04]; <0,0001 0,08 [0,04; 0,11]; <0,0001
Thrombozytopenie					
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,1796)					
Positiv	173	10 (5,8)	176	5 (2,8)	2,10 [0,70; 6,27]; 0,1846 2,03 [0,71; 5,83]; 0,1860 0,03 [-0,01; 0,07]; 0,1759

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Negativ	200	8 (4,0)	191	0 (0,0)	16,91 [0,97; 295,06]; 0,0526 16,24 [0,94; 279,42]; 0,0548 0,04 [0,01; 0,07]; 0,0064
Alter (Interaktionstest: p=0,7885)					
<50	690	27 (3,9)	663	8 (1,2)	3,33 [1,50; 7,39]; 0,0030 3,24 [1,48; 7,09]; 0,0032 0,03 [0,01; 0,04]; 0,0015
50-64	192	8 (4,2)	209	4 (1,9)	2,23 [0,66; 7,52]; 0,1968 2,18 [0,67; 7,11]; 0,1978 0,02 [-0,01; 0,06]; 0,1917
≥65	29	2 (6,9)	32	0 (0,0)	5,91 [0,27; 128,38]; 0,2581 5,50 [0,27; 110,01]; 0,2647 0,07 [-0,04; 0,18]; 0,2079
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,7424)					
Anthrazyklin	7	1 (14,3)	13	0 (0,0)	6,23 [0,22; 174,88]; 0,2822 5,25 [0,24; 114,29]; 0,2914 0,14 [-0,14; 0,43]; 0,3300
Anthrazyklin und Taxan	861	35 (4,1)	840	11 (1,3)	3,19 [1,61; 6,33]; 0,0009 3,10 [1,59; 6,07]; 0,0009 0,03 [0,01; 0,04]; 0,0004
Taxan	43	1 (2,3)	50	1 (2,0)	1,17 [0,07; 19,23]; 0,9141 1,16 [0,07; 18,04]; 0,9141 0,00 [-0,06; 0,06]; 0,9145
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2395)					
Brusterhaltend	220	11 (5,0)	235	0 (0,0)	25,85 [1,51; 441,43]; 0,0247 24,56 [1,46; 414,32]; 0,0264 0,05 [0,02; 0,08]; 0,0010
Einseitige Mastektomie	355	14 (3,9)	352	6 (1,7)	2,37 [0,90; 6,23]; 0,0810 2,31 [0,90; 5,95]; 0,0819 0,02 [0,00; 0,05]; 0,0715
Beidseitige Mastektomie	336	12 (3,6)	315	6 (1,9)	1,91 [0,71; 5,15]; 0,2021 1,87 [0,71; 4,94]; 0,2030 0,02 [-0,01; 0,04]; 0,1901
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,8038)					
Ja	41	2 (4,9)	35	0 (0,0)	4,49 [0,21; 96,80]; 0,3374 4,29 [0,21; 86,39]; 0,3423 0,05 [-0,03; 0,13]; 0,2386
Nein	870	35 (4,0)	866	12 (1,4)	2,98 [1,54; 5,79]; 0,0012 2,90 [1,52; 5,56]; 0,0013 0,03 [0,01; 0,04]; 0,0007

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Bilaterale Oophorektomie (Interaktionstest: p=0,7181)					
Ja	189	5 (2,7)	176	2 (1,1)	2,36 [0,45; 12,35]; 0,3076 2,33 [0,46; 11,85]; 0,3087 0,02 [-0,01; 0,04]; 0,2860
Nein	722	32 (4,4)	728	10 (1,4)	3,33 [1,62; 6,83]; 0,0010 3,23 [1,60; 6,51]; 0,0011 0,03 [0,01; 0,05]; 0,0005
BRCA-Mutationsstatus (Interaktionstest: p=0,6048)					
BRCA1	574	26 (4,5)	580	7 (1,2)	3,88 [1,67; 9,02]; 0,0016 3,75 [1,64; 8,58]; 0,0017 0,03 [0,01; 0,05]; 0,0007
BRCA2	232	5 (2,2)	215	2 (0,9)	2,35 [0,45; 12,22]; 0,3113 2,32 [0,45; 11,82]; 0,3122 0,01 [-0,01; 0,03]; 0,2895
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,8437)					
2, 3 oder 4	392	10 (2,6)	383	4 (1,0)	2,48 [0,77; 7,98]; 0,1275 2,44 [0,77; 7,72]; 0,1283 0,02 [0,00; 0,03]; 0,1131
5 oder 6	22	3 (13,6)	14	1 (7,1)	2,05 [0,19; 21,97]; 0,5521 1,91 [0,22; 16,58]; 0,5577 0,06 [-0,13; 0,26]; 0,5180
Ethnie (Interaktionstest: p=0,4787)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	17 (6,6)	271	6 (2,2)	3,10 [1,20; 8,00]; 0,0191 2,96 [1,19; 7,40]; 0,0199 0,04 [0,01; 0,08]; 0,0145
Kaukasisch	617	20 (3,2)	589	5 (0,9)	3,91 [1,46; 10,49]; 0,0067 3,82 [1,44; 10,11]; 0,0070 0,02 [0,01; 0,04]; 0,0030
Schwarz oder afroamerikanisch	19	0 (0,0)	29	1 (3,5)	0,49 [0,02; 12,59]; 0,6647 0,50 [0,02; 11,67]; 0,6663 -0,03 [-0,14; 0,07]; 0,5148
Ethnische Abstammung (Interaktionstest: p=0,7271)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	32 (4,0)	803	12 (1,5)	2,75 [1,41; 5,39]; 0,0031 2,68 [1,39; 5,17]; 0,0032 0,03 [0,01; 0,04]; 0,0020

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Unbekannt, nicht erfasst, verweigert	79	4 (5,1)	77	0 (0,0)	9,24 [0,49; 174,56]; 0,1381 8,78 [0,48; 160,29]; 0,1428 0,05 [0,00; 0,10]; 0,0636
Hormonrezeptorstatus (Interaktionstest: p=0,2028)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	2 (1,3)	0,92 [0,13; 6,62]; 0,9354 0,92 [0,13; 6,47]; 0,9354 0,00 [-0,03; 0,02]; 0,9355
TNBC	741	35 (4,7)	749	10 (1,3)	3,66 [1,80; 7,45]; 0,0003 3,54 [1,76; 7,09]; 0,0004 0,03 [0,02; 0,05]; 0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6387)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	1 (1,1)	0,88 [0,05; 14,33]; 0,9306 0,88 [0,06; 13,94]; 0,9306 0,00 [-0,03; 0,03]; 0,9308
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	1 (1,6)	0,98 [0,06; 16,09]; 0,9910 0,98 [0,06; 15,40]; 0,9910 0,00 [-0,04; 0,04]; 0,9910
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	15 (4,3)	362	5 (1,4)	3,22 [1,16; 8,95]; 0,0252 3,12 [1,15; 8,49]; 0,0259 0,03 [0,00; 0,05]; 0,0191
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	20 (5,1)	387	5 (1,3)	4,10 [1,52; 11,03]; 0,0053 3,94 [1,49; 10,39]; 0,0056 0,04 [0,01; 0,06]; 0,0024
Menopausenstatus (Interaktionstest: p=0,6179)					
Postmenopausal	346	16 (4,6)	356	4 (1,1)	4,27 [1,41; 12,89]; 0,0101 4,12 [1,39; 12,19]; 0,0106 0,04 [0,01; 0,06]; 0,0055
Prämenopausal	563	21 (3,7)	544	7 (1,3)	2,97 [1,25; 7,05]; 0,0134 2,90 [1,24; 6,76]; 0,0138 0,02 [0,01; 0,04]; 0,0089
Region (Interaktionstest: p=0,5611)					
Asien-Pazifik und Südafrika	301	17 (5,7)	317	7 (2,2)	2,65 [1,08; 6,49]; 0,0327 2,56 [1,08; 6,08]; 0,0335 0,03 [0,00; 0,07]; 0,0280
Europa	473	12 (2,5)	444	4 (0,9)	2,86 [0,92; 8,94]; 0,0703 2,82 [0,92; 8,67]; 0,0711 0,02 [0,00; 0,03]; 0,0545
Nordamerika	121	8 (6,6)	131	1 (0,8)	9,20 [1,13; 74,71]; 0,0378 8,66 [1,10; 68,24]; 0,0404 0,06 [0,01; 0,11]; 0,0141
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Art der vorherigen Chemotherapie (Interaktionstest: p=0,6972)					
Adjuvant	457	21 (4,6)	450	6 (1,3)	3,56 [1,42; 8,92]; 0,0066 3,45 [1,40; 8,46]; 0,0069 0,03 [0,01; 0,05]; 0,0036
Neoadjuvant	454	16 (3,5)	454	6 (1,3)	2,73 [1,06; 7,03]; 0,0379 2,67 [1,05; 6,75]; 0,0386 0,02 [0,00; 0,04]; 0,0305
Sponsor (Interaktionstest: p=0,3221)					
AZ	801	29 (3,6)	796	11 (1,4)	2,68 [1,33; 5,40]; 0,0058 2,62 [1,32; 5,21]; 0,0060 0,02 [0,01; 0,04]; 0,0041
NRG Oncology	110	8 (7,3)	108	1 (0,9)	8,39 [1,03; 68,29]; 0,0467 7,85 [1,00; 61,74]; 0,0501 0,06 [0,01; 0,12]; 0,0163
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,2314)					
Ja	243	9 (3,7)	236	5 (2,1)	1,78 [0,59; 5,38]; 0,3093 1,75 [0,59; 5,14]; 0,3100 0,02 [-0,01; 0,05]; 0,3008
Nein	668	28 (4,2)	668	7 (1,1)	4,13 [1,79; 9,52]; 0,0009 4,00 [1,76; 9,09]; 0,0009 0,03 [0,01; 0,05]; 0,0003
Fatigue und Asthenie					
Alter (Interaktionstest: p=0,5833)					
<50	690	293 (42,5)	663	190 (28,7)	1,84 [1,47; 2,30]; <0,0001 1,48 [1,28; 1,72]; <0,0001 0,14 [0,09; 0,19]; <0,0001
50-64	192	78 (40,6)	209	55 (26,3)	1,92 [1,26; 2,92]; 0,0025 1,54 [1,16; 2,05]; 0,0027 0,14 [0,05; 0,23]; 0,0022
≥65	29	8 (27,6)	32	9 (28,1)	0,97 [0,32; 2,99]; 0,9626 0,98 [0,44; 2,20]; 0,9626 -0,01 [-0,23; 0,22]; 0,9626
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,9241)					
Anthrazyklin	7	2 (28,6)	13	2 (15,4)	2,20 [0,24; 20,40]; 0,4877 1,86 [0,33; 10,49]; 0,4834 0,13 [-0,26; 0,52]; 0,5052
Anthrazyklin und Taxan	861	362 (42,0)	840	239 (28,5)	1,82 [1,49; 2,23]; <0,0001 1,48 [1,29; 1,69]; <0,0001 0,14 [0,09; 0,18]; <0,0001
Taxan	43	15 (34,9)	50	13 (26,0)	1,52 [0,63; 3,71]; 0,3531 1,34 [0,72; 2,50]; 0,3534 0,09 [-0,10; 0,28]; 0,3525

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,3491)					
Brusterhaltend	220	87 (39,6)	235	73 (31,1)	1,45 [0,99; 2,14]; 0,0588 1,27 [0,99; 1,64]; 0,0594 0,08 [0,00; 0,17]; 0,0578
Einseitige Mastektomie	355	114 (32,1)	352	77 (21,9)	1,69 [1,21; 2,37]; 0,0023 1,47 [1,14; 1,88]; 0,0025 0,10 [0,04; 0,17]; 0,0020
Beidseitige Mastektomie	336	178 (53,0)	315	104 (33,0)	2,29 [1,66; 3,14]; <0,0001 1,60 [1,33; 1,93]; <0,0001 0,20 [0,13; 0,27]; <0,0001
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,0028)					
Ja	41	21 (51,2)	35	22 (62,9)	0,62 [0,25; 1,56]; 0,3089 0,81 [0,55; 1,21]; 0,3066 -0,12 [-0,34; 0,11]; 0,3030
Nein	870	358 (41,2)	866	232 (26,8)	1,91 [1,56; 2,34]; <0,0001 1,54 [1,34; 1,76]; <0,0001 0,14 [0,10; 0,19]; <0,0001
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,1221)					
Positiv	173	66 (38,2)	176	50 (28,4)	1,55 [0,99; 2,43]; 0,0541 1,34 [0,99; 1,82]; 0,0554 0,10 [0,00; 0,20]; 0,0523
Negativ	200	78 (39,0)	191	39 (20,4)	2,49 [1,59; 3,92]; <0,0001 1,91 [1,37; 2,65]; 0,0001 0,19 [0,10; 0,27]; <0,0001
Bilaterale Oophorektomie (Interaktionstest: p=0,9524)					
Ja	189	96 (50,8)	176	61 (34,7)	1,95 [1,28; 2,97]; 0,0020 1,47 [1,15; 1,88]; 0,0024 0,16 [0,06; 0,26]; 0,0016
Nein	722	283 (39,2)	728	193 (26,5)	1,79 [1,43; 2,23]; <0,0001 1,48 [1,27; 1,72]; <0,0001 0,13 [0,08; 0,17]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,8078)					
BRCA1	574	246 (42,9)	580	166 (28,6)	1,87 [1,46; 2,39]; <0,0001 1,50 [1,28; 1,76]; <0,0001 0,14 [0,09; 0,20]; <0,0001
BRCA2	232	106 (45,7)	215	68 (31,6)	1,82 [1,24; 2,68]; 0,0024 1,44 [1,13; 1,84]; 0,0028 0,14 [0,05; 0,23]; 0,0020

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,1310)					
2, 3 oder 4	392	173 (44,1)	383	115 (30,0)	1,84 [1,37; 2,47]; <0,0001 1,47 [1,22; 1,78]; <0,0001 0,14 [0,07; 0,21]; <0,0001
5 oder 6	22	13 (59,1)	14	2 (14,3)	8,67 [1,55; 48,47]; 0,0139 4,14 [1,09; 15,63]; 0,0363 0,45 [0,17; 0,72]; 0,0014
Ethnie (Interaktionstest: p=0,0016)					
Andere	16	7 (43,8)	15	10 (66,7)	0,39 [0,09; 1,67]; 0,2045 0,66 [0,34; 1,27]; 0,2116 -0,23 [-0,57; 0,11]; 0,1872
Asiatisch	259	75 (29,0)	271	34 (12,6)	2,84 [1,81; 4,45]; <0,0001 2,31 [1,60; 3,33]; <0,0001 0,16 [0,10; 0,23]; <0,0001
Kaukasisch	617	284 (46,0)	589	202 (34,3)	1,63 [1,30; 2,06]; <0,0001 1,34 [1,17; 1,54]; <0,0001 0,12 [0,06; 0,17]; <0,0001
Schwarz oder afroamerikanisch	19	13 (68,4)	29	8 (27,6)	5,69 [1,61; 20,14]; 0,0071 2,48 [1,28; 4,82]; 0,0073 0,41 [0,14; 0,67]; 0,0025
Ethnische Abstammung (Interaktionstest: p=0,3799)					
Hispanisch	34	8 (23,5)	24	7 (29,2)	0,75 [0,23; 2,44]; 0,6297 0,81 [0,34; 1,92]; 0,6283 -0,06 [-0,29; 0,17]; 0,6326
Nicht-hispanisch	798	325 (40,7)	803	217 (27,0)	1,86 [1,50; 2,29]; <0,0001 1,51 [1,31; 1,74]; <0,0001 0,14 [0,09; 0,18]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	46 (58,2)	77	30 (39,0)	2,18 [1,15; 4,14]; 0,0168 1,49 [1,07; 2,09]; 0,0192 0,19 [0,04; 0,35]; 0,0142
Hormonrezeptorstatus (Interaktionstest: p=0,9882)					
ER- und/oder PgR-positiv, HER2-positiv	168	72 (42,9)	155	45 (29,0)	1,83 [1,15; 2,91]; 0,0102 1,48 [1,09; 2,00]; 0,0114 0,14 [0,03; 0,24]; 0,0088
TNBC	741	306 (41,3)	749	209 (27,9)	1,82 [1,46; 2,26]; <0,0001 1,48 [1,28; 1,71]; <0,0001 0,13 [0,09; 0,18]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8844)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	44 (42,3)	92	24 (26,1)	2,08 [1,13; 3,81]; 0,0181 1,62 [1,08; 2,45]; 0,0210 0,16 [0,03; 0,29]; 0,0150

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	28 (43,8)	63	21 (33,3)	1,56 [0,76; 3,20]; 0,2290 1,31 [0,84; 2,05]; 0,2323 0,10 [-0,06; 0,27]; 0,2251
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	155 (44,5)	362	112 (30,9)	1,79 [1,32; 2,44]; 0,0002 1,44 [1,19; 1,75]; 0,0002 0,14 [0,07; 0,21]; 0,0002
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	151 (38,4)	387	97 (25,1)	1,87 [1,37; 2,54]; <0,0001 1,53 [1,24; 1,90]; <0,0001 0,13 [0,07; 0,20]; <0,0001
Menopausenstatus (Interaktionstest: p=0,1404)					
Postmenopausal	346	149 (43,1)	356	116 (32,6)	1,56 [1,15; 2,13]; 0,0043 1,32 [1,09; 1,60]; 0,0045 0,10 [0,03; 0,18]; 0,0040
Prämenopausal	563	228 (40,5)	544	137 (25,2)	2,02 [1,56; 2,61]; <0,0001 1,61 [1,35; 1,92]; <0,0001 0,15 [0,10; 0,21]; <0,0001
Region (Interaktionstest: p=0,3751)					
Asien-Pazifik und Südafrika	301	96 (31,9)	317	58 (18,3)	2,09 [1,44; 3,04]; 0,0001 1,74 [1,31; 2,32]; 0,0001 0,14 [0,07; 0,20]; <0,0001
Europa	473	212 (44,8)	444	138 (31,1)	1,80 [1,37; 2,36]; <0,0001 1,44 [1,22; 1,71]; <0,0001 0,14 [0,08; 0,20]; <0,0001
Nordamerika	121	67 (55,4)	131	57 (43,5)	1,61 [0,98; 2,65]; 0,0605 1,27 [0,99; 1,64]; 0,0611 0,12 [0,00; 0,24]; 0,0581
Südamerika	16	4 (25,0)	12	1 (8,3)	3,67 [0,35; 38,03]; 0,2763 3,00 [0,38; 23,53]; 0,2958 0,17 [-0,10; 0,43]; 0,2152
Art der vorherigen Chemotherapie (Interaktionstest: p=0,9064)					
Adjuvant	457	179 (39,2)	450	118 (26,2)	1,81 [1,37; 2,40]; <0,0001 1,49 [1,23; 1,81]; <0,0001 0,13 [0,07; 0,19]; <0,0001
Neoadjuvant	454	200 (44,1)	454	136 (30,0)	1,84 [1,40; 2,42]; <0,0001 1,47 [1,23; 1,75]; <0,0001 0,14 [0,08; 0,20]; <0,0001
Sponsor (Interaktionstest: p=0,3607)					
AZ	801	319 (39,8)	796	209 (26,3)	1,86 [1,50; 2,30]; <0,0001 1,52 [1,31; 1,75]; <0,0001 0,14 [0,09; 0,18]; <0,0001
NRG Oncology	110	60 (54,6)	108	45 (41,7)	1,68 [0,98; 2,87]; 0,0578 1,31 [0,99; 1,73]; 0,0602 0,13 [0,00; 0,26]; 0,0550

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,9751)					
Ja	243	104 (42,8)	236	68 (28,8)	1,85 [1,26; 2,70]; 0,0015 1,49 [1,16; 1,90]; 0,0017 0,14 [0,05; 0,22]; 0,0012
Nein	668	275 (41,2)	668	186 (27,8)	1,81 [1,44; 2,28]; <0,0001 1,48 [1,27; 1,72]; <0,0001 0,13 [0,08; 0,18]; <0,0001
Neue primäre Malignität (ausgenommen MDS/AML)					
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	1 (0,3)	383	2 (0,5)	0,49 [0,04; 5,40]; 0,5578 0,49 [0,04; 5,37]; 0,5579 0,00 [-0,01; 0,01]; 0,5509
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Alter (Interaktionstest: p=0,9094)					
<50	690	1 (0,1)	663	5 (0,8)	0,19 [0,02; 1,64]; 0,1312 0,19 [0,02; 1,64]; 0,1317 -0,01 [-0,01; 0,00]; 0,0959
50-64	192	0 (0,0)	209	3 (1,4)	0,15 [0,01; 2,99]; 0,2157 0,16 [0,01; 2,99]; 0,2172 -0,01 [-0,03; 0,00]; 0,1333
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,2811)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	0 (0,0)	840	6 (0,7)	0,07 [0,00; 1,32]; 0,0770 0,08 [0,00; 1,33]; 0,0775 -0,01 [-0,01; 0,00]; 0,0224
Taxan	43	1 (2,3)	50	2 (4,0)	0,57 [0,05; 6,53]; 0,6525 0,58 [0,05; 6,19]; 0,6532 -0,02 [-0,09; 0,05]; 0,6419
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,8828)					
Brusterhaltend	220	0 (0,0)	235	1 (0,4)	0,35 [0,01; 8,75]; 0,5261 0,36 [0,01; 8,69]; 0,5263 0,00 [-0,02; 0,01]; 0,4840
Einseitige Mastektomie	355	0 (0,0)	352	1 (0,3)	0,33 [0,01; 8,12]; 0,4972 0,33 [0,01; 8,09]; 0,4974 0,00 [-0,01; 0,00]; 0,4765

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	1 (0,3)	315	6 (1,9)	0,15 [0,02; 1,28]; 0,0838 0,16 [0,02; 1,29]; 0,0849 -0,02 [-0,03; 0,00]; 0,0516
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,9860)					
Ja	41	0 (0,0)	35	2 (5,7)	0,16 [0,01; 3,48]; 0,2444 0,17 [0,01; 3,46]; 0,2498 -0,06 [-0,15; 0,03]; 0,2097
Nein	870	1 (0,1)	866	6 (0,7)	0,16 [0,02; 1,37]; 0,0955 0,17 [0,02; 1,38]; 0,0960 -0,01 [-0,01; 0,00]; 0,0576
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,9765)					
Positiv	173	0 (0,0)	176	3 (1,7)	0,14 [0,01; 2,79]; 0,1992 0,15 [0,01; 2,79]; 0,2009 -0,02 [-0,04; 0,00]; 0,1288
Negativ	200	0 (0,0)	191	3 (1,6)	0,13 [0,01; 2,62]; 0,1852 0,14 [0,01; 2,62]; 0,1867 -0,02 [-0,04; 0,00]; 0,1263
Bilaterale Oophorektomie (Interaktionstest: p=0,8235)					
Ja	189	0 (0,0)	176	3 (1,7)	0,13 [0,01; 2,55]; 0,1795 0,13 [0,01; 2,56]; 0,1812 -0,02 [-0,04; 0,00]; 0,1248
Nein	722	1 (0,1)	728	5 (0,7)	0,20 [0,02; 1,72]; 0,1429 0,20 [0,02; 1,72]; 0,1434 -0,01 [-0,01; 0,00]; 0,1026
BRCA-Mutationsstatus (Interaktionstest: p=0,7562)					
BRCA1	574	1 (0,2)	580	6 (1,0)	0,17 [0,02; 1,39]; 0,0980 0,17 [0,02; 1,39]; 0,0986 -0,01 [-0,02; 0,00]; 0,0585
BRCA2	232	0 (0,0)	215	1 (0,5)	0,31 [0,01; 7,59]; 0,4710 0,31 [0,01; 7,54]; 0,4713 0,00 [-0,02; 0,01]; 0,4682
Ethnie (Interaktionstest: p=0,6300)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	0 (0,0)	271	1 (0,4)	0,35 [0,01; 8,57]; 0,5180 0,35 [0,01; 8,52]; 0,5183 0,00 [-0,01; 0,01]; 0,4820
Kaukasisch	617	1 (0,2)	589	7 (1,2)	0,13 [0,02; 1,10]; 0,0614 0,14 [0,02; 1,11]; 0,0620 -0,01 [-0,02; 0,00]; 0,0307

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,6749)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	1 (0,1)	803	7 (0,9)	0,14 [0,02; 1,16]; 0,0688 0,14 [0,02; 1,17]; 0,0693 -0,01 [-0,01; 0,00]; 0,0335
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	1 (1,3)	0,32 [0,01; 8,00]; 0,4883 0,32 [0,01; 7,86]; 0,4892 -0,01 [-0,05; 0,02]; 0,4675
Hormonrezeptorstatus (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv, HER2-positiv	168	0 (0,0)	155	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
TNBC	741	1 (0,1)	749	8 (1,1)	0,13 [0,02; 1,00]; 0,0504 0,13 [0,02; 1,01]; 0,0509 -0,01 [-0,02; 0,00]; 0,0194
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3128)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	1 (0,3)	362	2 (0,6)	0,52 [0,05; 5,75]; 0,5927 0,52 [0,05; 5,71]; 0,5928 0,00 [-0,01; 0,01]; 0,5837
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	0 (0,0)	387	6 (1,6)	0,07 [0,00; 1,33]; 0,0773 0,08 [0,00; 1,34]; 0,0784 -0,02 [-0,03; 0,00]; 0,0218
Menopausenstatus (Interaktionstest: p=0,5090)					
Postmenopausal	346	0 (0,0)	356	5 (1,4)	0,09 [0,01; 1,67]; 0,1071 0,09 [0,01; 1,69]; 0,1082 -0,01 [-0,03; 0,00]; 0,0397
Prämenopausal	563	1 (0,2)	544	3 (0,6)	0,32 [0,03; 3,09]; 0,3256 0,32 [0,03; 3,09]; 0,3259 0,00 [-0,01; 0,00]; 0,3040

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Region (Interaktionstest: p=0,4654)					
Asien-Pazifik und Südafrika	301	0 (0,0)	317	3 (1,0)	0,15 [0,01; 2,90]; 0,2086 0,15 [0,01; 2,90]; 0,2096 -0,01 [-0,02; 0,00]; 0,1331
Europa	473	0 (0,0)	444	4 (0,9)	0,10 [0,01; 1,93]; 0,1283 0,10 [0,01; 1,93]; 0,1291 -0,01 [-0,02; 0,00]; 0,0700
Nordamerika	121	1 (0,8)	131	1 (0,8)	1,08 [0,07; 17,51]; 0,9550 1,08 [0,07; 17,12]; 0,9550 0,00 [-0,02; 0,02]; 0,9551
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,3229)					
Adjuvant	457	0 (0,0)	450	6 (1,3)	0,07 [0,00; 1,33]; 0,0775 0,08 [0,00; 1,34]; 0,0784 -0,01 [-0,02; 0,00]; 0,0220
Neoadjuvant	454	1 (0,2)	454	2 (0,4)	0,50 [0,05; 5,52]; 0,5708 0,50 [0,05; 5,49]; 0,5709 0,00 [-0,01; 0,01]; 0,5630
Sponsor (Interaktionstest: p=0,1837)					
AZ	801	0 (0,0)	796	7 (0,9)	0,07 [0,00; 1,15]; 0,0624 0,07 [0,00; 1,16]; 0,0630 -0,01 [-0,02; 0,00]; 0,0128
NRG Oncology	110	1 (0,9)	108	1 (0,9)	0,98 [0,06; 15,90]; 0,9896 0,98 [0,06; 15,50]; 0,9896 0,00 [-0,03; 0,03]; 0,9896
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4975)					
Ja	243	1 (0,4)	236	3 (1,3)	0,32 [0,03; 3,11]; 0,3265 0,32 [0,03; 3,09]; 0,3272 -0,01 [-0,03; 0,01]; 0,3043
Nein	668	0 (0,0)	668	5 (0,8)	0,09 [0,00; 1,64]; 0,1037 0,09 [0,01; 1,64]; 0,1043 -0,01 [-0,01; 0,00]; 0,0402
Pneumonitis					
Alter (Interaktionstest: p=0,1450)					
<50	690	8 (1,2)	663	6 (0,9)	1,28 [0,44; 3,72]; 0,6447 1,28 [0,45; 3,67]; 0,6447 0,00 [-0,01; 0,01]; 0,6430
50-64	192	1 (0,5)	209	5 (2,4)	0,21 [0,02; 1,85]; 0,1606 0,22 [0,03; 1,85]; 0,1622 -0,02 [-0,04; 0,00]; 0,1121

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,3454)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	8 (0,9)	840	11 (1,3)	0,71 [0,28; 1,77]; 0,4577 0,71 [0,29; 1,76]; 0,4578 0,00 [-0,01; 0,01]; 0,4563
Taxan	43	1 (2,3)	50	0 (0,0)	3,56 [0,14; 89,80]; 0,4400 3,48 [0,15; 83,21]; 0,4417 0,02 [-0,04; 0,08]; 0,4478
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,7623)					
Brusterhaltend	220	1 (0,5)	235	2 (0,9)	0,53 [0,05; 5,91]; 0,6074 0,53 [0,05; 5,85]; 0,6075 0,00 [-0,02; 0,01]; 0,5977
Einseitige Mastektomie	355	4 (1,1)	352	6 (1,7)	0,66 [0,18; 2,35]; 0,5183 0,66 [0,19; 2,32]; 0,5185 -0,01 [-0,02; 0,01]; 0,5156
Beidseitige Mastektomie	336	4 (1,2)	315	3 (1,0)	1,25 [0,28; 5,64]; 0,7689 1,25 [0,28; 5,54]; 0,7690 0,00 [-0,01; 0,02]; 0,7677
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,4511)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	8 (0,9)	866	11 (1,3)	0,72 [0,29; 1,80]; 0,4845 0,72 [0,29; 1,79]; 0,4845 0,00 [-0,01; 0,01]; 0,4827
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,4397)					
Positiv	173	2 (1,2)	176	3 (1,7)	0,67 [0,11; 4,09]; 0,6683 0,68 [0,11; 4,01]; 0,6684 -0,01 [-0,03; 0,02]; 0,6658
Negativ	200	1 (0,5)	191	0 (0,0)	2,88 [0,12; 71,12]; 0,5180 2,87 [0,12; 69,92]; 0,5183 0,00 [-0,01; 0,02]; 0,4812
Bilaterale Oophorektomie (Interaktionstest: p=0,6178)					
Ja	189	1 (0,5)	176	2 (1,1)	0,46 [0,04; 5,15]; 0,5308 0,47 [0,04; 5,09]; 0,5310 -0,01 [-0,02; 0,01]; 0,5259

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Nein	722	8 (1,1)	728	9 (1,2)	0,90 [0,34; 2,33]; 0,8207 0,90 [0,35; 2,31]; 0,8207 0,00 [-0,01; 0,01]; 0,8205
BRCA-Mutationsstatus (Interaktionstest: p=0,6096)					
BRCA1	574	4 (0,7)	580	5 (0,9)	0,81 [0,22; 3,02]; 0,7502 0,81 [0,22; 3,00]; 0,7502 0,00 [-0,01; 0,01]; 0,7496
BRCA2	232	2 (0,9)	215	4 (1,9)	0,46 [0,08; 2,53]; 0,3710 0,46 [0,09; 2,50]; 0,3715 -0,01 [-0,03; 0,01]; 0,3656
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,3756)					
2, 3 oder 4	392	3 (0,8)	383	7 (1,8)	0,41 [0,11; 1,61]; 0,2040 0,42 [0,11; 1,61]; 0,2047 -0,01 [-0,03; 0,01]; 0,1917
5 oder 6	22	1 (4,6)	14	0 (0,0)	2,02 [0,08; 53,19]; 0,6727 1,96 [0,09; 44,92]; 0,6747 0,05 [-0,09; 0,18]; 0,5117
Ethnie (Interaktionstest: p=0,5148)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	6 (2,3)	271	6 (2,2)	1,05 [0,33; 3,29]; 0,9368 1,05 [0,34; 3,20]; 0,9368 0,00 [-0,02; 0,03]; 0,9368
Kaukasisch	617	3 (0,5)	589	5 (0,9)	0,57 [0,14; 2,40]; 0,4439 0,57 [0,14; 2,39]; 0,4440 0,00 [-0,01; 0,01]; 0,4408
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,5485)					
Hispanisch	34	0 (0,0)	24	1 (4,2)	0,23 [0,01; 5,82]; 0,3703 0,24 [0,01; 5,61]; 0,3733 -0,04 [-0,14; 0,06]; 0,4190
Nicht-hispanisch	798	8 (1,0)	803	10 (1,3)	0,80 [0,32; 2,05]; 0,6456 0,81 [0,32; 2,03]; 0,6456 0,00 [-0,01; 0,01]; 0,6448
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	0 (0,0)	2,96 [0,12; 73,83]; 0,5081 2,92 [0,12; 70,72]; 0,5090 0,01 [-0,02; 0,05]; 0,4733

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Hormonrezeptorstatus (Interaktionstest: p=0,8104)					
ER- und/oder PgR-positiv, HER2-positiv	168	3 (1,8)	155	4 (2,6)	0,69 [0,15; 3,12]; 0,6259 0,69 [0,16; 3,04]; 0,6260 -0,01 [-0,04; 0,02]; 0,6264
TNBC	741	6 (0,8)	749	7 (0,9)	0,87 [0,29; 2,59]; 0,7957 0,87 [0,29; 2,57]; 0,7957 0,00 [-0,01; 0,01]; 0,7955
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7116)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	3 (3,3)	0,29 [0,03; 2,82]; 0,2848 0,29 [0,03; 2,79]; 0,2865 -0,02 [-0,06; 0,02]; 0,2700
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	1 (1,6)	2,00 [0,18; 22,63]; 0,5755 1,97 [0,18; 21,17]; 0,5762 0,02 [-0,04; 0,07]; 0,5669
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	3 (0,9)	362	4 (1,1)	0,78 [0,17; 3,50]; 0,7439 0,78 [0,18; 3,46]; 0,7440 0,00 [-0,02; 0,01]; 0,7427
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	3 (0,8)	387	3 (0,8)	0,98 [0,20; 4,91]; 0,9849 0,98 [0,20; 4,85]; 0,9849 0,00 [-0,01; 0,01]; 0,9849
Menopausenstatus (Interaktionstest: p=0,3137)					
Postmenopausal	346	2 (0,6)	356	5 (1,4)	0,41 [0,08; 2,12]; 0,2861 0,41 [0,08; 2,11]; 0,2867 -0,01 [-0,02; 0,01]; 0,2673
Prämenopausal	563	7 (1,2)	544	6 (1,1)	1,13 [0,38; 3,38]; 0,8285 1,13 [0,38; 3,33]; 0,8285 0,00 [-0,01; 0,01]; 0,8282
Region (Interaktionstest: p=0,7647)					
Asien-Pazifik und Südafrika	301	7 (2,3)	317	7 (2,2)	1,05 [0,37; 3,04]; 0,9219 1,05 [0,37; 2,97]; 0,9219 0,00 [-0,02; 0,02]; 0,9220
Europa	473	1 (0,2)	444	2 (0,5)	0,47 [0,04; 5,18]; 0,5361 0,47 [0,04; 5,16]; 0,5362 0,00 [-0,01; 0,01]; 0,5310
Nordamerika	121	1 (0,8)	131	2 (1,5)	0,54 [0,05; 6,00]; 0,6141 0,54 [0,05; 5,89]; 0,6144 -0,01 [-0,03; 0,02]; 0,6042
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4008)					
Adjuvant	457	5 (1,1)	450	4 (0,9)	1,23 [0,33; 4,62]; 0,7557 1,23 [0,33; 4,55]; 0,7557 0,00 [-0,01; 0,01]; 0,7550
Neoadjuvant	454	4 (0,9)	454	7 (1,5)	0,57 [0,17; 1,95]; 0,3690 0,57 [0,17; 1,94]; 0,3692 -0,01 [-0,02; 0,01]; 0,3626
Sponsor (Interaktionstest: p=0,6538)					
AZ	801	8 (1,0)	796	9 (1,1)	0,88 [0,34; 2,30]; 0,7974 0,88 [0,34; 2,28]; 0,7975 0,00 [-0,01; 0,01]; 0,7974
NRG Oncology	110	1 (0,9)	108	2 (1,9)	0,49 [0,04; 5,44]; 0,5585 0,49 [0,05; 5,33]; 0,5589 -0,01 [-0,04; 0,02]; 0,5512
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4754)					
Ja	243	2 (0,8)	236	4 (1,7)	0,48 [0,09; 2,65]; 0,4011 0,49 [0,09; 2,63]; 0,4016 -0,01 [-0,03; 0,01]; 0,3930
Nein	668	7 (1,1)	668	7 (1,1)	1,00 [0,35; 2,87]; 1,0000 1,00 [0,35; 2,84]; 1,0000 0,00 [-0,01; 0,01]; 1,0000

Datenschnitt: 12.07.2021; Analyse-Set: Safety-Analysis-Set
a: Die Berechnung von OR, RR und RD erfolgte auf Basis der Vierfeldertafel.

Anhang 4-G13: Subgruppenanalysen: Schwere UESI

Tabelle 6.7.1: Subgruppenergebnisse für schwere UESI aus RCT mit dem zu bewertenden Arzneimittel

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Anämie					
Alter (Interaktionstest: p=0,3292)					
<50	690	28 (4,1)	663	0 (0,0)	57,09 [3,48; 936,97]; 0,0046 54,77 [3,35; 895,32]; 0,0050 0,04 [0,03; 0,06]; <0,0001
50-64	192	9 (4,7)	209	2 (1,0)	5,09 [1,09; 23,86]; 0,0390 4,90 [1,07; 22,39]; 0,0404 0,04 [0,00; 0,07]; 0,0253
≥65	29	4 (13,8)	32	0 (0,0)	11,47 [0,59; 223,00]; 0,1071 9,90 [0,56; 176,29]; 0,1187 0,14 [0,00; 0,27]; 0,0443
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,0759)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,000
Anthrazyklin und Taxan	861	39 (4,5)	840	1 (0,1)	39,81 [5,46; 290,41]; 0,0003 38,05 [5,24; 276,31]; 0,0003 0,04 [0,03; 0,06]; <0,0001
Taxan	43	2 (4,7)	50	1 (2,0)	2,39 [0,21; 27,31]; 0,4832 2,33 [0,22; 24,77]; 0,4844 0,03 [-0,05; 0,10]; 0,4822
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,5030)					
Brusterhaltend	220	14 (6,4)	235	0 (0,0)	33,07 [1,96; 557,85]; 0,0152 30,97 [1,86; 516,04]; 0,0168 0,06 [0,03; 0,10]; 0,0002
Einseitige Mastektomie	355	13 (3,7)	352	0 (0,0)	27,79 [1,65; 469,28]; 0,0211 26,77 [1,60; 448,63]; 0,0223 0,04 [0,02; 0,06]; 0,0004
Beidseitige Mastektomie	336	14 (4,2)	315	2 (0,6)	6,80 [1,53; 30,18]; 0,0116 6,56 [1,50; 28,64]; 0,0123 0,04 [0,01; 0,06]; 0,0027
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,2479)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	40 (4,6)	866	2 (0,2)	20,82 [5,02; 86,42]; <0,0001 19,91 [4,83; 82,12]; <0,0001 0,04 [0,03; 0,06]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,6603)					
Positiv	173	9 (5,2)	176	1 (0,6)	9,60 [1,20; 76,64]; 0,0328 9,16 [1,17; 71,50]; 0,0347 0,05 [0,01; 0,08]; 0,0093
Negativ	200	10 (5,0)	191	0 (0,0)	21,11 [1,23; 362,81]; 0,0356 20,06 [1,18; 339,97]; 0,0378 0,05 [0,02; 0,08]; 0,0019
Bilaterale Oophorektomie (Interaktionstest: p=0,8178)					
Ja	189	6 (3,2)	176	0 (0,0)	12,50 [0,70; 223,61]; 0,0860 12,11 [0,69; 213,41]; 0,0884 0,03 [0,00; 0,06]; 0,0212
Nein	722	35 (4,9)	728	2 (0,3)	18,49 [4,43; 77,18]; <0,0001 17,65 [4,26; 73,09]; <0,0001 0,05 [0,03; 0,06]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,4588)					
BRCA1	574	27 (4,7)	580	1 (0,2)	28,58 [3,87; 211,04]; 0,0010 27,28 [3,72; 200,10]; 0,0011 0,05 [0,03; 0,06]; <0,0001
BRCA2	232	10 (4,3)	215	1 (0,5)	9,64 [1,22; 75,95]; 0,0314 9,27 [1,20; 71,79]; 0,0330 0,04 [0,01; 0,07]; 0,0065
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,2137)					
2, 3 oder 4	392	14 (3,6)	383	0 (0,0)	29,38 [1,75; 494,32]; 0,0189 28,34 [1,70; 473,34]; 0,0199 0,04 [0,02; 0,05]; 0,0002
5 oder 6	22	1 (4,6)	14	0 (0,0)	2,02 [0,08; 53,19]; 0,6727 1,96 [0,09; 44,92]; 0,6747 0,05 [-0,09; 0,18]; 0,5117
Ethnie (Interaktionstest: p=0,8336)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,000
Asiatisch	259	12 (4,6)	271	0 (0,0)	27,42 [1,62; 465,62]; 0,0219 26,15 [1,56; 439,47]; 0,0234 0,05 [0,02; 0,07]; 0,0006
Kaukasisch	617	27 (4,4)	589	2 (0,3)	13,43 [3,18; 56,74]; 0,0004 12,89 [3,08; 53,95]; 0,0005 0,04 [0,02; 0,06]; <0,0001
Schwarz oder afroamerikanisch	19	2 (10,5)	29	0 (0,0)	8,43 [0,38; 185,87]; 0,1768 7,50 [0,38; 148,13]; 0,1856 0,11 [-0,05; 0,26]; 0,1747

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,0989)					
Hispanisch	34	3 (8,8)	24	0 (0,0)	5,44 [0,27; 110,44]; 0,2698 5,00 [0,27; 92,56]; 0,2798 0,09 [-0,03; 0,20]; 0,1277
Nicht-hispanisch	798	37 (4,6)	803	1 (0,1)	38,99 [5,34; 284,90]; 0,0003 37,23 [5,12; 270,70]; 0,0004 0,05 [0,03; 0,06]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	1 (1,3)	0,97 [0,06; 15,86]; 0,9854 0,97 [0,06; 15,31]; 0,9854 0,00 [-0,04; 0,03]; 0,9854
Hormonrezeptorstatus (Interaktionstest: p=0,3025)					
ER- und/oder PgR-positiv, HER2-positiv	168	8 (4,8)	155	1 (0,7)	7,70 [0,95; 62,29]; 0,0557 7,38 [0,93; 58,34]; 0,0581 0,04 [0,01; 0,08]; 0,0196
TNBC	741	33 (4,5)	749	1 (0,1)	34,86 [4,76; 255,59]; 0,0005 33,36 [4,57; 243,25]; 0,0005 0,04 [0,03; 0,06]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6477)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	4 (3,9)	92	0 (0,0)	8,28 [0,44; 155,97]; 0,1580 7,97 [0,43; 146,09]; 0,1618 0,04 [0,00; 0,08]; 0,0692
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	4 (6,3)	63	1 (1,6)	4,13 [0,45; 38,05]; 0,2102 3,94 [0,45; 34,26]; 0,2144 0,05 [-0,02; 0,11]; 0,1716
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	12 (3,5)	362	0 (0,0)	26,93 [1,59; 456,64]; 0,0226 26,00 [1,55; 437,50]; 0,0237 0,03 [0,01; 0,05]; 0,0007
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	21 (5,3)	387	1 (0,3)	21,79 [2,92; 162,81]; 0,0027 20,68 [2,80; 152,98]; 0,0030 0,05 [0,03; 0,07]; <0,0001
Menopausenstatus (Interaktionstest: p=0,3230)					
Postmenopausal	346	18 (5,2)	356	2 (0,6)	9,71 [2,24; 42,19]; 0,0024 9,26 [2,16; 39,61]; 0,0027 0,05 [0,02; 0,07]; 0,0002
Prämenopausal	563	23 (4,1)	544	0 (0,0)	47,35 [2,87; 781,48]; 0,0070 45,42 [2,77; 745,86]; 0,0075 0,04 [0,02; 0,06]; <0,0001
Region (Interaktionstest: p=0,5312)					
Asien-Pazifik und Südafrika	301	13 (4,3)	317	0 (0,0)	29,71 [1,76; 502,09]; 0,0187 28,43 [1,70; 476,15]; 0,0199 0,04 [0,02; 0,07]; 0,0004

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	22 (4,7)	444	1 (0,2)	21,61 [2,90; 161,01]; 0,0027 20,65 [2,80; 152,57]; 0,0030 0,04 [0,02; 0,06]; <0,0001
Nordamerika	121	5 (4,1)	131	1 (0,8)	5,60 [0,65; 48,66]; 0,1181 5,41 [0,64; 45,68]; 0,1207 0,03 [0,00; 0,07]; 0,0861
Südamerika	16	1 (6,3)	12	0 (0,0)	2,42 [0,09; 64,70]; 0,5982 2,29 [0,10; 51,85]; 0,6017 0,06 [-0,11; 0,23]; 0,4728
Art der vorherigen Chemotherapie (Interaktionstest: p=0,5401)					
Adjuvant	457	25 (5,5)	450	2 (0,4)	12,96 [3,05; 55,06]; 0,0005 12,31 [2,93; 51,66]; 0,0006 0,05 [0,03; 0,07]; <0,0001
Neoadjuvant	454	16 (3,5)	454	0 (0,0)	34,20 [2,05; 571,86]; 0,0140 33,00 [1,99; 548,40]; 0,0148 0,04 [0,02; 0,05]; <0,0001
Sponsor (Interaktionstest: p=0,1812)					
AZ	801	36 (4,5)	796	1 (0,1)	37,41 [5,12; 273,54]; 0,0004 35,78 [4,92; 260,30]; 0,0004 0,04 [0,03; 0,06]; <0,0001
NRG Oncology	110	5 (4,6)	108	1 (0,9)	5,10 [0,59; 44,35]; 0,1402 4,91 [0,58; 41,33]; 0,1433 0,04 [-0,01; 0,08]; 0,0983
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4775)					
Ja	243	11 (4,5)	236	1 (0,4)	11,14 [1,43; 87,00]; 0,0215 10,68 [1,39; 82,10]; 0,0228 0,04 [0,01; 0,07]; 0,0034
Nein	668	30 (4,5)	668	1 (0,2)	31,36 [4,26; 230,66]; 0,0007 30,00 [4,10; 219,35]; 0,0008 0,04 [0,03; 0,06]; <0,0001
Erbrechen					
Alter (Interaktionstest: p=0,8312)					
<50	690	2 (0,3)	663	0 (0,0)	4,82 [0,23; 100,55]; 0,3104 4,80 [0,23; 99,89]; 0,3107 0,00 [0,00; 0,01]; 0,2500
50-64	192	3 (1,6)	209	0 (0,0)	7,74 [0,40; 150,80]; 0,1769 7,62 [0,40; 146,51]; 0,1783 0,02 [0,00; 0,04]; 0,1247
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,000
Anthrazyklin und Taxan	861	5 (0,6)	840	0 (0,0)	10,79 [0,60; 195,52]; 0,1075 10,73 [0,59; 193,78]; 0,1079 0,01 [0,00; 0,01]; 0,0408
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,8967)					
Brusterhaltend	220	0 (0,0)	235	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Einseitige Mastektomie	355	2 (0,6)	352	0 (0,0)	4,99 [0,24; 104,22]; 0,3003 4,96 [0,24; 102,90]; 0,3008 0,01 [0,00; 0,02]; 0,2461
Beidseitige Mastektomie	336	3 (0,9)	315	0 (0,0)	6,62 [0,34; 128,72]; 0,2118 6,56 [0,34; 126,57]; 0,2127 0,01 [0,00; 0,02]; 0,1340
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,000
Nein	870	5 (0,6)	866	0 (0,0)	11,01 [0,61; 199,47]; 0,1045 10,95 [0,61; 197,71]; 0,1050 0,01 [0,00; 0,01]; 0,0405
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Bilaterale Oophorektomie (Interaktionstest: p=0,8475)					
Ja	189	2 (1,1)	176	0 (0,0)	4,71 [0,22; 98,72]; 0,3185 4,66 [0,23; 96,35]; 0,3195 0,01 [-0,01; 0,03]; 0,2490
Nein	722	3 (0,4)	728	0 (0,0)	7,09 [0,37; 137,46]; 0,1955 7,06 [0,37; 136,40]; 0,1959 0,00 [0,00; 0,01]; 0,1318

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
BRCA-Mutationsstatus (Interaktionstest: p=0,9686)					
BRCA1	574	2 (0,4)	580	0 (0,0)	5,07 [0,24; 105,83]; 0,2951 5,05 [0,24; 105,00]; 0,2954 0,00 [0,00; 0,01]; 0,2457
BRCA2	232	2 (0,9)	215	0 (0,0)	4,67 [0,22; 97,92]; 0,3204 4,64 [0,22; 96,00]; 0,3213 0,01 [-0,01; 0,02]; 0,2504
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	2 (0,5)	383	0 (0,0)	4,91 [0,23; 102,61]; 0,3048 4,89 [0,24; 101,43]; 0,3053 0,01 [0,00; 0,01]; 0,2476
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,000
Ethnie (Interaktionstest: p=0,6484)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,000
Asiatisch	259	1 (0,4)	271	0 (0,0)	3,15 [0,13; 77,70]; 0,4828 3,14 [0,13; 76,69]; 0,4831 0,00 [-0,01; 0,01]; 0,4719
Kaukasisch	617	4 (0,7)	589	0 (0,0)	8,65 [0,46; 160,97]; 0,1482 8,59 [0,46; 159,24]; 0,1488 0,01 [0,00; 0,01]; 0,0736
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,000
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,000
Nicht-hispanisch	798	5 (0,6)	803	0 (0,0)	11,14 [0,61; 201,77]; 0,1029 11,07 [0,61; 199,84]; 0,1034 0,01 [0,00; 0,01]; 0,0402
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,000
Hormonrezeptorstatus (Interaktionstest: p=0,9095)					
ER- und/oder PgR-positiv, HER2-positiv	168	3 (1,8)	155	0 (0,0)	6,58 [0,34; 128,36]; 0,2141 6,46 [0,34; 124,10]; 0,2159 0,02 [-0,01; 0,04]; 0,1319

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
TNBC	741	2 (0,3)	749	0 (0,0)	5,07 [0,24; 105,73]; 0,2951 5,05 [0,24; 105,09]; 0,2954 0,00 [0,00; 0,01]; 0,2460
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,9471)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	0 (0,0)	2,68 [0,11; 66,63]; 0,5474 2,66 [0,11; 64,44]; 0,5480 0,01 [-0,02; 0,04]; 0,4873
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	0 (0,0)	5,08 [0,24; 107,95]; 0,2973 4,92 [0,24; 100,55]; 0,3004 0,03 [-0,02; 0,08]; 0,2342
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	2 (0,6)	362	0 (0,0)	5,23 [0,25; 109,35]; 0,2861 5,20 [0,25; 107,94]; 0,2866 0,01 [0,00; 0,02]; 0,2424
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	0 (0,0)	387	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Menopausenstatus (Interaktionstest: p=NC)					
Postmenopausal	346	5 (1,5)	356	0 (0,0)	11,48 [0,63; 208,46]; 0,0989 11,32 [0,63; 203,89]; 0,1000 0,01 [0,00; 0,03]; 0,0387
Prämenopausal	563	0 (0,0)	544	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,000
Region (Interaktionstest: p=0,9700)					
Asien-Pazifik und Südafrika	301	1 (0,3)	317	0 (0,0)	3,17 [0,13; 78,11]; 0,4804 3,16 [0,13; 77,24]; 0,4807 0,00 [-0,01; 0,01]; 0,4716
Europa	473	2 (0,4)	444	0 (0,0)	4,71 [0,23; 98,45]; 0,3174 4,69 [0,23; 97,51]; 0,3178 0,00 [0,00; 0,01]; 0,2514
Nordamerika	121	2 (1,7)	131	0 (0,0)	5,50 [0,26; 115,77]; 0,2726 5,41 [0,26; 111,56]; 0,2742 0,02 [-0,01; 0,04]; 0,2343
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,8707)					
Adjuvant	457	2 (0,4)	450	0 (0,0)	4,95 [0,24; 103,29]; 0,3026 4,92 [0,24; 102,27]; 0,3031 0,00 [0,00; 0,01]; 0,2473
Neoadjuvant	454	3 (0,7)	454	0 (0,0)	7,05 [0,36; 136,81]; 0,1970 7,00 [0,36; 135,13]; 0,1976 0,01 [0,00; 0,02]; 0,1314

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Sponsor (Interaktionstest: p=0,8719)					
AZ	801	3 (0,4)	796	0 (0,0)	6,98 [0,36; 135,40]; 0,1989 6,96 [0,36; 134,45]; 0,1993 0,00 [0,00; 0,01]; 0,1327
NRG Oncology	110	2 (1,8)	108	0 (0,0)	5,00 [0,24; 105,37]; 0,3007 4,91 [0,24; 101,10]; 0,3025 0,02 [-0,01; 0,05]; 0,2408
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,6096)					
Ja	243	1 (0,4)	236	0 (0,0)	2,93 [0,12; 72,18]; 0,5116 2,91 [0,12; 71,17]; 0,5119 0,00 [-0,01; 0,02]; 0,4798
Nein	668	4 (0,6)	668	0 (0,0)	9,05 [0,49; 168,50]; 0,1397 9,00 [0,49; 166,83]; 0,1402 0,01 [0,00; 0,01]; 0,0723
Übelkeit					
Alter (Interaktionstest: p=0,7776)					
<50	690	1 (0,1)	663	0 (0,0)	2,89 [0,12; 70,99]; 0,5164 2,88 [0,12; 70,64]; 0,5165 0,00 [0,00; 0,01]; 0,4830
50-64	192	2 (1,0)	209	0 (0,0)	5,50 [0,26; 115,26]; 0,2722 5,44 [0,26; 112,61]; 0,2732 0,01 [-0,01; 0,03]; 0,2369
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,000
Anthrazyklin und Taxan	861	3 (0,4)	840	0 (0,0)	6,85 [0,35; 132,88]; 0,2032 6,83 [0,35; 132,01]; 0,2036 0,00 [0,00; 0,01]; 0,1337
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,7756)					
Brusterhaltend	220	2 (0,9)	235	0 (0,0)	5,39 [0,26; 112,88]; 0,2778 5,34 [0,26; 110,60]; 0,2787 0,01 [-0,01; 0,02]; 0,2388
Einseitige Mastektomie	355	0 (0,0)	352	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	1 (0,3)	315	0 (0,0)	2,82 [0,11; 69,51]; 0,5258 2,81 [0,12; 68,80]; 0,5260 0,00 [-0,01; 0,01]; 0,4848
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,000
Nein	870	3 (0,3)	866	0 (0,0)	6,99 [0,36; 135,56]; 0,1986 6,97 [0,36; 134,69]; 0,1989 0,00 [0,00; 0,01]; 0,1327
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Bilaterale Oophorektomie (Interaktionstest: p=0,7930)					
Ja	189	1 (0,5)	176	0 (0,0)	2,81 [0,11; 69,41]; 0,5279 2,79 [0,11; 68,16]; 0,5283 0,01 [-0,01; 0,02]; 0,4839
Nein	722	2 (0,3)	728	0 (0,0)	5,06 [0,24; 105,49]; 0,2958 5,04 [0,24; 104,83]; 0,2961 0,00 [0,00; 0,01]; 0,2462
BRCA-Mutationsstatus (Interaktionstest: p=0,9702)					
BRCA1	574	1 (0,2)	580	0 (0,0)	3,04 [0,12; 74,70]; 0,4967 3,03 [0,12; 74,26]; 0,4968 0,00 [0,00; 0,01]; 0,4771
BRCA2	232	1 (0,4)	215	0 (0,0)	2,79 [0,11; 68,92]; 0,5301 2,78 [0,11; 67,90]; 0,5304 0,00 [-0,01; 0,02]; 0,4852
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	1 (0,3)	383	0 (0,0)	2,94 [0,12; 72,36]; 0,5096 2,93 [0,12; 71,73]; 0,5098 0,00 [0,00; 0,01]; 0,4803
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,9789)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,000
Asiatisch	259	0 (0,0)	271	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Kaukasisch	617	2 (0,3)	589	0 (0,0)	4,79 [0,23; 99,96]; 0,3123 4,77 [0,23; 99,22]; 0,3127 0,00 [0,00; 0,01]; 0,2504
Schwarz oder afroamerikanisch	19	1 (5,3)	29	0 (0,0)	4,78 [0,18; 123,74]; 0,3456 4,50 [0,19; 105,03]; 0,3494 0,05 [-0,07; 0,18]; 0,4062
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,000
Nicht-hispanisch	798	3 (0,4)	803	0 (0,0)	7,07 [0,36; 137,10]; 0,1960 7,04 [0,36; 136,14]; 0,1964 0,00 [0,00; 0,01]; 0,1321
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,000
Hormonrezeptorstatus (Interaktionstest: p=0,7890)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	0 (0,0)	2,79 [0,11; 68,88]; 0,5315 2,77 [0,11; 67,48]; 0,5318 0,01 [-0,01; 0,02]; 0,4846
TNBC	741	2 (0,3)	749	0 (0,0)	5,07 [0,24; 105,73]; 0,2951 5,05 [0,24; 105,09]; 0,2954 0,00 [0,00; 0,01]; 0,2460
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7649)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	0 (0,0)	2,68 [0,11; 66,63]; 0,5474 2,66 [0,11; 64,44]; 0,5480 0,01 [-0,02; 0,04]; 0,4873
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	2 (0,6)	362	0 (0,0)	5,23 [0,25; 109,35]; 0,2861 5,20 [0,25; 107,94]; 0,2866 0,01 [0,00; 0,02]; 0,2424
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	0 (0,0)	387	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Menopausenstatus (Interaktionstest: p=0,7987)					
Postmenopausal	346	2 (0,6)	356	0 (0,0)	5,17 [0,25; 108,16]; 0,2893 5,14 [0,25; 106,76]; 0,2898 0,01 [0,00; 0,02]; 0,2432
Prämenopausal	563	1 (0,2)	544	0 (0,0)	2,90 [0,12; 71,44]; 0,5141 2,90 [0,12; 71,01]; 0,5143 0,00 [0,00; 0,01]; 0,4821
Region (Interaktionstest: p=0,8696)					
Asien-Pazifik und Südafrika	301	0 (0,0)	317	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Europa	473	2 (0,4)	444	0 (0,0)	4,71 [0,23; 98,45]; 0,3174 4,69 [0,23; 97,51]; 0,3178 0,00 [0,00; 0,01]; 0,2514
Nordamerika	121	1 (0,8)	131	0 (0,0)	3,27 [0,13; 81,13]; 0,4690 3,25 [0,13; 78,93]; 0,4696 0,01 [-0,01; 0,03]; 0,4653
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,000
Art der vorherigen Chemotherapie (Interaktionstest: p=NC)					
Adjuvant	457	0 (0,0)	450	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,000
Neoadjuvant	454	3 (0,7)	454	0 (0,0)	7,05 [0,36; 136,81]; 0,1970 7,00 [0,36; 135,13]; 0,1976 0,01 [0,00; 0,02]; 0,1314
Sponsor (Interaktionstest: p=0,8160)					
AZ	801	2 (0,3)	796	0 (0,0)	4,98 [0,24; 103,92]; 0,3002 4,97 [0,24; 103,33]; 0,3005 0,00 [0,00; 0,01]; 0,2475
NRG Oncology	110	1 (0,9)	108	0 (0,0)	2,97 [0,12; 73,78]; 0,5061 2,95 [0,12; 71,53]; 0,5068 0,01 [-0,02; 0,03]; 0,4751
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,8102)					
Ja	243	1 (0,4)	236	0 (0,0)	2,93 [0,12; 72,18]; 0,5116 2,91 [0,12; 71,17]; 0,5119 0,00 [-0,01; 0,02]; 0,4798
Nein	668	2 (0,3)	668	0 (0,0)	5,02 [0,24; 104,66]; 0,2983 5,00 [0,24; 103,95]; 0,2986 0,00 [0,00; 0,01]; 0,2467

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Neutropenie					
Alter (Interaktionstest: p=0,8996)					
<50	690	25 (3,6)	663	3 (0,5)	8,27 [2,49; 27,53]; 0,0006 8,01 [2,43; 26,39]; 0,0006 0,03 [0,02; 0,05]; <0,0001
50-64	192	7 (3,7)	209	0 (0,0)	16,94 [0,96; 298,64]; 0,0533 16,32 [0,94; 283,87]; 0,0553 0,04 [0,01; 0,06]; 0,0109
≥65	29	3 (10,3)	32	0 (0,0)	8,58 [0,42; 173,69]; 0,1611 7,70 [0,41; 143,00]; 0,1709 0,10 [-0,02; 0,23]; 0,0971
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,000
Anthrazyklin und Taxan	861	35 (4,1)	840	3 (0,4)	11,82 [3,62; 38,59]; <0,0001 11,38 [3,51; 36,87]; <0,0001 0,04 [0,02; 0,05]; <0,0001
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,4547)					
Brusterhaltend	220	8 (3,6)	235	2 (0,9)	4,40 [0,92; 20,93]; 0,0629 4,27 [0,92; 19,90]; 0,0643 0,03 [0,00; 0,06]; 0,0462
Einseitige Mastektomie	355	13 (3,7)	352	1 (0,3)	13,34 [1,74; 102,55]; 0,0128 12,89 [1,70; 98,01]; 0,0135 0,03 [0,01; 0,05]; 0,0011
Beidseitige Mastektomie	336	14 (4,2)	315	0 (0,0)	28,37 [1,69; 477,62]; 0,0202 27,19 [1,63; 453,94]; 0,0215 0,04 [0,02; 0,06]; 0,0002
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,5688)					
Ja	41	2 (4,9)	35	0 (0,0)	4,49 [0,21; 96,80]; 0,3374 4,29 [0,21; 86,39]; 0,3423 0,05 [-0,03; 0,13]; 0,2386
Nein	870	33 (3,8)	866	3 (0,4)	11,34 [3,47; 37,12]; <0,0001 10,95 [3,37; 35,57]; <0,0001 0,03 [0,02; 0,05]; <0,0001

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8583)					
Positiv	173	11 (6,4)	176	0 (0,0)	24,98 [1,46; 427,33]; 0,0263 23,40 [1,39; 393,97]; 0,0287 0,06 [0,03; 0,10]; 0,0010
Negativ	200	8 (4,0)	191	0 (0,0)	16,91 [0,97; 295,06]; 0,0526 16,24 [0,94; 279,42]; 0,0548 0,04 [0,01; 0,07]; 0,0064
Bilaterale Oophorektomie (Interaktionstest: p=0,5896)					
Ja	189	10 (5,3)	176	0 (0,0)	20,65 [1,20; 355,07]; 0,0370 19,56 [1,15; 331,39]; 0,0394 0,05 [0,02; 0,09]; 0,0019
Nein	722	25 (3,5)	728	3 (0,4)	8,67 [2,61; 28,84]; 0,0004 8,40 [2,55; 27,71]; 0,0005 0,03 [0,02; 0,04]; <0,0001
BRCA-Mutationsstatus (Interaktionstest: p=0,8590)					
BRCA1	574	27 (4,7)	580	3 (0,5)	9,49 [2,86; 31,47]; 0,0002 9,09 [2,77; 29,81]; 0,0003 0,04 [0,02; 0,06]; <0,0001
BRCA2	232	6 (2,6)	215	0 (0,0)	12,37 [0,69; 220,89]; 0,0872 12,05 [0,68; 212,65]; 0,0892 0,03 [0,00; 0,05]; 0,0218
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=0,1570)					
2, 3 oder 4	392	12 (3,1)	383	2 (0,5)	6,02 [1,34; 27,06]; 0,0193 5,86 [1,32; 26,02]; 0,0200 0,03 [0,01; 0,04]; 0,0072
5 oder 6	22	1 (4,6)	14	1 (7,1)	0,62 [0,04; 10,78]; 0,7421 0,64 [0,04; 9,37]; 0,7419 -0,03 [-0,19; 0,13]; 0,7512
Ethnie (Interaktionstest: p=0,2068)					
Andere	16	1 (6,3)	15	0 (0,0)	3,00 [0,11; 79,50]; 0,5111 2,82 [0,12; 64,39]; 0,5153 0,06 [-0,10; 0,22]; 0,4425
Asiatisch	259	11 (4,3)	271	2 (0,7)	5,97 [1,31; 27,18]; 0,0210 5,75 [1,29; 25,71]; 0,0219 0,04 [0,01; 0,06]; 0,0097
Kaukasisch	617	23 (3,7)	589	0 (0,0)	46,60 [2,82; 769,05]; 0,0072 44,87 [2,73; 737,04]; 0,0077 0,04 [0,02; 0,05]; <0,0001
Schwarz oder afroamerikanisch	19	0 (0,0)	29	1 (3,5)	0,49 [0,02; 12,59]; 0,6647 0,50 [0,02; 11,67]; 0,6663 -0,03 [-0,14; 0,07]; 0,5148

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,9058)					
Hispanisch	34	3 (8,8)	24	0 (0,0)	5,44 [0,27; 110,44]; 0,2698 5,00 [0,27; 92,56]; 0,2798 0,09 [-0,03; 0,20]; 0,1277
Nicht-hispanisch	798	29 (3,6)	803	3 (0,4)	10,06 [3,05; 33,15]; 0,0001 9,73 [2,98; 31,80]; 0,0002 0,03 [0,02; 0,05]; <0,0001
Unbekannt, nicht erfasst, verweigert	79	3 (3,8)	77	0 (0,0)	7,09 [0,36; 139,61]; 0,1976 6,82 [0,36; 129,97]; 0,2014 0,04 [-0,01; 0,09]; 0,1225
Hormonrezeptorstatus (Interaktionstest: p=0,7525)					
ER- und/oder PgR-positiv, HER2-positiv	168	3 (1,8)	155	0 (0,0)	6,58 [0,34; 128,36]; 0,2141 6,46 [0,34; 124,10]; 0,2159 0,02 [-0,01; 0,04]; 0,1319
TNBC	741	32 (4,3)	749	3 (0,4)	11,22 [3,42; 36,81]; <0,0001 10,78 [3,32; 35,06]; <0,0001 0,04 [0,02; 0,05]; <0,0001
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,5125)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	2 (1,9)	92	0 (0,0)	4,51 [0,21; 95,21]; 0,3328 4,43 [0,22; 91,07]; 0,3347 0,02 [-0,01; 0,05]; 0,2495
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	0 (0,0)	3,00 [0,12; 75,04]; 0,5036 2,95 [0,12; 71,17]; 0,5047 0,02 [-0,03; 0,06]; 0,4701
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	12 (3,5)	362	3 (0,8)	4,27 [1,20; 15,28]; 0,0254 4,16 [1,18; 14,62]; 0,0262 0,03 [0,00; 0,05]; 0,0161
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	20 (5,1)	387	0 (0,0)	42,54 [2,56; 705,83]; 0,0089 40,38 [2,45; 665,23]; 0,0097 0,05 [0,03; 0,07]; <0,0001
Menopausenstatus (Interaktionstest: p=0,2724)					
Postmenopausal	346	16 (4,6)	356	0 (0,0)	35,60 [2,13; 595,68]; 0,0130 33,95 [2,04; 563,70]; 0,0139 0,05 [0,02; 0,07]; <0,0001
Prämenopausal	563	19 (3,4)	544	3 (0,6)	6,30 [1,85; 21,41]; 0,0032 6,12 [1,82; 20,56]; 0,0034 0,03 [0,01; 0,04]; 0,0006
Region (Interaktionstest: p=0,8217)					
Asien-Pazifik und Südafrika	301	15 (5,0)	317	2 (0,6)	8,26 [1,87; 36,44]; 0,0053 7,90 [1,82; 34,25]; 0,0058 0,04 [0,02; 0,07]; 0,0011

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	14 (3,0)	444	1 (0,2)	13,51 [1,77; 103,19]; 0,0121 13,14 [1,74; 99,52]; 0,0126 0,03 [0,01; 0,04]; 0,0007
Nordamerika	121	5 (4,1)	131	0 (0,0)	12,42 [0,68; 226,96]; 0,0893 11,90 [0,67; 212,99]; 0,0924 0,04 [0,00; 0,08]; 0,0344
Südamerika	16	1 (6,3)	12	0 (0,0)	2,42 [0,09; 64,70]; 0,5982 2,29 [0,10; 51,85]; 0,6017 0,06 [-0,11; 0,23]; 0,4728
Art der vorherigen Chemotherapie (Interaktionstest: p=0,1582)					
Adjuvant	457	21 (4,6)	450	0 (0,0)	44,38 [2,68; 734,88]; 0,0081 42,34 [2,57; 696,90]; 0,0088 0,05 [0,03; 0,07]; <0,0001
Neoadjuvant	454	14 (3,1)	454	3 (0,7)	4,78 [1,37; 16,76]; 0,0144 4,67 [1,35; 16,13]; 0,0149 0,02 [0,01; 0,04]; 0,0069
Sponsor (Interaktionstest: p=0,9582)					
AZ	801	30 (3,8)	796	3 (0,4)	10,29 [3,13; 33,84]; 0,0001 9,94 [3,05; 32,43]; 0,0001 0,03 [0,02; 0,05]; <0,0001
NRG Oncology	110	5 (4,6)	108	0 (0,0)	11,31 [0,62; 207,13]; 0,1020 10,80 [0,60; 193,00]; 0,1057 0,05 [0,00; 0,09]; 0,0353
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,5758)					
Ja	243	7 (2,9)	236	1 (0,4)	6,97 [0,85; 57,10]; 0,0704 6,80 [0,84; 54,83]; 0,0719 0,02 [0,00; 0,05]; 0,0331
Nein	668	28 (4,2)	668	2 (0,3)	14,57 [3,46; 61,41]; 0,0003 14,00 [3,35; 58,53]; 0,0003 0,04 [0,02; 0,05]; <0,0001
Thrombozytopenie					
Alter (Interaktionstest: p=NC)					
<50	690	0 (0,0)	663	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,000
50-64	192	1 (0,5)	209	0 (0,0)	3,28 [0,13; 81,05]; 0,4676 3,26 [0,13; 79,65]; 0,4680 0,01 [-0,01; 0,02]; 0,4670
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,000
Anthrazyklin und Taxan	861	1 (0,1)	840	0 (0,0)	2,93 [0,12; 72,03]; 0,5105 2,93 [0,12; 71,75]; 0,5106 0,00 [0,00; 0,00]; 0,4814
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=NC)					
Brusterhaltend	220	0 (0,0)	235	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Einseitige Mastektomie	355	1 (0,3)	352	0 (0,0)	2,98 [0,12; 73,48]; 0,5038 2,97 [0,12; 72,77]; 0,5040 0,00 [0,00; 0,01]; 0,4784
Beidseitige Mastektomie	336	0 (0,0)	315	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,000
Nein	870	1 (0,1)	866	0 (0,0)	2,99 [0,12; 73,49]; 0,5026 2,99 [0,12; 73,20]; 0,5027 0,00 [0,00; 0,00]; 0,4792
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Bilaterale Oophorektomie (Interaktionstest: p=NC)					
Ja	189	1 (0,5)	176	0 (0,0)	2,81 [0,11; 69,41]; 0,5279 2,79 [0,11; 68,16]; 0,5283 0,01 [-0,01; 0,02]; 0,4839
Nein	722	0 (0,0)	728	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
BRCA-Mutationsstatus (Interaktionstest: p=NC)					
BRCA1	574	1 (0,2)	580	0 (0,0)	3,04 [0,12; 74,70]; 0,4967 3,03 [0,12; 74,26]; 0,4968 0,00 [0,00; 0,01]; 0,4771
BRCA2	232	0 (0,0)	215	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	1 (0,3)	383	0 (0,0)	2,94 [0,12; 72,36]; 0,5096 2,93 [0,12; 71,73]; 0,5098 0,00 [0,00; 0,01]; 0,4803
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,000
Ethnie (Interaktionstest: p=NC)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,000
Asiatisch	259	0 (0,0)	271	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Kaukasisch	617	1 (0,2)	589	0 (0,0)	2,87 [0,12; 70,56]; 0,5190 2,86 [0,12; 70,17]; 0,5191 0,00 [0,00; 0,01]; 0,4836
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,000
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,000
Nicht-hispanisch	798	0 (0,0)	803	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,000
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	0 (0,0)	2,96 [0,12; 73,83]; 0,5081 2,92 [0,12; 70,72]; 0,5090 0,01 [-0,02; 0,05]; 0,4733
Hormonrezeptorstatus (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv, HER2-positiv	168	0 (0,0)	155	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
TNBC	741	1 (0,1)	749	0 (0,0)	3,04 [0,12; 74,66]; 0,4966 3,03 [0,12; 74,32]; 0,4967 0,00 [0,00; 0,01]; 0,4774
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,000
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	1 (0,3)	362	0 (0,0)	3,13 [0,13; 77,08]; 0,4852 3,12 [0,13; 76,34]; 0,4854 0,00 [0,00; 0,01]; 0,4732
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	0 (0,0)	387	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Menopausenstatus (Interaktionstest: p=NC)					
Postmenopausal	346	1 (0,3)	356	0 (0,0)	3,10 [0,13; 76,25]; 0,4894 3,09 [0,13; 75,51]; 0,4896 0,00 [-0,01; 0,01]; 0,4744
Prämenopausal	563	0 (0,0)	544	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,000
Region (Interaktionstest: p=NC)					
Asien-Pazifik und Südafrika	301	0 (0,0)	317	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Europa	473	1 (0,2)	444	0 (0,0)	2,82 [0,11; 69,46]; 0,5255 2,82 [0,12; 68,96]; 0,5257 0,00 [0,00; 0,01]; 0,4853
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,000
Art der vorherigen Chemotherapie (Interaktionstest: p=NC)					
Adjuvant	457	0 (0,0)	450	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,000
Neoadjuvant	454	1 (0,2)	454	0 (0,0)	3,01 [0,12; 74,00]; 0,5006 3,00 [0,12; 73,45]; 0,5007 0,00 [0,00; 0,01]; 0,4779

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Sponsor (Interaktionstest: p=NC)					
AZ	801	1 (0,1)	796	0 (0,0)	2,99 [0,12; 73,38]; 0,5033 2,98 [0,12; 73,07]; 0,5033 0,00 [0,00; 0,00]; 0,4793
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,000
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=NC)					
Ja	243	0 (0,0)	236	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Nein	668	1 (0,2)	668	0 (0,0)	3,00 [0,12; 73,89]; 0,5008 3,00 [0,12; 73,51]; 0,5009 0,00 [0,00; 0,01]; 0,4784
Fatigue und Asthenie					
Alter (Interaktionstest: p=0,6321)					
<50	690	7 (1,0)	663	2 (0,3)	3,39 [0,70; 16,36]; 0,1290 3,36 [0,70; 16,13]; 0,1295 0,01 [0,00; 0,02]; 0,1028
50-64	192	3 (1,6)	209	0 (0,0)	7,74 [0,40; 150,80]; 0,1769 7,62 [0,40; 146,51]; 0,1783 0,02 [0,00; 0,04]; 0,1247
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,8968)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,000
Anthrazyklin und Taxan	861	9 (1,1)	840	2 (0,2)	4,43 [0,95; 20,55]; 0,0575 4,39 [0,95; 20,26]; 0,0579 0,01 [0,00; 0,02]; 0,0361
Taxan	43	1 (2,3)	50	0 (0,0)	3,56 [0,14; 89,80]; 0,4400 3,48 [0,15; 83,21]; 0,4417 0,02 [-0,04; 0,08]; 0,4478
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,2899)					
Brusterhaltend	220	3 (1,4)	235	0 (0,0)	7,58 [0,39; 147,57]; 0,1812 7,48 [0,39; 143,89]; 0,1825 0,01 [0,00; 0,03]; 0,1261
Einseitige Mastektomie	355	5 (1,4)	352	0 (0,0)	11,06 [0,61; 200,82]; 0,1041 10,91 [0,61; 196,52]; 0,1053 0,01 [0,00; 0,03]; 0,0394

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Beidseitige Mastektomie	336	2 (0,6)	315	2 (0,6)	0,94 [0,13; 6,69]; 0,9484 0,94 [0,13; 6,62]; 0,9484 0,00 [-0,01; 0,01]; 0,9484
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7572)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815
Nein	870	9 (1,0)	866	2 (0,2)	4,52 [0,97; 20,96]; 0,0543 4,48 [0,97; 20,67]; 0,0546 0,01 [0,00; 0,02]; 0,0344
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8533)					
Positiv	173	3 (1,7)	176	0 (0,0)	7,25 [0,37; 141,34]; 0,1913 7,12 [0,37; 136,84]; 0,1930 0,02 [0,00; 0,04]; 0,1271
Negativ	200	2 (1,0)	191	0 (0,0)	4,82 [0,23; 101,13]; 0,3108 4,78 [0,23; 98,84]; 0,3118 0,01 [-0,01; 0,03]; 0,2471
Bilaterale Oophorektomie (Interaktionstest: p=0,7544)					
Ja	189	4 (2,1)	176	1 (0,6)	3,78 [0,42; 34,18]; 0,2360 3,72 [0,42; 33,01]; 0,2374 0,02 [-0,01; 0,04]; 0,1934
Nein	722	6 (0,8)	728	1 (0,1)	6,09 [0,73; 50,73]; 0,0947 6,05 [0,73; 50,13]; 0,0952 0,01 [0,00; 0,01]; 0,0572
BRCA-Mutationsstatus (Interaktionstest: p=0,9371)					
BRCA1	574	8 (1,4)	580	2 (0,3)	4,08 [0,86; 19,32]; 0,0759 4,04 [0,86; 18,95]; 0,0765 0,01 [0,00; 0,02]; 0,0550
BRCA2	232	2 (0,9)	215	0 (0,0)	4,67 [0,22; 97,92]; 0,3204 4,64 [0,22; 96,00]; 0,3213 0,01 [-0,01; 0,02]; 0,2504
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	4 (1,0)	383	2 (0,5)	1,96 [0,36; 10,79]; 0,4374 1,95 [0,36; 10,61]; 0,4376 0,00 [-0,01; 0,02]; 0,4269
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnie (Interaktionstest: p=0,9793)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,000
Asiatisch	259	0 (0,0)	271	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Kaukasisch	617	9 (1,5)	589	2 (0,3)	4,34 [0,93; 20,19]; 0,0609 4,30 [0,93; 19,80]; 0,0615 0,01 [0,00; 0,02]; 0,0378
Schwarz oder afroamerikanisch	19	1 (5,3)	29	0 (0,0)	4,78 [0,18; 123,74]; 0,3456 4,50 [0,19; 105,03]; 0,3494 0,05 [-0,07; 0,18]; 0,4062
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,000
Nicht-hispanisch	798	10 (1,3)	803	2 (0,3)	5,08 [1,11; 23,27]; 0,0362 5,03 [1,11; 22,89]; 0,0366 0,01 [0,00; 0,02]; 0,0199
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,000
Hormonrezeptorstatus (Interaktionstest: p=0,9392)					
ER- und/oder PgR-positiv, HER2-positiv	168	2 (1,2)	155	0 (0,0)	4,67 [0,22; 98,03]; 0,3211 4,62 [0,22; 95,39]; 0,3223 0,01 [-0,01; 0,03]; 0,2492
TNBC	741	8 (1,1)	749	2 (0,3)	4,08 [0,86; 19,26]; 0,0761 4,04 [0,86; 18,98]; 0,0766 0,01 [0,00; 0,02]; 0,0552
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,5125)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	2 (1,9)	92	0 (0,0)	4,51 [0,21; 95,21]; 0,3328 4,43 [0,22; 91,07]; 0,3347 0,02 [-0,01; 0,05]; 0,2495
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	3 (0,9)	362	2 (0,6)	1,57 [0,26; 9,42]; 0,6248 1,56 [0,26; 9,28]; 0,6248 0,00 [-0,01; 0,02]; 0,6233
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	5 (1,3)	387	0 (0,0)	10,97 [0,60; 199,10]; 0,1053 10,83 [0,60; 195,24]; 0,1063 0,01 [0,00; 0,02]; 0,0397

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Menopausenstatus (Interaktionstest: p=0,8252)					
Postmenopausal	346	4 (1,2)	356	1 (0,3)	4,15 [0,46; 37,34]; 0,2039 4,12 [0,46; 36,64]; 0,2047 0,01 [0,00; 0,02]; 0,1711
Prämenopausal	563	6 (1,1)	544	1 (0,2)	5,85 [0,70; 48,75]; 0,1025 5,80 [0,70; 48,00]; 0,1032 0,01 [0,00; 0,02]; 0,0607
Region (Interaktionstest: p=0,8331)					
Asien-Pazifik und Südafrika	301	0 (0,0)	317	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Europa	473	8 (1,7)	444	2 (0,5)	3,80 [0,80; 18,00]; 0,0923 3,75 [0,80; 17,59]; 0,0931 0,01 [0,00; 0,03]; 0,0651
Nordamerika	121	2 (1,7)	131	0 (0,0)	5,50 [0,26; 115,77]; 0,2726 5,41 [0,26; 111,56]; 0,2742 0,02 [-0,01; 0,04]; 0,2343
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,3870)					
Adjuvant	457	5 (1,1)	450	0 (0,0)	10,95 [0,60; 198,63]; 0,1055 10,83 [0,60; 195,32]; 0,1064 0,01 [0,00; 0,02]; 0,0399
Neoadjuvant	454	5 (1,1)	454	2 (0,4)	2,52 [0,49; 13,04]; 0,2715 2,50 [0,49; 12,82]; 0,2719 0,01 [0,00; 0,02]; 0,2547
Sponsor (Interaktionstest: p=0,9030)					
AZ	801	8 (1,0)	796	2 (0,3)	4,01 [0,85; 18,92]; 0,0798 3,98 [0,85; 18,66]; 0,0803 0,01 [0,00; 0,02]; 0,0576
NRG Oncology	110	2 (1,8)	108	0 (0,0)	5,00 [0,24; 105,37]; 0,3007 4,91 [0,24; 101,10]; 0,3025 0,02 [-0,01; 0,05]; 0,2408
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,5284)					
Ja	243	4 (1,7)	236	0 (0,0)	8,89 [0,48; 165,98]; 0,1435 8,74 [0,47; 161,48]; 0,1451 0,02 [0,00; 0,03]; 0,0709
Nein	668	6 (0,9)	668	2 (0,3)	3,02 [0,61; 15,01]; 0,1771 3,00 [0,61; 14,81]; 0,1775 0,01 [0,00; 0,01]; 0,1557

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
MDS/AML					
Alter (Interaktionstest: p=NC)					
<50	690	1 (0,1)	663	1 (0,2)	0,96 [0,06; 15,39]; 0,9775 0,96 [0,06; 15,33]; 0,9775 0,00 [0,00; 0,00]; 0,9775
50-64	192	0 (0,0)	209	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,000
Anthrazyklin und Taxan	861	1 (0,1)	840	1 (0,1)	0,98 [0,06; 15,62]; 0,9861 0,98 [0,06; 15,57]; 0,9861 0,00 [0,00; 0,00]; 0,9861
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=NC)					
Brusterhaltend	220	0 (0,0)	235	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Einseitige Mastektomie	355	1 (0,3)	352	1 (0,3)	0,99 [0,06; 15,91]; 0,9952 0,99 [0,06; 15,79]; 0,9952 0,00 [-0,01; 0,01]; 0,9952
Beidseitige Mastektomie	336	0 (0,0)	315	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,000
Nein	870	1 (0,1)	866	1 (0,1)	1,00 [0,06; 15,94]; 0,9974 1,00 [0,06; 15,89]; 0,9974 0,00 [0,00; 0,00]; 0,9974

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	1 (0,6)	176	0 (0,0)	3,07 [0,12; 75,87]; 0,4931 3,05 [0,13; 74,40]; 0,4935 0,01 [-0,01; 0,02]; 0,4735
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Bilaterale Oophorektomie (Interaktionstest: p=NC)					
Ja	189	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Nein	722	1 (0,1)	728	1 (0,1)	1,01 [0,06; 16,15]; 0,9953 1,01 [0,06; 16,09]; 0,9953 0,00 [0,00; 0,00]; 0,9953
BRCA-Mutationsstatus (Interaktionstest: p=NC)					
BRCA1	574	0 (0,0)	580	1 (0,2)	0,34 [0,01; 8,27]; 0,5048 0,34 [0,01; 8,25]; 0,5049 0,00 [-0,01; 0,00]; 0,4794
BRCA2	232	0 (0,0)	215	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	0 (0,0)	383	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,000
Ethnie (Interaktionstest: p=NC)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,000
Asiatisch	259	1 (0,4)	271	1 (0,4)	1,05 [0,07; 16,82]; 0,9744 1,05 [0,07; 16,64]; 0,9744 0,00 [-0,01; 0,01]; 0,9744
Kaukasisch	617	0 (0,0)	589	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,000
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,000
Nicht-hispanisch	798	1 (0,1)	803	1 (0,1)	1,01 [0,06; 16,12]; 0,9965 1,01 [0,06; 16,06]; 0,9965 0,00 [0,00; 0,00]; 0,9965
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,000
Hormonrezeptorstatus (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv, HER2-positiv	168	0 (0,0)	155	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
TNBC	741	1 (0,1)	749	1 (0,1)	1,01 [0,06; 16,19]; 0,9939 1,01 [0,06; 16,13]; 0,9939 0,00 [0,00; 0,00]; 0,9939
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3531)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,000
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	0 (0,0)	362	1 (0,3)	0,35 [0,01; 8,52]; 0,5159 0,35 [0,01; 8,48]; 0,5161 0,00 [-0,01; 0,00]; 0,4820
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	1 (0,3)	387	0 (0,0)	2,96 [0,12; 72,93]; 0,5065 2,95 [0,12; 72,30]; 0,5067 0,00 [0,00; 0,01]; 0,4794
Menopausenstatus (Interaktionstest: p=0,3549)					
Postmenopausal	346	0 (0,0)	356	1 (0,3)	0,34 [0,01; 8,42]; 0,5116 0,34 [0,01; 8,39]; 0,5118 0,00 [-0,01; 0,00]; 0,4807
Prämenopausal	563	1 (0,2)	544	0 (0,0)	2,90 [0,12; 71,44]; 0,5141 2,90 [0,12; 71,01]; 0,5143 0,00 [0,00; 0,01]; 0,4821
Region (Interaktionstest: p=NC)					
Asien-Pazifik und Südafrika	301	1 (0,3)	317	1 (0,3)	1,05 [0,07; 16,92]; 0,9707 1,05 [0,07; 16,76]; 0,9707 0,00 [-0,01; 0,01]; 0,9708

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	0 (0,0)	444	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,000
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,3444)					
Adjuvant	457	1 (0,2)	450	0 (0,0)	2,96 [0,12; 72,87]; 0,5066 2,95 [0,12; 72,33]; 0,5068 0,00 [0,00; 0,01]; 0,4797
Neoadjuvant	454	0 (0,0)	454	1 (0,2)	0,33 [0,01; 8,19]; 0,5006 0,33 [0,01; 8,16]; 0,5007 0,00 [-0,01; 0,00]; 0,4779
Sponsor (Interaktionstest: p=NC)					
AZ	801	1 (0,1)	796	1 (0,1)	0,99 [0,06; 15,92]; 0,9965 0,99 [0,06; 15,86]; 0,9965 0,00 [0,00; 0,00]; 0,9965
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,000
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=NC)					
Ja	243	0 (0,0)	236	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,000
Nein	668	1 (0,2)	668	1 (0,2)	1,00 [0,06; 16,02]; 1,000 1,00 [0,06; 15,95]; 1,000 0,00 [0,00; 0,00]; 1,000
Neue primäre Malignität (ausgenommen MDS/AML)					
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	2 (0,5)	383	4 (1,0)	0,49 [0,09; 2,67]; 0,4062 0,49 [0,09; 2,65]; 0,4065 -0,01 [-0,02; 0,01]; 0,3979
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,000
Alter (Interaktionstest: p=0,6441)					
<50	690	1 (0,1)	663	4 (0,6)	0,24 [0,03; 2,14]; 0,2012 0,24 [0,03; 2,14]; 0,2015 0,00 [-0,01; 0,00]; 0,1697

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
50-64	192	3 (1,6)	209	4 (1,9)	0,81 [0,18; 3,68]; 0,7887 0,82 [0,19; 3,60]; 0,7888 0,00 [-0,03; 0,02]; 0,7875
≥65	29	0 (0,0)	32	1 (3,1)	0,36 [0,01; 9,09]; 0,5320 0,37 [0,02; 8,66]; 0,5340 -0,03 [-0,12; 0,05]; 0,4688
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,000
Anthrazyklin und Taxan	861	4 (0,5)	840	9 (1,1)	0,43 [0,13; 1,40]; 0,1627 0,43 [0,13; 1,40]; 0,1630 -0,01 [-0,01; 0,00]; 0,1525
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,7080)					
Brusterhaltend	220	1 (0,5)	235	1 (0,4)	1,07 [0,07; 17,19]; 0,9627 1,07 [0,07; 16,97]; 0,9627 0,00 [-0,01; 0,01]; 0,9628
Einseitige Mastektomie	355	3 (0,8)	352	6 (1,7)	0,49 [0,12; 1,98]; 0,3179 0,50 [0,12; 1,97]; 0,3183 -0,01 [-0,03; 0,01]; 0,3084
Beidseitige Mastektomie	336	0 (0,0)	315	2 (0,6)	0,19 [0,01; 3,90]; 0,2787 0,19 [0,01; 3,89]; 0,2793 -0,01 [-0,02; 0,00]; 0,2403
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,000
Nein	870	4 (0,5)	866	9 (1,0)	0,44 [0,13; 1,43]; 0,1730 0,44 [0,14; 1,43]; 0,1734 -0,01 [-0,01; 0,00]; 0,1616
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,3619)					
Positiv	173	0 (0,0)	176	3 (1,7)	0,14 [0,01; 2,79]; 0,1992 0,15 [0,01; 2,79]; 0,2009 -0,02 [-0,04; 0,00]; 0,1288
Negativ	200	1 (0,5)	191	1 (0,5)	0,95 [0,06; 15,37]; 0,9740 0,96 [0,06; 15,16]; 0,9740 0,00 [-0,01; 0,01]; 0,9740

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Bilaterale Oophorektomie (Interaktionstest: p=0,5643)					
Ja	189	1 (0,5)	176	1 (0,6)	0,93 [0,06; 15,00]; 0,9597 0,93 [0,06; 14,77]; 0,9597 0,00 [-0,02; 0,01]; 0,9597
Nein	722	3 (0,4)	728	8 (1,1)	0,38 [0,10; 1,42]; 0,1492 0,38 [0,10; 1,42]; 0,1496 -0,01 [-0,02; 0,00]; 0,1327
BRCA-Mutationsstatus (Interaktionstest: p=0,7458)					
BRCA1	574	2 (0,4)	580	7 (1,2)	0,29 [0,06; 1,38]; 0,1197 0,29 [0,06; 1,38]; 0,1203 -0,01 [-0,02; 0,00]; 0,0961
BRCA2	232	1 (0,4)	215	2 (0,9)	0,46 [0,04; 5,12]; 0,5285 0,46 [0,04; 5,07]; 0,5287 0,00 [-0,02; 0,01]; 0,5240
Ethnie (Interaktionstest: p=0,9650)					
Andere	16	0 (0,0)	15	1 (6,7)	0,29 [0,01; 7,76]; 0,4628 0,31 [0,01; 7,15]; 0,4675 -0,07 [-0,23; 0,10]; 0,4252
Asiatisch	259	1 (0,4)	271	2 (0,7)	0,52 [0,05; 5,78]; 0,5958 0,52 [0,05; 5,73]; 0,5959 0,00 [-0,02; 0,01]; 0,5866
Kaukasisch	617	3 (0,5)	589	6 (1,0)	0,47 [0,12; 1,91]; 0,2937 0,48 [0,12; 1,90]; 0,2940 -0,01 [-0,02; 0,00]; 0,2865
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,000
Ethnische Abstammung (Interaktionstest: p=0,8480)					
Hispanisch	34	0 (0,0)	24	1 (4,2)	0,23 [0,01; 5,82]; 0,3703 0,24 [0,01; 5,61]; 0,3733 -0,04 [-0,14; 0,06]; 0,4190
Nicht-hispanisch	798	4 (0,5)	803	7 (0,9)	0,57 [0,17; 1,96]; 0,3756 0,58 [0,17; 1,96]; 0,3758 0,00 [-0,01; 0,00]; 0,3691
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	1 (1,3)	0,32 [0,01; 8,00]; 0,4883 0,32 [0,01; 7,86]; 0,4892 -0,01 [-0,05; 0,02]; 0,4675
Hormonrezeptorstatus (Interaktionstest: p=0,7126)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	3 (1,9)	0,30 [0,03; 2,95]; 0,3039 0,31 [0,03; 2,93]; 0,3049 -0,01 [-0,04; 0,01]; 0,2858

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
TNBC	741	3 (0,4)	749	6 (0,8)	0,50 [0,13; 2,02]; 0,3330 0,51 [0,13; 2,01]; 0,3332 0,00 [-0,01; 0,00]; 0,3227
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,6534)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	2 (2,2)	0,17 [0,01; 3,66]; 0,2598 0,18 [0,01; 3,64]; 0,2619 -0,02 [-0,06; 0,01]; 0,2289
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	1 (1,6)	0,98 [0,06; 16,09]; 0,9910 0,98 [0,06; 15,40]; 0,9910 0,00 [-0,04; 0,04]; 0,9910
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	2 (0,6)	362	2 (0,6)	1,04 [0,15; 7,43]; 0,9684 1,04 [0,15; 7,34]; 0,9684 0,00 [-0,01; 0,01]; 0,9685
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	1 (0,3)	387	4 (1,0)	0,24 [0,03; 2,20]; 0,2083 0,25 [0,03; 2,19]; 0,2090 -0,01 [-0,02; 0,00]; 0,1743
Menopausenstatus (Interaktionstest: p=0,2986)					
Postmenopausal	346	3 (0,9)	356	4 (1,1)	0,77 [0,17; 3,46]; 0,7330 0,77 [0,17; 3,42]; 0,7331 0,00 [-0,02; 0,01]; 0,7318
Prämenopausal	563	1 (0,2)	544	5 (0,9)	0,19 [0,02; 1,65]; 0,1323 0,19 [0,02; 1,65]; 0,1329 -0,01 [-0,02; 0,00]; 0,0964
Region (Interaktionstest: p=0,8785)					
Asien-Pazifik und Südafrika	301	1 (0,3)	317	2 (0,6)	0,52 [0,05; 5,82]; 0,5996 0,53 [0,05; 5,78]; 0,5997 0,00 [-0,01; 0,01]; 0,5903
Europa	473	3 (0,6)	444	4 (0,9)	0,70 [0,16; 3,15]; 0,6446 0,70 [0,16; 3,13]; 0,6446 0,00 [-0,01; 0,01]; 0,6447
Nordamerika	121	0 (0,0)	131	2 (1,5)	0,21 [0,01; 4,49]; 0,3200 0,22 [0,01; 4,46]; 0,3215 -0,02 [-0,04; 0,01]; 0,2474
Südamerika	16	0 (0,0)	12	1 (8,3)	0,23 [0,01; 6,22]; 0,3843 0,25 [0,01; 5,76]; 0,3902 -0,08 [-0,27; 0,11]; 0,3933
Art der vorherigen Chemotherapie (Interaktionstest: p=0,8425)					
Adjuvant	457	2 (0,4)	450	5 (1,1)	0,39 [0,08; 2,03]; 0,2635 0,39 [0,08; 2,02]; 0,2639 -0,01 [-0,02; 0,00]; 0,2478
Neoadjuvant	454	2 (0,4)	454	4 (0,9)	0,50 [0,09; 2,73]; 0,4219 0,50 [0,09; 2,72]; 0,4221 0,00 [-0,01; 0,01]; 0,4125

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Sponsor (Interaktionstest: p=0,8102)					
AZ	801	4 (0,5)	796	8 (1,0)	0,49 [0,15; 1,65]; 0,2515 0,50 [0,15; 1,64]; 0,2518 -0,01 [-0,01; 0,00]; 0,2423
NRG Oncology	110	0 (0,0)	108	1 (0,9)	0,32 [0,01; 8,05]; 0,4919 0,33 [0,01; 7,95]; 0,4926 -0,01 [-0,03; 0,02]; 0,4709
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,5177)					
Ja	243	0 (0,0)	236	2 (0,9)	0,19 [0,01; 4,03]; 0,2885 0,19 [0,01; 4,03]; 0,2894 -0,01 [-0,02; 0,01]; 0,2418
Nein	668	4 (0,6)	668	7 (1,1)	0,57 [0,17; 1,95]; 0,3699 0,57 [0,17; 1,94]; 0,3701 0,00 [-0,01; 0,01]; 0,3636

Datenschnitt: 12.07.2021; Analyse-Set: Safety-Analysis-Set
a: Die Berechnung von OR, RR und RD erfolgte auf Basis der Vierfeldertafel.

Anhang 4-G14: Subgruppenanalysen: Schwerwiegende UESI

Tabelle 6.8.1: Subgruppenergebnisse für schwerwiegende UESI aus RCT mit dem zu bewertenden Arzneimittel

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Anämie					
Alter (Interaktionstest: p=0,9665)					
<50	690	11 (1,6)	663	1 (0,2)	10,72 [1,38; 83,30]; 0,0233 10,57 [1,37; 81,64]; 0,0238 0,01 [0,00; 0,02]; 0,0039
50-64	192	4 (2,1)	209	0 (0,0)	10,00 [0,53; 187,02]; 0,1232 9,79 [0,53; 180,70]; 0,1250 0,02 [0,00; 0,04]; 0,0669
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,4765)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	14 (1,6)	840	1 (0,1)	13,87 [1,82; 105,70]; 0,0112 13,66 [1,80; 103,64]; 0,0115 0,02 [0,01; 0,02]; 0,0008
Taxan	43	1 (2,3)	50	0 (0,0)	3,56 [0,14; 89,80]; 0,4400 3,48 [0,15; 83,21]; 0,4417 0,02 [-0,04; 0,08]; 0,4478
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,7611)					
Brusterhaltend	220	6 (2,7)	235	0 (0,0)	14,27 [0,80; 254,86]; 0,0707 13,88 [0,79; 244,99]; 0,0725 0,03 [0,00; 0,05]; 0,0203
Einseitige Mastektomie	355	4 (1,1)	352	1 (0,3)	4,00 [0,44; 35,97]; 0,2160 3,97 [0,45; 35,31]; 0,2168 0,01 [0,00; 0,02]; 0,1796
Beidseitige Mastektomie	336	5 (1,5)	315	0 (0,0)	10,47 [0,58; 190,11]; 0,1124 10,31 [0,57; 185,78]; 0,1136 0,01 [0,00; 0,03]; 0,0403
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	15 (1,7)	866	1 (0,1)	15,18 [2,00; 115,14]; 0,0085 14,93 [1,98; 112,79]; 0,0088 0,02 [0,01; 0,03]; 0,0004

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8536)					
Positiv	173	3 (1,7)	176	0 (0,0)	7,25 [0,37; 141,34]; 0,1913 7,12 [0,37; 136,84]; 0,1930 0,02 [0,00; 0,04]; 0,1271
Negativ	200	5 (2,5)	191	0 (0,0)	10,77 [0,59; 196,20]; 0,1084 10,51 [0,58; 188,74]; 0,1105 0,03 [0,00; 0,05]; 0,0385
Bilaterale Oophorektomie (Interaktionstest: p=0,5782)					
Ja	189	2 (1,1)	176	0 (0,0)	4,71 [0,22; 98,72]; 0,3185 4,66 [0,23; 96,35]; 0,3195 0,01 [-0,01; 0,03]; 0,2490
Nein	722	13 (1,8)	728	1 (0,1)	13,33 [1,74; 102,17]; 0,0127 13,11 [1,72; 99,94]; 0,0130 0,02 [0,01; 0,03]; 0,0012
BRCA-Mutationsstatus (Interaktionstest: p=0,8982)					
BRCA1	574	8 (1,4)	580	1 (0,2)	8,18 [1,02; 65,64]; 0,0478 8,08 [1,01; 64,42]; 0,0485 0,01 [0,00; 0,02]; 0,0186
BRCA2	232	5 (2,2)	215	0 (0,0)	10,42 [0,57; 189,57]; 0,1133 10,20 [0,57; 183,33]; 0,1152 0,02 [0,00; 0,04]; 0,0395
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	5 (1,3)	383	1 (0,3)	4,94 [0,57; 42,44]; 0,1459 4,89 [0,57; 41,62]; 0,1467 0,01 [0,00; 0,02]; 0,1040
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,8071)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	3 (1,2)	271	0 (0,0)	7,41 [0,38; 144,15]; 0,1860 7,32 [0,38; 141,08]; 0,1871 0,01 [0,00; 0,03]; 0,1277
Kaukasisch	617	12 (1,9)	589	1 (0,2)	11,66 [1,51; 89,98]; 0,0185 11,46 [1,49; 87,82]; 0,0190 0,02 [0,01; 0,03]; 0,0023
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Ethnische Abstammung (Interaktionstest: p=0,5579)					
Hispanisch	34	1 (2,9)	24	0 (0,0)	2,19 [0,09; 56,18]; 0,6348 2,14 [0,09; 50,47]; 0,6363 0,03 [-0,06; 0,12]; 0,5060
Nicht-hispanisch	798	13 (1,6)	803	1 (0,1)	13,28 [1,73; 101,77]; 0,0128 13,08 [1,72; 99,76]; 0,0131 0,02 [0,01; 0,02]; 0,0012
Unbekannt, nicht erfasst, verweigert	79	1 (1,3)	77	0 (0,0)	2,96 [0,12; 73,83]; 0,5081 2,92 [0,12; 70,72]; 0,5090 0,01 [-0,02; 0,05]; 0,4733
Hormonrezeptorstatus (Interaktionstest: p=0,8725)					
ER- und/oder PgR-positiv, HER2-positiv	168	4 (2,4)	155	0 (0,0)	8,51 [0,45; 159,32]; 0,1521 8,31 [0,45; 153,06]; 0,1544 0,02 [0,00; 0,05]; 0,0709
TNBC	741	11 (1,5)	749	1 (0,1)	11,27 [1,45; 87,52]; 0,0205 11,12 [1,44; 85,90]; 0,0209 0,01 [0,00; 0,02]; 0,0036
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8368)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	2 (1,9)	92	0 (0,0)	4,51 [0,21; 95,21]; 0,3328 4,43 [0,22; 91,07]; 0,3347 0,02 [-0,01; 0,05]; 0,2495
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	2 (3,1)	63	0 (0,0)	5,08 [0,24; 107,95]; 0,2973 4,92 [0,24; 100,55]; 0,3004 0,03 [-0,02; 0,08]; 0,2342
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	3 (0,9)	362	1 (0,3)	3,14 [0,32; 30,32]; 0,3229 3,12 [0,33; 29,86]; 0,3233 0,01 [-0,01; 0,02]; 0,3017
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	8 (2,0)	387	0 (0,0)	17,09 [0,98; 297,09]; 0,0514 16,74 [0,97; 289,05]; 0,0525 0,02 [0,01; 0,04]; 0,0070
Menopausenstatus (Interaktionstest: p=0,9395)					
Postmenopausal	346	4 (1,2)	356	0 (0,0)	9,37 [0,50; 174,65]; 0,1339 9,26 [0,50; 171,34]; 0,1349 0,01 [0,00; 0,02]; 0,0703
Prämenopausal	563	11 (2,0)	544	1 (0,2)	10,82 [1,39; 84,10]; 0,0228 10,63 [1,38; 82,05]; 0,0234 0,02 [0,01; 0,03]; 0,0038
Region (Interaktionstest: p=0,8457)					
Asien-Pazifik und Südafrika	301	4 (1,3)	317	0 (0,0)	9,61 [0,51; 179,16]; 0,1297 9,48 [0,51; 175,27]; 0,1308 0,01 [0,00; 0,03]; 0,0693

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Europa	473	10 (2,1)	444	1 (0,2)	9,57 [1,22; 75,05]; 0,0316 9,39 [1,21; 73,03]; 0,0324 0,02 [0,01; 0,03]; 0,0069
Nordamerika	121	1 (0,8)	131	0 (0,0)	3,27 [0,13; 81,13]; 0,4690 3,25 [0,13; 78,93]; 0,4696 0,01 [-0,01; 0,03]; 0,4653
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,4336)					
Adjuvant	457	10 (2,2)	450	0 (0,0)	21,14 [1,24; 361,86]; 0,0352 20,68 [1,22; 351,84]; 0,0362 0,02 [0,01; 0,04]; 0,0023
Neoadjuvant	454	5 (1,1)	454	1 (0,2)	5,04 [0,59; 43,35]; 0,1403 5,00 [0,59; 42,63]; 0,1410 0,01 [0,00; 0,02]; 0,1008
Sponsor (Interaktionstest: p=0,4207)					
AZ	801	14 (1,8)	796	1 (0,1)	14,14 [1,86; 107,80]; 0,0106 13,91 [1,83; 105,55]; 0,0109 0,02 [0,01; 0,03]; 0,0007
NRG Oncology	110	1 (0,9)	108	0 (0,0)	2,97 [0,12; 73,78]; 0,5061 2,95 [0,12; 71,53]; 0,5068 0,01 [-0,02; 0,03]; 0,4751
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,8511)					
Ja	243	6 (2,5)	236	0 (0,0)	12,95 [0,73; 231,09]; 0,0816 12,63 [0,72; 222,90]; 0,0834 0,02 [0,00; 0,05]; 0,0214
Nein	668	9 (1,4)	668	1 (0,2)	9,11 [1,15; 72,10]; 0,0363 9,00 [1,14; 70,84]; 0,0369 0,01 [0,00; 0,02]; 0,0109
Erbrechen					
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	2 (0,2)	840	0 (0,0)	4,89 [0,23; 102,00]; 0,3059 4,88 [0,23; 101,46]; 0,3061 0,00 [0,00; 0,01]; 0,2491
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	2 (0,2)	866	0 (0,0)	4,99 [0,24; 104,06]; 0,2998 4,98 [0,24; 103,52]; 0,3000 0,00 [0,00; 0,01]; 0,2474
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	1 (0,3)	383	0 (0,0)	2,94 [0,12; 72,36]; 0,5096 2,93 [0,12; 71,73]; 0,5098 0,00 [0,00; 0,01]; 0,4803
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	2 (0,3)	803	0 (0,0)	5,04 [0,24; 105,23]; 0,2965 5,03 [0,24; 104,63]; 0,2967 0,00 [0,00; 0,01]; 0,2465
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Menopausenstatus (Interaktionstest: p=NC)					
Postmenopausal	346	2 (0,6)	356	0 (0,0)	5,17 [0,25; 108,16]; 0,2893 5,14 [0,25; 106,76]; 0,2898 0,01 [0,00; 0,02]; 0,2432
Prämenopausal	563	0 (0,0)	544	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Alter (Interaktionstest: p=NC)					
<50	690	2 (0,3)	663	0 (0,0)	4,82 [0,23; 100,55]; 0,3104 4,80 [0,23; 99,89]; 0,3107 0,00 [0,00; 0,01]; 0,2500
50-64	192	0 (0,0)	209	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,9807)					
Brusterhaltend	220	0 (0,0)	235	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Einseitige Mastektomie	355	1 (0,3)	352	0 (0,0)	2,98 [0,12; 73,48]; 0,5038 2,97 [0,12; 72,77]; 0,5040 0,00 [0,00; 0,01]; 0,4784
Beidseitige Mastektomie	336	1 (0,3)	315	0 (0,0)	2,82 [0,11; 69,51]; 0,5258 2,81 [0,12; 68,80]; 0,5260 0,00 [-0,01; 0,01]; 0,4848
Bilaterale Oophorektomie (Interaktionstest: p=0,9726)					
Ja	189	1 (0,5)	176	0 (0,0)	2,81 [0,11; 69,41]; 0,5279 2,79 [0,11; 68,16]; 0,5283 0,01 [-0,01; 0,02]; 0,4839
Nein	722	1 (0,1)	728	0 (0,0)	3,03 [0,12; 74,48]; 0,4976 3,02 [0,12; 74,13]; 0,4977 0,00 [0,00; 0,01]; 0,4776
BRCA-Mutationsstatus (Interaktionstest: p=NC)					
BRCA1	574	2 (0,4)	580	0 (0,0)	5,07 [0,24; 105,83]; 0,2951 5,05 [0,24; 105,00]; 0,2954 0,00 [0,00; 0,01]; 0,2457
BRCA2	232	0 (0,0)	215	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Ethnie (Interaktionstest: p=NC)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	0 (0,0)	271	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Kaukasisch	617	2 (0,3)	589	0 (0,0)	4,79 [0,23; 99,96]; 0,3123 4,77 [0,23; 99,22]; 0,3127 0,00 [0,00; 0,01]; 0,2504
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Hormonrezeptorstatus (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv, HER2-positiv	168	0 (0,0)	155	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
TNBC	741	2 (0,3)	749	0 (0,0)	5,07 [0,24; 105,73]; 0,2951 5,05 [0,24; 105,09]; 0,2954 0,00 [0,00; 0,01]; 0,2460
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,9811)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	1 (0,3)	362	0 (0,0)	3,13 [0,13; 77,08]; 0,4852 3,12 [0,13; 76,34]; 0,4854 0,00 [0,00; 0,01]; 0,4732
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	1 (0,3)	387	0 (0,0)	2,96 [0,12; 72,93]; 0,5065 2,95 [0,12; 72,30]; 0,5067 0,00 [0,00; 0,01]; 0,4794
Region (Interaktionstest: p=0,9509)					
Asien-Pazifik und Südafrika	301	0 (0,0)	317	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Europa	473	1 (0,2)	444	0 (0,0)	2,82 [0,11; 69,46]; 0,5255 2,82 [0,12; 68,96]; 0,5257 0,00 [0,00; 0,01]; 0,4853
Nordamerika	121	1 (0,8)	131	0 (0,0)	3,27 [0,13; 81,13]; 0,4690 3,25 [0,13; 78,93]; 0,4696 0,01 [-0,01; 0,03]; 0,4653
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,9947)					
Adjuvant	457	1 (0,2)	450	0 (0,0)	2,96 [0,12; 72,87]; 0,5066 2,95 [0,12; 72,33]; 0,5068 0,00 [0,00; 0,01]; 0,4797

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Neoadjuvant	454	1 (0,2)	454	0 (0,0)	3,01 [0,12; 74,00]; 0,5006 3,00 [0,12; 73,45]; 0,5007 0,00 [0,00; 0,01]; 0,4779
Sponsor (Interaktionstest: p=0,9959)					
AZ	801	1 (0,1)	796	0 (0,0)	2,99 [0,12; 73,38]; 0,5033 2,98 [0,12; 73,07]; 0,5033 0,00 [0,00; 0,00]; 0,4793
NRG Oncology	110	1 (0,9)	108	0 (0,0)	2,97 [0,12; 73,78]; 0,5061 2,95 [0,12; 71,53]; 0,5068 0,01 [-0,02; 0,03]; 0,4751
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,9899)					
Ja	243	1 (0,4)	236	0 (0,0)	2,93 [0,12; 72,18]; 0,5116 2,91 [0,12; 71,17]; 0,5119 0,00 [-0,01; 0,02]; 0,4798
Nein	668	1 (0,2)	668	0 (0,0)	3,00 [0,12; 73,89]; 0,5008 3,00 [0,12; 73,51]; 0,5009 0,00 [0,00; 0,01]; 0,4784
Übelkeit					
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	1 (0,1)	840	0 (0,0)	2,93 [0,12; 72,03]; 0,5105 2,93 [0,12; 71,75]; 0,5106 0,00 [0,00; 0,00]; 0,4814
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	1 (0,1)	866	0 (0,0)	2,99 [0,12; 73,49]; 0,5026 2,99 [0,12; 73,20]; 0,5027 0,00 [0,00; 0,00]; 0,4792
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
	N	**n (%)**	**N**	**n (%)**	
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	0 (0,0)	383	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	1 (0,1)	803	0 (0,0)	3,02 [0,12; 74,31]; 0,4984 3,02 [0,12; 73,99]; 0,4985 0,00 [0,00; 0,00]; 0,4779
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=NC)					
Adjuvant	457	1 (0,2)	450	0 (0,0)	2,96 [0,12; 72,87]; 0,5066 2,95 [0,12; 72,33]; 0,5068 0,00 [0,00; 0,01]; 0,4797
Neoadjuvant	454	0 (0,0)	454	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Alter (Interaktionstest: p=NC)					
<50	690	1 (0,1)	663	0 (0,0)	2,89 [0,12; 70,99]; 0,5164 2,88 [0,12; 70,64]; 0,5165 0,00 [0,00; 0,01]; 0,4830
50-64	192	0 (0,0)	209	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=NC)					
Brusterhaltend	220	0 (0,0)	235	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Einseitige Mastektomie	355	0 (0,0)	352	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Beidseitige Mastektomie	336	1 (0,3)	315	0 (0,0)	2,82 [0,11; 69,51]; 0,5258 2,81 [0,12; 68,80]; 0,5260 0,00 [-0,01; 0,01]; 0,4848
Bilaterale Oophorektomie (Interaktionstest: p=NC)					
Ja	189	1 (0,5)	176	0 (0,0)	2,81 [0,11; 69,41]; 0,5279 2,79 [0,11; 68,16]; 0,5283 0,01 [-0,01; 0,02]; 0,4839
Nein	722	0 (0,0)	728	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
BRCA-Mutationsstatus (Interaktionstest: p=NC)					
BRCA1	574	1 (0,2)	580	0 (0,0)	3,04 [0,12; 74,70]; 0,4967 3,03 [0,12; 74,26]; 0,4968 0,00 [0,00; 0,01]; 0,4771
BRCA2	232	0 (0,0)	215	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Ethnie (Interaktionstest: p=NC)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	0 (0,0)	271	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Kaukasisch	617	1 (0,2)	589	0 (0,0)	2,87 [0,12; 70,56]; 0,5190 2,86 [0,12; 70,17]; 0,5191 0,00 [0,00; 0,01]; 0,4836
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Hormonrezeptorstatus (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv, HER2-positiv	168	0 (0,0)	155	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
TNBC	741	1 (0,1)	749	0 (0,0)	3,04 [0,12; 74,66]; 0,4966 3,03 [0,12; 74,32]; 0,4967 0,00 [0,00; 0,01]; 0,4774

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	0 (0,0)	362	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	1 (0,3)	387	0 (0,0)	2,96 [0,12; 72,93]; 0,5065 2,95 [0,12; 72,30]; 0,5067 0,00 [0,00; 0,01]; 0,4794
Menopausenstatus (Interaktionstest: p=NC)					
Postmenopausal	346	1 (0,3)	356	0 (0,0)	3,10 [0,13; 76,25]; 0,4894 3,09 [0,13; 75,51]; 0,4896 0,00 [-0,01; 0,01]; 0,4744
Prämenopausal	563	0 (0,0)	544	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Region (Interaktionstest: p=NC)					
Asien-Pazifik und Südafrika	301	0 (0,0)	317	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Europa	473	0 (0,0)	444	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Nordamerika	121	1 (0,8)	131	0 (0,0)	3,27 [0,13; 81,13]; 0,4690 3,25 [0,13; 78,93]; 0,4696 0,01 [-0,01; 0,03]; 0,4653
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Sponsor (Interaktionstest: p=NC)					
AZ	801	0 (0,0)	796	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
NRG Oncology	110	1 (0,9)	108	0 (0,0)	2,97 [0,12; 73,78]; 0,5061 2,95 [0,12; 71,53]; 0,5068 0,01 [-0,02; 0,03]; 0,4751

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=NC)					
Ja	243	1 (0,4)	236	0 (0,0)	2,93 [0,12; 72,18]; 0,5116 2,91 [0,12; 71,17]; 0,5119 0,00 [-0,01; 0,02]; 0,4798
Nein	668	0 (0,0)	668	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Neutropenie					
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	4 (0,5)	840	0 (0,0)	8,82 [0,47; 164,10]; 0,1444 8,78 [0,47; 162,84]; 0,1448 0,00 [0,00; 0,01]; 0,0733
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Alter (Interaktionstest: p=0,7449)					
<50	690	3 (0,4)	663	0 (0,0)	6,76 [0,35; 131,04]; 0,2067 6,73 [0,35; 129,97]; 0,2071 0,00 [0,00; 0,01]; 0,1342
50-64	192	1 (0,5)	209	0 (0,0)	3,28 [0,13; 81,05]; 0,4676 3,26 [0,13; 79,65]; 0,4680 0,01 [-0,01; 0,02]; 0,4670
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,6784)					
Brusterhaltend	220	3 (1,4)	235	0 (0,0)	7,58 [0,39; 147,57]; 0,1812 7,48 [0,39; 143,89]; 0,1825 0,01 [0,00; 0,03]; 0,1261
Einseitige Mastektomie	355	1 (0,3)	352	0 (0,0)	2,98 [0,12; 73,48]; 0,5038 2,97 [0,12; 72,77]; 0,5040 0,00 [0,00; 0,01]; 0,4784
Beidseitige Mastektomie	336	0 (0,0)	315	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,6524)					
Ja	41	1 (2,4)	35	0 (0,0)	2,63 [0,10; 66,62]; 0,5577 2,57 [0,11; 61,19]; 0,5592 0,02 [-0,04; 0,09]; 0,4815

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Nein	870	3 (0,3)	866	0 (0,0)	6,99 [0,36; 135,56]; 0,1986 6,97 [0,36; 134,69]; 0,1989 0,00 [0,00; 0,01]; 0,1327
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,8419)					
Positiv	173	1 (0,6)	176	0 (0,0)	3,07 [0,12; 75,87]; 0,4931 3,05 [0,13; 74,40]; 0,4935 0,01 [-0,01; 0,02]; 0,4735
Negativ	200	2 (1,0)	191	0 (0,0)	4,82 [0,23; 101,13]; 0,3108 4,78 [0,23; 98,84]; 0,3118 0,01 [-0,01; 0,03]; 0,2471
Bilaterale Oophorektomie (Interaktionstest: p=0,9711)					
Ja	189	2 (1,1)	176	0 (0,0)	4,71 [0,22; 98,72]; 0,3185 4,66 [0,23; 96,35]; 0,3195 0,01 [-0,01; 0,03]; 0,2490
Nein	722	2 (0,3)	728	0 (0,0)	5,06 [0,24; 105,49]; 0,2958 5,04 [0,24; 104,83]; 0,2961 0,00 [0,00; 0,01]; 0,2462
BRCA-Mutationsstatus (Interaktionstest: p=NC)					
BRCA1	574	4 (0,7)	580	0 (0,0)	9,16 [0,49; 170,48]; 0,1377 9,09 [0,49; 168,52]; 0,1383 0,01 [0,00; 0,01]; 0,0718
BRCA2	232	0 (0,0)	215	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	1 (0,3)	383	0 (0,0)	2,94 [0,12; 72,36]; 0,5096 2,93 [0,12; 71,73]; 0,5098 0,00 [0,00; 0,01]; 0,4803
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,9667)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	2 (0,8)	271	0 (0,0)	5,27 [0,25; 110,34]; 0,2840 5,23 [0,25; 108,44]; 0,2848 0,01 [-0,01; 0,02]; 0,2410
Kaukasisch	617	2 (0,3)	589	0 (0,0)	4,79 [0,23; 99,96]; 0,3123 4,77 [0,23; 99,22]; 0,3127 0,00 [0,00; 0,01]; 0,2504

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
	N	**n (%)**	**N**	**n (%)**	
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	4 (0,5)	803	0 (0,0)	9,10 [0,49; 169,33]; 0,1387 9,06 [0,49; 167,93]; 0,1392 0,01 [0,00; 0,01]; 0,0724
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Hormonrezeptorstatus (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv, HER2-positiv	168	0 (0,0)	155	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
TNBC	741	4 (0,5)	749	0 (0,0)	9,15 [0,49; 170,18]; 0,1378 9,10 [0,49; 168,67]; 0,1383 0,01 [0,00; 0,01]; 0,0722
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,7214)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	1 (0,3)	362	0 (0,0)	3,13 [0,13; 77,08]; 0,4852 3,12 [0,13; 76,34]; 0,4854 0,00 [0,00; 0,01]; 0,4732
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	3 (0,8)	387	0 (0,0)	6,95 [0,36; 134,92]; 0,2003 6,89 [0,36; 133,01]; 0,2011 0,01 [0,00; 0,02]; 0,1318
Menopausenstatus (Interaktionstest: p=0,9772)					
Postmenopausal	346	2 (0,6)	356	0 (0,0)	5,17 [0,25; 108,16]; 0,2893 5,14 [0,25; 106,76]; 0,2898 0,01 [0,00; 0,02]; 0,2432
Prämenopausal	563	2 (0,4)	544	0 (0,0)	4,85 [0,23; 101,22]; 0,3085 4,83 [0,23; 100,41]; 0,3089 0,00 [0,00; 0,01]; 0,2493

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Region (Interaktionstest: p=0,6652)					
Asien-Pazifik und Südafrika	301	3 (1,0)	317	0 (0,0)	7,45 [0,38; 144,75]; 0,1848 7,37 [0,38; 142,10]; 0,1858 0,01 [0,00; 0,02]; 0,1279
Europa	473	1 (0,2)	444	0 (0,0)	2,82 [0,11; 69,46]; 0,5255 2,82 [0,12; 68,96]; 0,5257 0,00 [0,00; 0,01]; 0,4853
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,7083)					
Adjuvant	457	3 (0,7)	450	0 (0,0)	6,94 [0,36; 134,71]; 0,2005 6,89 [0,36; 133,07]; 0,2012 0,01 [0,00; 0,02]; 0,1322
Neoadjuvant	454	1 (0,2)	454	0 (0,0)	3,01 [0,12; 74,00]; 0,5006 3,00 [0,12; 73,45]; 0,5007 0,00 [0,00; 0,01]; 0,4779
Sponsor (Interaktionstest: p=NC)					
AZ	801	4 (0,5)	796	0 (0,0)	8,99 [0,48; 167,23]; 0,1409 8,94 [0,48; 165,85]; 0,1414 0,00 [0,00; 0,01]; 0,0727
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,9894)					
Ja	243	2 (0,8)	236	0 (0,0)	4,90 [0,23; 102,53]; 0,3060 4,86 [0,23; 100,63]; 0,3068 0,01 [-0,01; 0,02]; 0,2465
Nein	668	2 (0,3)	668	0 (0,0)	5,02 [0,24; 104,66]; 0,2983 5,00 [0,24; 103,95]; 0,2986 0,00 [0,00; 0,01]; 0,2467
Thrombozytopenie					
Alter (Interaktionstest: p=NC)					
<50	690	0 (0,0)	663	1 (0,2)	0,32 [0,01; 7,86]; 0,4854 0,32 [0,01; 7,85]; 0,4855 0,00 [-0,01; 0,00]; 0,4742
50-64	192	0 (0,0)	209	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	0 (0,0)	840	1 (0,1)	0,32 [0,01; 7,98]; 0,4913 0,33 [0,01; 7,97]; 0,4913 0,00 [0,00; 0,00]; 0,4760
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=NC)					
Brusterhaltend	220	0 (0,0)	235	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Einseitige Mastektomie	355	0 (0,0)	352	1 (0,3)	0,33 [0,01; 8,12]; 0,4972 0,33 [0,01; 8,09]; 0,4974 0,00 [-0,01; 0,00]; 0,4765
Beidseitige Mastektomie	336	0 (0,0)	315	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	0 (0,0)	866	1 (0,1)	0,33 [0,01; 8,15]; 0,4990 0,33 [0,01; 8,13]; 0,4991 0,00 [0,00; 0,00]; 0,4782
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Bilaterale Oophorektomie (Interaktionstest: p=NC)					
Ja	189	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Nein	722	0 (0,0)	728	1 (0,1)	0,34 [0,01; 8,25]; 0,5040 0,34 [0,01; 8,24]; 0,5041 0,00 [-0,01; 0,00]; 0,4794
BRCA-Mutationsstatus (Interaktionstest: p=NC)					
BRCA1	574	0 (0,0)	580	1 (0,2)	0,34 [0,01; 8,27]; 0,5048 0,34 [0,01; 8,25]; 0,5049 0,00 [-0,01; 0,00]; 0,4794
BRCA2	232	0 (0,0)	215	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	0 (0,0)	383	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
5 oder 6	22	0 (0,0)	14	1 (7,1)	0,20 [0,01; 5,27]; 0,3349 0,22 [0,01; 4,99]; 0,3399 -0,07 [-0,23; 0,09]; 0,3907
Ethnie (Interaktionstest: p=NC)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	0 (0,0)	271	1 (0,4)	0,35 [0,01; 8,57]; 0,5180 0,35 [0,01; 8,52]; 0,5183 0,00 [-0,01; 0,01]; 0,4820
Kaukasisch	617	0 (0,0)	589	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	0 (0,0)	803	1 (0,1)	0,34 [0,01; 8,24]; 0,5032 0,34 [0,01; 8,22]; 0,5033 0,00 [0,00; 0,00]; 0,4793
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Hormonrezeptorstatus (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv, HER2-positiv	168	0 (0,0)	155	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
TNBC	741	0 (0,0)	749	1 (0,1)	0,34 [0,01; 8,27]; 0,5050 0,34 [0,01; 8,26]; 0,5051 0,00 [-0,01; 0,00]; 0,4797
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	0 (0,0)	362	1 (0,3)	0,35 [0,01; 8,52]; 0,5159 0,35 [0,01; 8,48]; 0,5161 0,00 [-0,01; 0,00]; 0,4820
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	0 (0,0)	387	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Menopausenstatus (Interaktionstest: p=NC)					
Postmenopausal	346	0 (0,0)	356	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Prämenopausal	563	0 (0,0)	544	1 (0,2)	0,32 [0,01; 7,91]; 0,4874 0,32 [0,01; 7,89]; 0,4875 0,00 [-0,01; 0,00]; 0,4745
Region (Interaktionstest: p=NC)					
Asien-Pazifik und Südafrika	301	0 (0,0)	317	1 (0,3)	0,35 [0,01; 8,62]; 0,5207 0,35 [0,01; 8,58]; 0,5209 0,00 [-0,01; 0,01]; 0,4831
Europa	473	0 (0,0)	444	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Art der vorherigen Chemotherapie (Interaktionstest: p=NC)					
Adjuvant	457	0 (0,0)	450	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Neoadjuvant	454	0 (0,0)	454	1 (0,2)	0,33 [0,01; 8,19]; 0,5006 0,33 [0,01; 8,16]; 0,5007 0,00 [-0,01; 0,00]; 0,4779
Sponsor (Interaktionstest: p=NC)					
AZ	801	0 (0,0)	796	1 (0,1)	0,33 [0,01; 8,13]; 0,4984 0,33 [0,01; 8,12]; 0,4985 0,00 [0,00; 0,00]; 0,4779
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=NC)					
Ja	243	0 (0,0)	236	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Nein	668	0 (0,0)	668	1 (0,2)	0,33 [0,01; 8,18]; 0,5008 0,33 [0,01; 8,17]; 0,5009 0,00 [-0,01; 0,00]; 0,4784
Fatigue und Asthenie					
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	0 (0,0)	383	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	1 (0,1)	803	0 (0,0)	3,02 [0,12; 74,31]; 0,4984 3,02 [0,12; 73,99]; 0,4985 0,00 [0,00; 0,00]; 0,4779
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Alter (Interaktionstest: p=NC)					
<50	690	0 (0,0)	663	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
50-64	192	1 (0,5)	209	0 (0,0)	3,28 [0,13; 81,05]; 0,4676 3,26 [0,13; 79,65]; 0,4680 0,01 [-0,01; 0,02]; 0,4670
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	1 (0,1)	840	0 (0,0)	2,93 [0,12; 72,03]; 0,5105 2,93 [0,12; 71,75]; 0,5106 0,00 [0,00; 0,00]; 0,4814
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=NC)					
Brusterhaltend	220	0 (0,0)	235	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Einseitige Mastektomie	355	1 (0,3)	352	0 (0,0)	2,98 [0,12; 73,48]; 0,5038 2,97 [0,12; 72,77]; 0,5040 0,00 [0,00; 0,01]; 0,4784
Beidseitige Mastektomie	336	0 (0,0)	315	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	1 (0,1)	866	0 (0,0)	2,99 [0,12; 73,49]; 0,5026 2,99 [0,12; 73,20]; 0,5027 0,00 [0,00; 0,00]; 0,4792
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Bilaterale Oophorektomie (Interaktionstest: p=NC)					
Ja	189	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Nein	722	1 (0,1)	728	0 (0,0)	3,03 [0,12; 74,48]; 0,4976 3,02 [0,12; 74,13]; 0,4977 0,00 [0,00; 0,01]; 0,4776
BRCA-Mutationsstatus (Interaktionstest: p=NC)					
BRCA1	574	1 (0,2)	580	0 (0,0)	3,04 [0,12; 74,70]; 0,4967 3,03 [0,12; 74,26]; 0,4968 0,00 [0,00; 0,01]; 0,4771
BRCA2	232	0 (0,0)	215	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Ethnie (Interaktionstest: p=NC)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	0 (0,0)	271	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Kaukasisch	617	1 (0,2)	589	0 (0,0)	2,87 [0,12; 70,56]; 0,5190 2,86 [0,12; 70,17]; 0,5191 0,00 [0,00; 0,01]; 0,4836
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Hormonrezeptorstatus (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	0 (0,0)	2,79 [0,11; 68,88]; 0,5315 2,77 [0,11; 67,48]; 0,5318 0,01 [-0,01; 0,02]; 0,4846
TNBC	741	0 (0,0)	749	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	1 (1,0)	92	0 (0,0)	2,68 [0,11; 66,63]; 0,5474 2,66 [0,11; 64,44]; 0,5480 0,01 [-0,02; 0,04]; 0,4873

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	0 (0,0)	362	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	0 (0,0)	387	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Menopausenstatus (Interaktionstest: p=NC)					
Postmenopausal	346	0 (0,0)	356	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Prämenopausal	563	1 (0,2)	544	0 (0,0)	2,90 [0,12; 71,44]; 0,5141 2,90 [0,12; 71,01]; 0,5143 0,00 [0,00; 0,01]; 0,4821
Region (Interaktionstest: p=NC)					
Asien-Pazifik und Südafrika	301	0 (0,0)	317	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Europa	473	1 (0,2)	444	0 (0,0)	2,82 [0,11; 69,46]; 0,5255 2,82 [0,12; 68,96]; 0,5257 0,00 [0,00; 0,01]; 0,4853
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=NC)					
Adjuvant	457	0 (0,0)	450	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Neoadjuvant	454	1 (0,2)	454	0 (0,0)	3,01 [0,12; 74,00]; 0,5006 3,00 [0,12; 73,45]; 0,5007 0,00 [0,00; 0,01]; 0,4779
Sponsor (Interaktionstest: p=NC)					
AZ	801	1 (0,1)	796	0 (0,0)	2,99 [0,12; 73,38]; 0,5033 2,98 [0,12; 73,07]; 0,5033 0,00 [0,00; 0,00]; 0,4793
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=NC)					
Ja	243	0 (0,0)	236	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Nein	668	1 (0,2)	668	0 (0,0)	3,00 [0,12; 73,89]; 0,5008 3,00 [0,12; 73,51]; 0,5009 0,00 [0,00; 0,01]; 0,4784
MDS/AML					
Alter (Interaktionstest: p=NC)					
<50	690	1 (0,1)	663	1 (0,2)	0,96 [0,06; 15,39]; 0,9775 0,96 [0,06; 15,33]; 0,9775 0,00 [0,00; 0,00]; 0,9775
50-64	192	0 (0,0)	209	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	1 (0,1)	840	1 (0,1)	0,98 [0,06; 15,62]; 0,9861 0,98 [0,06; 15,57]; 0,9861 0,00 [0,00; 0,00]; 0,9861
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=NC)					
Brusterhaltend	220	0 (0,0)	235	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Einseitige Mastektomie	355	1 (0,3)	352	1 (0,3)	0,99 [0,06; 15,91]; 0,9952 0,99 [0,06; 15,79]; 0,9952 0,00 [-0,01; 0,01]; 0,9952
Beidseitige Mastektomie	336	0 (0,0)	315	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Nein	870	1 (0,1)	866	1 (0,1)	1,00 [0,06; 15,94]; 0,9974 1,00 [0,06; 15,89]; 0,9974 0,00 [0,00; 0,00]; 0,9974
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	1 (0,6)	176	0 (0,0)	3,07 [0,12; 75,87]; 0,4931 3,05 [0,13; 74,40]; 0,4935 0,01 [-0,01; 0,02]; 0,4735
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Bilaterale Oophorektomie (Interaktionstest: p=NC)					
Ja	189	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Nein	722	1 (0,1)	728	1 (0,1)	1,01 [0,06; 16,15]; 0,9953 1,01 [0,06; 16,09]; 0,9953 0,00 [0,00; 0,00]; 0,9953
BRCA-Mutationsstatus (Interaktionstest: p=NC)					
BRCA1	574	0 (0,0)	580	1 (0,2)	0,34 [0,01; 8,27]; 0,5048 0,34 [0,01; 8,25]; 0,5049 0,00 [-0,01; 0,00]; 0,4794
BRCA2	232	0 (0,0)	215	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	0 (0,0)	383	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=NC)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	1 (0,4)	271	1 (0,4)	1,05 [0,07; 16,82]; 0,9744 1,05 [0,07; 16,64]; 0,9744 0,00 [-0,01; 0,01]; 0,9744
Kaukasisch	617	0 (0,0)	589	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	1 (0,1)	803	1 (0,1)	1,01 [0,06; 16,12]; 0,9965 1,01 [0,06; 16,06]; 0,9965 0,00 [0,00; 0,00]; 0,9965
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Hormonrezeptorstatus (Interaktionstest: p=NC)					
ER- und/oder PgR-positiv, HER2-positiv	168	0 (0,0)	155	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
TNBC	741	1 (0,1)	749	1 (0,1)	1,01 [0,06; 16,19]; 0,9939 1,01 [0,06; 16,13]; 0,9939 0,00 [0,00; 0,00]; 0,9939
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,3531)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	0 (0,0)	63	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,03; 0,03]; 1,0000
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	0 (0,0)	362	1 (0,3)	0,35 [0,01; 8,52]; 0,5159 0,35 [0,01; 8,48]; 0,5161 0,00 [-0,01; 0,00]; 0,4820
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	1 (0,3)	387	0 (0,0)	2,96 [0,12; 72,93]; 0,5065 2,95 [0,12; 72,30]; 0,5067 0,00 [0,00; 0,01]; 0,4794
Menopausenstatus (Interaktionstest: p=0,3549)					
Postmenopausal	346	0 (0,0)	356	1 (0,3)	0,34 [0,01; 8,42]; 0,5116 0,34 [0,01; 8,39]; 0,5118 0,00 [-0,01; 0,00]; 0,4807
Prämenopausal	563	1 (0,2)	544	0 (0,0)	2,90 [0,12; 71,44]; 0,5141 2,90 [0,12; 71,01]; 0,5143 0,00 [0,00; 0,01]; 0,4821

OlympiA-Studie Endpunkt Subgruppe	Olaparib		Placebo		Behandlungseffekt Olaparib vs. Placebo
	N	n (%)	N	n (%)	OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]
Region (Interaktionstest: p=NC)					
Asien-Pazifik und Südafrika	301	1 (0,3)	317	1 (0,3)	1,05 [0,07; 16,92]; 0,9707 1,05 [0,07; 16,76]; 0,9707 0,00 [-0,01; 0,01]; 0,9708
Europa	473	0 (0,0)	444	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,3444)					
Adjuvant	457	1 (0,2)	450	0 (0,0)	2,96 [0,12; 72,87]; 0,5066 2,95 [0,12; 72,33]; 0,5068 0,00 [0,00; 0,01]; 0,4797
Neoadjuvant	454	0 (0,0)	454	1 (0,2)	0,33 [0,01; 8,19]; 0,5006 0,33 [0,01; 8,16]; 0,5007 0,00 [-0,01; 0,00]; 0,4779
Sponsor (Interaktionstest: p=NC)					
AZ	801	1 (0,1)	796	1 (0,1)	0,99 [0,06; 15,92]; 0,9965 0,99 [0,06; 15,86]; 0,9965 0,00 [0,00; 0,00]; 0,9965
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=NC)					
Ja	243	0 (0,0)	236	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Nein	668	1 (0,2)	668	1 (0,2)	1,00 [0,06; 16,02]; 1,0000 1,00 [0,06; 15,95]; 1,0000 0,00 [0,00; 0,00]; 1,0000
Neue primäre Malignität (ausgenommen MDS/AML)					
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	2 (0,5)	383	6 (1,6)	0,32 [0,06; 1,61]; 0,1671 0,33 [0,07; 1,60]; 0,1678 -0,01 [-0,02; 0,00]; 0,1476
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Alter (Interaktionstest: p=0,4352)					
<50	690	1 (0,1)	663	9 (1,4)	0,11 [0,01; 0,83]; 0,0331 0,11 [0,01; 0,84]; 0,0336 -0,01 [-0,02; 0,00]; 0,0102
50-64	192	3 (1,6)	209	6 (2,9)	0,54 [0,13; 2,18]; 0,3841 0,54 [0,14; 2,15]; 0,3848 -0,01 [-0,04; 0,02]; 0,3706
≥65	29	0 (0,0)	32	1 (3,1)	0,36 [0,01; 9,09]; 0,5320 0,37 [0,02; 8,66]; 0,5340 -0,03 [-0,12; 0,05]; 0,4688
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=0,9103)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	4 (0,5)	840	14 (1,7)	0,28 [0,09; 0,84]; 0,0234 0,28 [0,09; 0,84]; 0,0237 -0,01 [-0,02; 0,00]; 0,0160
Taxan	43	0 (0,0)	50	2 (4,0)	0,22 [0,01; 4,77]; 0,3371 0,23 [0,01; 4,70]; 0,3411 -0,04 [-0,11; 0,03]; 0,2421
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,3136)					
Brusterhaltend	220	1 (0,5)	235	1 (0,4)	1,07 [0,07; 17,19]; 0,9627 1,07 [0,07; 16,97]; 0,9627 0,00 [-0,01; 0,01]; 0,9628
Einseitige Mastektomie	355	3 (0,9)	352	7 (2,0)	0,42 [0,11; 1,64]; 0,2115 0,42 [0,11; 1,63]; 0,2122 -0,01 [-0,03; 0,01]; 0,1982
Beidseitige Mastektomie	336	0 (0,0)	315	8 (2,5)	0,05 [0,00; 0,94]; 0,0449 0,06 [0,00; 0,95]; 0,0461 -0,03 [-0,04; -0,01]; 0,0065
Aschkenasische jüdische Abstammung (Interaktionstest: p=0,7566)					
Ja	41	0 (0,0)	35	2 (5,7)	0,16 [0,01; 3,48]; 0,2444 0,17 [0,01; 3,46]; 0,2498 -0,06 [-0,15; 0,03]; 0,2097
Nein	870	4 (0,5)	866	14 (1,6)	0,28 [0,09; 0,86]; 0,0257 0,28 [0,09; 0,86]; 0,0260 -0,01 [-0,02; 0,00]; 0,0173
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=0,6075)					
Positiv	173	0 (0,0)	176	5 (2,8)	0,09 [0,00; 1,64]; 0,1038 0,09 [0,01; 1,66]; 0,1061 -0,03 [-0,06; 0,00]; 0,0375

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Negativ	200	1 (0,5)	191	4 (2,1)	0,23 [0,03; 2,12]; 0,1970 0,24 [0,03; 2,12]; 0,1983 -0,02 [-0,04; 0,01]; 0,1656
Bilaterale Oophorektomie (Interaktionstest: p=0,8266)					
Ja	189	1 (0,5)	176	3 (1,7)	0,31 [0,03; 2,98]; 0,3081 0,31 [0,03; 2,96]; 0,3090 -0,01 [-0,03; 0,01]; 0,2893
Nein	722	3 (0,4)	728	13 (1,8)	0,23 [0,07; 0,81]; 0,0220 0,23 [0,07; 0,81]; 0,0224 -0,01 [-0,02; 0,00]; 0,0121
BRCA-Mutationsstatus (Interaktionstest: p=0,4472)					
BRCA1	574	2 (0,4)	580	13 (2,2)	0,15 [0,03; 0,68]; 0,0136 0,16 [0,04; 0,69]; 0,0140 -0,02 [-0,03; -0,01]; 0,0042
BRCA2	232	1 (0,4)	215	2 (0,9)	0,46 [0,04; 5,12]; 0,5285 0,46 [0,04; 5,07]; 0,5287 0,00 [-0,02; 0,01]; 0,5240
Ethnie (Interaktionstest: p=0,9538)					
Andere	16	0 (0,0)	15	1 (6,7)	0,29 [0,01; 7,76]; 0,4628 0,31 [0,01; 7,15]; 0,4675 -0,07 [-0,23; 0,10]; 0,4252
Asiatisch	259	1 (0,4)	271	3 (1,1)	0,35 [0,04; 3,35]; 0,3597 0,35 [0,04; 3,33]; 0,3603 -0,01 [-0,02; 0,01]; 0,3321
Kaukasisch	617	3 (0,5)	589	12 (2,0)	0,23 [0,07; 0,84]; 0,0254 0,24 [0,07; 0,84]; 0,0258 -0,02 [-0,03; 0,00]; 0,0163
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=0,9541)					
Hispanisch	34	0 (0,0)	24	1 (4,2)	0,23 [0,01; 5,82]; 0,3703 0,24 [0,01; 5,61]; 0,3733 -0,04 [-0,14; 0,06]; 0,4190
Nicht-hispanisch	798	4 (0,5)	803	13 (1,6)	0,31 [0,10; 0,94]; 0,0392 0,31 [0,10; 0,95]; 0,0396 -0,01 [-0,02; 0,00]; 0,0286
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	2 (2,6)	0,19 [0,01; 4,02]; 0,2862 0,20 [0,01; 4,00]; 0,2888 -0,03 [-0,07; 0,02]; 0,2335

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Hormonrezeptorstatus (Interaktionstest: p=0,8335)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	3 (1,9)	0,30 [0,03; 2,95]; 0,3039 0,31 [0,03; 2,93]; 0,3049 -0,01 [-0,04; 0,01]; 0,2858
TNBC	741	3 (0,4)	749	13 (1,7)	0,23 [0,07; 0,81]; 0,0223 0,23 [0,07; 0,82]; 0,0226 -0,01 [-0,02; 0,00]; 0,0122
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,5425)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	2 (2,2)	0,17 [0,01; 3,66]; 0,2598 0,18 [0,01; 3,64]; 0,2619 -0,02 [-0,06; 0,01]; 0,2289
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	1 (1,6)	0,98 [0,06; 16,09]; 0,9910 0,98 [0,06; 15,40]; 0,9910 0,00 [-0,04; 0,04]; 0,9910
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	2 (0,6)	362	4 (1,1)	0,52 [0,09; 2,84]; 0,4484 0,52 [0,10; 2,82]; 0,4486 -0,01 [-0,02; 0,01]; 0,4373
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	1 (0,3)	387	9 (2,3)	0,11 [0,01; 0,85]; 0,0345 0,11 [0,01; 0,86]; 0,0354 -0,02 [-0,04; 0,00]; 0,0103
Menopausenstatus (Interaktionstest: p=0,3546)					
Postmenopausal	346	3 (0,9)	356	8 (2,3)	0,38 [0,10; 1,45]; 0,1561 0,39 [0,10; 1,44]; 0,1569 -0,01 [-0,03; 0,00]; 0,1379
Prämenopausal	563	1 (0,2)	544	8 (1,5)	0,12 [0,01; 0,96]; 0,0453 0,12 [0,02; 0,96]; 0,0459 -0,01 [-0,02; 0,00]; 0,0178
Region (Interaktionstest: p=0,9758)					
Asien-Pazifik und Südafrika	301	1 (0,3)	317	5 (1,6)	0,21 [0,02; 1,79]; 0,1529 0,21 [0,02; 1,79]; 0,1539 -0,01 [-0,03; 0,00]; 0,1079
Europa	473	3 (0,6)	444	8 (1,8)	0,35 [0,09; 1,32]; 0,1206 0,35 [0,09; 1,32]; 0,1212 -0,01 [-0,03; 0,00]; 0,1093
Nordamerika	121	0 (0,0)	131	2 (1,5)	0,21 [0,01; 4,49]; 0,3200 0,22 [0,01; 4,46]; 0,3215 -0,02 [-0,04; 0,01]; 0,2474
Südamerika	16	0 (0,0)	12	1 (8,3)	0,23 [0,01; 6,22]; 0,3843 0,25 [0,01; 5,76]; 0,3902 -0,08 [-0,27; 0,11]; 0,3933

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Art der vorherigen Chemotherapie (Interaktionstest: p=0,6389)					
Adjuvant	457	2 (0,4)	450	10 (2,2)	0,19 [0,04; 0,89]; 0,0346 0,20 [0,04; 0,89]; 0,0353 -0,02 [-0,03; 0,00]; 0,0189
Neoadjuvant	454	2 (0,4)	454	6 (1,3)	0,33 [0,07; 1,65]; 0,1764 0,33 [0,07; 1,64]; 0,1770 -0,01 [-0,02; 0,00]; 0,1550
Sponsor (Interaktionstest: p=0,8225)					
AZ	801	4 (0,5)	796	14 (1,8)	0,28 [0,09; 0,86]; 0,0255 0,28 [0,09; 0,86]; 0,0258 -0,01 [-0,02; 0,00]; 0,0171
NRG Oncology	110	0 (0,0)	108	2 (1,9)	0,19 [0,01; 4,06]; 0,2898 0,20 [0,01; 4,04]; 0,2916 -0,02 [-0,05; 0,01]; 0,2377
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=0,4796)					
Ja	243	0 (0,0)	236	4 (1,7)	0,11 [0,01; 1,98]; 0,1331 0,11 [0,01; 1,99]; 0,1346 -0,02 [-0,04; 0,00]; 0,0692
Nein	668	4 (0,6)	668	12 (1,8)	0,33 [0,11; 1,03]; 0,0555 0,33 [0,11; 1,03]; 0,0559 -0,01 [-0,02; 0,00]; 0,0439
Pneumonitis					
Alter (Interaktionstest: p=0,1889)					
<50	690	3 (0,4)	663	0 (0,0)	6,76 [0,35; 131,04]; 0,2067 6,73 [0,35; 129,97]; 0,2071 0,00 [0,00; 0,01]; 0,1342
50-64	192	0 (0,0)	209	1 (0,5)	0,36 [0,01; 8,92]; 0,5335 0,36 [0,01; 8,85]; 0,5338 0,00 [-0,02; 0,01]; 0,4860
≥65	29	0 (0,0)	32	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,06; 0,06]; 1,0000
Vorherige neoadjuvante/adjuvante Chemotherapie (Interaktionstest: p=NC)					
Anthrazyklin	7	0 (0,0)	13	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,19; 0,19]; 1,0000
Anthrazyklin und Taxan	861	3 (0,4)	840	1 (0,1)	2,93 [0,30; 28,26]; 0,3517 2,93 [0,31; 28,08]; 0,3519 0,00 [0,00; 0,01]; 0,3257
Taxan	43	0 (0,0)	50	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,04; 0,04]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
Art der Brustoperation vor der Randomisierung (Interaktionstest: p=0,8301)					
Brusterhaltend	220	1 (0,5)	235	0 (0,0)	3,22 [0,13; 79,43]; 0,4748 3,20 [0,13; 78,23]; 0,4751 0,00 [-0,01; 0,02]; 0,4693
Einseitige Mastektomie	355	1 (0,3)	352	1 (0,3)	0,99 [0,06; 15,91]; 0,9952 0,99 [0,06; 15,79]; 0,9952 0,00 [-0,01; 0,01]; 0,9952
Beidseitige Mastektomie	336	1 (0,3)	315	0 (0,0)	2,82 [0,11; 69,51]; 0,5258 2,81 [0,12; 68,80]; 0,5260 0,00 [-0,01; 0,01]; 0,4848
Aschkenasische jüdische Abstammung (Interaktionstest: p=NC)					
Ja	41	0 (0,0)	35	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,05; 0,05]; 1,0000
Nein	870	3 (0,3)	866	1 (0,1)	2,99 [0,31; 28,83]; 0,3428 2,99 [0,31; 28,65]; 0,3430 0,00 [0,00; 0,01]; 0,3183
Axillärer Lymphknotenstatus bei der Operation vor der Randomisierung (für TNBC nur post-adjuvante) (Interaktionstest: p=NC)					
Positiv	173	1 (0,6)	176	1 (0,6)	1,02 [0,06; 16,40]; 0,9903 1,02 [0,06; 16,14]; 0,9903 0,00 [-0,02; 0,02]; 0,9903
Negativ	200	0 (0,0)	191	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Bilaterale Oophorektomie (Interaktionstest: p=NC)					
Ja	189	0 (0,0)	176	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Nein	722	3 (0,4)	728	1 (0,1)	3,03 [0,31; 29,23]; 0,3370 3,02 [0,32; 29,01]; 0,3373 0,00 [0,00; 0,01]; 0,3135
BRCA-Mutationsstatus (Interaktionstest: p=NC)					
BRCA1	574	0 (0,0)	580	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [0,00; 0,00]; 1,0000
BRCA2	232	1 (0,4)	215	0 (0,0)	2,79 [0,11; 68,92]; 0,5301 2,78 [0,11; 67,90]; 0,5304 0,00 [-0,01; 0,02]; 0,4852

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
CPS&EG-Score zu Baseline (nur post-neoadjuvante) (Interaktionstest: p=NC)					
2, 3 oder 4	392	1 (0,3)	383	0 (0,0)	2,94 [0,12; 72,36]; 0,5096 2,93 [0,12; 71,73]; 0,5098 0,00 [0,00; 0,01]; 0,4803
5 oder 6	22	0 (0,0)	14	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,11; 0,11]; 1,0000
Ethnie (Interaktionstest: p=0,8777)					
Andere	16	0 (0,0)	15	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,12; 0,12]; 1,0000
Asiatisch	259	2 (0,8)	271	1 (0,4)	2,10 [0,19; 23,31]; 0,5454 2,09 [0,19; 22,94]; 0,5455 0,00 [-0,01; 0,02]; 0,5394
Kaukasisch	617	1 (0,2)	589	0 (0,0)	2,87 [0,12; 70,56]; 0,5190 2,86 [0,12; 70,17]; 0,5191 0,00 [0,00; 0,01]; 0,4836
Schwarz oder afroamerikanisch	19	0 (0,0)	29	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,08; 0,08]; 1,0000
Ethnische Abstammung (Interaktionstest: p=NC)					
Hispanisch	34	0 (0,0)	24	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,07; 0,07]; 1,0000
Nicht-hispanisch	798	3 (0,4)	803	1 (0,1)	3,03 [0,31; 29,16]; 0,3380 3,02 [0,31; 28,96]; 0,3382 0,00 [0,00; 0,01]; 0,3143
Unbekannt, nicht erfasst, verweigert	79	0 (0,0)	77	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Hormonrezeptorstatus (Interaktionstest: p=0,8773)					
ER- und/oder PgR-positiv, HER2-positiv	168	1 (0,6)	155	0 (0,0)	2,79 [0,11; 68,88]; 0,5315 2,77 [0,11; 67,48]; 0,5318 0,01 [-0,01; 0,02]; 0,4846
TNBC	741	2 (0,3)	749	1 (0,1)	2,02 [0,18; 22,37]; 0,5651 2,02 [0,18; 22,25]; 0,5651 0,00 [0,00; 0,01]; 0,5577
Hormonrezeptorstatus nach Art der vorherigen Chemotherapie (Interaktionstest: p=0,8260)					
ER- und/oder PgR-positiv mit neoadjuvanter Chemotherapie	104	0 (0,0)	92	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo**
	N	**n (%)**	**N**	**n (%)**	**OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
ER- und/oder PgR-positiv mit adjuvanter Chemotherapie	64	1 (1,6)	63	0 (0,0)	3,00 [0,12; 75,04]; 0,5036 2,95 [0,12; 71,17]; 0,5047 0,02 [-0,03; 0,06]; 0,4701
ER- und PgR-negativ mit neoadjuvanter Chemotherapie	348	1 (0,3)	362	0 (0,0)	3,13 [0,13; 77,08]; 0,4852 3,12 [0,13; 76,34]; 0,4854 0,00 [0,00; 0,01]; 0,4732
ER- und PgR-negativ mit adjuvanter Chemotherapie	393	1 (0,3)	387	1 (0,3)	0,98 [0,06; 15,80]; 0,9913 0,98 [0,06; 15,69]; 0,9913 0,00 [-0,01; 0,01]; 0,9913
Menopausenstatus (Interaktionstest: p=NC)					
Postmenopausal	346	0 (0,0)	356	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Prämenopausal	563	3 (0,5)	544	1 (0,2)	2,91 [0,30; 28,05]; 0,3558 2,90 [0,30; 27,78]; 0,3560 0,00 [0,00; 0,01]; 0,3290
Region (Interaktionstest: p=0,8867)					
Asien-Pazifik und Südafrika	301	2 (0,7)	317	1 (0,3)	2,11 [0,19; 23,43]; 0,5420 2,11 [0,19; 23,11]; 0,5422 0,00 [-0,01; 0,01]; 0,5363
Europa	473	1 (0,2)	444	0 (0,0)	2,82 [0,11; 69,46]; 0,5255 2,82 [0,12; 68,96]; 0,5257 0,00 [0,00; 0,01]; 0,4853
Nordamerika	121	0 (0,0)	131	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000
Südamerika	16	0 (0,0)	12	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,13; 0,13]; 1,0000
Art der vorherigen Chemotherapie (Interaktionstest: p=0,8365)					
Adjuvant	457	2 (0,4)	450	1 (0,2)	1,97 [0,18; 21,84]; 0,5794 1,97 [0,18; 21,64]; 0,5795 0,00 [-0,01; 0,01]; 0,5711
Neoadjuvant	454	1 (0,2)	454	0 (0,0)	3,01 [0,12; 74,00]; 0,5006 3,00 [0,12; 73,45]; 0,5007 0,00 [0,00; 0,01]; 0,4779
Sponsor (Interaktionstest: p=NC)					
AZ	801	3 (0,4)	796	1 (0,1)	2,99 [0,31; 28,79]; 0,3435 2,98 [0,31; 28,60]; 0,3437 0,00 [0,00; 0,01]; 0,3188
NRG Oncology	110	0 (0,0)	108	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,02; 0,02]; 1,0000

OlympiA-Studie Endpunkt Subgruppe	**Olaparib**		**Placebo**		**Behandlungseffekt Olaparib vs. Placebo OR [95%-KI];p-Wert[a] RR [95%-KI]; p-Wert[a] RD [95%-KI]; p-Wert[a]**
	N	**n (%)**	**N**	**n (%)**	
Vorherige Platin-basierte Chemotherapie bei Brustkrebs (Interaktionstest: p=NC)					
Ja	243	0 (0,0)	236	0 (0,0)	NC [NC; NC]; NC NC [NC; NC]; NC 0,00 [-0,01; 0,01]; 1,0000
Nein	668	3 (0,5)	668	1 (0,2)	3,01 [0,31; 29,00]; 0,3406 3,00 [0,31; 28,77]; 0,3408 0,00 [0,00; 0,01]; 0,3164

Datenschnitt: 12.07.2021; Analyse-Set: Safety-Analysis-Set
a: Die Berechnung von OR, RR und RD erfolgte auf Basis der Vierfeldertafel.