Dossier zur Nutzenbewertung gemäß § 35a SGB V

Durvalumab (IMFINZI®)

AstraZeneca GmbH

Modul 4 A – Anhang 4-G

IMFINZI® in Kombination mit Carboplatin und Paclitaxel ist angezeigt zur Erstlinienbehandlung des primär fortgeschrittenen oder rezidivierenden Endometriumkarzinoms bei Erwachsenen, die für eine systemische Therapie infrage kommen, gefolgt von einer Erhaltungstherapie mit IMFINZI® in Kombination mit Olaparib beim Endometriumkarzinom mit Mismatch-Reparatur-Profizienz (pMMR)

Weitere Analysen und Kaplan-Meier-Kurven zu den in Abschnitt 4.3.1.3 gezeigten Ergebnissen

Stand: 21.08.2024

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Table 1.1.2.1D DUO-E (pMMR Durva/Ola): Summary of observation period (months) for efficacy endpoints
Patients with pMMR tumour status, DCO 12APR2023

		CTx + Durvalumab + Olaparib (N=191)	CTx (N=192)
Gesamtüberleben	n	191	192
	Mediane	17,25	16,54
	Min	0,2	0,2
	Max	33,4	32,9
Progressionsfreies Überleben	n	191	192
	Mediane	12,45	9,49
	Min	0,0	0,0
	Max	31,7	31,6
Progressionsfreies Überleben 2	n	191	192
	Mediane	13,31	12,45
	Min	0,0	0,0
	Max	31,7	31,6
Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod	n	191	192
	Mediane	14,32	10,94
	Min	0,2	0,2
	Max	33,4	32,9
Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod	n	191	192
	Mediane	16,30	15,47
	Min	0,2	0,2
	Max	33,4	32,9
Zeit bis zum Absetzen der Therapie od. Tod	n	191	192
	Mediane	13,01	9,30
	Min	0,0	0,0
	Max	33,2	32,9

Observation period for an efficacy endpoint is defined as the time from randomisation to the date of that event, if occurred or otherwise, to the date of the last evaluable assessment of that efficacy endpoint.
CTx = Carboplatin + Paclitaxel.
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Table 2.1.2 DUO-E (pMMR Durva/Ola): Summary of observation period (months) for PRO endpoints
Patients with pMMR tumour status, DCO 12APR2023

		CTx + Durvalumab + Olaparib (N=191)	CTx (N=192)
EORTC QLQ-C30	n	191	192
	Mediane	12,39	9,63
	Min	0,0	0,0
	Max	32,8	32,6
EORTC QLQ-EN24	n	191	192
	Mediane	11,66	9,61
	Min	0,0	0,0
	Max	32,8	32,6
EQ-5D visuelle Analogskala	n	191	192
	Mediane	11,66	9,59
	Min	0,0	0,0
	Max	32,8	32,6
PGIS	n	191	192
	Mediane	11,66	9,59
	Min	0,0	0,0
	Max	32,8	32,6
PGIC	n	191	192
	Mediane	13,27	10,33
	Min	0,0	0,0
	Max	32,8	32,6
PGI-TT	n	191	192
	Mediane	10,41	7,36
	Min	0,0	0,0
	Max	32,8	32,6

Observation period for PROs is defined as the time from randomisation to the earliest date of the last assessment of questionnaire, death or date of data cut-off (DCO). Patients without any baseline (excluding PGIC) or post baseline measurements are summarised with duration of 1 day.
CTx = Carboplatin + Paclitaxel.
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Table 3.1.2.1D DUO-E (pMMR Durva/Ola): Summary of observation period (months) for safety outcomes
Patients with pMMR tumour status, DCO 12APR2023

		CTx + Durvalumab + Olaparib (N=191)	CTx (N=190)
AE/AESI (excl. NPM and MDS/AML) [a]	n	191	190
	Mediane	12,45	10,14
	Min	0,2	0,2
	Max	33,2	32,9
AESI: NPM and MDS/AML [b]	n	191	190
	Mediane	17,05	16,49
	Min	0,2	0,2
	Max	33,3	32,9

[a] Observation period is defined as the duration from the date of first dose of study treatment until the initiation of the first subsequent anti-cancer therapy following discontinuation of study treatment or until the end of safety follow-up period (latest of either 30 days following discontinuation of olaparib/placebo or 90 days following discontinuation of durvalumab/placebo), whichever occurs first.
[b] Observation period is defined as the duration from the date of first dose of study treatment until study withdrawal or completion or lost to follow-up or death.

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Table 1.1.2.2D DUO-E (pMMR Durva/Ola): Summary of observation period (months) for overall survival
Patients with pMMR tumour status, DCO 18OCT2023

		CTx + Durvalumab + Olaparib (N=191)	CTx (N=192)
Gesamtüberleben	n	191	192
	Mediane	22,18	21,39
	Min	0,2	0,2
	Max	39,7	39,1

Observation period for an efficacy endpoint is defined as the time from randomisation to the date of that event, if occurred or otherwise, to the date of the last evaluable assessment of that efficacy endpoint.
CTx = Carboplatin + Paclitaxel.
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Table 3.1.2.2D DUO-E (pMMR Durva/Ola): Summary of observation period (months) for safety outcomes
Patients with pMMR tumour status, DCO 18OCT2023

		CTx + Durvalumab + Olaparib (N=191)	CTx (N=190)
AE/AESI (excl. NPM and MDS/AML) [a]	n	191	190
	Mediane	12,45	10,14
	Min	0,2	0,2
	Max	39,4	39,1
AESI: NPM and MDS/AML [b]	n	191	190
	Mediane	21,95	21,39
	Min	0,2	0,2
	Max	39,6	39,1

[a] Observation period is defined as the duration from the date of first dose of study treatment until the initiation of the first subsequent anti-cancer therapy following discontinuation of study treatment or until the end of safety follow-up period (latest of either 30 days following discontinuation of olaparib/placebo or 90 days following discontinuation of durvalumab/placebo), whichever occurs first.
[b] Observation period is defined as the duration from the date of first dose of study treatment until study withdrawal or completion or lost to follow-up or death.
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Table 1.2.1.2.2D DUO-E (pMMR Durva/Ola): Summary of analysis of overall survival (OS)
Patients with pMMR tumour status, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Gesamtüberleben	191	64 (33,5)	36,1 [29,8; NE]	192	75 (39,1)	33,4 [26,7; NE]	0,79	[0,56; 1,10]	0,1609

[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached).
[b] Estimated from Cox proportional hazards model stratified by disease status and region.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] p-value estimated using log-rank test stratified by disease status and region.

Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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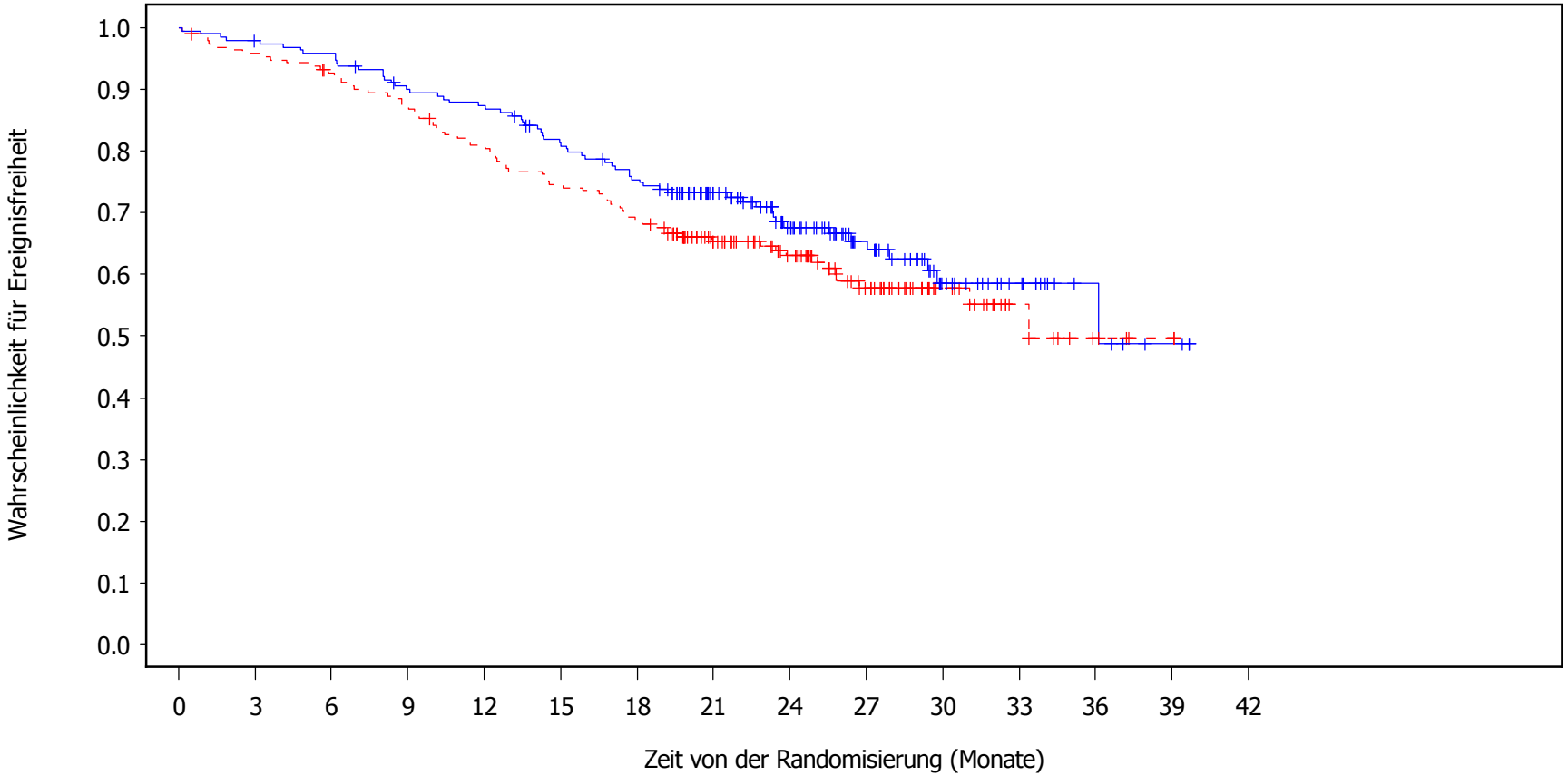
Figure 1.3.1.2.2D DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of overall survival (OS)
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	186	182	169	164	150	138	105	76	50	25	15	6	2	0	CTx + Durvalumab + Olaparib
192	183	175	165	152	140	129	98	77	50	25	10	4	1	0	CTx

CTx = Carboplatin + Paclitaxel.

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Table 1.2.3.2 DUO-E (pMMR Durva/Ola): Summary of analysis of second progression-free survival by investigator
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Progressionsfreies Überleben 2	191	58 (30,4)	NE [NE; NE]	192	76 (39,6)	19,5 [17,4;23,5]	0,66	[0,47; 0,93]	0,0171*

[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached).
[b] Estimated from Cox proportional hazards model stratified by disease status and region.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] p-value estimated using log-rank test stratified by disease status and region.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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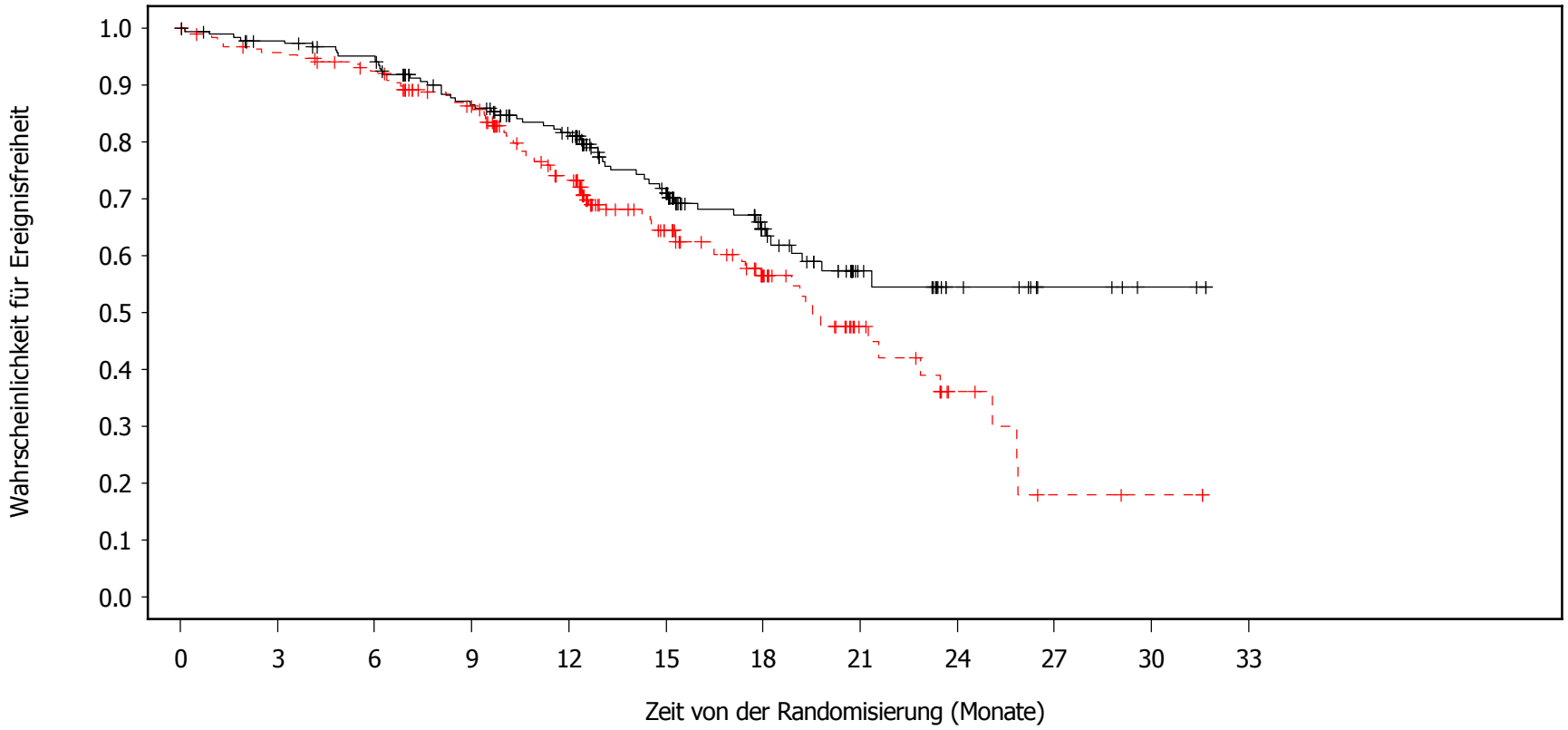
Figure 1.3.3.2 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of second progression-free survival by investigator
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	182	174	148	129	90	47	22	12	5	2	0	CTx + Durvalumab + Olaparib
192	181	171	149	113	67	40	18	7	2	1	0	CTx

CTx = Carboplatin + Paclitaxel.

Table 1.2.4.2 DUO-E (pMMR Durva/Ola): Summary of analysis of time to first subsequent cancer therapy or death
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod	191	94 (49,2)	19,1 [15,7;24,9]	192	132 (68,8)	11,7 [10,4;13,1]	0,55	[0,42; 0,71]	<0,0001*

[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached).
[b] Estimated from Cox proportional hazards model stratified by disease status and region.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] p-value estimated using log-rank test stratified by disease status and region.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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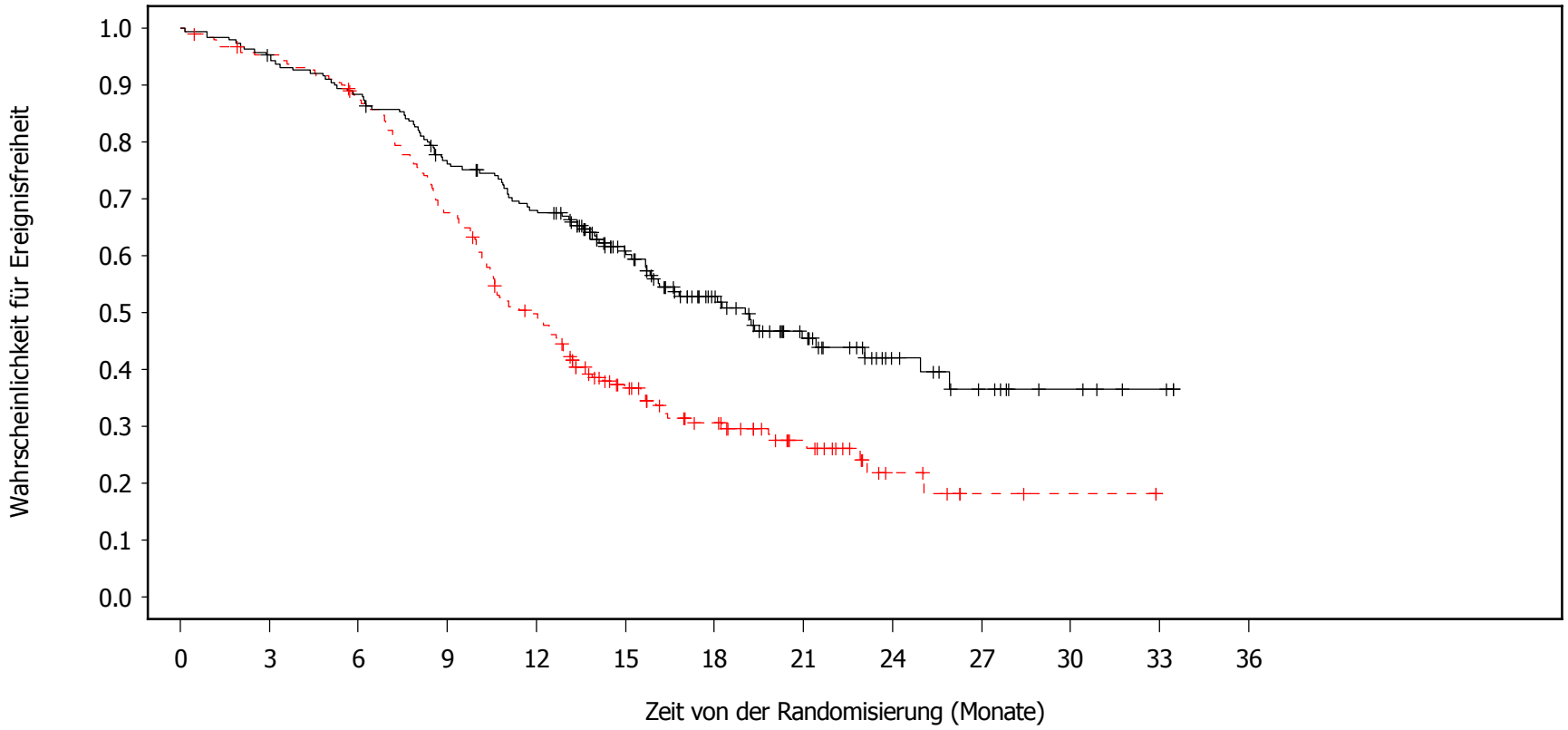
Figure 1.3.4.2 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first subsequent cancer therapy or death
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	181	168	143	125	88	56	35	17	10	5	2	0	CTx + Durvalumab + Olaparib
192	181	165	127	91	54	36	21	7	2	1	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Table 1.2.5.2 DUO-E (pMMR Durva/Ola): Summary of analysis of time to second subsequent cancer therapy or death
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod	191	51 (26,7)	NE [NE; NE]	192	72 (37,5)	25,1 [22,5; NE]	0,67	[0,47; 0,96]	0,0300*

[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached).
[b] Estimated from Cox proportional hazards model stratified by disease status and region.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] p-value estimated using log-rank test stratified by disease status and region.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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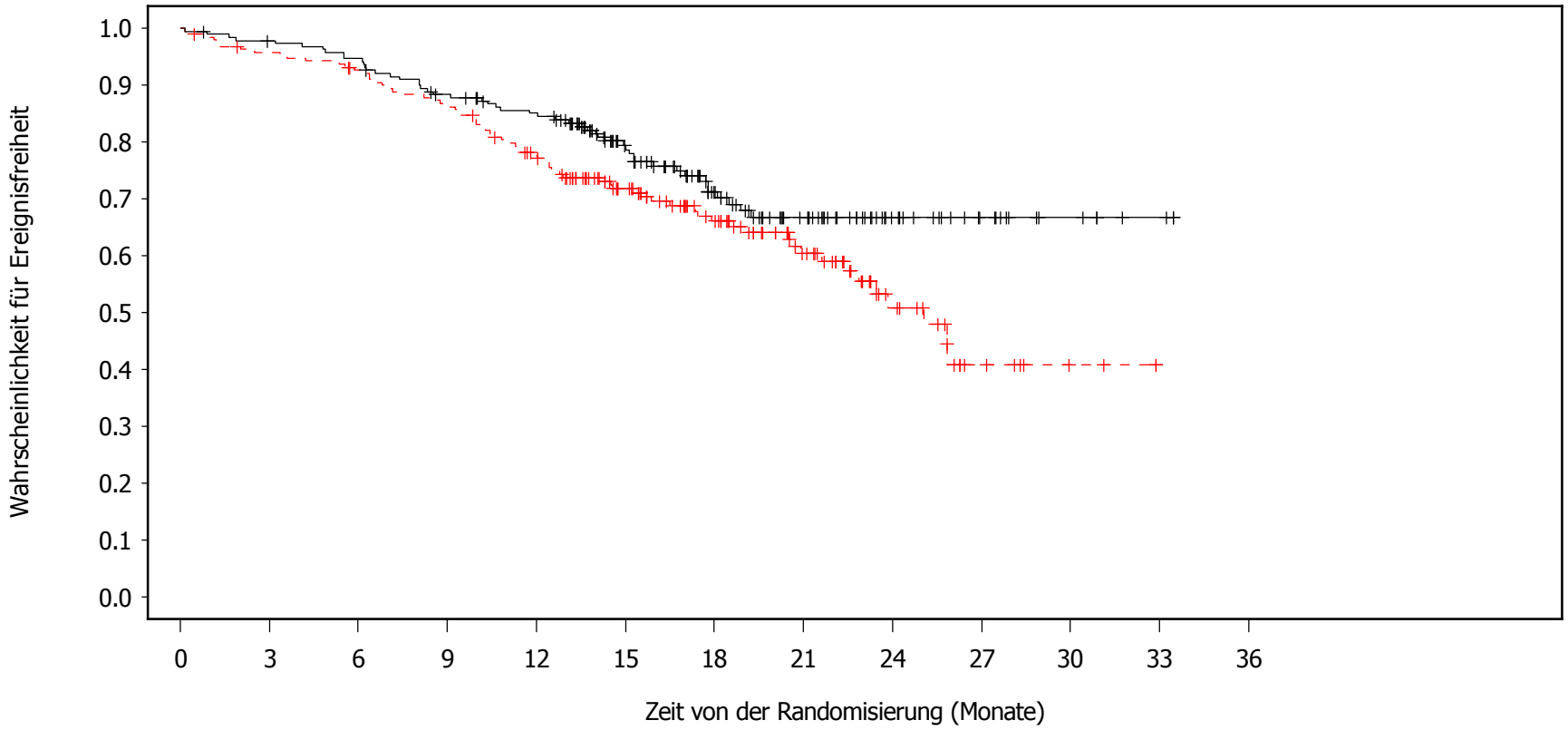
Figure 1.3.5.2 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to second subsequent cancer therapy or death
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	185	179	164	154	108	69	47	24	13	6	2	0	CTx + Durvalumab + Olaparib
192	182	174	163	141	103	74	47	21	7	2	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Table 1.2.6.2 DUO-E (pMMR Durva/Ola): Summary of analysis of time to study treatment discontinuation or death
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Zeit bis zum Absetzen der Therapie od. Tod	191	117 (61,3)	13,4 [10,6;15,6]	192	161 (83,9)	9,3 [8,0; 9,9]	0,54	[0,42; 0,69]	<0,0001*

[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached).
[b] Estimated from Cox proportional hazards model stratified by disease status and region.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] p-value estimated using log-rank test stratified by disease status and region.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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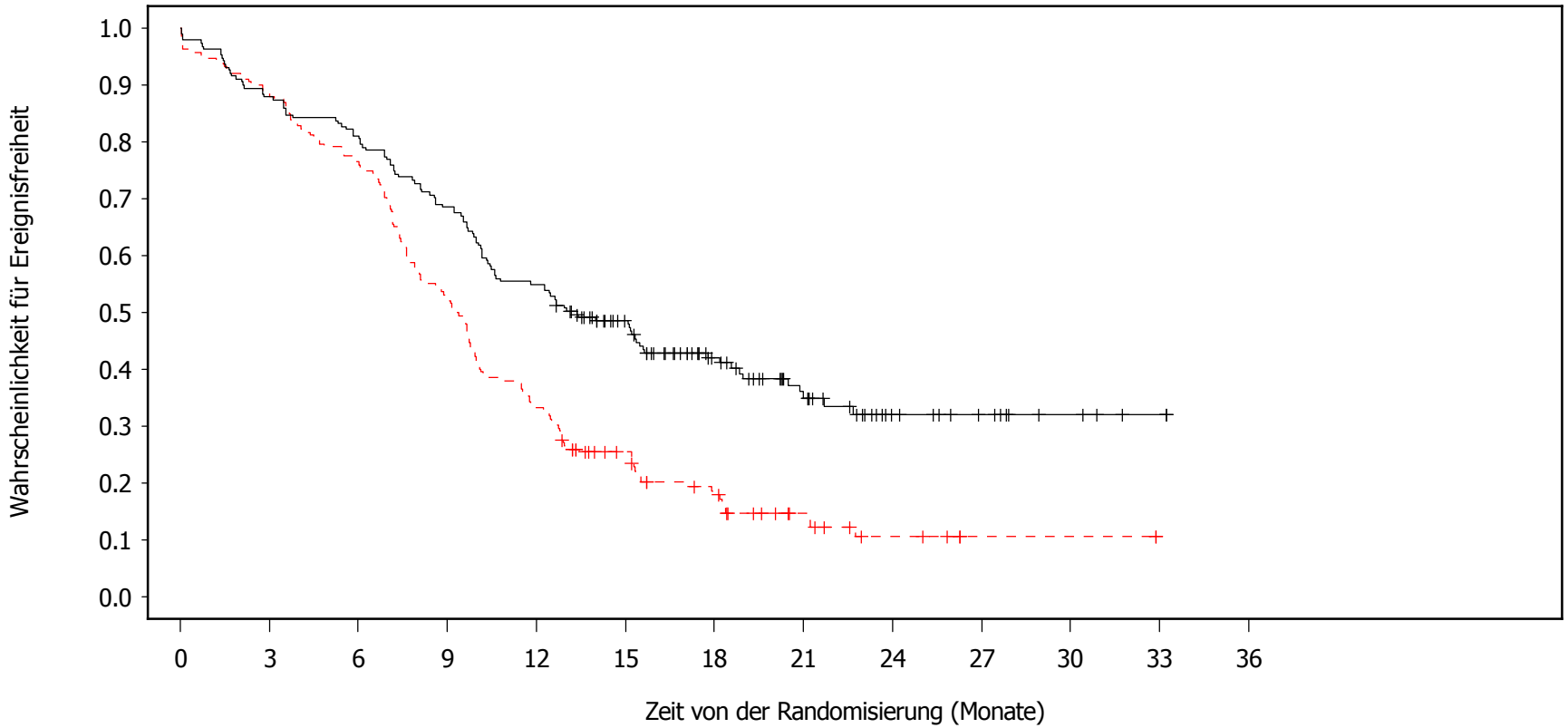
Figure 1.3.6.2 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to study treatment discontinuation or death
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	168	155	131	105	77	48	30	14	9	4	1	0	CTx + Durvalumab + Olaparib
192	170	147	102	64	39	24	12	5	1	1	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Table 2.2.6.2 DUO-E (pMMR Durva/Ola): Summary of analysis of time to first deterioration in PGI-TT
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
PGI-TT	191	138 (72,3)	0,8 [0,8; 0,8]	192	120 (62,5)	0,7 [0,7; 0,8]	0,99	[0,77; 1,28]	0,9412

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening
Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are
censored at the date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be
censored at Day 1.
[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached).
[b] Estimated from Cox proportional hazards model stratified by disease status and region.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] p-value estimated using log-rank test stratified by disease status and region.
Hazard ratio <1 favours CTx + Durvalumab + Olap. * p<0.05. CTx = Carboplatin + Paclitaxel.
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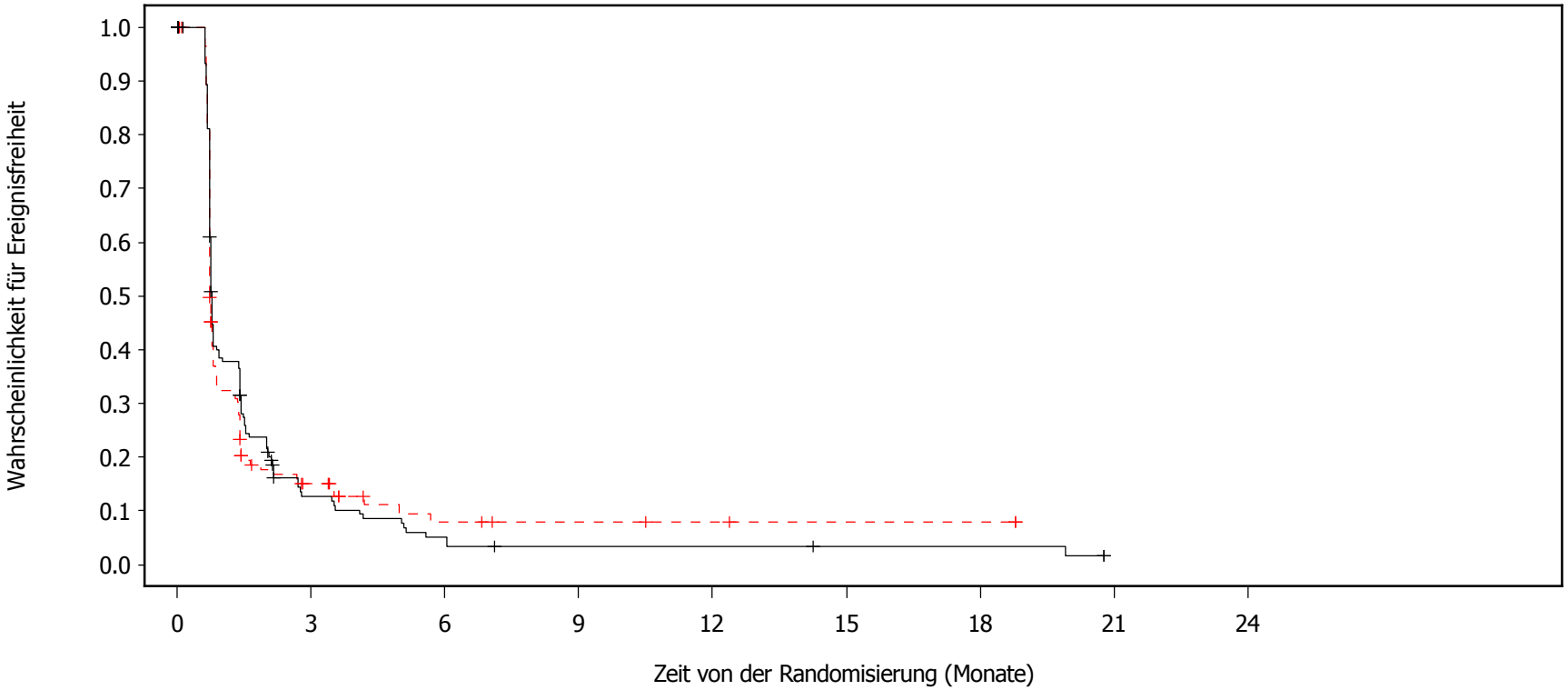
Figure 2.3.6.2.1 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - PGI-TT
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	15	6	3	3	2	2	0	0	CTx + Durvalumab + Olaparib
192	15	5	3	2	1	1	0	0	CTx

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening
Death is not considered an event. Patients with evaluable baseline and no clinically important deterioration are censored at the date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
CTx = Carboplatin + Paclitaxel.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainpr_v2.sas gttemainpr_v2bga 08MAY2024:15:32

Table 2.4.1.2.1 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Allgemeine over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	68,71 (21,684)	-1,86 (1,348)	141	68,91 (19,464)	-1,70 (1,407)	-0,16 [-3,987; 3,677]	0,9365
Tag 43 (Woche 6)	140	69,23 (21,966)	-3,81 (1,511)	134	67,54 (20,265)	-2,12 (1,560)	-1,69 [-5,957; 2,581]	0,4370
Tag 64 (Woche 9)	129	69,70 (21,824)	-3,04 (1,359)	124	68,15 (19,682)	-0,69 (1,404)	-2,35 [-6,196; 1,490]	0,2292
Tag 85 (Woche 12)	128	69,66 (21,603)	-4,69 (1,390)	118	69,14 (19,285)	-3,10 (1,452)	-1,60 [-5,551; 2,358]	0,4275
Tag 106 (Woche 15)	122	68,99 (21,541)	-3,50 (1,402)	117	69,09 (19,849)	-4,62 (1,449)	1,12 [-2,849; 5,085]	0,5794
Tag 127 (Woche 18)	113	71,02 (21,190)	-4,72 (1,540)	99	69,19 (19,027)	-5,15 (1,630)	0,44 [-3,979; 4,851]	0,8461
Tag 155 (Woche 22)	121	69,77 (21,439)	-5,20 (1,489)	109	70,80 (19,432)	0,53 (1,563)	-5,73 [-9,981; -1,483]	0,0084*
Tag 183 (Woche 26)	116	69,76 (21,718)	-3,63 (1,410)	106	71,23 (18,798)	0,27 (1,477)	-3,90 [-7,916; 0,120]	0,0572
Tag 211 (Woche 30)	104	70,59 (20,868)	-3,21 (1,449)	97	70,45 (18,789)	1,32 (1,511)	-4,52 [-8,645; -0,405]	0,0315*
Tag 239 (Woche 34)	102	69,28 (21,334)	-2,01 (1,388)	90	70,93 (19,322)	2,11 (1,474)	-4,12 [-8,106; -0,132]	0,0429*
Tag 267 (Woche 38)	100	69,42 (21,453)	-1,71 (1,419)	89	71,16 (18,208)	1,89 (1,507)	-3,60 [-7,673; 0,478]	0,0834
Tag 295 (Woche 42)	104	70,59 (20,933)	-4,28 (1,509)	90	71,30 (18,322)	-0,84 (1,618)	-3,44 [-7,797; 0,912]	0,1207
Tag 323 (Woche 46)	99	71,13 (21,306)	-2,01 (1,407)	77	72,62 (18,029)	1,80 (1,560)	-3,80 [-7,935; 0,327]	0,0710
Tag 351 (Woche 50)	84	69,25 (22,442)	0,10 (1,376)	81	71,19 (18,402)	-1,85 (1,431)	1,95 [-1,957; 5,865]	0,3261
Tag 379 (Woche 54)	77	71,00 (22,032)	-0,63 (1,699)	69	70,77 (18,448)	-2,13 (1,805)	1,50 [-3,380; 6,382]	0,5452
Tag 407 (Woche 58)	72	72,57 (20,576)	-1,29 (1,738)	58	69,68 (18,581)	-0,57 (1,911)	-0,72 [-5,816; 4,369]	0,7797
Tag 435 (Woche 62)	63	72,49 (20,556)	-1,84 (1,714)	50	67,67 (18,946)	-0,55 (1,904)	-1,28 [-6,353; 3,789]	0,6183

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.1 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Allgemeine over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	68,35 (21,560)	-2,78 (0,936)	149	68,23 (19,980)	-0,91 (0,989)	-1,88 [-4,554; 0,801]	0,1688
Hedges' g SMD							-0,16 [-0,378; 0,067]	0,1696

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbaa 27MAR2024:14:53

Nutzenbewertung nach AMNOG

Table 2.4.1.2.2 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Körper over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	79,66 (21,120)	-4,14 (1,361)	141	81,18 (17,643)	-1,94 (1,415)	-2,20 [-6,057; 1,657]	0,2625
Tag 43 (Woche 6)	140	80,62 (20,759)	-6,29 (1,562)	134	80,45 (18,700)	-3,99 (1,614)	-2,30 [-6,713; 2,113]	0,3058
Tag 64 (Woche 9)	129	80,26 (21,657)	-6,13 (1,514)	124	81,51 (18,010)	-5,14 (1,566)	-1,00 [-5,280; 3,283]	0,6466
Tag 85 (Woche 12)	128	80,63 (20,856)	-8,11 (1,577)	118	82,15 (17,430)	-6,83 (1,645)	-1,28 [-5,759; 3,201]	0,5746
Tag 106 (Woche 15)	122	80,22 (21,750)	-9,38 (1,642)	117	81,99 (17,666)	-7,25 (1,702)	-2,13 [-6,784; 2,515]	0,3669
Tag 127 (Woche 18)	113	81,71 (20,964)	-9,98 (1,707)	99	83,16 (16,088)	-7,68 (1,798)	-2,30 [-7,175; 2,576]	0,3541
Tag 155 (Woche 22)	121	80,17 (22,319)	-8,46 (1,599)	109	82,20 (17,640)	-4,67 (1,673)	-3,80 [-8,346; 0,755]	0,1018
Tag 183 (Woche 26)	116	79,71 (22,797)	-7,17 (1,528)	106	84,09 (16,422)	-3,54 (1,598)	-3,63 [-7,986; 0,719]	0,1015
Tag 211 (Woche 30)	104	81,35 (21,873)	-5,49 (1,454)	97	82,89 (16,185)	-2,43 (1,520)	-3,07 [-7,205; 1,073]	0,1460
Tag 239 (Woche 34)	102	81,11 (21,599)	-3,44 (1,375)	90	83,63 (16,026)	-2,25 (1,458)	-1,19 [-5,130; 2,757]	0,5543
Tag 267 (Woche 38)	100	82,47 (20,271)	-5,10 (1,508)	89	83,37 (15,767)	-0,56 (1,603)	-4,54 [-8,865; -0,207]	0,0401*
Tag 295 (Woche 42)	104	83,46 (19,574)	-5,78 (1,507)	90	82,81 (16,052)	-0,62 (1,612)	-5,16 [-9,497; -0,819]	0,0200*
Tag 323 (Woche 46)	99	81,89 (21,635)	-3,82 (1,341)	77	84,24 (15,743)	-1,18 (1,469)	-2,64 [-6,557; 1,268]	0,1845
Tag 351 (Woche 50)	84	82,70 (21,312)	-2,27 (1,374)	81	83,13 (16,265)	-2,57 (1,446)	0,30 [-3,621; 4,222]	0,8804
Tag 379 (Woche 54)	77	83,20 (20,365)	-3,21 (1,375)	69	83,09 (16,030)	-2,30 (1,469)	-0,92 [-4,871; 3,041]	0,6491
Tag 407 (Woche 58)	72	83,70 (19,441)	-3,03 (1,482)	58	82,64 (16,038)	-2,39 (1,621)	-0,65 [-4,966; 3,673]	0,7685
Tag 435 (Woche 62)	63	85,40 (18,927)	-2,67 (1,569)	50	82,27 (15,800)	-2,01 (1,723)	-0,66 [-5,248; 3,934]	0,7781

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.2 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Körper over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	79,63 (21,701)	-5,56 (1,071)	149	80,27 (19,107)	-3,37 (1,129)	-2,19 [-5,244; 0,873]	0,1608
Hedges' g SMD							-0,16 [-0,381; 0,064]	0,1617

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbab 27MAR2024:14:53

Nutzenbewertung nach AMNOG

Table 2.4.1.2.3 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Rolle over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	77,31 (29,417)	-3,25 (1,793)	141	82,03 (20,322)	-4,94 (1,860)	1,69 [-3,400; 6,775]	0,5143
Tag 43 (Woche 6)	140	80,00 (27,572)	-4,80 (1,993)	134	80,22 (21,646)	-2,23 (2,050)	-2,57 [-8,192; 3,059]	0,3698
Tag 64 (Woche 9)	129	79,46 (29,793)	-6,59 (1,848)	124	81,05 (20,967)	-6,40 (1,903)	-0,19 [-5,413; 5,030]	0,9425
Tag 85 (Woche 12)	128	78,52 (28,841)	-8,82 (1,930)	118	82,20 (21,096)	-9,60 (2,009)	0,79 [-4,699; 6,270]	0,7782
Tag 106 (Woche 15)	122	80,46 (28,321)	-9,52 (1,960)	117	81,77 (20,293)	-12,52 (2,023)	3,00 [-2,541; 8,547]	0,2872
Tag 127 (Woche 18)	113	80,83 (29,143)	-10,03 (2,137)	99	82,32 (20,178)	-12,64 (2,257)	2,60 [-3,515; 8,723]	0,4028
Tag 155 (Woche 22)	121	78,79 (30,200)	-8,47 (2,088)	109	81,96 (21,171)	-6,52 (2,184)	-1,95 [-7,902; 3,996]	0,5187
Tag 183 (Woche 26)	116	78,30 (30,945)	-8,57 (2,029)	106	83,49 (20,892)	-1,04 (2,119)	-7,53 [-13,316; -1,754]	0,0108*
Tag 211 (Woche 30)	104	80,45 (29,417)	-6,91 (1,913)	97	82,65 (19,971)	-1,56 (1,994)	-5,35 [-10,790; 0,094]	0,0541
Tag 239 (Woche 34)	102	80,88 (28,762)	-5,00 (1,875)	90	83,52 (19,592)	-1,52 (1,990)	-3,48 [-8,867; 1,903]	0,2042
Tag 267 (Woche 38)	100	82,17 (27,854)	-4,85 (2,025)	89	83,15 (19,703)	-1,60 (2,148)	-3,24 [-9,053; 2,566]	0,2726
Tag 295 (Woche 42)	104	81,09 (28,259)	-5,08 (1,857)	90	82,96 (20,140)	-0,75 (1,986)	-4,33 [-9,683; 1,022]	0,1124
Tag 323 (Woche 46)	99	79,46 (29,912)	-4,30 (1,891)	77	85,06 (19,606)	-0,05 (2,089)	-4,25 [-9,806; 1,308]	0,1333
Tag 351 (Woche 50)	84	81,55 (27,867)	-2,03 (1,933)	81	82,72 (20,488)	-1,93 (2,010)	-0,10 [-5,593; 5,390]	0,9710
Tag 379 (Woche 54)	77	83,98 (27,365)	-2,33 (1,927)	69	82,13 (20,476)	-1,99 (2,045)	-0,33 [-5,867; 5,200]	0,9056
Tag 407 (Woche 58)	72	84,72 (26,794)	-2,07 (2,213)	58	82,47 (20,334)	-3,94 (2,427)	1,86 [-4,607; 8,328]	0,5712
Tag 435 (Woche 62)	63	82,80 (27,593)	-5,19 (2,348)	50	81,67 (21,626)	-1,37 (2,603)	-3,82 [-10,738; 3,104]	0,2778

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbac 27MAR2024:14:53

Table 2.4.1.2.3 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Rolle over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	77,40 (29,669)	-5,75 (1,295)	149	80,76 (21,463)	-4,15 (1,363)	-1,60 [-5,300; 2,099]	0,3953
Hedges' g SMD							-0,10 [-0,319; 0,126]	0,3959

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbac 27MAR2024:14:53

Nutzenbewertung nach AMNOG

Table 2.4.1.2.4 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Emotionalität over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	75,59 (20,809)	3,57 (1,344)	141	75,53 (17,795)	5,15 (1,406)	-1,58 [-5,403; 2,249]	0,4179
Tag 43 (Woche 6)	140	75,60 (21,007)	4,26 (1,445)	134	73,94 (19,347)	3,23 (1,498)	1,02 [-3,070; 5,115]	0,6232
Tag 64 (Woche 9)	129	75,71 (20,519)	3,60 (1,405)	124	75,27 (18,249)	2,60 (1,456)	1,01 [-2,975; 4,988]	0,6191
Tag 85 (Woche 12)	128	75,20 (20,823)	1,45 (1,606)	118	75,21 (18,149)	3,71 (1,680)	-2,26 [-6,832; 2,313]	0,3315
Tag 106 (Woche 15)	122	76,09 (20,579)	1,16 (1,535)	117	76,00 (18,380)	1,07 (1,592)	0,09 [-4,259; 4,446]	0,9664
Tag 127 (Woche 18)	113	75,81 (20,411)	1,73 (1,595)	99	75,51 (18,854)	-0,51 (1,688)	2,24 [-2,334; 6,807]	0,3363
Tag 155 (Woche 22)	121	74,86 (20,440)	1,01 (1,712)	109	74,54 (18,970)	2,76 (1,799)	-1,76 [-6,642; 3,128]	0,4795
Tag 183 (Woche 26)	116	75,79 (20,647)	2,00 (1,617)	106	75,79 (18,385)	4,20 (1,696)	-2,20 [-6,809; 2,413]	0,3489
Tag 211 (Woche 30)	104	75,16 (21,030)	3,88 (1,626)	97	76,20 (18,595)	2,94 (1,700)	0,94 [-3,688; 5,572]	0,6891
Tag 239 (Woche 34)	102	76,14 (20,211)	2,72 (1,561)	90	77,13 (19,132)	3,20 (1,656)	-0,48 [-4,963; 3,996]	0,8318
Tag 267 (Woche 38)	100	76,00 (18,776)	5,04 (1,529)	89	76,69 (19,184)	3,22 (1,622)	1,82 [-2,566; 6,207]	0,4146
Tag 295 (Woche 42)	104	77,24 (18,442)	3,12 (1,578)	90	76,30 (18,942)	2,72 (1,685)	0,39 [-4,147; 4,936]	0,8642
Tag 323 (Woche 46)	99	78,79 (18,871)	4,23 (1,551)	77	76,62 (19,215)	3,35 (1,699)	0,88 [-3,647; 5,404]	0,7026
Tag 351 (Woche 50)	84	77,48 (18,825)	6,88 (1,495)	81	77,26 (19,321)	2,60 (1,556)	4,28 [0,036; 8,527]	0,0481*
Tag 379 (Woche 54)	77	79,33 (19,290)	6,60 (1,664)	69	77,42 (18,749)	0,88 (1,761)	5,71 [0,950; 10,479]	0,0189*
Tag 407 (Woche 58)	72	76,74 (20,977)	4,08 (1,765)	58	78,16 (18,125)	1,27 (1,938)	2,80 [-2,361; 7,963]	0,2861
Tag 435 (Woche 62)	63	77,78 (18,453)	4,52 (1,630)	50	77,00 (19,163)	1,55 (1,799)	2,97 [-1,818; 7,759]	0,2224

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.4 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Emotionalität over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	75,66 (20,621)	3,52 (1,119)	149	73,83 (19,254)	2,59 (1,182)	0,93 [-2,265; 4,134]	0,5659
Hedges' g SMD							0,06 [-0,157; 0,287]	0,5666

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.5 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Kognition over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	87,42 (16,486)	-0,19 (1,244)	141	87,12 (15,605)	-0,04 (1,300)	-0,15 [-3,694; 3,389]	0,9325
Tag 43 (Woche 6)	140	88,33 (15,956)	-3,62 (1,332)	134	86,57 (17,036)	-2,66 (1,377)	-0,97 [-4,740; 2,805]	0,6141
Tag 64 (Woche 9)	129	87,47 (16,540)	-4,16 (1,312)	124	86,56 (16,691)	-2,52 (1,357)	-1,64 [-5,360; 2,072]	0,3846
Tag 85 (Woche 12)	128	87,89 (16,431)	-6,84 (1,550)	118	87,01 (16,615)	-3,39 (1,621)	-3,44 [-7,858; 0,973]	0,1260
Tag 106 (Woche 15)	122	87,57 (16,257)	-5,13 (1,587)	117	86,75 (16,744)	-6,90 (1,643)	1,76 [-2,731; 6,261]	0,4404
Tag 127 (Woche 18)	113	86,28 (17,141)	-5,79 (1,474)	99	87,04 (15,893)	-5,26 (1,559)	-0,53 [-4,751; 3,695]	0,8056
Tag 155 (Woche 22)	121	86,64 (17,027)	-4,96 (1,462)	109	87,31 (16,957)	-4,91 (1,535)	-0,04 [-4,217; 4,128]	0,9833
Tag 183 (Woche 26)	116	86,64 (17,056)	-7,32 (1,600)	106	87,74 (16,793)	-4,06 (1,677)	-3,25 [-7,815; 1,309]	0,1615
Tag 211 (Woche 30)	104	87,02 (17,681)	-4,30 (1,477)	97	88,14 (15,767)	-4,16 (1,543)	-0,14 [-4,343; 4,069]	0,9490
Tag 239 (Woche 34)	102	86,76 (17,604)	-4,90 (1,405)	90	88,52 (15,329)	-3,82 (1,490)	-1,07 [-5,105; 2,960]	0,6009
Tag 267 (Woche 38)	100	87,00 (17,340)	-5,48 (1,457)	89	88,01 (16,086)	-5,85 (1,546)	0,37 [-3,818; 4,548]	0,8637
Tag 295 (Woche 42)	104	87,82 (16,623)	-6,55 (1,590)	90	86,48 (17,109)	-4,66 (1,700)	-1,90 [-6,482; 2,684]	0,4154
Tag 323 (Woche 46)	99	88,72 (15,763)	-3,32 (1,394)	77	86,80 (17,383)	-3,66 (1,534)	0,35 [-3,736; 4,430]	0,8671
Tag 351 (Woche 50)	84	88,10 (16,068)	-3,63 (1,587)	81	87,04 (17,280)	-5,27 (1,649)	1,63 [-2,874; 6,142]	0,4760
Tag 379 (Woche 54)	77	88,53 (14,116)	-5,00 (1,684)	69	87,44 (15,500)	-3,27 (1,785)	-1,73 [-6,567; 3,098]	0,4802
Tag 407 (Woche 58)	72	87,73 (14,533)	-3,94 (1,589)	58	88,51 (14,034)	-4,89 (1,747)	0,95 [-3,698; 5,606]	0,6865
Tag 435 (Woche 62)	63	88,62 (15,504)	-4,28 (1,611)	50	86,67 (16,148)	-5,17 (1,783)	0,89 [-3,857; 5,632]	0,7125

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.5 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Kognition over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	87,63 (16,312)	-4,67 (1,018)	149	86,13 (16,599)	-4,15 (1,075)	-0,52 [-3,438; 2,388]	0,7232
Hedges' g SMD							-0,04 [-0,262; 0,182]	0,7234

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Nutzenbewertung nach AMNOG

Table 2.4.1.2.6 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Sozial over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	78,71 (24,215)	-2,45 (1,692)	141	80,38 (21,938)	2,01 (1,764)	-4,47 [-9,273; 0,341]	0,0685
Tag 43 (Woche 6)	140	79,88 (23,442)	-4,00 (1,863)	134	78,86 (23,407)	-2,76 (1,922)	-1,25 [-6,510; 4,016]	0,6412
Tag 64 (Woche 9)	129	80,49 (23,117)	-2,93 (1,792)	124	79,30 (22,428)	-4,38 (1,850)	1,45 [-3,619; 6,515]	0,5741
Tag 85 (Woche 12)	128	79,17 (24,030)	-7,72 (1,865)	118	80,23 (22,217)	-5,90 (1,946)	-1,81 [-7,116; 3,488]	0,5011
Tag 106 (Woche 15)	122	80,87 (24,116)	-6,73 (1,982)	117	80,48 (22,134)	-4,43 (2,049)	-2,30 [-7,908; 3,311]	0,4205
Tag 127 (Woche 18)	113	80,83 (23,907)	-5,73 (1,985)	99	81,99 (20,984)	-7,05 (2,100)	1,32 [-4,365; 7,009]	0,6475
Tag 155 (Woche 22)	121	78,93 (24,699)	-6,00 (1,981)	109	80,58 (22,166)	-3,78 (2,076)	-2,22 [-7,863; 3,429]	0,4402
Tag 183 (Woche 26)	116	80,60 (24,958)	-4,18 (1,901)	106	82,39 (21,801)	0,30 (1,992)	-4,48 [-9,899; 0,936]	0,1046
Tag 211 (Woche 30)	104	81,57 (22,981)	-3,28 (1,787)	97	82,13 (20,588)	-0,60 (1,866)	-2,69 [-7,775; 2,396]	0,2987
Tag 239 (Woche 34)	102	79,90 (23,842)	-1,15 (1,779)	90	83,33 (20,297)	-0,52 (1,891)	-0,63 [-5,748; 4,480]	0,8074
Tag 267 (Woche 38)	100	80,17 (23,534)	-1,08 (1,725)	89	82,96 (21,611)	0,68 (1,835)	-1,76 [-6,718; 3,199]	0,4854
Tag 295 (Woche 42)	104	80,45 (23,276)	-1,79 (1,813)	90	83,33 (21,200)	2,12 (1,945)	-3,91 [-9,146; 1,322]	0,1424
Tag 323 (Woche 46)	99	80,47 (24,169)	-2,60 (1,820)	77	82,90 (21,625)	2,86 (2,012)	-5,47 [-10,811; -0,126]	0,0449*
Tag 351 (Woche 50)	84	80,16 (24,059)	-1,87 (1,806)	81	82,92 (21,727)	-0,33 (1,884)	-1,55 [-6,688; 3,595]	0,5541
Tag 379 (Woche 54)	77	80,30 (24,292)	-2,68 (2,051)	69	82,85 (20,205)	1,72 (2,187)	-4,40 [-10,308; 1,512]	0,1439
Tag 407 (Woche 58)	72	81,48 (24,475)	-2,23 (2,023)	58	83,33 (19,745)	0,37 (2,232)	-2,61 [-8,541; 3,329]	0,3877
Tag 435 (Woche 62)	63	80,69 (25,082)	-4,36 (2,228)	50	82,33 (22,185)	-0,89 (2,478)	-3,47 [-10,044; 3,111]	0,2997

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.6 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Sozial over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	78,94 (24,416)	-3,58 (1,225)	149	79,08 (23,100)	-1,21 (1,295)	-2,37 [-5,872; 1,139]	0,1850
Hedges' g SMD							-0,15 [-0,373; 0,072]	0,1858

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Nutzenbewertung nach AMNOG

Table 2.4.1.2.7 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Fatigue over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	28,60 (23,174)	7,10 (1,469)	141	27,42 (18,139)	4,44 (1,530)	2,66 [-1,513; 6,823]	0,2110
Tag 43 (Woche 6)	140	27,78 (22,872)	7,65 (1,553)	134	27,86 (18,719)	7,30 (1,601)	0,35 [-4,029; 4,737]	0,8737
Tag 64 (Woche 9)	129	28,42 (23,811)	8,64 (1,465)	124	27,33 (18,331)	8,23 (1,510)	0,41 [-3,727; 4,545]	0,8459
Tag 85 (Woche 12)	128	28,73 (24,212)	11,42 (1,683)	118	26,84 (18,279)	10,97 (1,755)	0,46 [-4,324; 5,239]	0,8507
Tag 106 (Woche 15)	122	28,14 (24,292)	11,78 (1,840)	117	25,93 (16,952)	12,76 (1,901)	-0,98 [-6,183; 4,228]	0,7120
Tag 127 (Woche 18)	113	27,93 (24,176)	11,59 (1,824)	99	25,81 (17,083)	12,79 (1,927)	-1,20 [-6,423; 4,026]	0,6518
Tag 155 (Woche 22)	121	29,20 (24,601)	10,83 (1,759)	109	25,99 (18,284)	4,61 (1,841)	6,23 [1,214; 11,239]	0,0151*
Tag 183 (Woche 26)	116	29,12 (25,110)	8,85 (1,780)	106	24,00 (18,023)	2,70 (1,862)	6,15 [1,069; 11,225]	0,0179*
Tag 211 (Woche 30)	104	27,35 (25,105)	8,58 (1,694)	97	24,63 (17,512)	3,19 (1,768)	5,39 [0,568; 10,215]	0,0286*
Tag 239 (Woche 34)	102	27,45 (24,056)	6,44 (1,647)	90	23,95 (17,060)	2,53 (1,751)	3,91 [-0,826; 8,646]	0,1052
Tag 267 (Woche 38)	100	26,67 (23,049)	6,40 (1,871)	89	24,84 (17,084)	3,82 (1,990)	2,58 [-2,800; 7,955]	0,3461
Tag 295 (Woche 42)	104	25,64 (22,759)	6,73 (1,775)	90	25,31 (17,312)	3,69 (1,902)	3,05 [-2,072; 8,165]	0,2423
Tag 323 (Woche 46)	99	25,70 (24,418)	5,62 (1,691)	77	24,82 (17,834)	1,07 (1,869)	4,55 [-0,410; 9,508]	0,0720
Tag 351 (Woche 50)	84	26,19 (23,563)	3,59 (1,688)	81	25,38 (17,850)	3,27 (1,759)	0,32 [-4,482; 5,114]	0,8970
Tag 379 (Woche 54)	77	24,68 (23,750)	1,64 (1,603)	69	25,12 (16,792)	3,28 (1,703)	-1,64 [-6,242; 2,962]	0,4834
Tag 407 (Woche 58)	72	23,46 (22,187)	6,48 (1,841)	58	23,75 (15,073)	4,56 (2,026)	1,92 [-3,454; 7,296]	0,4818
Tag 435 (Woche 62)	63	23,81 (22,477)	2,55 (1,849)	50	25,33 (16,502)	2,39 (2,049)	0,16 [-5,275; 5,605]	0,9524

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.7 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Fatigue over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	28,77 (23,739)	7,41 (1,097)	149	28,34 (18,782)	5,39 (1,158)	2,02 [-1,117; 5,153]	0,2062
Hedges' g SMD							0,14 [-0,079; 0,366]	0,2072

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.8 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Übelkeit und Erbrechen over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	4,19 (11,171)	3,08 (0,959)	141	6,74 (14,362)	1,40 (1,007)	1,69 [-1,053; 4,428]	0,2267
Tag 43 (Woche 6)	140	3,93 (11,061)	3,70 (1,094)	134	7,71 (15,786)	2,09 (1,136)	1,61 [-1,504; 4,719]	0,3103
Tag 64 (Woche 9)	129	3,49 (9,003)	4,94 (1,213)	124	6,72 (14,558)	2,67 (1,254)	2,27 [-1,171; 5,719]	0,1949
Tag 85 (Woche 12)	128	3,65 (8,858)	5,20 (1,218)	118	6,64 (13,977)	2,06 (1,277)	3,13 [-0,351; 6,620]	0,0778
Tag 106 (Woche 15)	122	3,96 (10,063)	4,82 (1,281)	117	5,98 (12,847)	2,46 (1,323)	2,35 [-1,282; 5,985]	0,2036
Tag 127 (Woche 18)	113	4,28 (10,152)	3,69 (1,278)	99	4,55 (11,861)	1,37 (1,356)	2,32 [-1,354; 5,992]	0,2147
Tag 155 (Woche 22)	121	3,86 (9,804)	8,55 (1,358)	109	6,27 (13,568)	0,00 (1,428)	8,55 [4,660; 12,440]	<0,0001*
Tag 183 (Woche 26)	116	4,17 (10,280)	6,81 (1,265)	106	5,50 (12,955)	0,15 (1,325)	6,66 [3,052; 10,274]	0,0003*
Tag 211 (Woche 30)	104	3,37 (9,108)	5,76 (1,348)	97	6,53 (13,514)	-0,24 (1,406)	6,00 [2,147; 9,850]	0,0024*
Tag 239 (Woche 34)	102	3,43 (9,185)	4,75 (1,210)	90	6,11 (13,558)	-1,27 (1,286)	6,02 [2,531; 9,513]	0,0008*
Tag 267 (Woche 38)	100	3,33 (8,864)	4,38 (1,213)	89	6,18 (13,620)	-0,10 (1,289)	4,49 [0,989; 7,989]	0,0122*
Tag 295 (Woche 42)	104	3,53 (9,194)	3,81 (1,223)	90	6,67 (13,866)	1,51 (1,316)	2,30 [-1,248; 5,857]	0,2026
Tag 323 (Woche 46)	99	4,04 (11,926)	3,19 (1,224)	77	6,71 (14,116)	0,02 (1,367)	3,17 [-0,453; 6,795]	0,0861
Tag 351 (Woche 50)	84	2,98 (8,643)	1,45 (1,001)	81	7,41 (14,434)	-1,19 (1,041)	2,65 [-0,218; 5,513]	0,0700
Tag 379 (Woche 54)	77	3,03 (8,855)	4,16 (1,495)	69	5,56 (11,669)	1,23 (1,581)	2,93 [-1,374; 7,241]	0,1807
Tag 407 (Woche 58)	72	3,24 (9,124)	2,44 (1,223)	58	4,60 (10,257)	0,06 (1,342)	2,38 [-1,208; 5,962]	0,1923
Tag 435 (Woche 62)	63	2,65 (8,036)	1,17 (1,161)	50	5,00 (10,780)	-0,28 (1,277)	1,45 [-1,968; 4,865]	0,4033

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.8 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Übelkeit und Erbrechen over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	4,50 (11,425)	4,23 (0,694)	149	7,49 (15,431)	0,70 (0,737)	3,53 [1,531; 5,526]	0,0006*
Hedges' g SMD							0,39 [0,170; 0,619]	0,0006*

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Nutzenbewertung nach AMNOG

Table 2.4.1.2.9 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Schmerzen over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	26,56 (28,024)	-0,71 (1,737)	141	21,39 (23,682)	-0,12 (1,797)	-0,59 [-5,502; 4,327]	0,8142
Tag 43 (Woche 6)	140	25,60 (28,018)	-1,13 (1,897)	134	21,89 (24,983)	0,81 (1,943)	-1,93 [-7,271; 3,406]	0,4767
Tag 64 (Woche 9)	129	24,55 (26,605)	-3,06 (1,811)	124	21,51 (24,581)	-0,07 (1,859)	-2,99 [-8,094; 2,116]	0,2501
Tag 85 (Woche 12)	128	24,74 (27,508)	0,01 (1,955)	118	20,76 (23,764)	2,90 (2,032)	-2,89 [-8,443; 2,653]	0,3053
Tag 106 (Woche 15)	122	24,45 (26,172)	-0,39 (1,941)	117	19,37 (21,549)	0,99 (1,998)	-1,37 [-6,864; 4,116]	0,6226
Tag 127 (Woche 18)	113	24,78 (27,559)	-0,95 (2,065)	99	17,00 (19,775)	3,03 (2,184)	-3,98 [-9,919; 1,956]	0,1879
Tag 155 (Woche 22)	121	25,48 (27,477)	-1,32 (2,004)	109	18,81 (23,141)	-1,22 (2,093)	-0,09 [-5,812; 5,625]	0,9743
Tag 183 (Woche 26)	116	25,72 (27,749)	0,58 (1,909)	106	18,08 (22,434)	-2,19 (1,991)	2,77 [-2,673; 8,223]	0,3169
Tag 211 (Woche 30)	104	23,56 (26,542)	0,71 (1,862)	97	18,56 (21,500)	2,04 (1,941)	-1,33 [-6,637; 3,975]	0,6217
Tag 239 (Woche 34)	102	23,37 (26,144)	-2,84 (1,802)	90	17,78 (21,608)	0,47 (1,916)	-3,31 [-8,505; 1,876]	0,2098
Tag 267 (Woche 38)	100	21,17 (23,790)	-3,32 (2,085)	89	17,23 (21,387)	3,42 (2,225)	-6,74 [-12,743; -0,735]	0,0280*
Tag 295 (Woche 42)	104	21,15 (23,482)	0,30 (1,872)	90	17,04 (20,900)	-0,52 (2,018)	0,82 [-4,592; 6,242]	0,7646
Tag 323 (Woche 46)	99	21,38 (24,748)	-2,16 (1,876)	77	17,53 (21,780)	-0,06 (2,084)	-2,10 [-7,617; 3,426]	0,4556
Tag 351 (Woche 50)	84	20,63 (22,198)	-4,25 (1,903)	81	18,72 (21,471)	1,73 (1,985)	-5,99 [-11,400; -0,576]	0,0303*
Tag 379 (Woche 54)	77	21,00 (21,697)	-3,30 (2,068)	69	18,36 (22,351)	1,58 (2,206)	-4,88 [-10,834; 1,079]	0,1080
Tag 407 (Woche 58)	72	20,83 (22,854)	-3,17 (2,007)	58	16,95 (22,619)	-0,66 (2,226)	-2,51 [-8,416; 3,388]	0,4020
Tag 435 (Woche 62)	63	18,25 (20,677)	-3,11 (2,293)	50	19,00 (22,840)	-2,22 (2,548)	-0,89 [-7,640; 5,858]	0,7946

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.9 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Schmerzen over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	26,07 (27,718)	-1,65 (1,233)	149	22,71 (25,425)	0,58 (1,298)	-2,24 [-5,756; 1,285]	0,2124
Hedges' g SMD							-0,14 [-0,364; 0,081]	0,2132

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.10 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Dyspnoe over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	12,47 (20,858)	3,46 (1,543)	141	12,77 (20,953)	1,39 (1,612)	2,07 [-2,318; 6,461]	0,3538
Tag 43 (Woche 6)	140	11,90 (20,804)	7,19 (1,673)	134	11,94 (19,774)	5,62 (1,724)	1,57 [-3,158; 6,295]	0,5142
Tag 64 (Woche 9)	129	13,18 (22,600)	6,63 (1,671)	124	12,37 (20,591)	6,05 (1,722)	0,58 [-4,140; 5,298]	0,8094
Tag 85 (Woche 12)	128	12,24 (22,084)	7,89 (1,729)	118	11,58 (19,184)	8,00 (1,805)	-0,11 [-5,027; 4,811]	0,9656
Tag 106 (Woche 15)	122	12,02 (22,703)	9,90 (1,879)	117	12,54 (20,401)	8,20 (1,940)	1,70 [-3,615; 7,012]	0,5298
Tag 127 (Woche 18)	113	12,09 (22,740)	8,78 (1,966)	99	12,79 (20,596)	7,18 (2,084)	1,60 [-4,043; 7,235]	0,5779
Tag 155 (Woche 22)	121	12,95 (23,322)	4,13 (1,670)	109	12,23 (20,113)	4,04 (1,752)	0,09 [-4,675; 4,852]	0,9709
Tag 183 (Woche 26)	116	12,64 (23,531)	2,34 (1,730)	106	10,69 (18,714)	0,25 (1,811)	2,09 [-2,842; 7,022]	0,4048
Tag 211 (Woche 30)	104	13,46 (23,920)	1,49 (1,613)	97	11,34 (19,177)	1,64 (1,681)	-0,15 [-4,742; 4,436]	0,9477
Tag 239 (Woche 34)	102	12,42 (22,942)	1,65 (1,571)	90	10,37 (18,458)	1,90 (1,669)	-0,24 [-4,757; 4,273]	0,9160
Tag 267 (Woche 38)	100	11,33 (21,825)	3,40 (1,980)	89	11,61 (18,870)	2,44 (2,104)	0,96 [-4,735; 6,646]	0,7411
Tag 295 (Woche 42)	104	10,90 (22,004)	3,43 (1,851)	90	12,96 (19,796)	2,32 (1,984)	1,11 [-4,241; 6,453]	0,6840
Tag 323 (Woche 46)	99	10,44 (22,155)	2,20 (1,799)	77	11,69 (19,320)	1,66 (1,994)	0,55 [-4,744; 5,840]	0,8384
Tag 351 (Woche 50)	84	10,32 (21,938)	1,09 (1,880)	81	12,35 (19,325)	4,44 (1,949)	-3,35 [-8,689; 1,988]	0,2174
Tag 379 (Woche 54)	77	10,82 (22,583)	-0,09 (1,823)	69	10,63 (17,613)	3,14 (1,935)	-3,23 [-8,475; 2,005]	0,2249
Tag 407 (Woche 58)	72	9,72 (20,508)	-0,53 (1,747)	58	9,77 (16,530)	1,40 (1,925)	-1,93 [-7,044; 3,191]	0,4586
Tag 435 (Woche 62)	63	7,41 (18,399)	2,26 (2,016)	50	9,33 (15,119)	4,58 (2,219)	-2,32 [-8,201; 3,565]	0,4374

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.10 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Dyspnoe over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	12,47 (21,623)	3,84 (1,074)	149	12,98 (21,121)	3,78 (1,135)	0,06 [-3,018; 3,132]	0,9709
Hedges' g SMD							0,00 [-0,218; 0,226]	0,9710

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbaj 27MAR2024:14:53

Nutzenbewertung nach AMNOG

Table 2.4.1.2.11 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Schlaflosigkeit over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	26,88 (28,197)	-0,45 (1,978)	141	26,71 (26,791)	0,00 (2,067)	-0,45 [-6,078; 5,177]	0,8749
Tag 43 (Woche 6)	140	26,67 (28,610)	-3,12 (2,010)	134	28,36 (27,575)	-2,38 (2,074)	-0,74 [-6,418; 4,944]	0,7987
Tag 64 (Woche 9)	129	27,39 (29,002)	-1,66 (1,998)	124	27,42 (26,899)	-5,13 (2,061)	3,47 [-2,180; 9,115]	0,2278
Tag 85 (Woche 12)	128	27,08 (28,905)	-2,30 (2,132)	118	26,55 (25,620)	-6,16 (2,228)	3,86 [-2,212; 9,925]	0,2120
Tag 106 (Woche 15)	122	25,41 (28,119)	-3,02 (1,864)	117	25,36 (24,231)	-3,49 (1,925)	0,48 [-4,794; 5,752]	0,8583
Tag 127 (Woche 18)	113	27,14 (28,012)	-1,29 (2,101)	99	27,27 (25,361)	-2,55 (2,226)	1,26 [-4,767; 7,284]	0,6813
Tag 155 (Woche 22)	121	27,27 (27,889)	-3,01 (2,042)	109	25,69 (26,695)	-5,48 (2,144)	2,47 [-3,360; 8,297]	0,4051
Tag 183 (Woche 26)	116	26,72 (27,878)	0,18 (2,202)	106	26,10 (26,026)	-7,93 (2,306)	8,11 [1,836; 14,387]	0,0115*
Tag 211 (Woche 30)	104	25,64 (28,720)	-1,36 (2,035)	97	23,71 (25,891)	-7,92 (2,123)	6,55 [0,766; 12,342]	0,0266*
Tag 239 (Woche 34)	102	26,14 (26,793)	-3,63 (2,087)	90	24,81 (24,764)	-4,80 (2,217)	1,16 [-4,833; 7,157]	0,7031
Tag 267 (Woche 38)	100	26,33 (26,077)	-4,20 (2,266)	89	25,09 (24,247)	-6,56 (2,407)	2,36 [-4,149; 8,868]	0,4760
Tag 295 (Woche 42)	104	25,96 (25,844)	-5,25 (1,906)	90	25,93 (26,806)	-7,71 (2,041)	2,45 [-3,046; 7,949]	0,3808
Tag 323 (Woche 46)	99	25,59 (26,440)	-3,77 (1,953)	77	26,84 (27,058)	-5,66 (2,164)	1,89 [-3,849; 7,633]	0,5169
Tag 351 (Woche 50)	84	26,19 (25,909)	-4,68 (2,253)	81	26,34 (27,242)	-3,30 (2,336)	-1,38 [-7,776; 5,009]	0,6703
Tag 379 (Woche 54)	77	23,81 (26,412)	-8,23 (2,086)	69	26,09 (27,338)	-5,12 (2,212)	-3,10 [-9,096; 2,887]	0,3083
Tag 407 (Woche 58)	72	24,54 (27,404)	-7,49 (2,221)	58	24,14 (24,814)	-4,68 (2,449)	-2,81 [-9,325; 3,705]	0,3960
Tag 435 (Woche 62)	63	25,93 (27,070)	-6,24 (2,250)	50	26,67 (26,937)	-4,87 (2,502)	-1,37 [-8,015; 5,274]	0,6844

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.11 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Schlaflosigkeit over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	27,40 (28,429)	-3,50 (1,293)	149	27,74 (26,959)	-4,93 (1,366)	1,42 [-2,276; 5,123]	0,4495
Hedges' g SMD							0,09 [-0,137; 0,308]	0,4502

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.12 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Appetitverlust over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	14,19 (23,090)	2,05 (1,623)	141	19,86 (26,720)	-0,48 (1,714)	2,53 [-2,120; 7,177]	0,2853
Tag 43 (Woche 6)	140	13,33 (22,899)	2,76 (1,980)	134	20,40 (27,086)	-1,29 (2,061)	4,05 [-1,587; 9,688]	0,1584
Tag 64 (Woche 9)	129	12,92 (22,170)	3,68 (1,890)	124	19,62 (27,221)	1,60 (1,964)	2,08 [-3,295; 7,458]	0,4467
Tag 85 (Woche 12)	128	12,76 (22,573)	6,32 (1,840)	118	18,36 (26,365)	0,57 (1,932)	5,74 [0,483; 11,006]	0,0325*
Tag 106 (Woche 15)	122	12,57 (22,809)	5,92 (2,099)	117	17,66 (24,980)	1,90 (2,173)	4,02 [-1,938; 9,983]	0,1851
Tag 127 (Woche 18)	113	13,27 (22,947)	4,40 (1,970)	99	16,84 (25,365)	2,88 (2,094)	1,52 [-4,154; 7,186]	0,5989
Tag 155 (Woche 22)	121	13,50 (23,404)	11,01 (2,146)	109	19,27 (27,327)	-3,56 (2,266)	14,58 [8,419; 20,733]	<0,0001*
Tag 183 (Woche 26)	116	12,93 (22,745)	8,38 (2,198)	106	17,61 (26,907)	-4,38 (2,307)	12,76 [6,472; 19,045]	<0,0001*
Tag 211 (Woche 30)	104	10,58 (19,300)	10,30 (2,059)	97	19,24 (27,986)	-6,28 (2,149)	16,58 [10,687; 22,483]	<0,0001*
Tag 239 (Woche 34)	102	10,13 (19,220)	9,22 (2,114)	90	16,67 (26,084)	-5,48 (2,234)	14,70 [8,614; 20,784]	<0,0001*
Tag 267 (Woche 38)	100	9,67 (17,913)	4,48 (2,066)	89	17,60 (26,633)	-3,92 (2,182)	8,40 [2,443; 14,357]	0,0059*
Tag 295 (Woche 42)	104	8,97 (17,522)	2,74 (1,802)	90	18,52 (27,871)	-3,95 (1,921)	6,69 [1,461; 11,922]	0,0124*
Tag 323 (Woche 46)	99	10,77 (20,663)	3,36 (1,967)	77	19,48 (27,226)	-4,70 (2,188)	8,05 [2,215; 13,891]	0,0071*
Tag 351 (Woche 50)	84	9,13 (18,907)	2,31 (2,135)	81	18,11 (27,411)	-2,86 (2,197)	5,18 [-0,910; 11,261]	0,0951
Tag 379 (Woche 54)	77	7,79 (17,011)	1,74 (2,267)	69	17,39 (27,182)	-3,92 (2,368)	5,66 [-0,865; 12,179]	0,0887
Tag 407 (Woche 58)	72	6,48 (15,462)	0,81 (1,894)	58	16,67 (25,170)	-4,48 (2,026)	5,29 [-0,234; 10,808]	0,0604
Tag 435 (Woche 62)	63	6,88 (17,101)	2,20 (2,313)	50	16,67 (25,422)	-4,73 (2,502)	6,93 [0,140; 13,720]	0,0455*

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.12 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Appetitverlust over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	14,93 (24,330)	4,81 (1,172)	149	20,58 (27,013)	-2,53 (1,244)	7,34 [3,966; 10,712]	<0,0001*
Hedges' g SMD							0,49 [0,260; 0,711]	<0,0001*

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Nutzenbewertung nach AMNOG

Table 2.4.1.2.13 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Verstopfung over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	16,34 (24,432)	5,24 (1,994)	141	23,17 (26,709)	2,85 (2,103)	2,39 [-3,340; 8,113]	0,4128
Tag 43 (Woche 6)	140	16,43 (24,808)	2,41 (1,879)	134	24,38 (27,165)	-1,88 (1,958)	4,28 [-1,079; 9,649]	0,1170
Tag 64 (Woche 9)	129	15,25 (24,298)	4,39 (1,980)	124	23,39 (25,848)	-0,78 (2,057)	5,17 [-0,480; 10,821]	0,0727
Tag 85 (Woche 12)	128	15,63 (24,369)	3,33 (2,072)	118	23,45 (25,527)	-0,02 (2,182)	3,35 [-2,603; 9,304]	0,2689
Tag 106 (Woche 15)	122	16,12 (24,705)	2,69 (1,998)	117	21,37 (23,350)	0,11 (2,069)	2,58 [-3,100; 8,269]	0,3715
Tag 127 (Woche 18)	113	14,75 (24,372)	0,04 (2,226)	99	21,21 (22,057)	-0,95 (2,364)	0,99 [-5,437; 7,419]	0,7617
Tag 155 (Woche 22)	121	14,88 (24,324)	1,18 (1,931)	109	21,41 (25,061)	-5,32 (2,031)	6,50 [0,958; 12,050]	0,0217*
Tag 183 (Woche 26)	116	14,94 (24,611)	-1,49 (1,868)	106	20,44 (23,263)	-8,72 (1,956)	7,23 [1,886; 12,582]	0,0082*
Tag 211 (Woche 30)	104	14,74 (25,368)	-1,23 (2,119)	97	20,96 (23,234)	-7,00 (2,207)	5,77 [-0,282; 11,827]	0,0616
Tag 239 (Woche 34)	102	13,07 (23,054)	-0,63 (2,125)	90	20,00 (22,789)	-6,53 (2,240)	5,90 [-0,208; 12,010]	0,0582
Tag 267 (Woche 38)	100	14,00 (23,774)	-0,03 (1,963)	89	20,22 (22,818)	-5,99 (2,076)	5,96 [0,312; 11,612]	0,0387*
Tag 295 (Woche 42)	104	13,46 (23,464)	-1,24 (2,016)	90	19,63 (22,841)	-6,80 (2,145)	5,55 [-0,264; 11,372]	0,0613
Tag 323 (Woche 46)	99	12,79 (23,186)	-0,29 (2,017)	77	22,08 (23,327)	-3,69 (2,227)	3,40 [-2,563; 9,364]	0,2624
Tag 351 (Woche 50)	84	15,08 (24,492)	-2,01 (2,170)	81	21,40 (23,751)	-4,21 (2,246)	2,20 [-3,980; 8,380]	0,4837
Tag 379 (Woche 54)	77	16,02 (25,137)	-0,88 (2,310)	69	22,22 (24,028)	-2,33 (2,463)	1,45 [-5,234; 8,132]	0,6694
Tag 407 (Woche 58)	72	16,67 (25,637)	-2,86 (2,218)	58	20,69 (24,043)	-6,34 (2,451)	3,48 [-3,057; 10,019]	0,2948
Tag 435 (Woche 62)	63	15,87 (25,299)	-0,06 (2,431)	50	20,00 (22,335)	-2,64 (2,708)	2,57 [-4,634; 9,782]	0,4814

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.13 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Verstopfung over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	15,95 (24,382)	0,50 (1,189)	149	25,28 (28,117)	-3,54 (1,264)	4,05 [0,614; 7,480]	0,0210*
Hedges' g SMD							0,26 [0,041; 0,487]	0,0205*

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.14 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Diarrhö over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	6,67 (17,979)	0,89 (1,125)	141	5,67 (15,915)	1,02 (1,175)	-0,12 [-3,325; 3,077]	0,9394
Tag 43 (Woche 6)	140	6,19 (17,695)	4,30 (1,586)	134	5,72 (16,106)	4,51 (1,628)	-0,21 [-4,683; 4,263]	0,9264
Tag 64 (Woche 9)	129	6,46 (18,199)	5,30 (1,425)	124	5,65 (14,553)	2,50 (1,462)	2,79 [-1,224; 6,814]	0,1722
Tag 85 (Woche 12)	128	7,55 (19,267)	1,96 (1,300)	118	4,80 (11,755)	4,42 (1,353)	-2,46 [-6,158; 1,237]	0,1913
Tag 106 (Woche 15)	122	6,83 (17,638)	5,59 (1,737)	117	3,99 (10,865)	5,14 (1,788)	0,45 [-4,464; 5,370]	0,8562
Tag 127 (Woche 18)	113	7,37 (19,280)	5,34 (1,596)	99	5,05 (12,012)	3,70 (1,690)	1,64 [-2,942; 6,224]	0,4812
Tag 155 (Woche 22)	121	7,99 (19,732)	3,34 (1,400)	109	3,67 (10,482)	0,64 (1,466)	2,70 [-1,305; 6,708]	0,1854
Tag 183 (Woche 26)	116	6,61 (18,241)	2,99 (1,560)	106	4,40 (11,339)	0,30 (1,631)	2,69 [-1,761; 7,139]	0,2352
Tag 211 (Woche 30)	104	6,41 (18,036)	1,97 (1,477)	97	3,44 (10,189)	1,01 (1,540)	0,96 [-3,254; 5,172]	0,6542
Tag 239 (Woche 34)	102	8,82 (20,406)	-1,02 (1,393)	90	3,33 (10,056)	1,76 (1,474)	-2,78 [-6,799; 1,241]	0,1745
Tag 267 (Woche 38)	100	7,00 (17,275)	1,00 (1,466)	89	3,37 (10,107)	1,01 (1,561)	-0,01 [-4,243; 4,228]	0,9973
Tag 295 (Woche 42)	104	5,13 (13,755)	0,76 (1,272)	90	3,70 (10,534)	1,40 (1,371)	-0,64 [-4,321; 3,047]	0,7337
Tag 323 (Woche 46)	99	6,06 (15,330)	0,17 (1,236)	77	3,03 (9,645)	1,29 (1,391)	-1,13 [-4,802; 2,545]	0,5455
Tag 351 (Woche 50)	84	6,75 (17,759)	-0,10 (1,391)	81	3,70 (10,541)	2,51 (1,438)	-2,61 [-6,562; 1,348]	0,1951
Tag 379 (Woche 54)	77	6,93 (18,207)	2,21 (1,409)	69	3,38 (10,138)	1,09 (1,498)	1,12 [-2,951; 5,189]	0,5880
Tag 407 (Woche 58)	72	4,63 (15,121)	-0,02 (1,414)	58	3,45 (10,240)	3,11 (1,572)	-3,13 [-7,301; 1,036]	0,1397
Tag 435 (Woche 62)	63	4,76 (13,194)	1,06 (1,741)	50	3,33 (10,102)	5,23 (1,955)	-4,17 [-9,337; 0,995]	0,1126

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.14 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Diarrhö over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	6,75 (17,824)	2,10 (0,747)	149	5,59 (15,694)	2,39 (0,790)	-0,29 [-2,431; 1,854]	0,7914
Hedges' g SMD							-0,03 [-0,252; 0,192]	0,7914

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprban 27MAR2024:14:53

Nutzenbewertung nach AMNOG

Table 2.4.1.2.15 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Finanzielle Schwierigkeiten over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	155	21,08 (28,684)	1,72 (1,776)	141	17,02 (24,758)	-2,83 (1,852)	4,55 [-0,505; 9,603]	0,0775
Tag 43 (Woche 6)	140	21,90 (29,320)	-0,32 (1,602)	134	18,66 (25,367)	-1,09 (1,651)	0,77 [-3,759; 5,300]	0,7379
Tag 64 (Woche 9)	129	21,45 (28,807)	2,25 (1,800)	124	17,47 (25,312)	0,12 (1,857)	2,12 [-2,970; 7,218]	0,4124
Tag 85 (Woche 12)	128	20,83 (28,677)	6,32 (1,903)	118	16,67 (24,557)	-0,58 (1,987)	6,90 [1,479; 12,320]	0,0128*
Tag 106 (Woche 15)	122	20,49 (27,920)	4,18 (1,867)	117	17,66 (25,735)	0,31 (1,931)	3,87 [-1,417; 9,162]	0,1506
Tag 127 (Woche 18)	113	21,24 (27,481)	2,99 (1,782)	99	14,81 (23,436)	0,44 (1,887)	2,55 [-2,570; 7,669]	0,3278
Tag 155 (Woche 22)	121	20,94 (27,599)	2,53 (1,821)	109	14,98 (24,210)	1,00 (1,915)	1,53 [-3,677; 6,744]	0,5628
Tag 183 (Woche 26)	116	20,69 (28,710)	2,98 (1,756)	106	15,41 (25,271)	-1,07 (1,844)	4,05 [-0,967; 9,068]	0,1132
Tag 211 (Woche 30)	104	21,79 (29,658)	1,09 (1,927)	97	15,46 (23,601)	-1,10 (2,014)	2,19 [-3,310; 7,687]	0,4340
Tag 239 (Woche 34)	102	21,90 (29,103)	-1,59 (1,673)	90	14,44 (22,926)	-0,65 (1,777)	-0,94 [-5,755; 3,880]	0,7020
Tag 267 (Woche 38)	100	21,33 (27,018)	-0,18 (1,905)	89	15,36 (24,647)	1,66 (2,022)	-1,85 [-7,327; 3,635]	0,5079
Tag 295 (Woche 42)	104	19,87 (27,290)	-2,26 (1,912)	90	15,93 (24,595)	1,70 (2,047)	-3,96 [-9,480; 1,562]	0,1591
Tag 323 (Woche 46)	99	19,53 (28,575)	0,00 (1,847)	77	16,88 (26,832)	1,15 (2,035)	-1,14 [-6,561; 4,271]	0,6775
Tag 351 (Woche 50)	84	20,24 (28,349)	-0,90 (1,936)	81	18,11 (26,378)	0,05 (2,017)	-0,95 [-6,460; 4,563]	0,7349
Tag 379 (Woche 54)	77	20,35 (29,198)	-1,06 (2,230)	69	17,87 (25,295)	2,58 (2,373)	-3,64 [-10,065; 2,779]	0,2648
Tag 407 (Woche 58)	72	21,30 (29,234)	1,35 (2,138)	58	16,67 (23,570)	-1,59 (2,348)	2,94 [-3,329; 9,208]	0,3564
Tag 435 (Woche 62)	63	17,99 (27,321)	-1,30 (2,068)	50	17,33 (25,413)	1,35 (2,293)	-2,65 [-8,749; 3,441]	0,3913

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.1.2.15 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-C30 Finanzielle Schwierigkeiten over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	163	20,65 (28,499)	1,05 (1,284)	149	18,34 (25,538)	0,09 (1,356)	0,96 [-2,716; 4,639]	0,6073
Hedges' g SMD							0,06 [-0,164; 0,280]	0,6075

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Hinweis zu den MMRM-Analysen des EORTC QLQ-EN24 Fragebogens

Die Veränderung gegenüber dem Ausgangswert wurde mithilfe eines Mixed Models for Repeated Measures (MMRM) bestimmt. Hierfür wurden alle verfügbaren Visiten mit mindestens 25% nicht-fehlender Daten verwendet.

Im Fall der Skalen sexuelles Vergnügen und sexuelle/vaginale Probleme des EORTC QLQ-EN24 Fragebogens lagen für alle Visiten weniger als 25% nicht-fehlende Daten vor. Entsprechend erfolgte für die genannten Skalen keine Bestimmung der Veränderung gegenüber dem Ausgangswert.

Table 2.4.2.2.1 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Sexuelles Interesse over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	90,80 (19,438)	-0,99 (1,542)	136	89,22 (19,408)	4,05 (1,586)	-5,04 [-9,399; -0,683]	0,0235*
Tag 43 (Woche 6)	132	90,15 (18,756)	1,13 (1,168)	130	89,74 (19,399)	2,32 (1,188)	-1,20 [-4,475; 2,084]	0,4737
Tag 64 (Woche 9)	122	90,98 (18,200)	1,06 (1,233)	122	89,62 (19,677)	3,04 (1,250)	-1,98 [-5,435; 1,477]	0,2606
Tag 85 (Woche 12)	120	90,00 (20,544)	3,06 (1,072)	117	88,89 (20,057)	3,69 (1,094)	-0,64 [-3,652; 2,380]	0,6784
Tag 106 (Woche 15)	115	89,57 (20,880)	1,84 (1,489)	117	90,60 (17,964)	1,92 (1,503)	-0,08 [-4,244; 4,089]	0,9709
Tag 127 (Woche 18)	107	89,41 (20,780)	3,72 (1,265)	98	89,46 (19,499)	2,96 (1,311)	0,75 [-2,833; 4,342]	0,6792
Tag 155 (Woche 22)	114	90,64 (20,083)	3,11 (1,199)	108	88,89 (20,381)	3,02 (1,231)	0,09 [-3,293; 3,475]	0,9577
Tag 183 (Woche 26)	113	89,68 (20,451)	2,49 (1,325)	105	89,84 (18,561)	1,33 (1,370)	1,16 [-2,590; 4,912]	0,5430
Tag 211 (Woche 30)	100	91,67 (17,963)	3,59 (1,374)	96	89,58 (19,534)	-0,55 (1,411)	4,14 [0,258; 8,016]	0,0367*
Tag 239 (Woche 34)	98	90,14 (19,856)	1,16 (1,315)	89	91,76 (15,309)	-0,08 (1,374)	1,24 [-2,509; 4,982]	0,5161
Tag 267 (Woche 38)	96	90,28 (18,680)	2,25 (1,276)	88	90,91 (17,307)	1,04 (1,332)	1,21 [-2,427; 4,841]	0,5137
Tag 295 (Woche 42)	99	90,24 (19,779)	3,02 (1,510)	89	90,26 (17,554)	-0,38 (1,586)	3,40 [-0,910; 7,718]	0,1215
Tag 323 (Woche 46)	94	89,01 (20,962)	4,19 (1,218)	76	90,35 (18,711)	2,32 (1,318)	1,86 [-1,675; 5,398]	0,3008
Tag 351 (Woche 50)	82	88,62 (20,434)	3,73 (1,349)	81	89,71 (18,739)	2,61 (1,380)	1,12 [-2,683; 4,924]	0,5620
Tag 379 (Woche 54)	75	89,78 (19,738)	5,33 (1,679)	68	91,18 (16,906)	2,46 (1,763)	2,88 [-1,926; 7,682]	0,2388
Tag 407 (Woche 58)	70	90,00 (19,119)	4,43 (1,304)	57	89,47 (19,063)	2,96 (1,417)	1,47 [-2,333; 5,269]	0,4468

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
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Table 2.4.2.2.1 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Sexuelles Interesse over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	88,36 (22,527)	2,16 (1,464)	50	90,67 (17,868)	3,07 (1,608)	-0,91 [-5,208; 3,380]	0,6750
Durchschnitt über alle Visiten	156	90,38 (19,678)	2,66 (0,909)	148	88,96 (19,973)	2,11 (0,942)	0,56 [-2,019; 3,134]	0,6706
Hedges' g SMD							0,05 [-0,176; 0,274]	0,6709

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbap 27MAR2024:14:53

Nutzenbewertung nach AMNOG

Table 2.4.2.2.2 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Sexuelle Aktivität over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	93,56 (15,858)	1,79 (1,098)	136	93,14 (17,740)	2,11 (1,129)	-0,32 [-3,422; 2,781]	0,8388
Tag 43 (Woche 6)	132	92,68 (16,636)	1,34 (1,113)	130	94,62 (14,851)	1,12 (1,132)	0,23 [-2,901; 3,352]	0,8872
Tag 64 (Woche 9)	122	93,17 (16,564)	0,59 (1,256)	122	94,54 (15,067)	1,77 (1,274)	-1,18 [-4,699; 2,347]	0,5118
Tag 85 (Woche 12)	120	93,61 (14,524)	1,72 (1,179)	117	94,59 (15,135)	1,92 (1,204)	-0,20 [-3,518; 3,115]	0,9049
Tag 106 (Woche 15)	115	91,88 (17,984)	1,63 (1,206)	117	95,73 (12,017)	1,25 (1,219)	0,37 [-3,009; 3,753]	0,8287
Tag 127 (Woche 18)	107	92,52 (16,064)	3,06 (0,974)	98	94,22 (15,893)	2,79 (1,009)	0,27 [-2,492; 3,033]	0,8472
Tag 155 (Woche 22)	114	92,69 (17,036)	1,76 (0,981)	108	93,52 (16,085)	2,98 (1,008)	-1,22 [-3,988; 1,549]	0,3868
Tag 183 (Woche 26)	113	91,74 (18,111)	2,38 (1,222)	105	95,24 (12,599)	0,42 (1,263)	1,96 [-1,501; 5,428]	0,2657
Tag 211 (Woche 30)	100	92,67 (17,459)	1,60 (1,166)	96	94,10 (16,037)	-1,22 (1,198)	2,82 [-0,474; 6,108]	0,0931
Tag 239 (Woche 34)	98	92,52 (16,943)	1,94 (1,273)	89	95,88 (12,123)	-1,06 (1,332)	2,99 [-0,640; 6,627]	0,1060
Tag 267 (Woche 38)	96	92,01 (17,931)	-0,61 (1,249)	88	95,45 (12,566)	-0,53 (1,303)	-0,08 [-3,640; 3,483]	0,9654
Tag 295 (Woche 42)	99	92,59 (17,532)	1,96 (1,198)	89	95,13 (12,862)	-1,37 (1,259)	3,32 [-0,105; 6,749]	0,0574
Tag 323 (Woche 46)	94	91,84 (18,084)	2,70 (1,085)	76	95,61 (12,581)	-0,92 (1,174)	3,62 [0,467; 6,777]	0,0246*
Tag 351 (Woche 50)	82	91,46 (18,747)	2,34 (1,159)	81	95,06 (13,029)	1,66 (1,186)	0,68 [-2,597; 3,951]	0,6843
Tag 379 (Woche 54)	75	90,67 (19,421)	1,99 (1,160)	68	95,10 (13,214)	0,00 (1,215)	2,00 [-1,324; 5,316]	0,2374
Tag 407 (Woche 58)	70	90,48 (19,776)	3,34 (1,063)	57	94,74 (13,786)	-0,10 (1,151)	3,44 [0,339; 6,532]	0,0298*

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
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Table 2.4.2.2.2 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Sexuelle Aktivität over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	92,06 (18,660)	1,15 (1,196)	50	96,00 (10,942)	0,15 (1,313)	1,00 [-2,515; 4,507]	0,5765
Durchschnitt über alle Visiten	156	92,74 (16,632)	1,80 (0,803)	148	93,02 (17,498)	0,65 (0,832)	1,16 [-1,117; 3,434]	0,3173
Hedges' g SMD							0,11 [-0,110; 0,340]	0,3178

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbaq 27MAR2024:14:53

Nutzenbewertung nach AMNOG

Table 2.4.2.2.3 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Lymphödem over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	10,69 (18,496)	5,27 (1,658)	136	11,03 (20,809)	2,52 (1,703)	2,75 [-1,927; 7,424]	0,2482
Tag 43 (Woche 6)	132	10,86 (19,207)	8,90 (1,883)	130	10,51 (20,767)	6,72 (1,915)	2,18 [-3,101; 7,463]	0,4171
Tag 64 (Woche 9)	122	11,48 (19,531)	6,72 (1,656)	122	9,84 (19,610)	7,76 (1,679)	-1,04 [-5,683; 3,596]	0,6584
Tag 85 (Woche 12)	120	10,97 (19,265)	9,98 (1,918)	117	11,54 (21,825)	7,56 (1,957)	2,42 [-2,964; 7,813]	0,3765
Tag 106 (Woche 15)	115	10,00 (18,835)	13,08 (1,946)	117	9,97 (18,577)	7,54 (1,966)	5,54 [0,100; 10,987]	0,0460*
Tag 127 (Woche 18)	107	11,21 (19,797)	13,05 (2,028)	98	11,56 (22,502)	9,82 (2,098)	3,23 [-2,510; 8,968]	0,2689
Tag 155 (Woche 22)	114	11,11 (19,666)	10,55 (2,029)	108	10,65 (21,791)	8,79 (2,080)	1,76 [-3,956; 7,478]	0,5448
Tag 183 (Woche 26)	113	11,50 (19,806)	12,35 (1,775)	105	8,73 (17,156)	6,40 (1,831)	5,96 [0,936; 10,978]	0,0202*
Tag 211 (Woche 30)	100	12,00 (19,831)	8,15 (2,006)	96	9,38 (19,013)	8,48 (2,059)	-0,34 [-6,000; 5,325]	0,9067
Tag 239 (Woche 34)	98	11,05 (17,900)	4,09 (1,778)	89	8,61 (18,311)	7,58 (1,858)	-3,49 [-8,557; 1,576]	0,1760
Tag 267 (Woche 38)	96	10,07 (17,518)	5,00 (1,579)	88	7,58 (16,553)	4,42 (1,658)	0,58 [-3,924; 5,088]	0,7995
Tag 295 (Woche 42)	99	8,75 (16,383)	8,15 (1,744)	89	8,05 (16,688)	6,41 (1,840)	1,74 [-3,244; 6,725]	0,4924
Tag 323 (Woche 46)	94	10,11 (17,320)	7,13 (1,777)	76	7,24 (16,851)	7,43 (1,931)	-0,30 [-5,465; 4,868]	0,9096
Tag 351 (Woche 50)	82	10,16 (17,521)	8,02 (1,892)	81	7,82 (16,891)	8,96 (1,957)	-0,94 [-6,297; 4,418]	0,7302
Tag 379 (Woche 54)	75	9,11 (16,955)	7,38 (1,759)	68	7,35 (17,369)	8,44 (1,864)	-1,06 [-6,099; 3,984]	0,6799
Tag 407 (Woche 58)	70	7,86 (13,526)	6,86 (2,039)	57	8,48 (18,930)	5,67 (2,220)	1,19 [-4,737; 7,116]	0,6929

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbar 27MAR2024:14:53

Table 2.4.2.2.3 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Lymphödem over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	7,41 (13,312)	6,21 (1,977)	50	9,67 (19,946)	6,36 (2,174)	-0,14 [-5,930; 5,648]	0,9617
Durchschnitt über alle Visiten	156	11,11 (18,869)	8,29 (1,237)	148	11,71 (21,688)	7,11 (1,284)	1,18 [-2,328; 4,686]	0,5086
Hedges' g SMD							0,08 [-0,149; 0,301]	0,5095

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbar 27MAR2024:14:53

Nutzenbewertung nach AMNOG

Table 2.4.2.2.4 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Urologische Symptome over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	15,98 (14,975)	1,01 (1,069)	136	15,07 (17,109)	0,19 (1,098)	0,81 [-2,202; 3,830]	0,5956
Tag 43 (Woche 6)	132	16,60 (15,968)	0,95 (1,164)	130	15,83 (18,730)	-0,16 (1,180)	1,11 [-2,151; 4,373]	0,5032
Tag 64 (Woche 9)	122	17,35 (15,621)	1,47 (1,281)	122	15,57 (17,926)	0,89 (1,293)	0,58 [-3,003; 4,167]	0,7495
Tag 85 (Woche 12)	120	17,50 (15,671)	2,31 (1,375)	117	15,74 (18,039)	-1,07 (1,398)	3,38 [-0,481; 7,240]	0,0859
Tag 106 (Woche 15)	115	16,59 (14,622)	2,31 (1,390)	117	15,67 (18,085)	1,06 (1,399)	1,25 [-2,637; 5,129]	0,5281
Tag 127 (Woche 18)	107	16,82 (15,860)	0,66 (1,364)	98	15,48 (18,382)	-1,75 (1,412)	2,41 [-1,453; 6,281]	0,2201
Tag 155 (Woche 22)	114	16,45 (15,618)	-0,74 (1,188)	108	14,81 (17,845)	-3,08 (1,219)	2,34 [-1,008; 5,696]	0,1698
Tag 183 (Woche 26)	113	16,89 (15,962)	-2,12 (1,195)	105	13,73 (15,970)	-1,74 (1,237)	-0,38 [-3,775; 3,005]	0,8233
Tag 211 (Woche 30)	100	15,92 (15,628)	-1,52 (1,247)	96	15,19 (17,396)	-1,85 (1,281)	0,34 [-3,183; 3,858]	0,8504
Tag 239 (Woche 34)	98	16,58 (15,807)	-4,57 (1,134)	89	15,26 (18,644)	-2,33 (1,186)	-2,24 [-5,478; 0,988]	0,1727
Tag 267 (Woche 38)	96	16,41 (15,364)	-3,28 (1,132)	88	14,30 (17,090)	-2,88 (1,187)	-0,40 [-3,634; 2,833]	0,8073
Tag 295 (Woche 42)	99	15,57 (15,414)	-2,66 (1,235)	89	14,79 (17,260)	-4,10 (1,304)	1,43 [-2,103; 4,971]	0,4253
Tag 323 (Woche 46)	94	15,60 (15,661)	-3,25 (1,065)	76	15,24 (17,815)	-4,29 (1,160)	1,04 [-2,062; 4,141]	0,5098
Tag 351 (Woche 50)	82	16,16 (15,895)	-4,04 (1,260)	81	14,81 (17,678)	-3,62 (1,297)	-0,43 [-3,992; 3,136]	0,8133
Tag 379 (Woche 54)	75	17,00 (16,119)	-0,98 (1,390)	68	13,85 (17,433)	-2,92 (1,468)	1,94 [-2,057; 5,928]	0,3402
Tag 407 (Woche 58)	70	16,90 (15,540)	-3,77 (1,293)	57	13,01 (15,351)	-3,03 (1,423)	-0,75 [-4,547; 3,057]	0,6994

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
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Table 2.4.2.2.4 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Urologische Symptome over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	16,93 (15,552)	-3,28 (1,269)	50	12,50 (15,361)	-3,61 (1,418)	0,33 [-3,442; 4,104]	0,8627
Durchschnitt über alle Visiten	156	16,67 (15,755)	-1,27 (0,762)	148	15,99 (18,172)	-2,02 (0,792)	0,75 [-1,413; 2,915]	0,4952
Hedges' g SMD							0,08 [-0,147; 0,303]	0,4957

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbas 27MAR2024:14:53

Table 2.4.2.2.5 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Gastrointestinale Symptome over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	11,63 (11,832)	-0,37 (0,824)	136	12,60 (13,521)	-1,22 (0,848)	0,84 [-1,484; 3,171]	0,4762
Tag 43 (Woche 6)	132	11,77 (12,186)	-0,54 (0,914)	130	13,38 (14,197)	-1,36 (0,932)	0,82 [-1,751; 3,391]	0,5305
Tag 64 (Woche 9)	122	12,51 (11,986)	1,06 (0,948)	122	12,84 (13,393)	-1,75 (0,962)	2,81 [0,150; 5,466]	0,0384*
Tag 85 (Woche 12)	120	12,78 (12,631)	-0,84 (0,979)	117	13,11 (13,839)	-1,60 (1,000)	0,76 [-1,994; 3,513]	0,5877
Tag 106 (Woche 15)	115	12,35 (12,243)	0,65 (0,991)	117	12,48 (12,641)	-1,29 (1,001)	1,93 [-0,840; 4,707]	0,1710
Tag 127 (Woche 18)	107	12,59 (12,021)	0,72 (1,072)	98	12,59 (13,802)	-1,44 (1,111)	2,16 [-0,879; 5,198]	0,1629
Tag 155 (Woche 22)	114	12,69 (12,095)	-0,63 (0,950)	108	12,59 (13,498)	-2,60 (0,975)	1,98 [-0,704; 4,657]	0,1478
Tag 183 (Woche 26)	113	12,80 (12,349)	0,30 (1,040)	105	11,81 (12,274)	-2,29 (1,075)	2,60 [-0,349; 5,540]	0,0838
Tag 211 (Woche 30)	100	12,00 (11,566)	-0,39 (1,025)	96	11,81 (13,967)	-1,01 (1,053)	0,62 [-2,278; 3,512]	0,6752
Tag 239 (Woche 34)	98	12,04 (11,394)	-1,90 (0,980)	89	11,24 (12,415)	-1,04 (1,025)	-0,86 [-3,657; 1,929]	0,5429
Tag 267 (Woche 38)	96	12,71 (12,200)	-0,54 (1,188)	88	10,98 (12,131)	-0,64 (1,243)	0,11 [-3,284; 3,494]	0,9513
Tag 295 (Woche 42)	99	11,45 (11,270)	0,26 (0,995)	89	11,09 (12,183)	-3,02 (1,048)	3,28 [0,440; 6,128]	0,0238*
Tag 323 (Woche 46)	94	11,06 (11,591)	-1,43 (1,061)	76	11,75 (12,690)	-1,24 (1,151)	-0,20 [-3,278; 2,888]	0,9008
Tag 351 (Woche 50)	82	11,87 (11,381)	-0,89 (1,038)	81	11,36 (12,447)	-1,53 (1,066)	0,64 [-2,290; 3,569]	0,6675
Tag 379 (Woche 54)	75	12,00 (12,106)	-1,08 (1,048)	68	9,80 (10,523)	-1,27 (1,111)	0,20 [-2,812; 3,207]	0,8974
Tag 407 (Woche 58)	70	11,24 (11,152)	-0,34 (0,994)	57	9,59 (10,001)	-2,08 (1,093)	1,74 [-1,169; 4,642]	0,2400

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
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Table 2.4.2.2.5 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Gastrointestinale Symptome over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	10,79 (9,685)	-1,15 (0,988)	50	9,47 (10,441)	-1,83 (1,102)	0,68 [-2,224; 3,587]	0,6439
Durchschnitt über alle Visiten	156	11,67 (12,084)	-0,42 (0,661)	148	13,60 (13,842)	-1,60 (0,688)	1,18 [-0,696; 3,060]	0,2164
Hedges' g SMD							0,14 [-0,083; 0,367]	0,2170

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbat 27MAR2024:14:53

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Table 2.4.2.2.6 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	16,67 (25,835)	11,07 (1,967)	136	14,95 (22,706)	9,37 (2,014)	1,70 [-3,841; 7,241]	0,5463
Tag 43 (Woche 6)	132	16,04 (24,315)	15,29 (2,342)	130	15,00 (22,719)	13,66 (2,377)	1,63 [-4,936; 8,201]	0,6250
Tag 64 (Woche 9)	122	15,57 (23,932)	15,59 (2,419)	122	15,16 (23,178)	15,56 (2,451)	0,03 [-6,749; 6,807]	0,9932
Tag 85 (Woche 12)	120	15,28 (24,501)	19,82 (2,204)	117	15,24 (23,116)	15,63 (2,244)	4,19 [-1,999; 10,380]	0,1838
Tag 106 (Woche 15)	115	14,93 (23,916)	18,48 (2,332)	117	14,39 (21,654)	17,56 (2,357)	0,92 [-5,605; 7,443]	0,7818
Tag 127 (Woche 18)	107	15,42 (24,731)	19,18 (2,311)	98	14,97 (22,891)	15,61 (2,385)	3,57 [-2,966; 10,105]	0,2833
Tag 155 (Woche 22)	114	17,69 (26,726)	17,25 (2,200)	108	14,35 (23,065)	14,26 (2,253)	2,99 [-3,204; 9,192]	0,3426
Tag 183 (Woche 26)	113	17,99 (27,561)	15,71 (2,110)	105	13,17 (21,767)	12,24 (2,175)	3,47 [-2,498; 9,438]	0,2535
Tag 211 (Woche 30)	100	17,67 (26,677)	12,47 (1,967)	96	13,02 (21,792)	7,61 (2,021)	4,86 [-0,701; 10,412]	0,0866
Tag 239 (Woche 34)	98	13,95 (23,411)	11,99 (1,993)	89	12,36 (20,951)	7,43 (2,080)	4,56 [-1,107; 10,228]	0,1143
Tag 267 (Woche 38)	96	16,32 (24,421)	12,05 (2,174)	88	13,45 (21,717)	8,14 (2,272)	3,91 [-2,279; 10,104]	0,2147
Tag 295 (Woche 42)	99	14,14 (23,129)	12,79 (2,091)	89	12,36 (20,494)	6,14 (2,200)	6,65 [0,676; 12,618]	0,0292*
Tag 323 (Woche 46)	94	14,54 (25,310)	11,24 (2,126)	76	14,69 (22,602)	8,59 (2,291)	2,66 [-3,496; 8,808]	0,3962
Tag 351 (Woche 50)	82	16,46 (25,592)	9,20 (2,285)	81	12,96 (21,731)	9,57 (2,362)	-0,37 [-6,840; 6,109]	0,9116
Tag 379 (Woche 54)	75	15,11 (25,138)	10,89 (2,209)	68	12,99 (20,330)	8,13 (2,330)	2,75 [-3,573; 9,081]	0,3920
Tag 407 (Woche 58)	70	16,67 (24,899)	11,22 (2,191)	57	12,57 (19,990)	7,97 (2,386)	3,25 [-3,142; 9,635]	0,3178

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
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Table 2.4.2.2.6 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	13,76 (23,291)	7,96 (2,136)	50	11,67 (18,823)	5,86 (2,355)	2,10 [-4,162; 8,368]	0,5087
Durchschnitt über alle Visiten	156	17,52 (26,894)	13,66 (1,528)	148	15,09 (22,448)	10,78 (1,582)	2,88 [-1,452; 7,202]	0,1921
Hedges' g SMD							0,15 [-0,076; 0,375]	0,1928

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbau 27MAR2024:14:53

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Table 2.4.2.2.7 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Rücken- und Beckenschmerzen over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	26,21 (26,985)	-5,94 (1,797)	136	24,75 (25,659)	-7,70 (1,847)	1,76 [-3,309; 6,831]	0,4947
Tag 43 (Woche 6)	132	28,03 (28,185)	-5,70 (1,906)	130	26,67 (26,705)	-6,77 (1,931)	1,06 [-4,271; 6,396]	0,6952
Tag 64 (Woche 9)	122	25,96 (26,595)	-6,27 (1,792)	122	25,41 (25,732)	-8,96 (1,811)	2,69 [-2,323; 7,706]	0,2916
Tag 85 (Woche 12)	120	26,39 (27,635)	-6,03 (1,904)	117	26,21 (26,562)	-5,33 (1,939)	-0,69 [-6,039; 4,654]	0,7988
Tag 106 (Woche 15)	115	23,77 (24,884)	-5,46 (1,938)	117	23,93 (23,912)	-6,37 (1,948)	0,91 [-4,500; 6,314]	0,7414
Tag 127 (Woche 18)	107	25,55 (24,902)	-7,35 (2,102)	98	23,47 (23,550)	-7,00 (2,182)	-0,36 [-6,323; 5,611]	0,9066
Tag 155 (Woche 22)	114	25,73 (25,488)	-3,09 (2,165)	108	24,38 (26,809)	-4,25 (2,223)	1,16 [-4,951; 7,268]	0,7091
Tag 183 (Woche 26)	113	25,96 (26,627)	-2,13 (2,174)	105	23,81 (25,618)	-3,92 (2,249)	1,79 [-4,372; 7,948]	0,5682
Tag 211 (Woche 30)	100	24,33 (25,450)	-6,51 (2,134)	96	23,26 (24,240)	0,16 (2,190)	-6,67 [-12,691; -0,650]	0,0300*
Tag 239 (Woche 34)	98	25,17 (25,803)	-6,54 (2,101)	89	23,60 (25,723)	-3,02 (2,196)	-3,52 [-9,501; 2,471]	0,2486
Tag 267 (Woche 38)	96	23,26 (24,718)	-5,31 (2,191)	88	23,86 (26,236)	-3,38 (2,288)	-1,93 [-8,163; 4,311]	0,5434
Tag 295 (Woche 42)	99	22,90 (23,156)	-2,56 (2,007)	89	22,85 (24,922)	-4,03 (2,110)	1,47 [-4,262; 7,194]	0,6147
Tag 323 (Woche 46)	94	24,11 (24,638)	-1,80 (2,215)	76	24,12 (26,443)	0,70 (2,414)	-2,51 [-8,958; 3,948]	0,4451
Tag 351 (Woche 50)	82	26,02 (25,133)	-4,41 (2,234)	81	25,10 (26,104)	-3,52 (2,280)	-0,88 [-7,175; 5,407]	0,7820
Tag 379 (Woche 54)	75	24,89 (23,945)	-4,91 (2,297)	68	23,53 (27,655)	-2,57 (2,416)	-2,33 [-8,908; 4,242]	0,4848
Tag 407 (Woche 58)	70	26,67 (25,124)	-5,02 (2,056)	57	25,73 (28,184)	-4,11 (2,249)	-0,91 [-6,919; 5,109]	0,7667

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
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Table 2.4.2.2.7 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Rücken- und Beckenschmerzen over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	24,34 (23,346)	-5,06 (2,248)	50	23,33 (26,298)	-4,31 (2,495)	-0,75 [-7,384; 5,887]	0,8239
Durchschnitt über alle Visiten	156	26,92 (27,334)	-4,95 (1,297)	148	26,13 (26,808)	-4,38 (1,346)	-0,57 [-4,248; 3,107]	0,7603
Hedges' g SMD							-0,03 [-0,260; 0,190]	0,7607

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbav 27MAR2024:14:53

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Table 2.4.2.2.8 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	15,17 (24,839)	15,34 (2,382)	136	12,50 (21,445)	16,36 (2,442)	-1,02 [-7,743; 5,694]	0,7643
Tag 43 (Woche 6)	132	15,40 (24,507)	22,52 (2,514)	130	12,05 (20,754)	23,77 (2,551)	-1,25 [-8,306; 5,806]	0,7277
Tag 64 (Woche 9)	122	14,75 (23,880)	26,72 (2,643)	122	11,48 (19,996)	25,74 (2,677)	0,98 [-6,432; 8,392]	0,7949
Tag 85 (Woche 12)	120	15,83 (24,810)	30,38 (2,443)	117	13,39 (22,768)	32,52 (2,485)	-2,14 [-9,003; 4,719]	0,5394
Tag 106 (Woche 15)	115	16,23 (24,727)	36,67 (2,672)	117	11,11 (18,570)	35,34 (2,694)	1,32 [-6,160; 8,805]	0,7282
Tag 127 (Woche 18)	107	15,89 (23,943)	35,06 (2,595)	98	13,61 (23,369)	37,71 (2,679)	-2,65 [-9,996; 4,693]	0,4780
Tag 155 (Woche 22)	114	16,37 (25,182)	32,23 (2,665)	108	12,35 (21,661)	31,81 (2,726)	0,42 [-7,091; 7,934]	0,9122
Tag 183 (Woche 26)	113	16,81 (25,246)	34,02 (2,597)	105	10,79 (18,774)	31,23 (2,677)	2,79 [-4,571; 10,150]	0,4564
Tag 211 (Woche 30)	100	16,33 (24,387)	30,22 (2,503)	96	11,81 (20,508)	28,85 (2,566)	1,37 [-5,697; 8,442]	0,7025
Tag 239 (Woche 34)	98	16,33 (25,438)	26,93 (2,517)	89	11,24 (17,367)	26,80 (2,625)	0,14 [-7,039; 7,314]	0,9699
Tag 267 (Woche 38)	96	14,93 (23,630)	24,57 (2,486)	88	10,61 (17,901)	26,32 (2,603)	-1,76 [-8,857; 5,345]	0,6268
Tag 295 (Woche 42)	99	15,82 (25,352)	25,34 (2,556)	89	10,86 (17,961)	23,91 (2,689)	1,43 [-5,893; 8,754]	0,7009
Tag 323 (Woche 46)	94	15,96 (25,272)	25,81 (2,595)	76	8,77 (16,661)	24,40 (2,821)	1,41 [-6,167; 8,986]	0,7144
Tag 351 (Woche 50)	82	13,82 (23,975)	22,45 (2,665)	81	9,88 (17,033)	24,49 (2,758)	-2,04 [-9,603; 5,519]	0,5953
Tag 379 (Woche 54)	75	14,67 (24,037)	23,25 (2,437)	68	8,33 (14,541)	20,89 (2,596)	2,36 [-4,673; 9,398]	0,5089
Tag 407 (Woche 58)	70	13,81 (23,736)	20,49 (2,642)	57	8,77 (14,809)	23,85 (2,902)	-3,36 [-11,106; 4,391]	0,3939

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
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Table 2.4.2.2.8 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	14,81 (26,625)	21,52 (2,890)	50	8,00 (15,879)	24,66 (3,216)	-3,15 [-11,707; 5,415]	0,4692
Durchschnitt über alle Visiten	156	15,81 (24,958)	26,68 (1,746)	148	12,61 (21,439)	26,98 (1,810)	-0,30 [-5,256; 4,651]	0,9044
Hedges' g SMD							-0,01 [-0,239; 0,211]	0,9044

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbaw 27MAR2024:14:53

Nutzenbewertung nach AMNOG

Table 2.4.2.2.9 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Muskulärer Schmerz over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	14,94 (23,548)	8,17 (2,136)	136	14,71 (21,760)	6,29 (2,195)	1,87 [-4,151; 7,898]	0,5410
Tag 43 (Woche 6)	132	15,66 (23,458)	7,95 (2,326)	130	13,59 (19,773)	13,00 (2,354)	-5,05 [-11,561; 1,464]	0,1281
Tag 64 (Woche 9)	122	15,30 (23,530)	9,52 (2,343)	122	13,39 (19,002)	9,97 (2,363)	-0,46 [-7,009; 6,094]	0,8907
Tag 85 (Woche 12)	120	15,83 (24,046)	11,17 (2,270)	117	14,25 (21,135)	11,88 (2,306)	-0,71 [-7,077; 5,657]	0,8264
Tag 106 (Woche 15)	115	15,07 (23,876)	12,49 (2,246)	117	13,96 (20,171)	13,38 (2,253)	-0,89 [-7,156; 5,367]	0,7788
Tag 127 (Woche 18)	107	15,26 (22,562)	9,76 (2,272)	98	12,59 (20,596)	10,68 (2,356)	-0,92 [-7,370; 5,527]	0,7786
Tag 155 (Woche 22)	114	14,33 (23,030)	8,40 (2,184)	108	12,65 (20,743)	6,52 (2,241)	1,88 [-4,282; 8,043]	0,5484
Tag 183 (Woche 26)	113	15,04 (23,567)	8,84 (2,229)	105	12,70 (19,271)	8,90 (2,306)	-0,06 [-6,376; 6,259]	0,9854
Tag 211 (Woche 30)	100	14,33 (22,351)	7,86 (2,265)	96	13,19 (19,634)	13,22 (2,324)	-5,36 [-11,748; 1,037]	0,1002
Tag 239 (Woche 34)	98	14,97 (23,016)	9,33 (2,239)	89	12,36 (19,057)	12,89 (2,343)	-3,56 [-9,944; 2,829]	0,2736
Tag 267 (Woche 38)	96	14,24 (22,029)	9,35 (2,183)	88	11,74 (18,250)	14,80 (2,289)	-5,44 [-11,676; 0,787]	0,0865
Tag 295 (Woche 42)	99	11,78 (20,378)	6,22 (1,911)	89	13,11 (19,213)	12,17 (2,011)	-5,95 [-11,405; -0,488]	0,0329*
Tag 323 (Woche 46)	94	12,41 (20,730)	9,75 (2,062)	76	11,40 (18,501)	12,35 (2,257)	-2,60 [-8,613; 3,413]	0,3951
Tag 351 (Woche 50)	82	13,01 (20,120)	10,81 (2,321)	81	12,76 (19,414)	16,90 (2,375)	-6,09 [-12,629; 0,452]	0,0679
Tag 379 (Woche 54)	75	12,44 (20,337)	8,52 (2,259)	68	13,24 (19,222)	15,11 (2,381)	-6,59 [-13,063; -0,126]	0,0457*
Tag 407 (Woche 58)	70	12,86 (20,691)	8,14 (2,462)	57	14,04 (18,843)	12,47 (2,701)	-4,34 [-11,553; 2,874]	0,2367

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
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Table 2.4.2.2.9 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Muskulärer Schmerz over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	12,70 (21,939)	9,99 (2,614)	50	11,33 (18,578)	12,41 (2,911)	-2,42 [-10,141; 5,304]	0,5369
Durchschnitt über alle Visiten	156	15,38 (23,151)	9,19 (1,308)	148	14,86 (21,747)	11,94 (1,359)	-2,75 [-6,456; 0,964]	0,1462
Hedges' g SMD							-0,17 [-0,392; 0,059]	0,1470

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbax 27MAR2024:14:53

Table 2.4.2.2.10 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Haarausfall over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	5,98 (16,039)	69,97 (2,631)	136	4,90 (15,988)	66,55 (2,705)	3,42 [-4,006; 10,856]	0,3650
Tag 43 (Woche 6)	132	6,31 (17,048)	64,83 (3,121)	130	5,38 (17,014)	64,93 (3,165)	-0,10 [-8,852; 8,658]	0,9826
Tag 64 (Woche 9)	122	7,38 (17,934)	54,39 (3,517)	122	5,46 (17,334)	50,01 (3,550)	4,37 [-5,469; 14,216]	0,3825
Tag 85 (Woche 12)	120	6,94 (17,763)	47,27 (3,618)	117	5,41 (17,484)	52,51 (3,682)	-5,24 [-15,406; 4,928]	0,3113
Tag 106 (Woche 15)	115	6,96 (17,932)	57,11 (3,834)	117	5,70 (17,666)	49,72 (3,856)	7,39 [-3,319; 18,099]	0,1754
Tag 127 (Woche 18)	107	6,85 (17,578)	48,53 (3,803)	98	4,08 (14,569)	42,42 (3,945)	6,11 [-4,694; 16,911]	0,2665
Tag 155 (Woche 22)	114	6,43 (17,105)	37,36 (3,930)	108	4,32 (15,178)	34,22 (4,035)	3,14 [-7,956; 14,235]	0,5779
Tag 183 (Woche 26)	113	7,08 (18,067)	20,57 (3,319)	105	4,76 (15,627)	10,73 (3,430)	9,84 [0,432; 19,244]	0,0404*
Tag 211 (Woche 30)	100	6,67 (17,082)	12,79 (2,973)	96	5,21 (15,543)	7,75 (3,056)	5,04 [-3,364; 13,434]	0,2389
Tag 239 (Woche 34)	98	6,46 (17,029)	5,87 (2,501)	89	5,62 (17,578)	7,35 (2,619)	-1,48 [-8,616; 5,648]	0,6823
Tag 267 (Woche 38)	96	7,29 (17,574)	1,46 (2,319)	88	4,92 (15,610)	7,10 (2,433)	-5,64 [-12,261; 0,986]	0,0950
Tag 295 (Woche 42)	99	7,41 (17,532)	3,41 (2,168)	89	3,75 (13,705)	4,50 (2,295)	-1,10 [-7,325; 5,131]	0,7291
Tag 323 (Woche 46)	94	8,16 (18,084)	5,25 (1,952)	76	5,70 (17,544)	0,28 (2,126)	4,97 [-0,716; 10,663]	0,0864
Tag 351 (Woche 50)	82	7,32 (17,391)	3,73 (2,030)	81	4,53 (16,460)	3,11 (2,093)	0,62 [-5,136; 6,368]	0,8331
Tag 379 (Woche 54)	75	8,44 (19,057)	2,92 (2,423)	68	4,41 (13,994)	5,37 (2,560)	-2,45 [-9,420; 4,519]	0,4889
Tag 407 (Woche 58)	70	8,57 (19,400)	3,04 (1,887)	57	4,68 (14,691)	-1,17 (2,067)	4,21 [-1,322; 9,745]	0,1350

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
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Table 2.4.2.2.10 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Haarausfall over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	7,41 (18,399)	3,82 (1,865)	50	2,67 (9,135)	-0,49 (2,089)	4,31 [-1,242; 9,865]	0,1273
Durchschnitt über alle Visiten	156	6,20 (16,419)	26,02 (1,609)	148	4,95 (16,202)	23,82 (1,666)	2,20 [-2,359; 6,761]	0,3430
Hedges' g SMD							0,11 [-0,116; 0,334]	0,3434

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbay 27MAR2024:14:53

Nutzenbewertung nach AMNOG

Table 2.4.2.2.11 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Geschmacksveränderung over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	145	6,67 (15,516)	14,56 (2,188)	136	9,56 (22,188)	12,33 (2,257)	2,24 [-3,951; 8,422]	0,4776
Tag 43 (Woche 6)	132	5,81 (14,560)	18,98 (2,413)	130	8,46 (21,290)	15,72 (2,456)	3,27 [-3,514; 10,045]	0,3440
Tag 64 (Woche 9)	122	5,74 (13,342)	17,66 (2,543)	122	8,47 (21,667)	19,65 (2,581)	-2,00 [-9,131; 5,136]	0,5821
Tag 85 (Woche 12)	120	5,56 (13,891)	22,89 (2,640)	117	8,26 (21,843)	19,04 (2,694)	3,85 [-3,575; 11,281]	0,3082
Tag 106 (Woche 15)	115	5,80 (14,816)	21,94 (2,694)	117	7,41 (20,110)	19,88 (2,722)	2,07 [-5,472; 9,605]	0,5900
Tag 127 (Woche 18)	107	6,85 (16,342)	17,79 (2,539)	98	6,46 (19,535)	17,76 (2,630)	0,03 [-7,164; 7,232]	0,9926
Tag 155 (Woche 22)	114	6,73 (16,699)	18,61 (2,253)	108	8,95 (23,061)	8,44 (2,315)	10,18 [3,815; 16,537]	0,0018*
Tag 183 (Woche 26)	113	6,78 (16,158)	19,86 (2,277)	105	7,30 (20,663)	2,47 (2,353)	17,39 [10,941; 23,832]	<0,0001*
Tag 211 (Woche 30)	100	7,00 (16,613)	19,99 (2,329)	96	7,99 (20,940)	2,70 (2,398)	17,29 [10,709; 23,870]	<0,0001*
Tag 239 (Woche 34)	98	5,10 (12,978)	14,56 (2,176)	89	5,99 (17,811)	0,88 (2,275)	13,68 [7,484; 19,873]	<0,0001*
Tag 267 (Woche 38)	96	5,90 (16,037)	10,75 (1,956)	88	7,58 (21,279)	-0,25 (2,052)	11,00 [5,418; 16,586]	0,0001*
Tag 295 (Woche 42)	99	6,73 (17,156)	12,60 (1,996)	89	5,99 (17,811)	0,12 (2,107)	12,47 [6,758; 18,190]	<0,0001*
Tag 323 (Woche 46)	94	7,09 (18,207)	9,86 (2,057)	76	7,89 (22,356)	3,35 (2,235)	6,51 [0,526; 12,495]	0,0331*
Tag 351 (Woche 50)	82	5,28 (16,118)	11,66 (2,407)	81	7,41 (21,082)	6,15 (2,485)	5,51 [-1,306; 12,335]	0,1125
Tag 379 (Woche 54)	75	4,89 (15,200)	12,36 (2,281)	68	6,37 (18,445)	4,62 (2,408)	7,74 [1,203; 14,279]	0,0205*
Tag 407 (Woche 58)	70	4,29 (14,930)	10,40 (2,184)	57	5,26 (18,676)	0,15 (2,384)	10,24 [3,880; 16,608]	0,0017*

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbaz 27MAR2024:14:53

Table 2.4.2.2.11 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EORTC QLQ-EN24 Geschmacksveränderung over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 435 (Woche 62)	63	4,76 (16,781)	9,43 (2,277)	50	4,00 (12,848)	1,76 (2,529)	7,67 [0,979; 14,367]	0,0249*
Durchschnitt über alle Visiten	156	7,05 (16,937)	15,52 (1,459)	148	9,23 (21,585)	7,93 (1,518)	7,60 [3,453; 11,741]	0,0004*
Hedges' g SMD							0,41 [0,186; 0,640]	0,0004*

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
Sexual enjoyment and sexual/vaginal problems from QLQ-EN24 are not analysed as there is exccessive missing data (>75% missing data).
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbaz 27MAR2024:14:53

Table 2.4.3.2.1 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EQ-5D-5L Visuelle Analogskala over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	144	73,38 (20,120)	-2,74 (1,285)	135	72,53 (18,069)	-0,12 (1,326)	-2,62 [-6,252; 1,004]	0,1557
Tag 43 (Woche 6)	131	73,69 (19,885)	-1,97 (1,474)	127	70,94 (19,377)	-0,96 (1,515)	-1,00 [-5,156; 3,151]	0,6351
Tag 64 (Woche 9)	121	74,14 (19,661)	-2,68 (1,488)	119	71,92 (18,895)	-1,22 (1,523)	-1,46 [-5,651; 2,728]	0,4927
Tag 85 (Woche 12)	120	74,60 (19,667)	-4,19 (1,401)	116	72,48 (18,576)	-2,76 (1,438)	-1,43 [-5,377; 2,523]	0,4775
Tag 106 (Woche 15)	114	75,07 (19,442)	-4,38 (1,417)	116	71,95 (19,341)	-2,54 (1,438)	-1,84 [-5,817; 2,133]	0,3624
Tag 127 (Woche 18)	107	75,15 (19,322)	-2,83 (1,547)	97	73,11 (17,422)	-2,59 (1,612)	-0,24 [-4,640; 4,159]	0,9143
Tag 155 (Woche 22)	114	74,52 (19,404)	-3,86 (1,394)	107	72,79 (19,341)	-1,32 (1,440)	-2,54 [-6,487; 1,401]	0,2054
Tag 183 (Woche 26)	113	75,10 (19,248)	-2,30 (1,375)	104	73,72 (18,467)	-0,93 (1,428)	-1,36 [-5,266; 2,537]	0,4917
Tag 211 (Woche 30)	100	75,92 (18,495)	-3,13 (1,334)	94	72,90 (17,684)	0,94 (1,381)	-4,07 [-7,855; -0,290]	0,0349*
Tag 239 (Woche 34)	98	76,21 (17,642)	-3,04 (1,385)	88	74,36 (17,553)	0,64 (1,452)	-3,68 [-7,630; 0,272]	0,0678
Tag 267 (Woche 38)	96	76,72 (17,694)	-3,94 (1,580)	87	75,00 (17,717)	1,59 (1,657)	-5,53 [-10,035; -1,023]	0,0164*
Tag 295 (Woche 42)	99	77,17 (17,383)	-4,06 (1,490)	88	75,07 (16,478)	-0,06 (1,569)	-4,00 [-8,257; 0,252]	0,0651
Tag 323 (Woche 46)	94	77,28 (17,306)	-2,57 (1,478)	75	74,61 (17,904)	0,97 (1,605)	-3,54 [-7,837; 0,749]	0,1052
Tag 351 (Woche 50)	82	75,59 (17,629)	-0,40 (1,417)	78	73,64 (17,289)	0,35 (1,475)	-0,74 [-4,772; 3,287]	0,7171
Tag 379 (Woche 54)	74	75,92 (18,413)	-1,17 (1,535)	67	72,75 (18,332)	-0,66 (1,623)	-0,51 [-4,921; 3,892]	0,8184
Tag 407 (Woche 58)	71	77,21 (16,379)	-1,55 (1,550)	56	72,86 (17,318)	-1,22 (1,703)	-0,34 [-4,886; 4,213]	0,8843
Tag 435 (Woche 62)	63	78,16 (16,451)	-1,56 (1,617)	49	73,04 (15,324)	1,41 (1,783)	-2,96 [-7,729; 1,804]	0,2216

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.3.2.1 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in EQ-5D-5L Visuelle Analogskala over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	156	72,45 (20,354)	-2,73 (0,963)	147	71,84 (18,725)	-0,50 (1,006)	-2,23 [-4,966; 0,509]	0,1102
Hedges' g SMD							-0,18 [-0,409; 0,042]	0,1110

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/mmrmpr.sas gmmrmprbba 27MAR2024:14:53

Table 2.4.4.2.1 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in PGIS over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	144	2,22 (1,455)	0,31 (0,092)	133	2,05 (1,278)	0,14 (0,095)	0,17 [-0,094; 0,429]	0,2089
Tag 43 (Woche 6)	130	2,12 (1,431)	0,32 (0,099)	125	2,12 (1,348)	0,10 (0,101)	0,21 [-0,063; 0,493]	0,1290
Tag 64 (Woche 9)	121	2,11 (1,353)	0,21 (0,093)	118	2,04 (1,297)	0,11 (0,096)	0,10 [-0,161; 0,365]	0,4445
Tag 85 (Woche 12)	120	2,18 (1,420)	0,25 (0,096)	113	2,04 (1,288)	0,06 (0,099)	0,19 [-0,086; 0,458]	0,1794
Tag 106 (Woche 15)	114	2,17 (1,407)	0,31 (0,103)	113	1,99 (1,271)	0,30 (0,105)	0,01 [-0,279; 0,302]	0,9404
Tag 127 (Woche 18)	105	2,12 (1,364)	0,28 (0,106)	94	1,93 (1,264)	0,11 (0,111)	0,17 [-0,137; 0,470]	0,2802
Tag 155 (Woche 22)	114	2,20 (1,409)	0,20 (0,103)	105	1,93 (1,258)	0,01 (0,107)	0,20 [-0,093; 0,492]	0,1810
Tag 183 (Woche 26)	113	2,19 (1,407)	0,15 (0,096)	99	1,91 (1,246)	-0,05 (0,102)	0,20 [-0,077; 0,475]	0,1560
Tag 211 (Woche 30)	100	2,15 (1,359)	0,17 (0,100)	91	1,91 (1,151)	0,04 (0,105)	0,13 [-0,151; 0,421]	0,3546
Tag 239 (Woche 34)	98	2,16 (1,360)	0,02 (0,097)	87	1,90 (1,230)	-0,12 (0,102)	0,14 [-0,137; 0,419]	0,3191
Tag 267 (Woche 38)	96	2,11 (1,321)	0,05 (0,100)	86	1,83 (1,150)	0,04 (0,106)	0,01 [-0,280; 0,296]	0,9568
Tag 295 (Woche 42)	98	2,16 (1,345)	0,09 (0,098)	86	1,84 (1,157)	0,04 (0,105)	0,05 [-0,230; 0,336]	0,7137
Tag 323 (Woche 46)	94	2,07 (1,354)	0,24 (0,108)	74	1,82 (1,163)	0,16 (0,119)	0,08 [-0,237; 0,397]	0,6181
Tag 351 (Woche 50)	81	2,20 (1,355)	-0,03 (0,094)	78	1,91 (1,164)	0,00 (0,098)	-0,03 [-0,303; 0,235]	0,8039
Tag 379 (Woche 54)	74	2,12 (1,374)	-0,02 (0,099)	67	1,81 (1,171)	0,01 (0,105)	-0,03 [-0,313; 0,259]	0,8544
Tag 407 (Woche 58)	71	1,92 (1,262)	0,03 (0,112)	56	1,79 (1,140)	0,10 (0,125)	-0,07 [-0,404; 0,255]	0,6558
Tag 435 (Woche 62)	63	2,00 (1,332)	-0,09 (0,101)	48	1,71 (1,148)	0,06 (0,115)	-0,15 [-0,458; 0,148]	0,3135

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Table 2.4.4.2.1 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in PGIS over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Durchschnitt über alle Visiten	156	2,26 (1,450)	0,15 (0,064)	145	2,10 (1,345)	0,07 (0,067)	0,08 [-0,101; 0,263]	0,3833
Hedges' g SMD							0,10 [-0,126; 0,327]	0,3837

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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Nutzenbewertung nach AMNOG

Table 2.4.5.2.1 DUO-E (pMMR Durva/Ola): Analysis of change from baseline in PGI-TT over time (mixed model for repeated measures), Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)			Behandlungseffekt	
Zeitpunkt	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	n [a]	Ausgangswert MW (SD) [b]	Veränderung MW (SE)	MWD [95%-KI]	p-Wert
Tag 22 (Woche 3)	140	1,34 (0,792)	1,02 (0,084)	132	1,32 (0,813)	0,95 (0,087)	0,08 [-0,161; 0,316]	0,5225
Tag 43 (Woche 6)	129	1,32 (0,739)	0,97 (0,089)	124	1,35 (0,865)	1,06 (0,091)	-0,08 [-0,332; 0,168]	0,5199
Tag 64 (Woche 9)	119	1,32 (0,724)	0,97 (0,080)	116	1,32 (0,840)	0,89 (0,082)	0,09 [-0,141; 0,312]	0,4585
Tag 85 (Woche 12)	116	1,29 (0,746)	1,06 (0,089)	112	1,31 (0,828)	1,00 (0,091)	0,06 [-0,190; 0,310]	0,6377
Tag 106 (Woche 15)	109	1,25 (0,669)	1,16 (0,097)	108	1,22 (0,646)	1,24 (0,099)	-0,07 [-0,342; 0,201]	0,6099
Tag 127 (Woche 18)	102	1,26 (0,688)	1,19 (0,101)	93	1,26 (0,706)	0,99 (0,106)	0,21 [-0,083; 0,493]	0,1619
Tag 155 (Woche 22)	108	1,31 (0,781)	1,08 (0,099)	103	1,28 (0,759)	0,95 (0,101)	0,13 [-0,149; 0,408]	0,3599
Tag 183 (Woche 26)	107	1,33 (0,798)	0,98 (0,086)	96	1,20 (0,626)	0,57 (0,091)	0,40 [0,158; 0,651]	0,0014*
Tag 211 (Woche 30)	92	1,23 (0,648)	0,87 (0,083)	86	1,24 (0,718)	0,53 (0,086)	0,33 [0,098; 0,569]	0,0057*
Tag 239 (Woche 34)	91	1,20 (0,521)	0,84 (0,088)	81	1,23 (0,746)	0,56 (0,093)	0,28 [0,028; 0,531]	0,0299*
Tag 267 (Woche 38)	88	1,27 (0,601)	0,84 (0,084)	75	1,24 (0,654)	0,53 (0,091)	0,31 [0,066; 0,553]	0,0130*
Tag 295 (Woche 42)	88	1,25 (0,572)	0,75 (0,085)	77	1,23 (0,647)	0,54 (0,091)	0,22 [-0,028; 0,461]	0,0821
Tag 323 (Woche 46)	85	1,25 (0,615)	0,80 (0,089)	62	1,21 (0,704)	0,60 (0,102)	0,20 [-0,065; 0,469]	0,1372
Tag 351 (Woche 50)	71	1,35 (0,678)	0,61 (0,087)	60	1,23 (0,722)	0,53 (0,094)	0,07 [-0,178; 0,328]	0,5611
Tag 379 (Woche 54)	66	1,24 (0,556)	0,54 (0,086)	53	1,26 (0,763)	0,50 (0,095)	0,04 [-0,212; 0,294]	0,7514
Durchschnitt über alle Visiten	154	1,33 (0,776)	0,91 (0,053)	143	1,35 (0,858)	0,76 (0,056)	0,15 [-0,001; 0,303]	0,0520
Hedges' g SMD							0,23 [-0,002; 0,454]	0,0525

[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from baseline score with treatment, visit, and treatment by visit interaction as fixed effects, baseline score as a covariate and baseline score by visit interaction. The analysis includes all visits with at least 25% non-missing data in both treatment arms. Patient is used as random effect in the model. A Toeplitz with heterogeneity matrix TOEPH is used to model within-subject error. SMD = standardised mean difference. * p<0.05.
CTx = Carboplatin + Paclitaxel.
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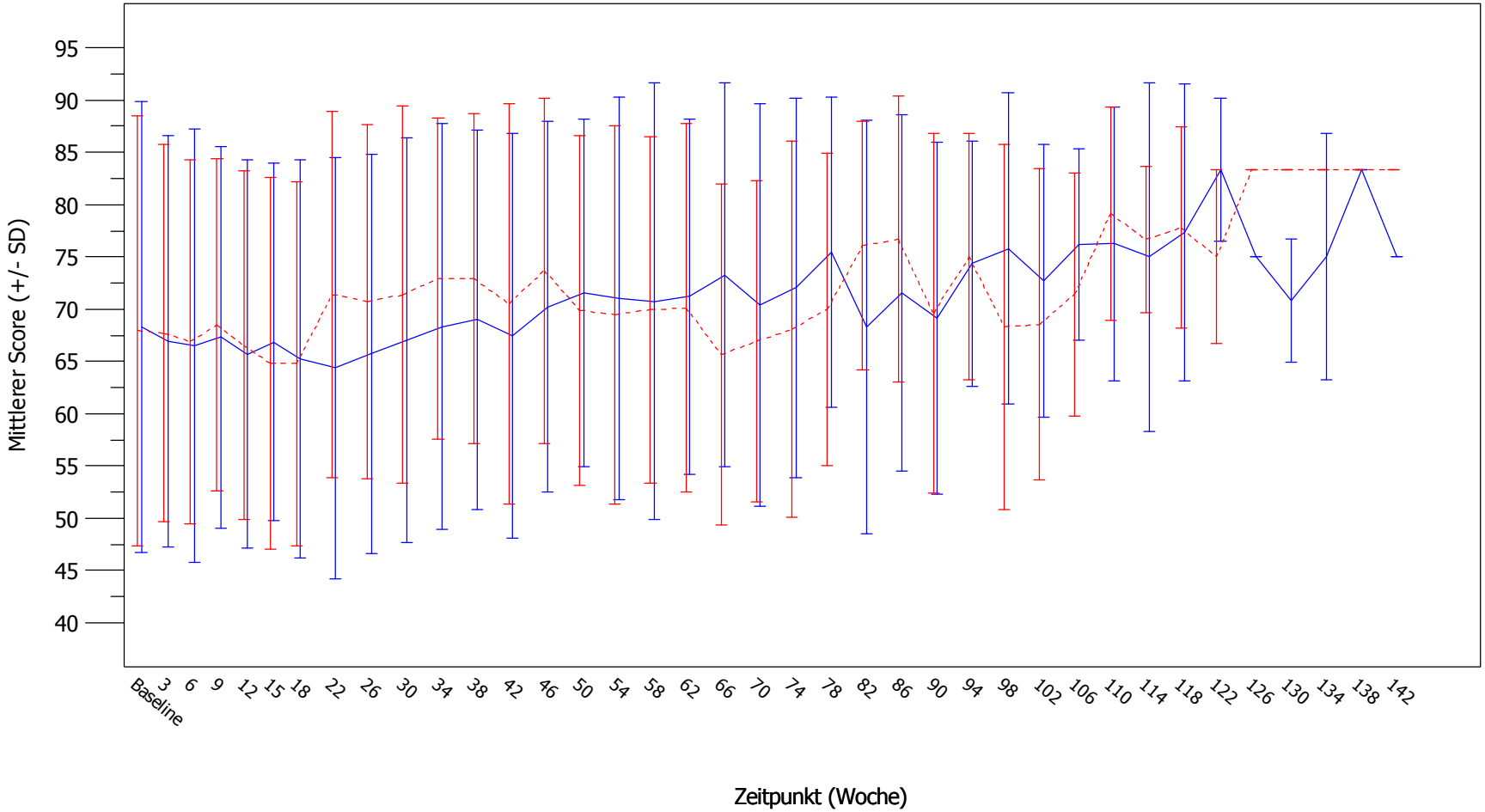
Figure 2.5.1.2.1 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Allgemeine Lebensqualität/Gesundheitsszustand across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



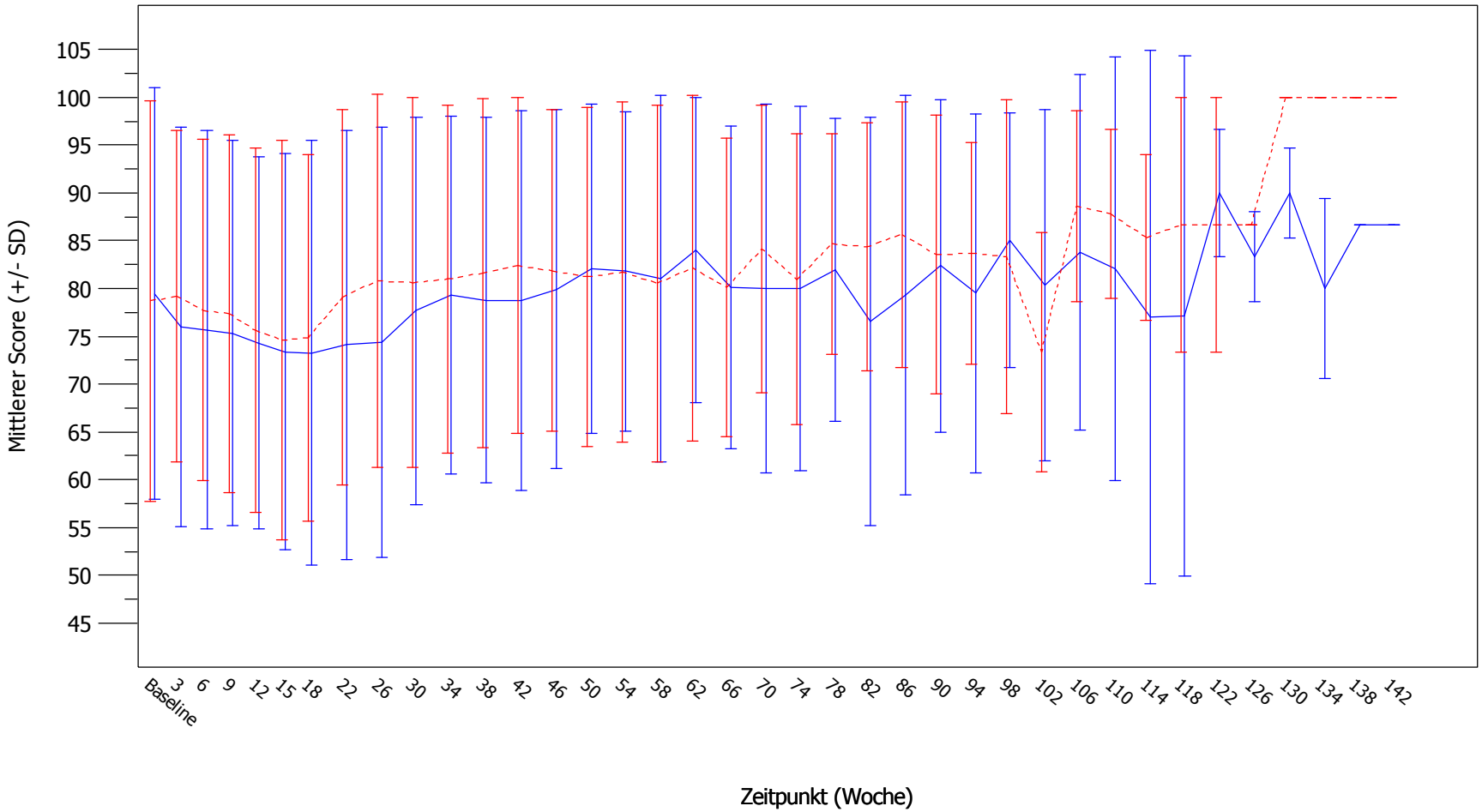
Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.1.2.2 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Funktionsskala: Körper across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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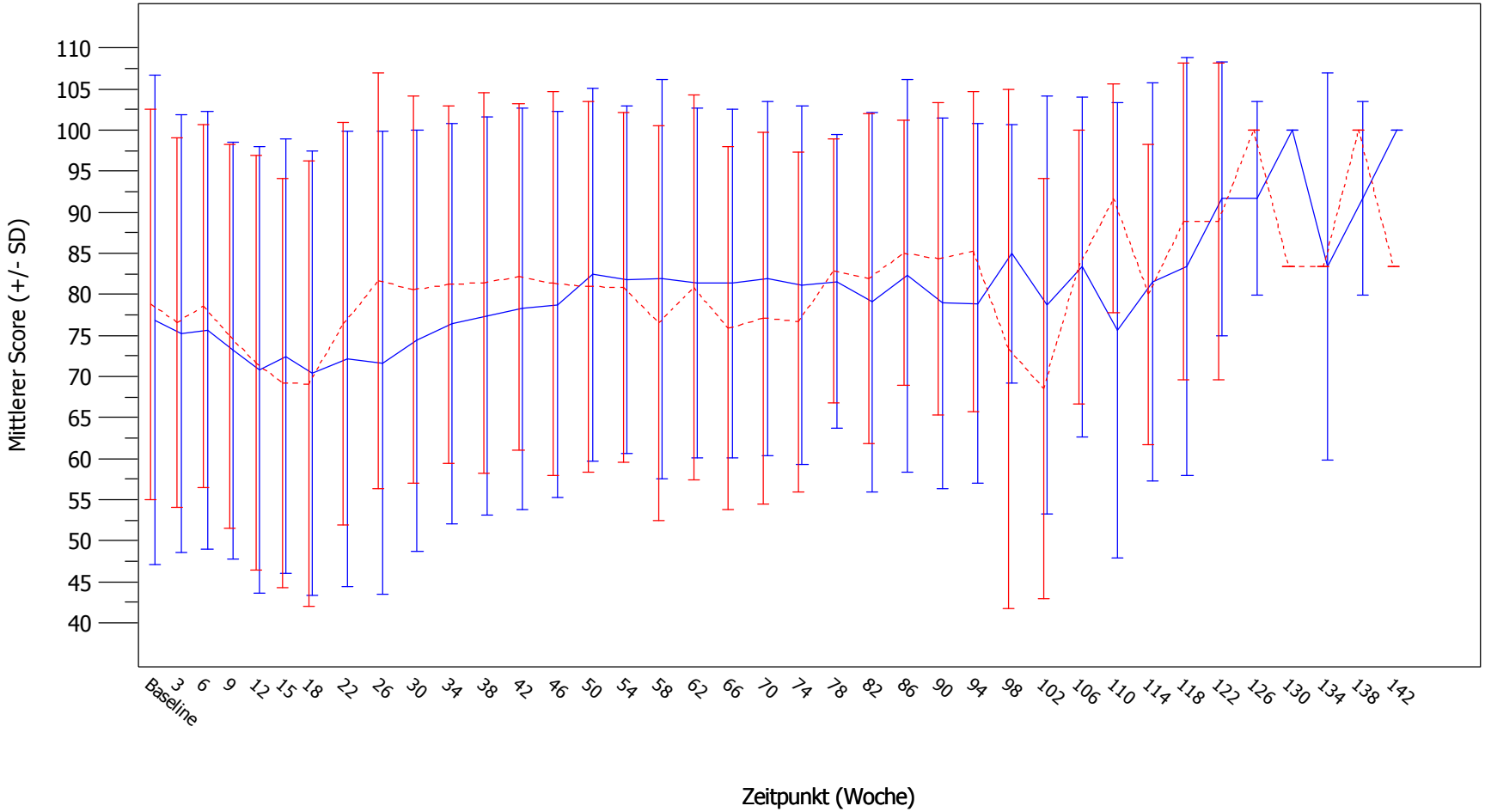
Figure 2.5.1.2.3 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Funktionsskala: Rolle across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



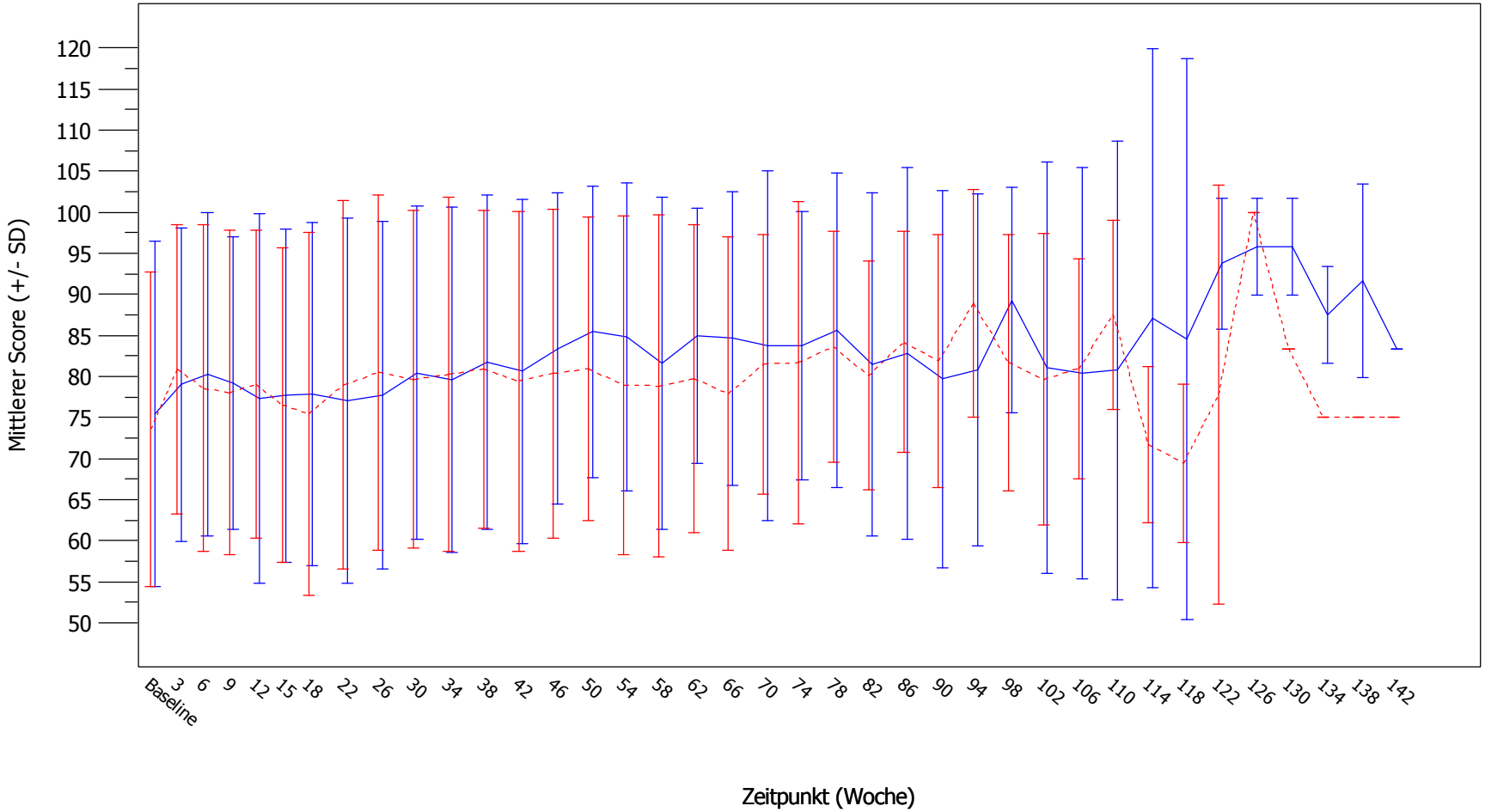
Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.1.2.4 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Funktionsskala: Emotionalität across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



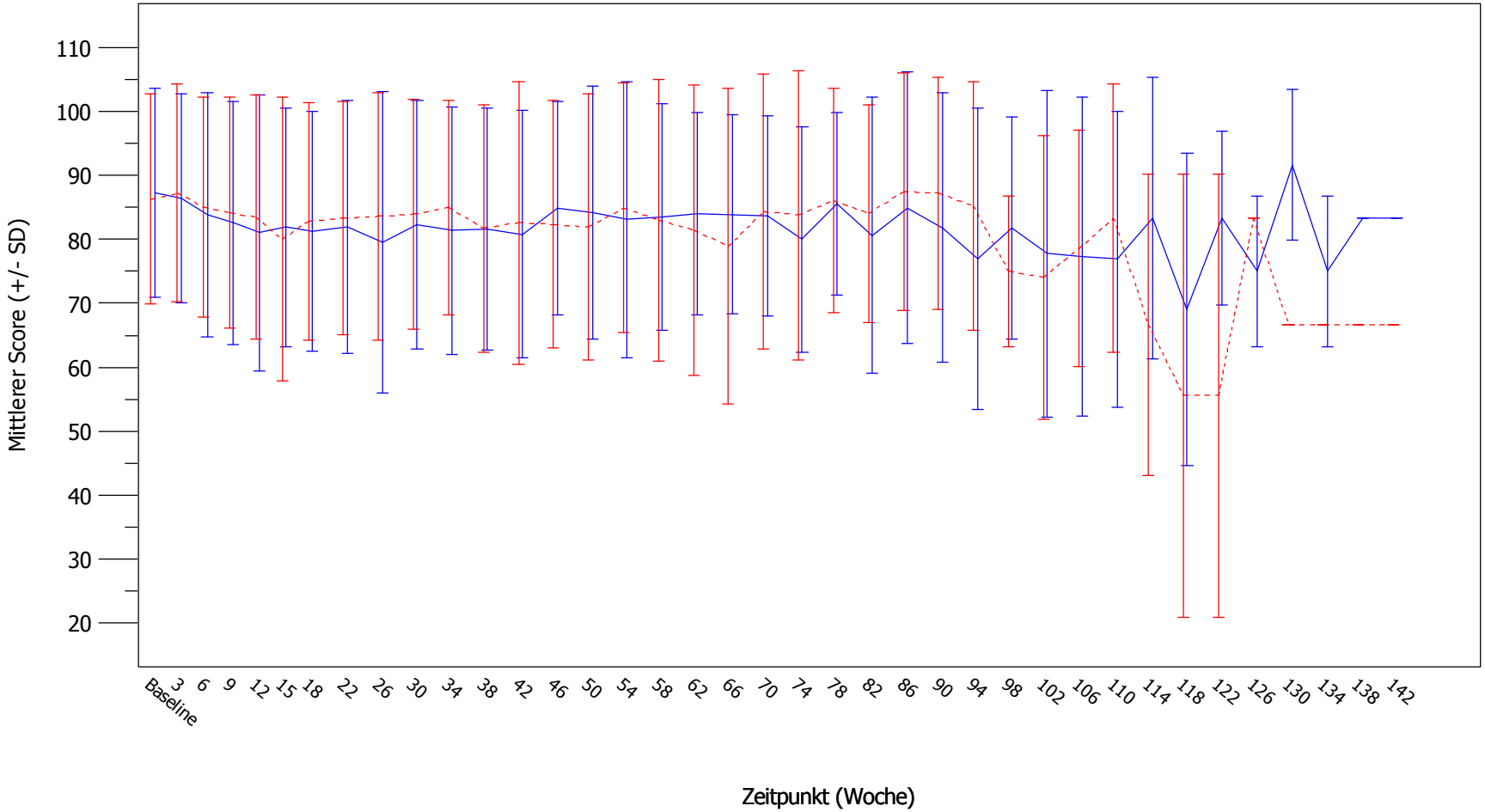
Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.1.2.5 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Funktionsskala: Kognition across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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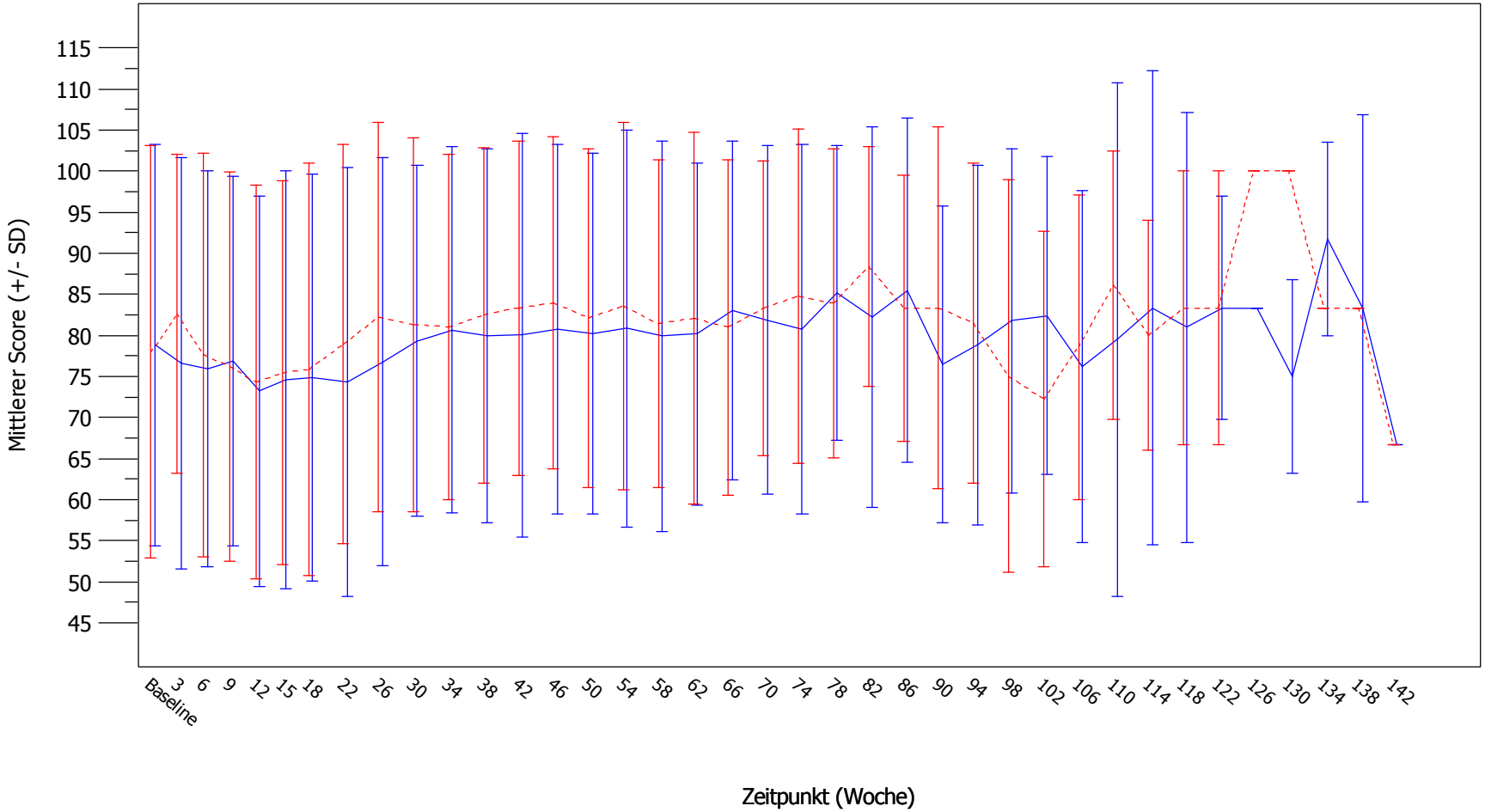
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.1.2.6 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Funktionsskala: Sozial across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023

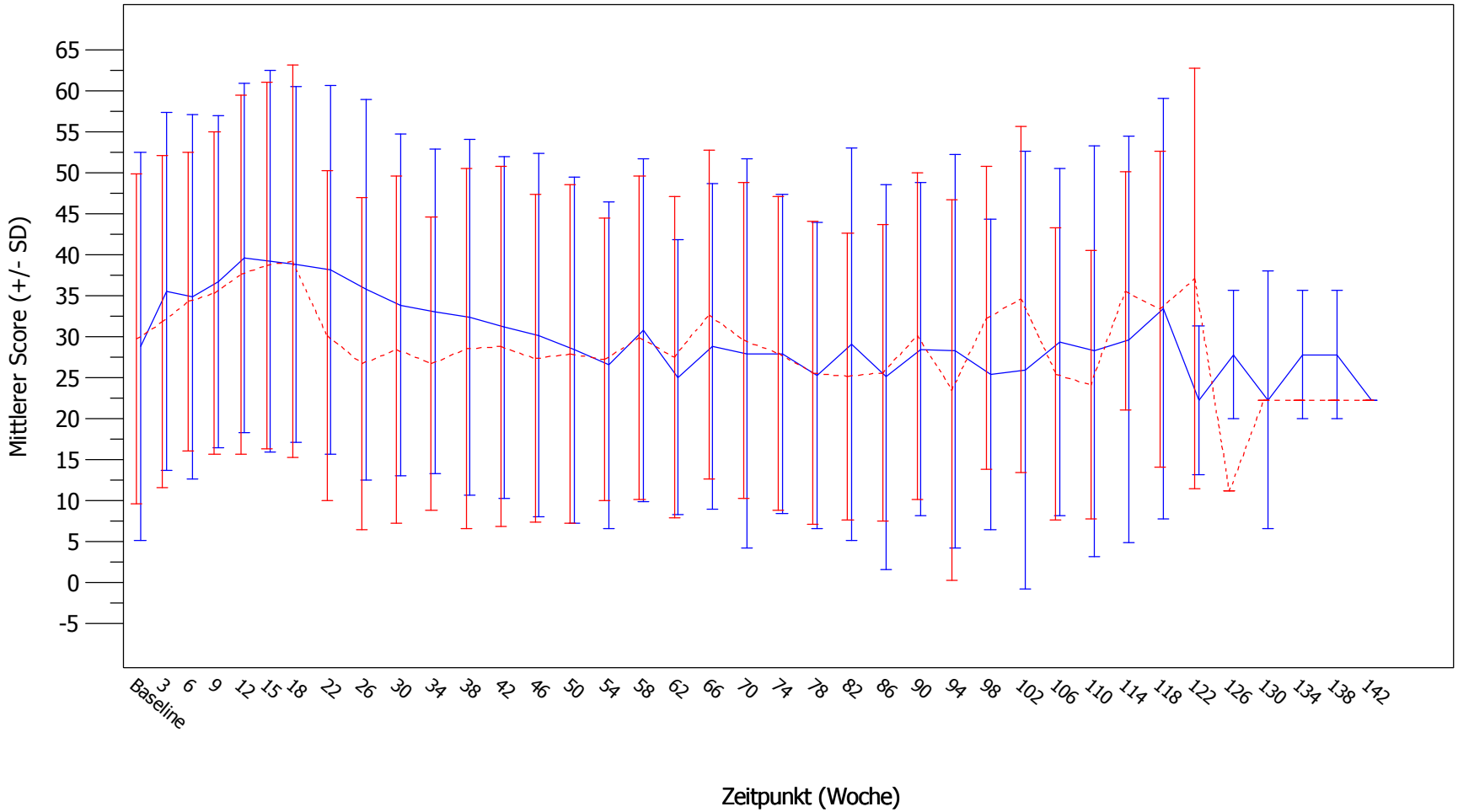


Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Figure 2.5.1.2.7 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Fatigue across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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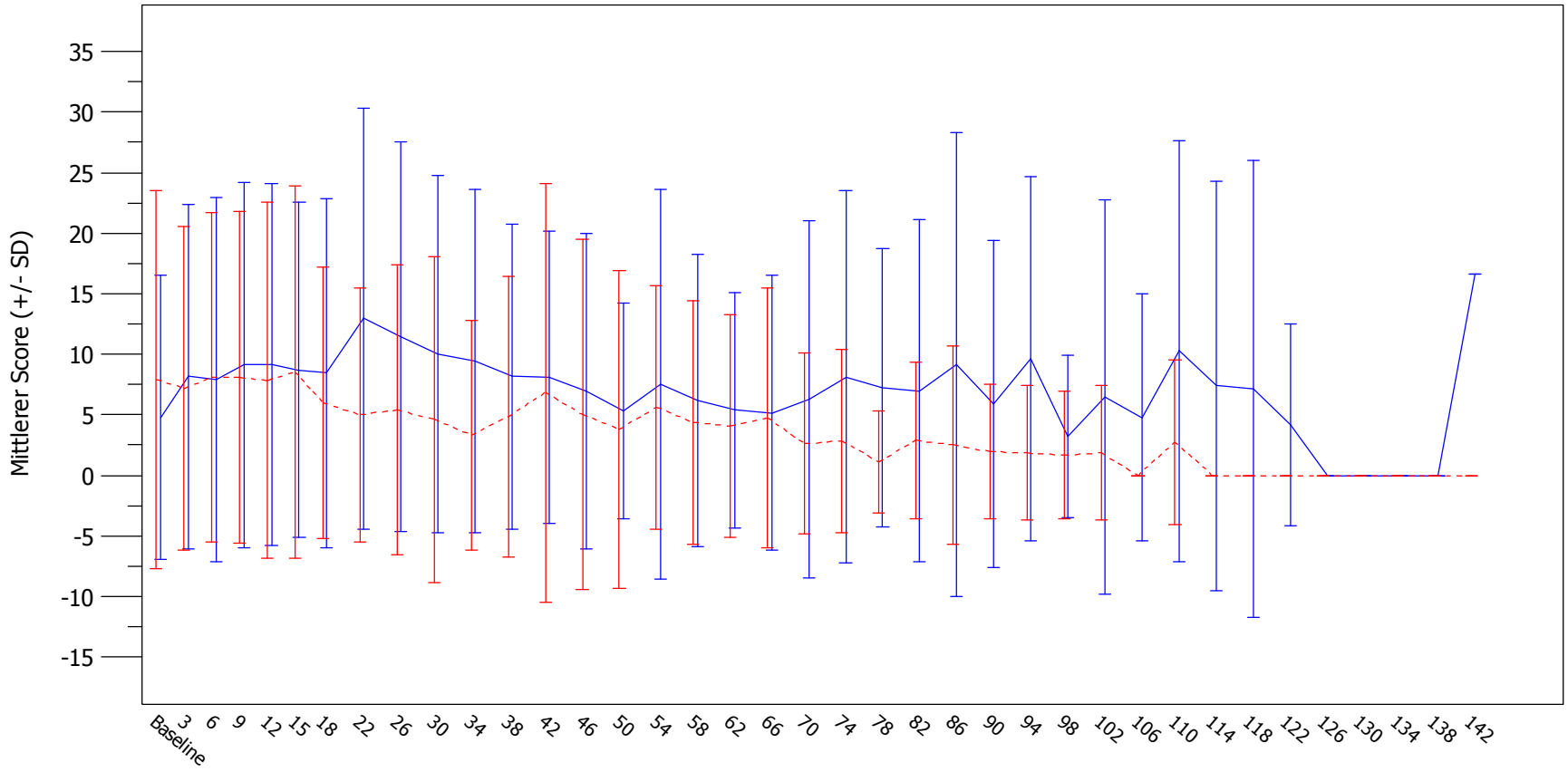
Figure 2.5.1.2.8 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Übelkeit und Erbrechen across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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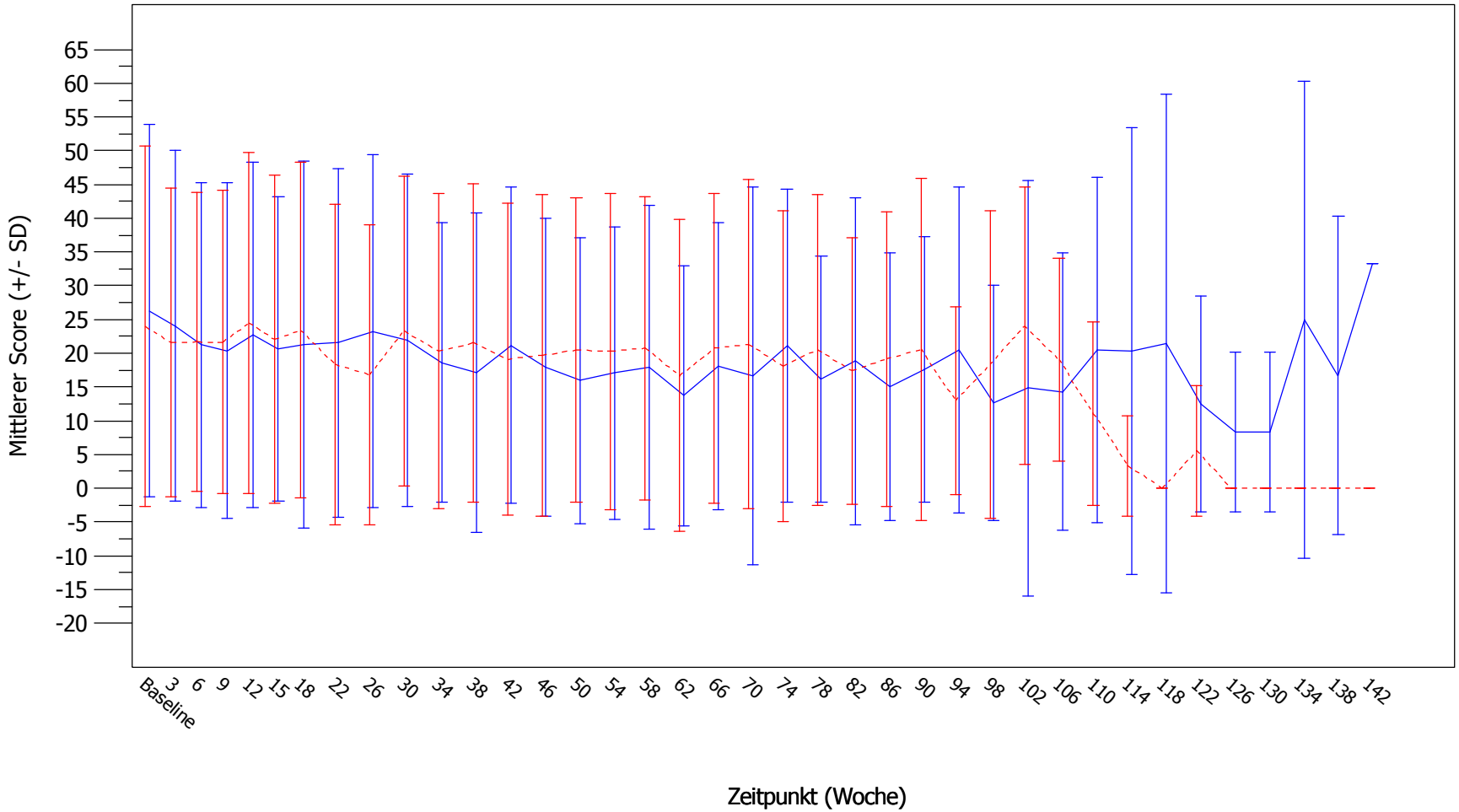
Figure 2.5.1.2.9 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Schmerzen across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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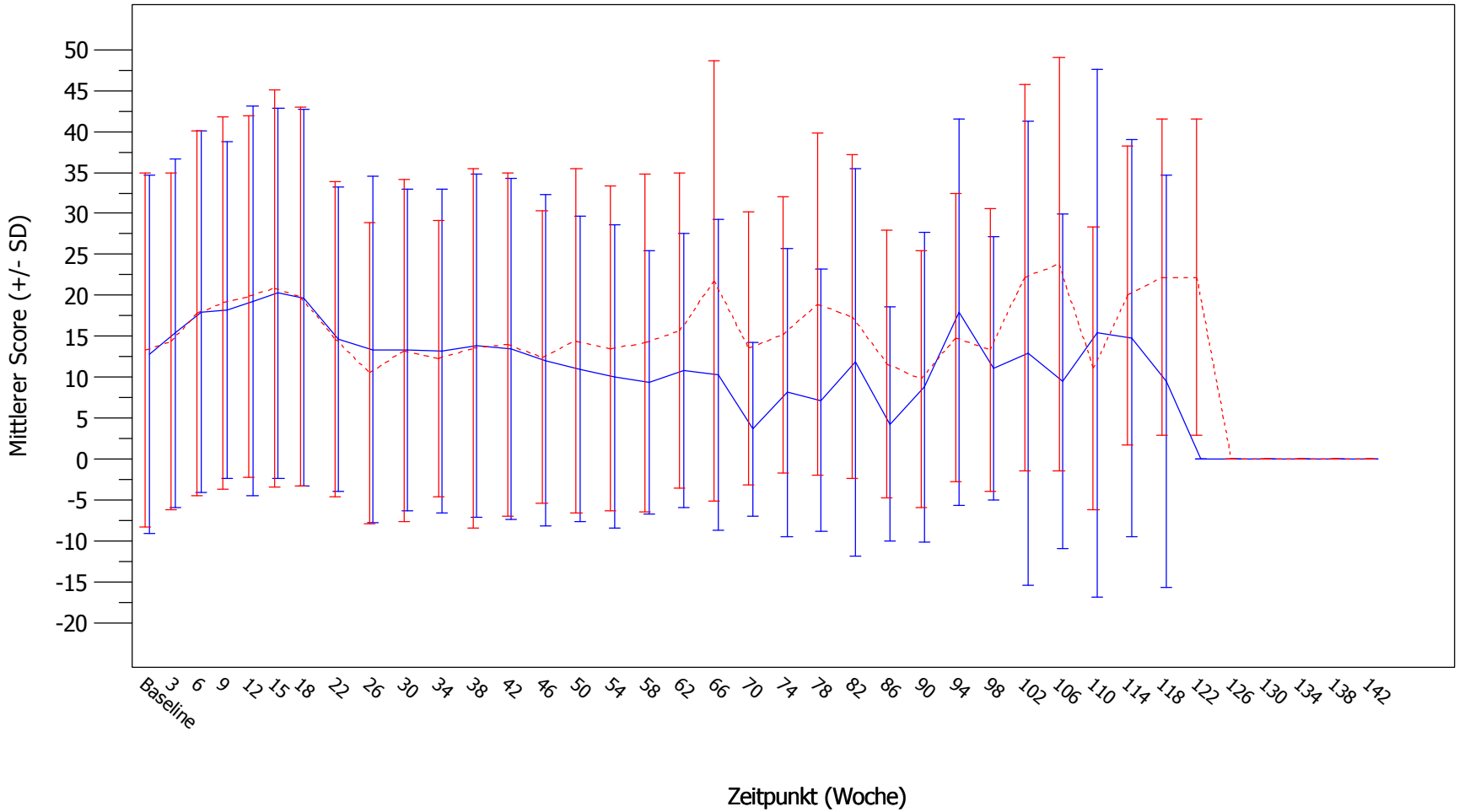
Figure 2.5.1.2.10 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Dyspnoe across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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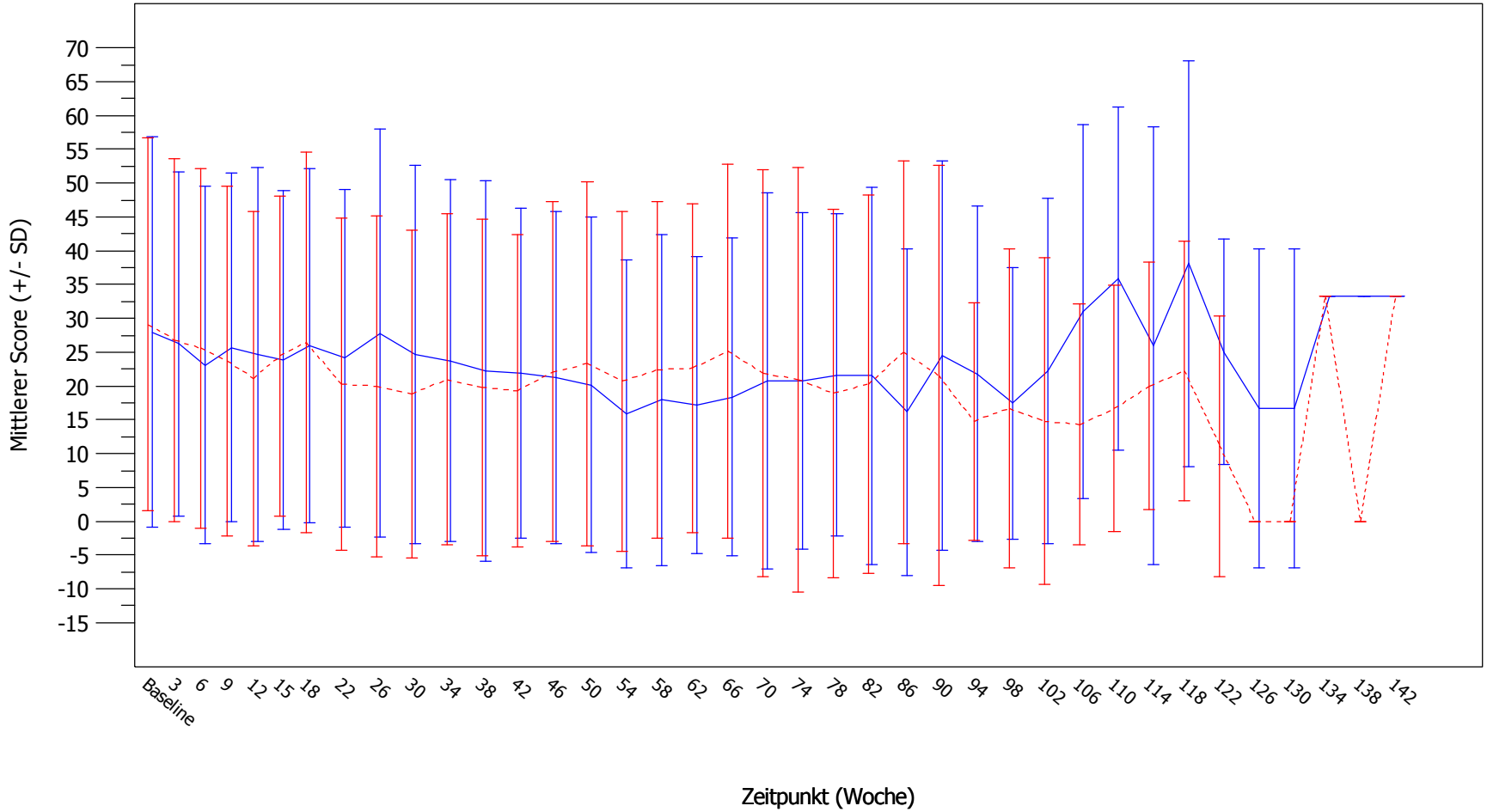
Figure 2.5.1.2.11 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Schlaflosigkeit across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023

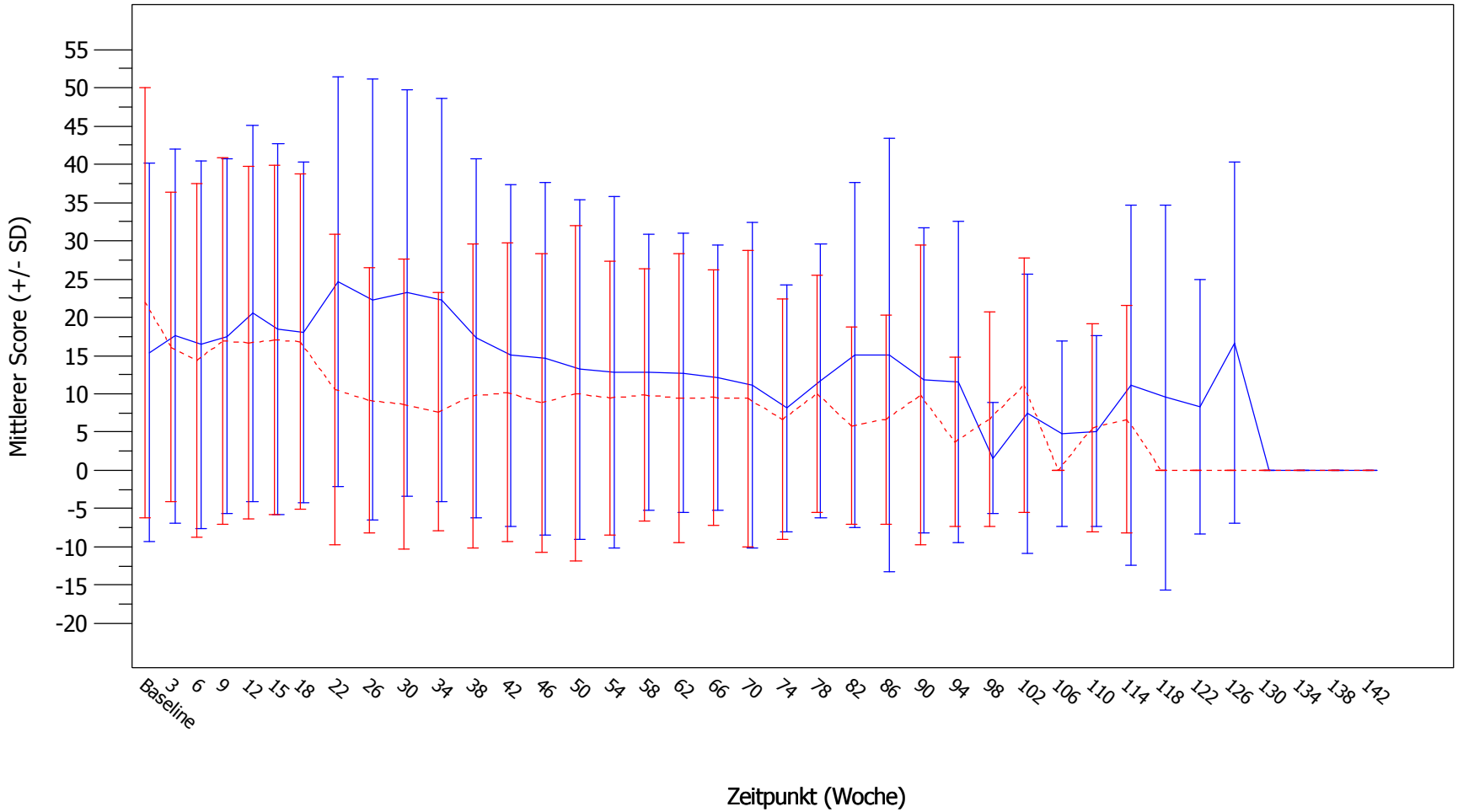


Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Figure 2.5.1.2.12 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Appetitverlust across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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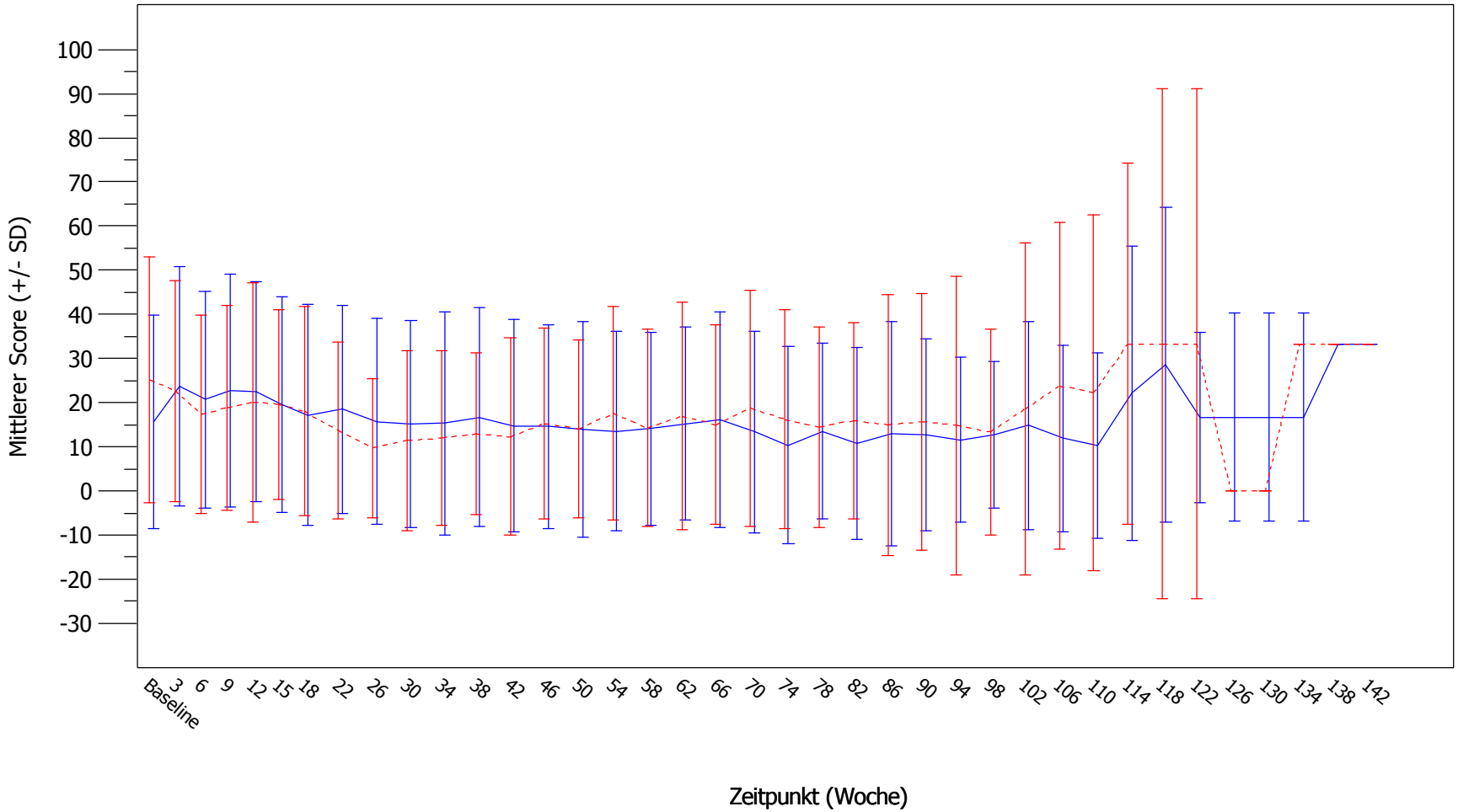
Figure 2.5.1.2.13 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Verstopfung across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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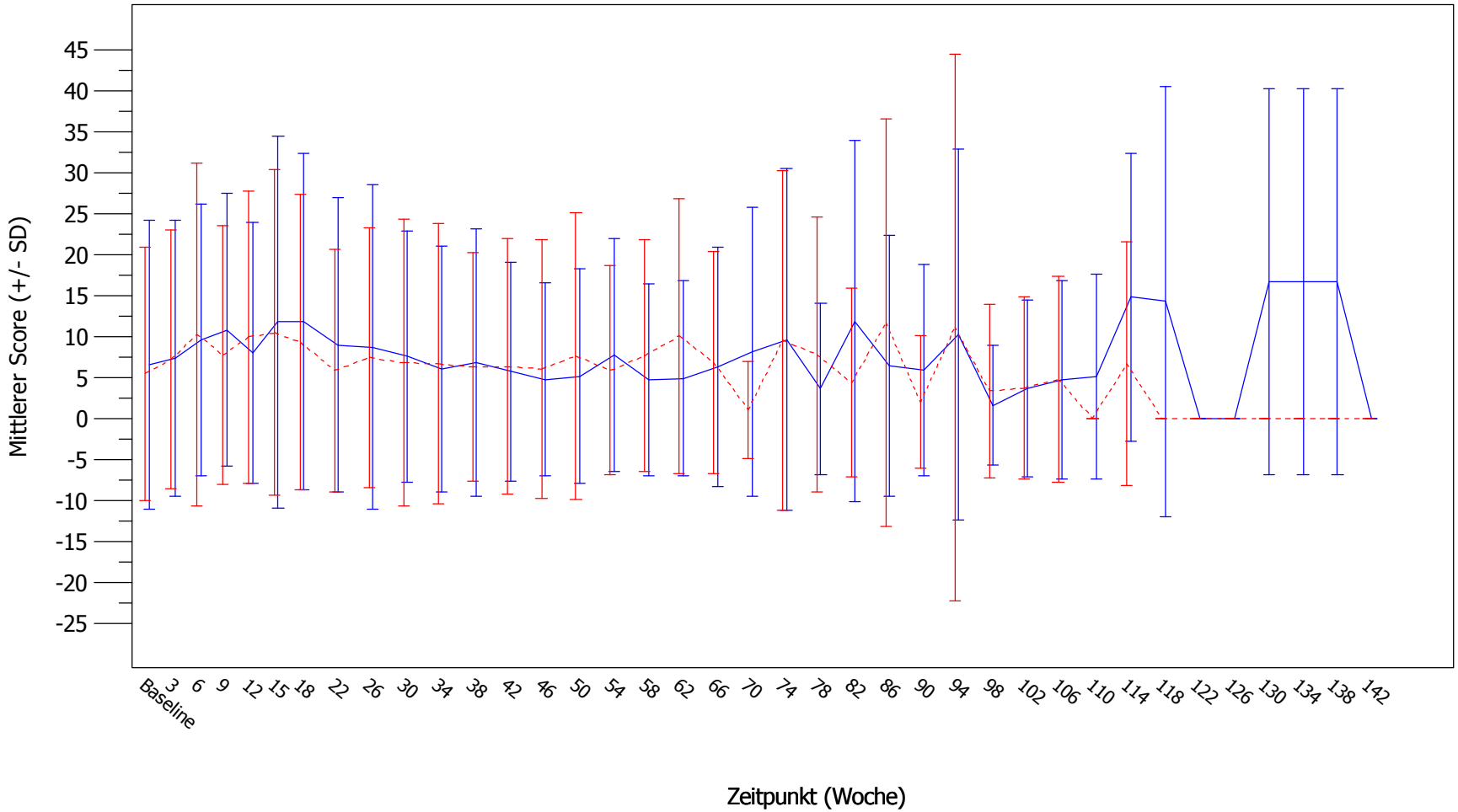
Figure 2.5.1.2.14 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Diarrhö across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023

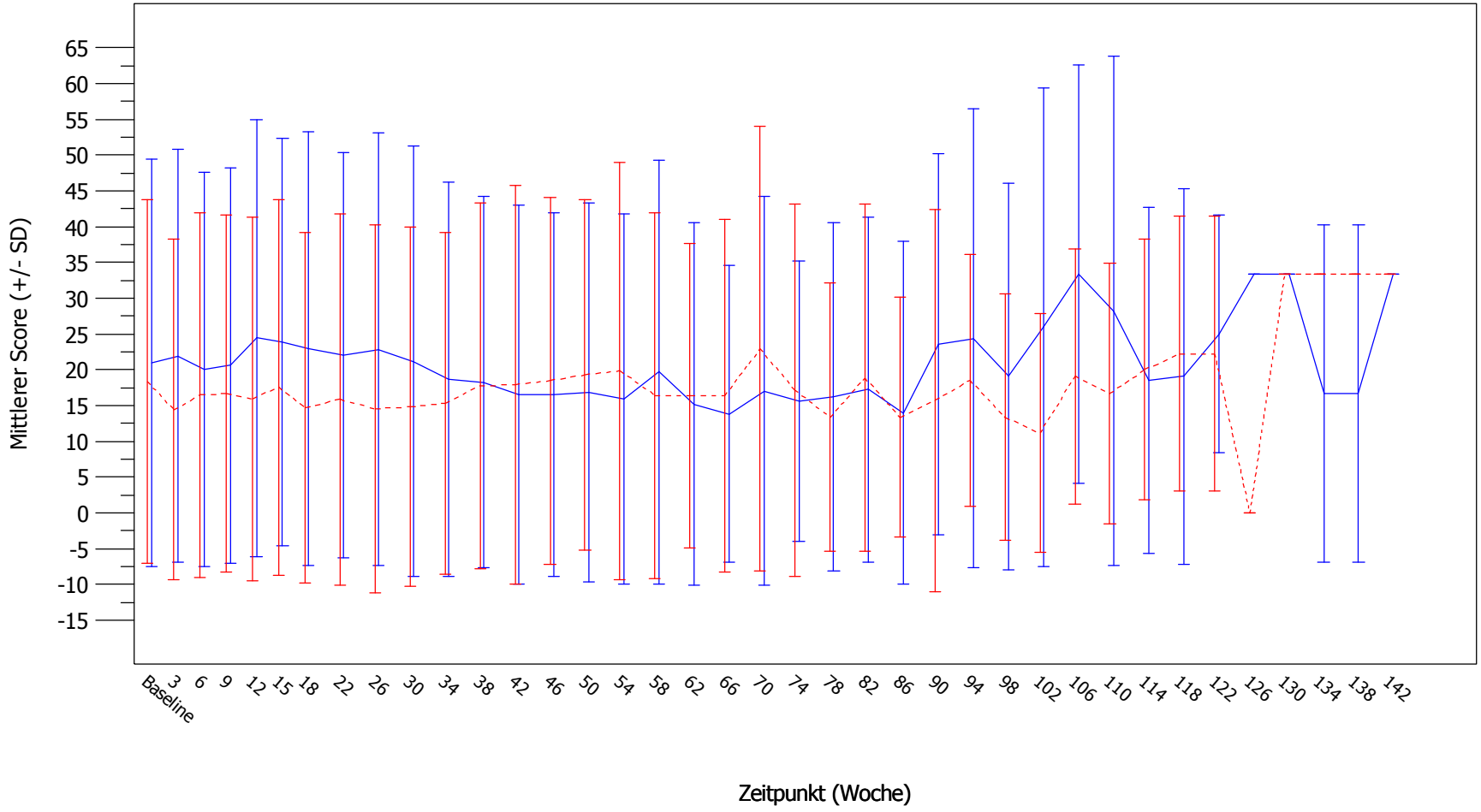


Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Figure 2.5.1.2.15 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-C30 Finanzielle Schwierigkeiten across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

167	169	150	139	138	130	122	130	127	115	111	108	111	105	91	86	78	68	58	45	45	37	31	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
158	153	146	138	134	131	111	120	117	108	100	96	95	83	83	74	61	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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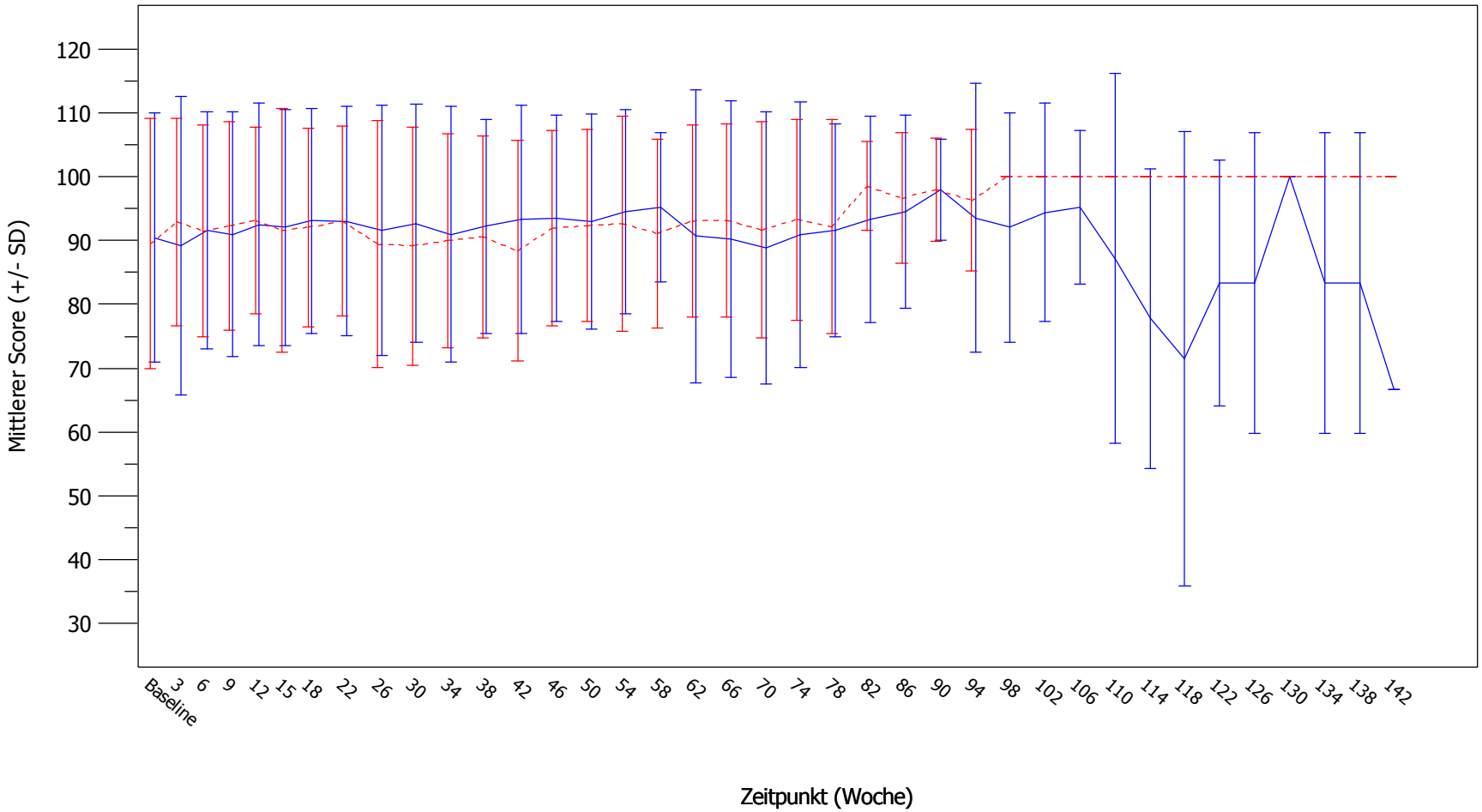
Figure 2.5.2.2.1 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Sexuelles Interesse across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



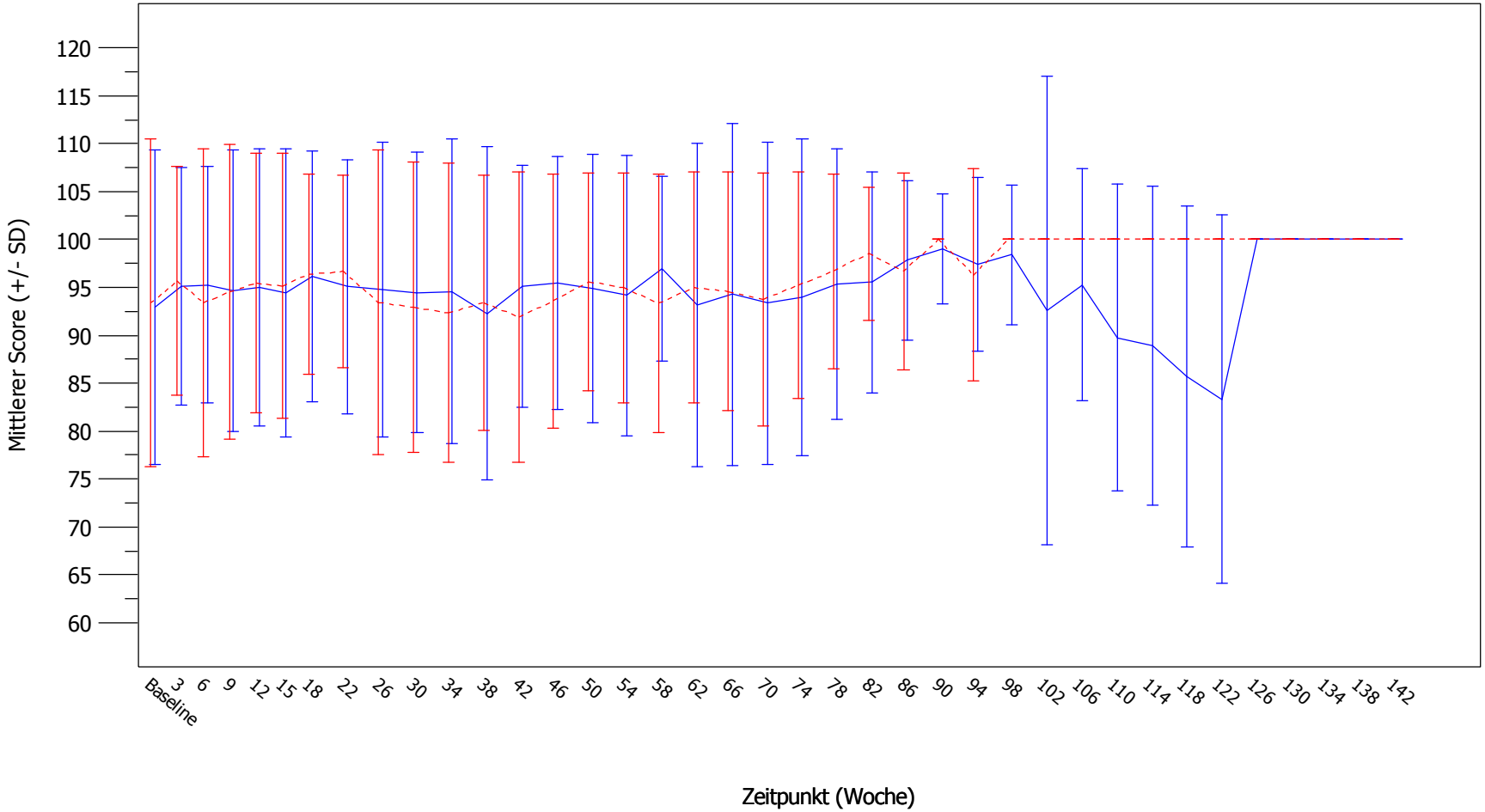
Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.2.2 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Sexuelle Aktivität across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023

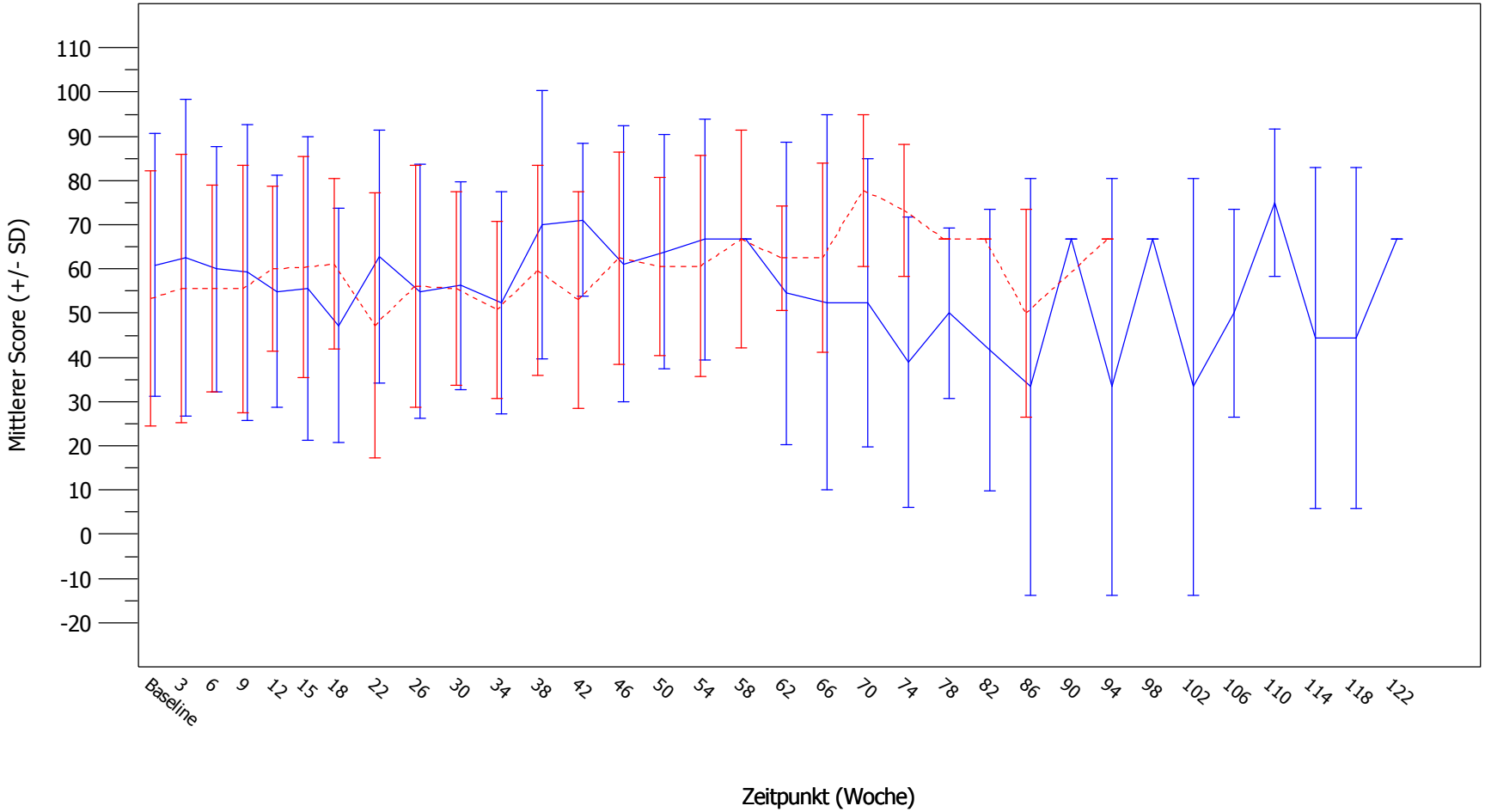


Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Figure 2.5.2.2.3 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Sexuelles Vergnügen across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



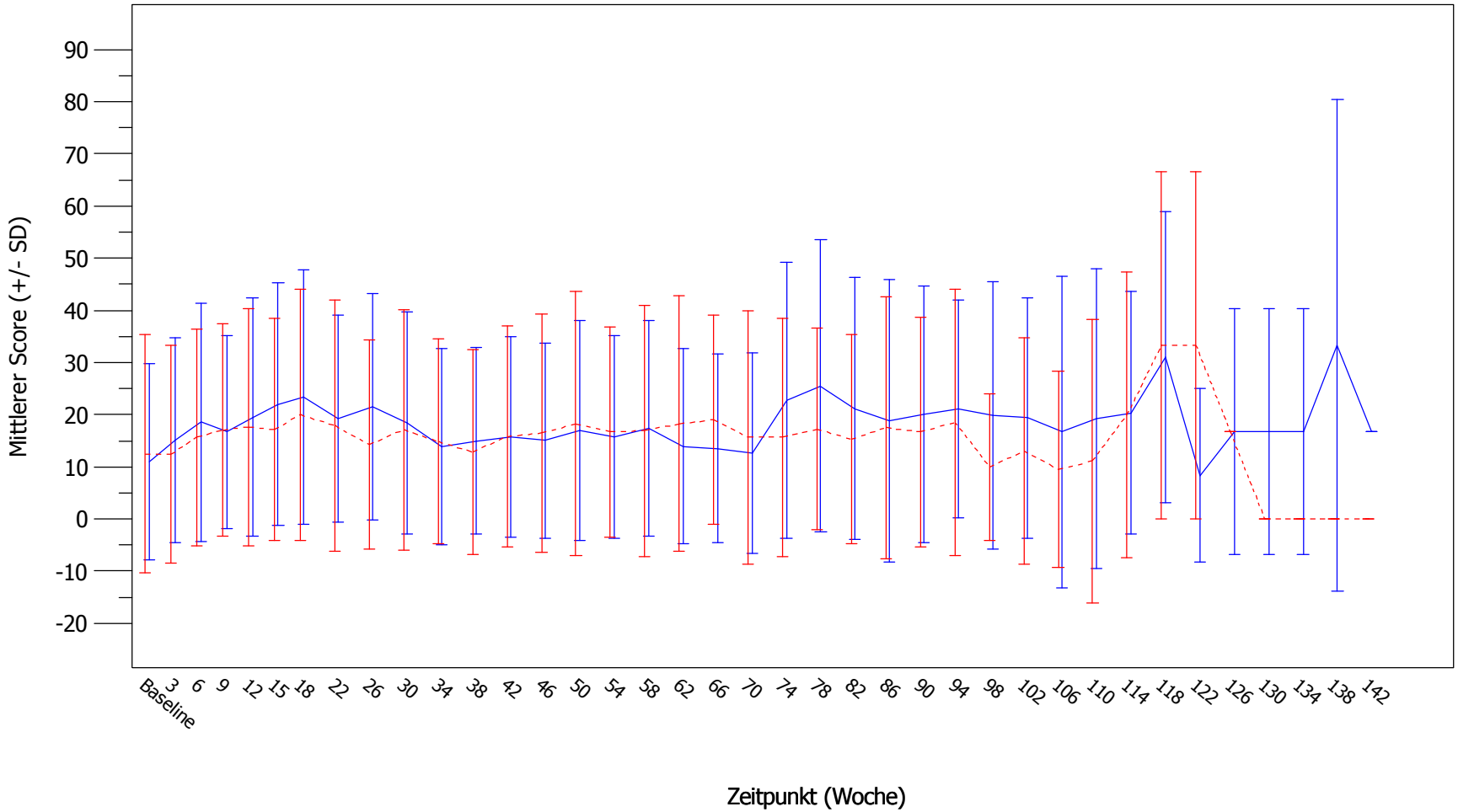
Anzahl Patienten:

29	24	20	18	17	18	12	17	17	16	14	20	15	12	12	13	7	11	7	7	6	4	4	2	1	2	1	2	2	4	3	3	2	CTx+Dur.+Ola.
25	18	24	18	15	16	12	12	19	21	21	19	22	16	11	11	12	8	8	6	5	3	1	2	0	1	0	0	0	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.2.4 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Lymphödem across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



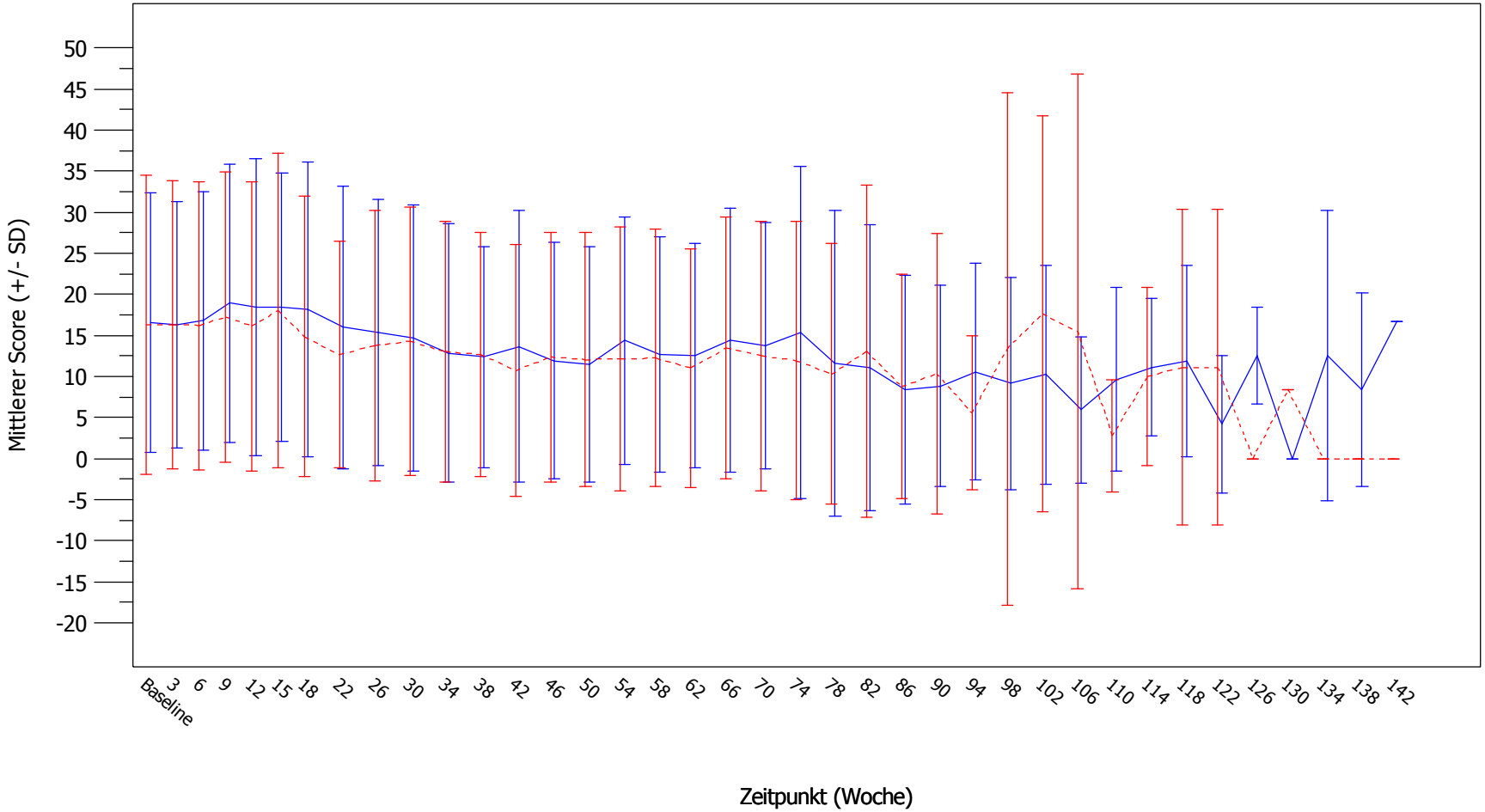
Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.2.5 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Urologische Symptome across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023

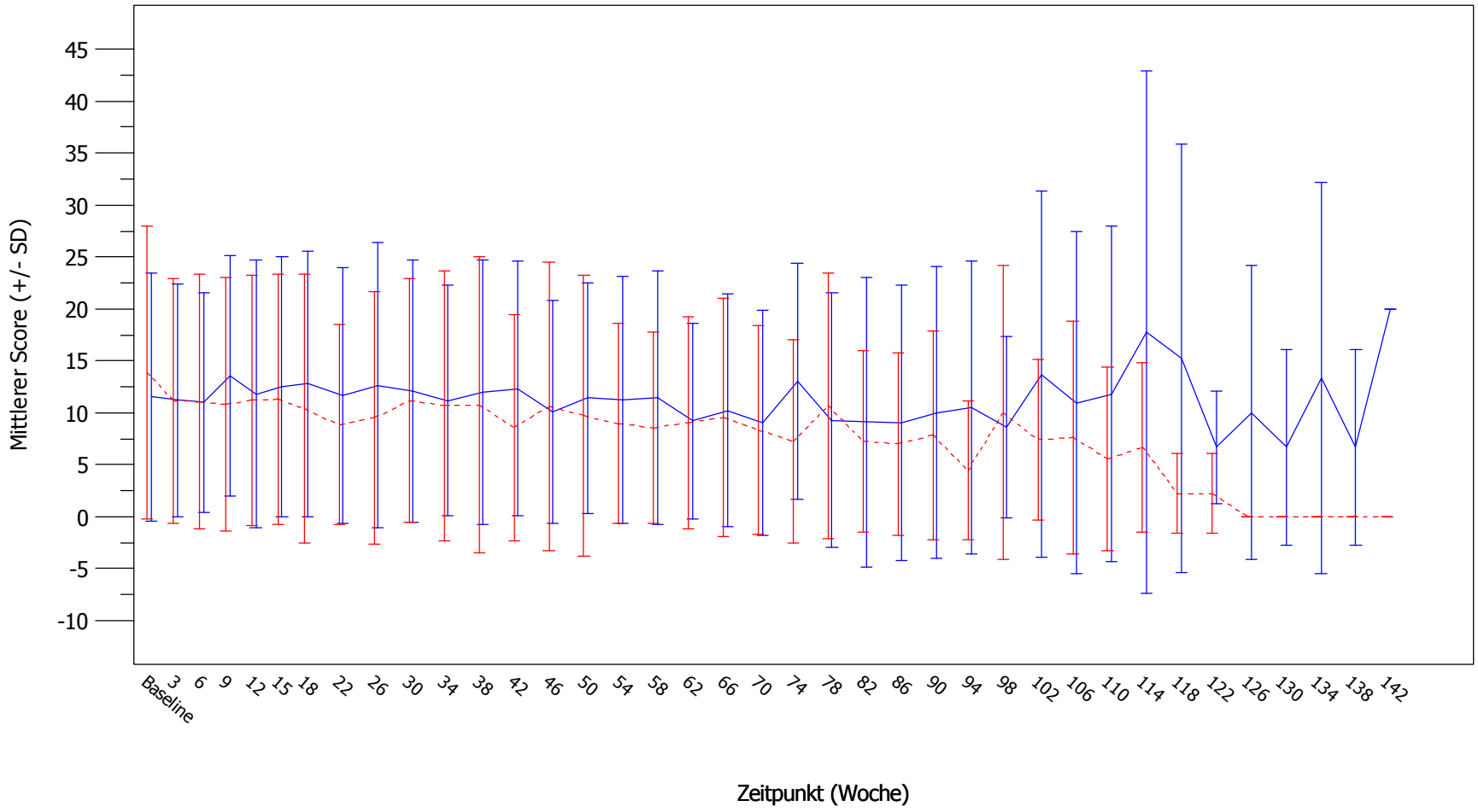


Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Figure 2.5.2.2.6 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Gastrointestinale Symptome across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



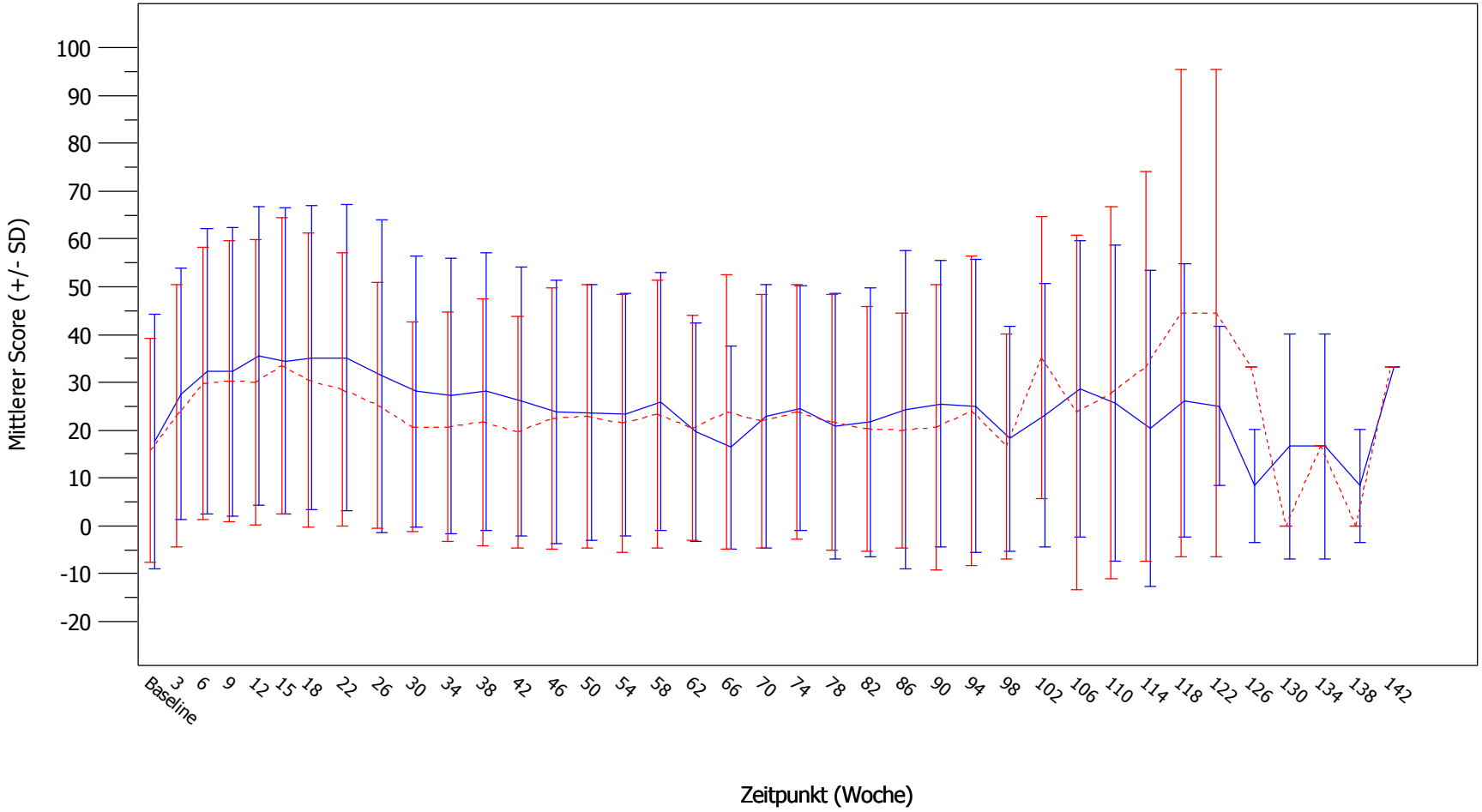
Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.2.7 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



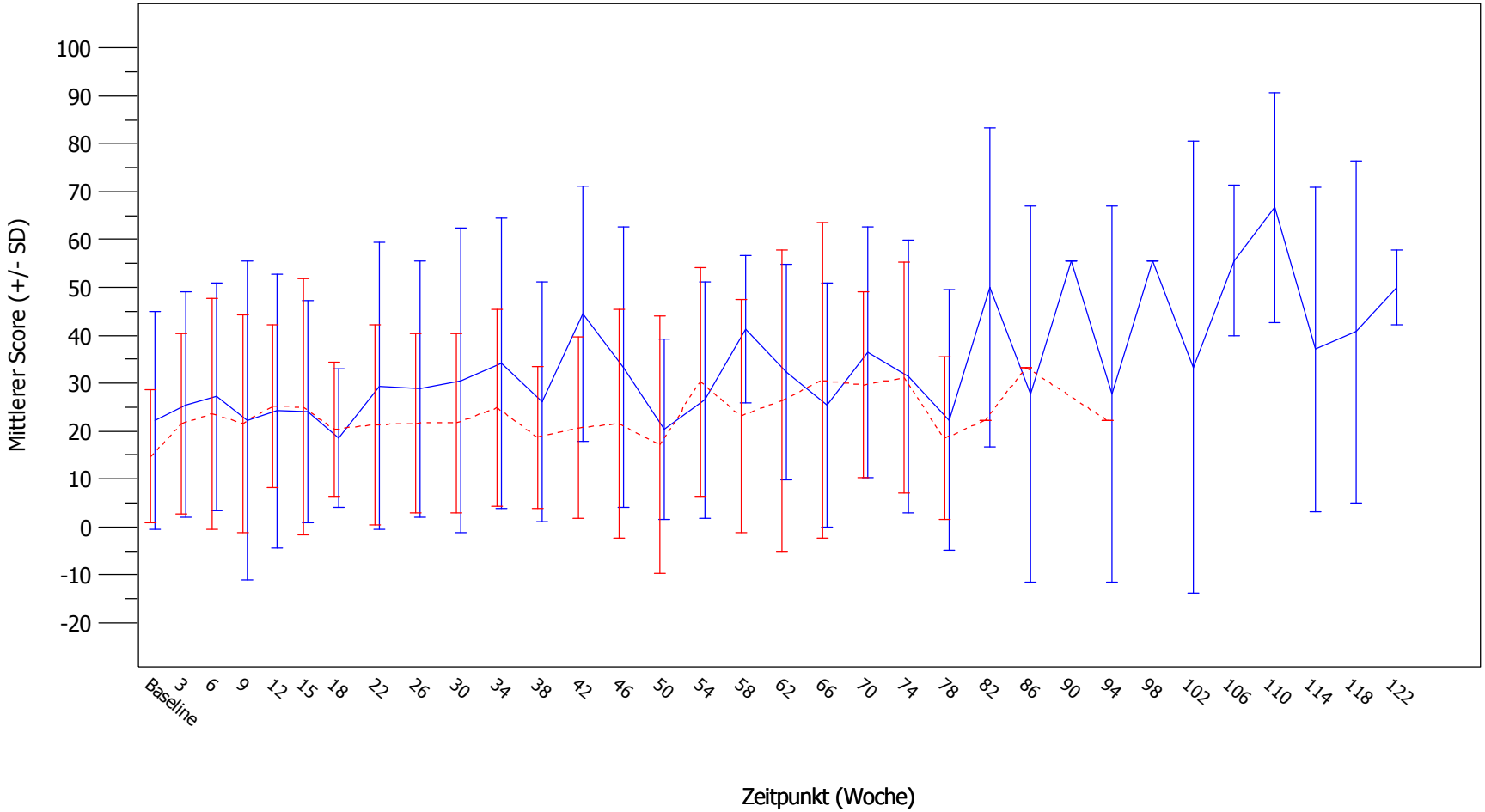
Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.2.8 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Sexuelle/vaginale Probleme across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



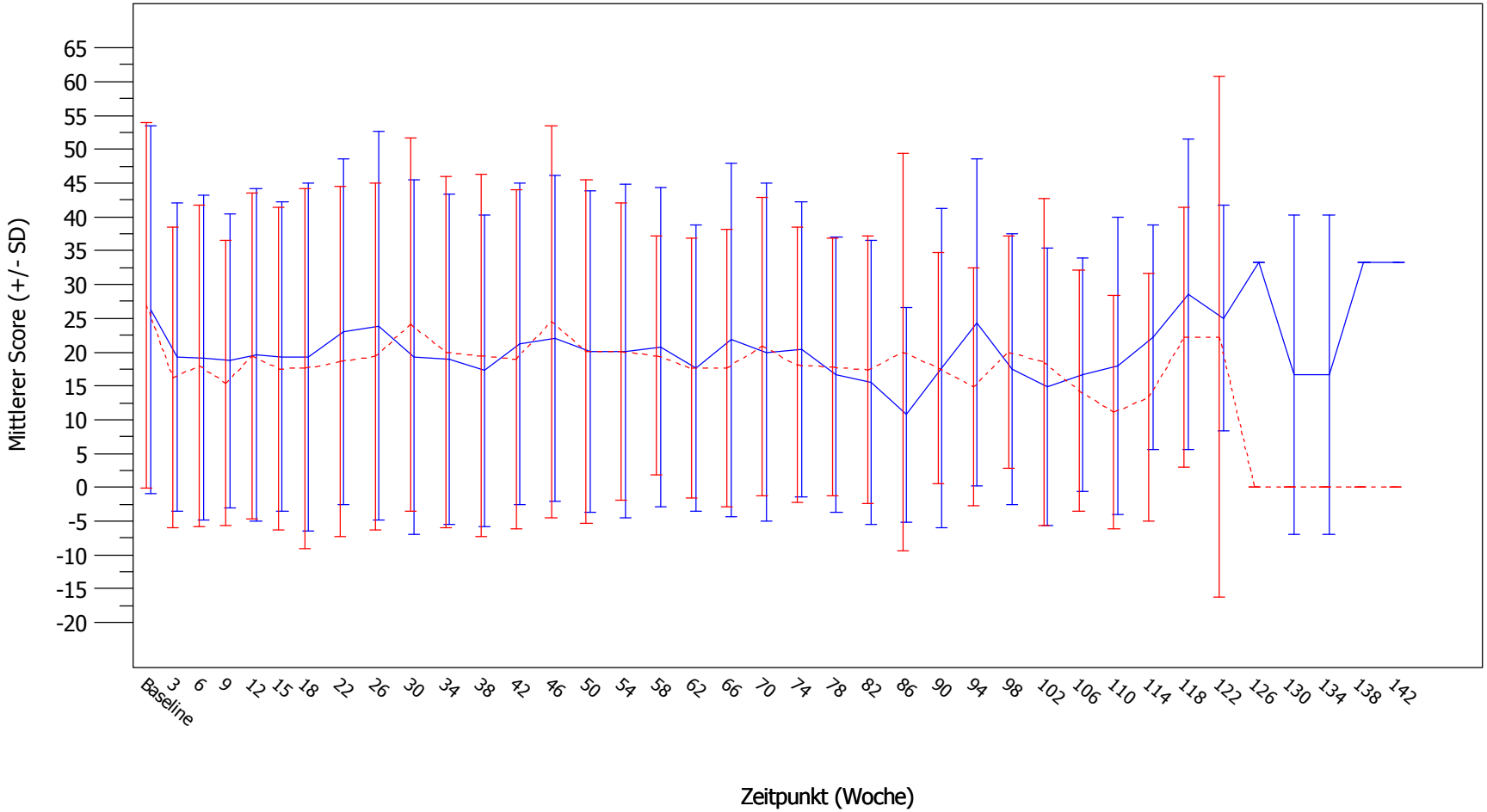
Anzahl Patienten:

29	24	20	18	17	18	12	17	17	16	14	20	15	12	12	13	7	11	7	7	6	4	4	2	1	2	1	2	2	4	3	3	2	CTx+Dur.+Ola.
25	18	24	18	15	16	12	12	19	21	21	19	22	16	11	11	12	8	8	6	5	3	1	2	0	1	0	0	0	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/fmeanpr.sas gfmeanprbbh 13MAR2024:16:00

Figure 2.5.2.2.9 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Rücken- und Beckenschmerzen across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



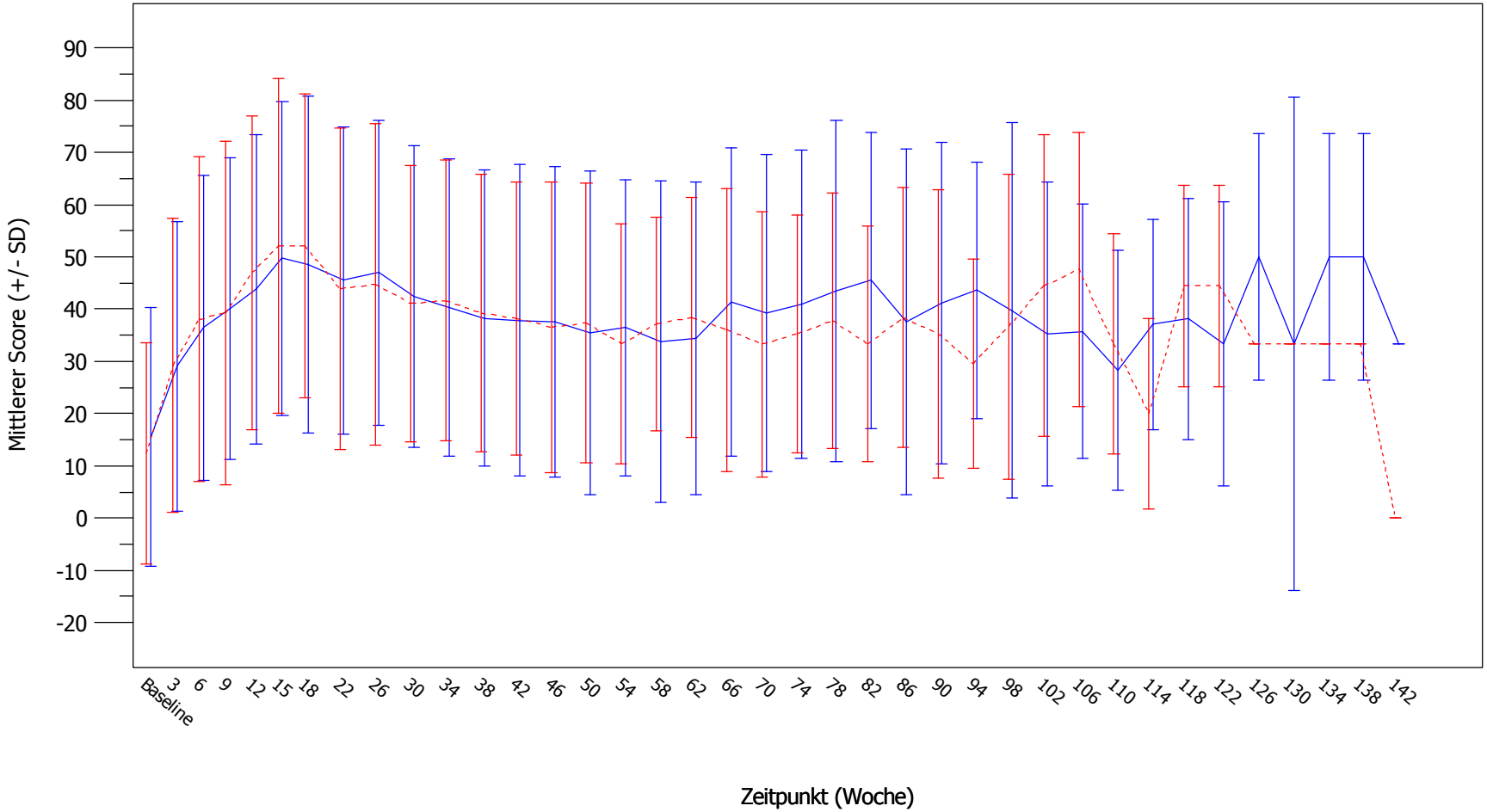
Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.2.10 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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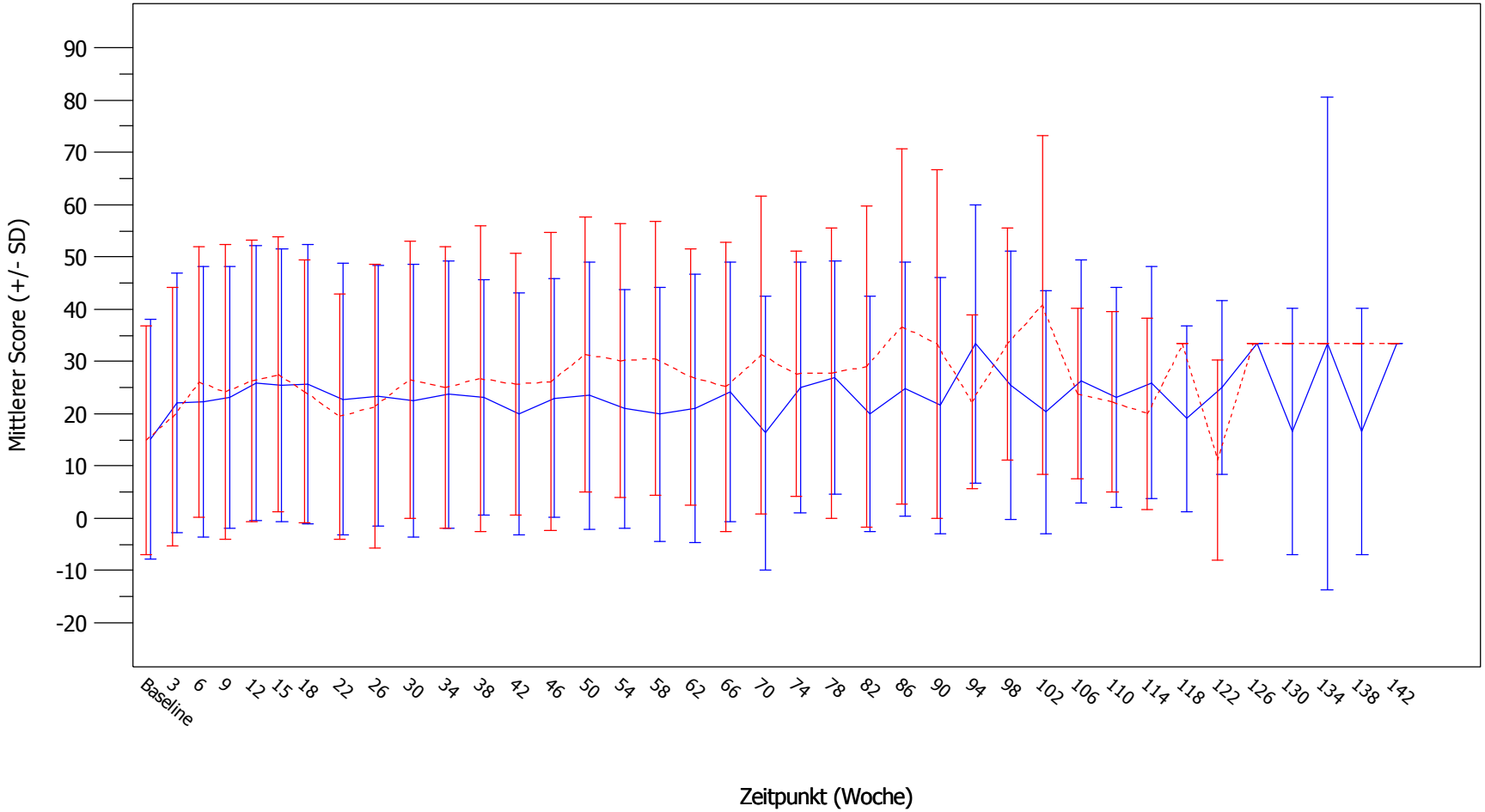
Figure 2.5.2.2.11 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Muskulärer Schmerz across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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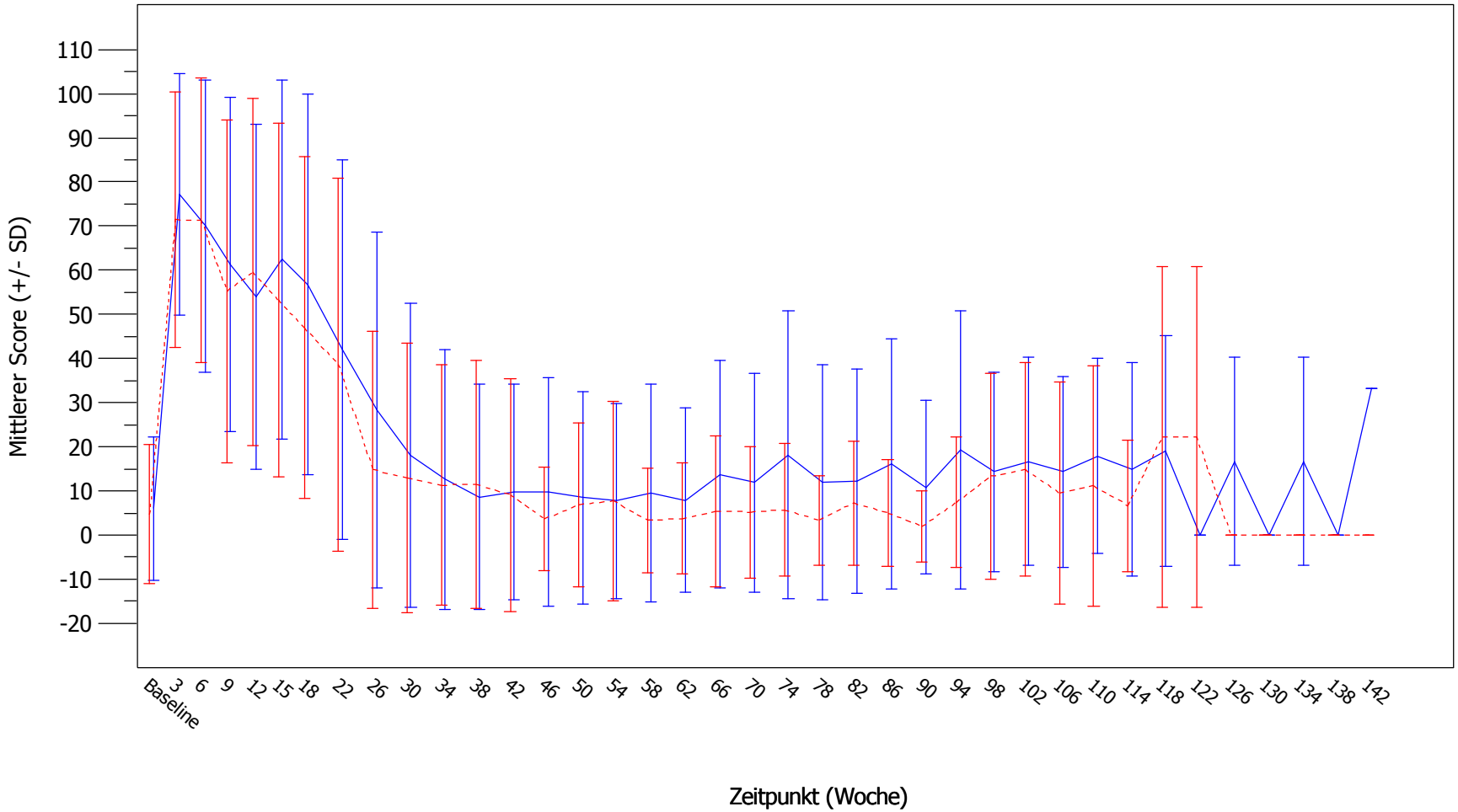
Figure 2.5.2.2.12 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Haarausfall across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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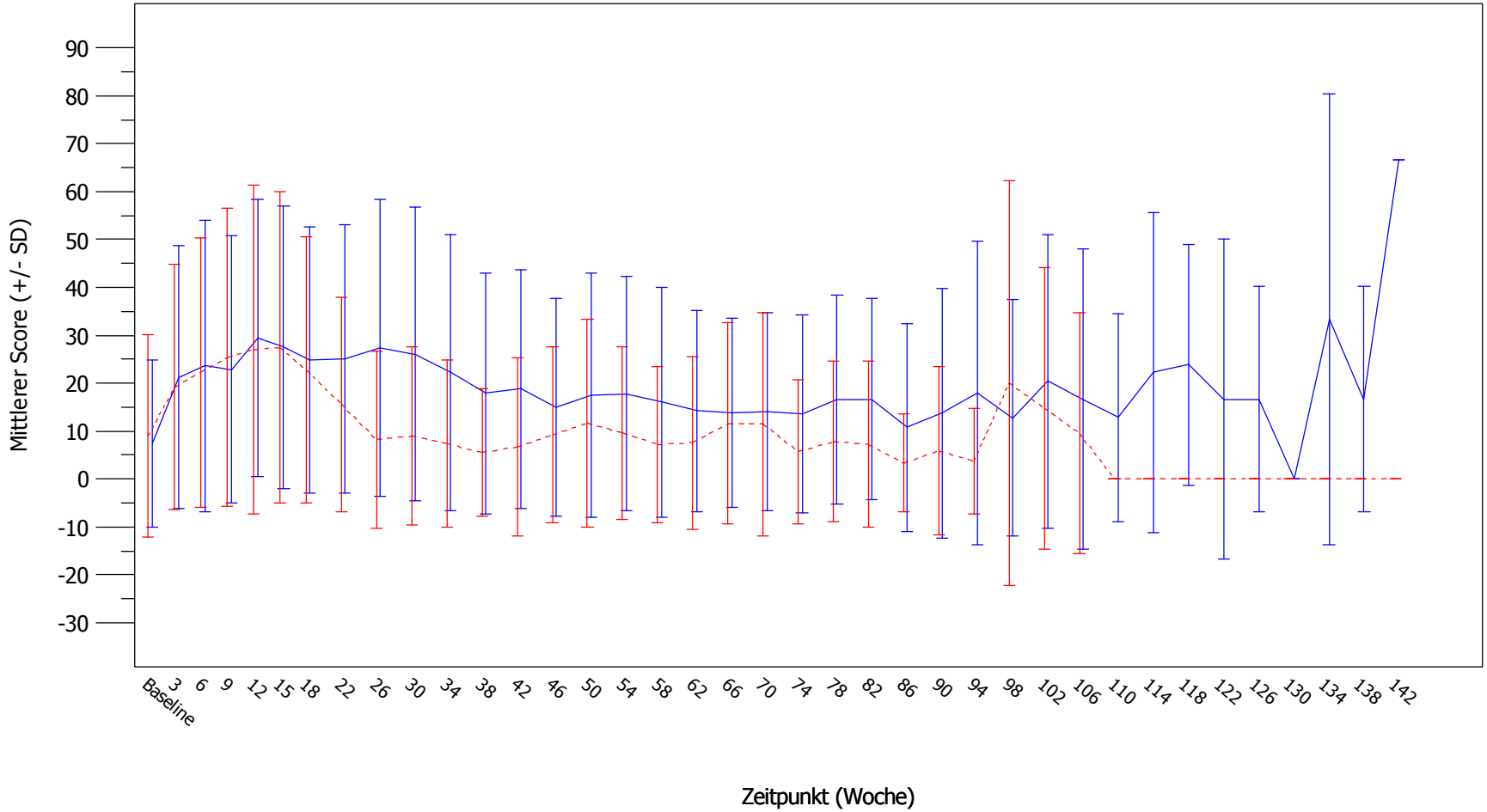
Figure 2.5.2.2.13 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EORTC QLQ-EN24 Geschmacksveränderung across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

161	163	148	137	134	126	121	129	127	114	111	108	110	103	91	86	77	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
156	146	141	134	132	131	110	120	117	108	100	96	95	83	83	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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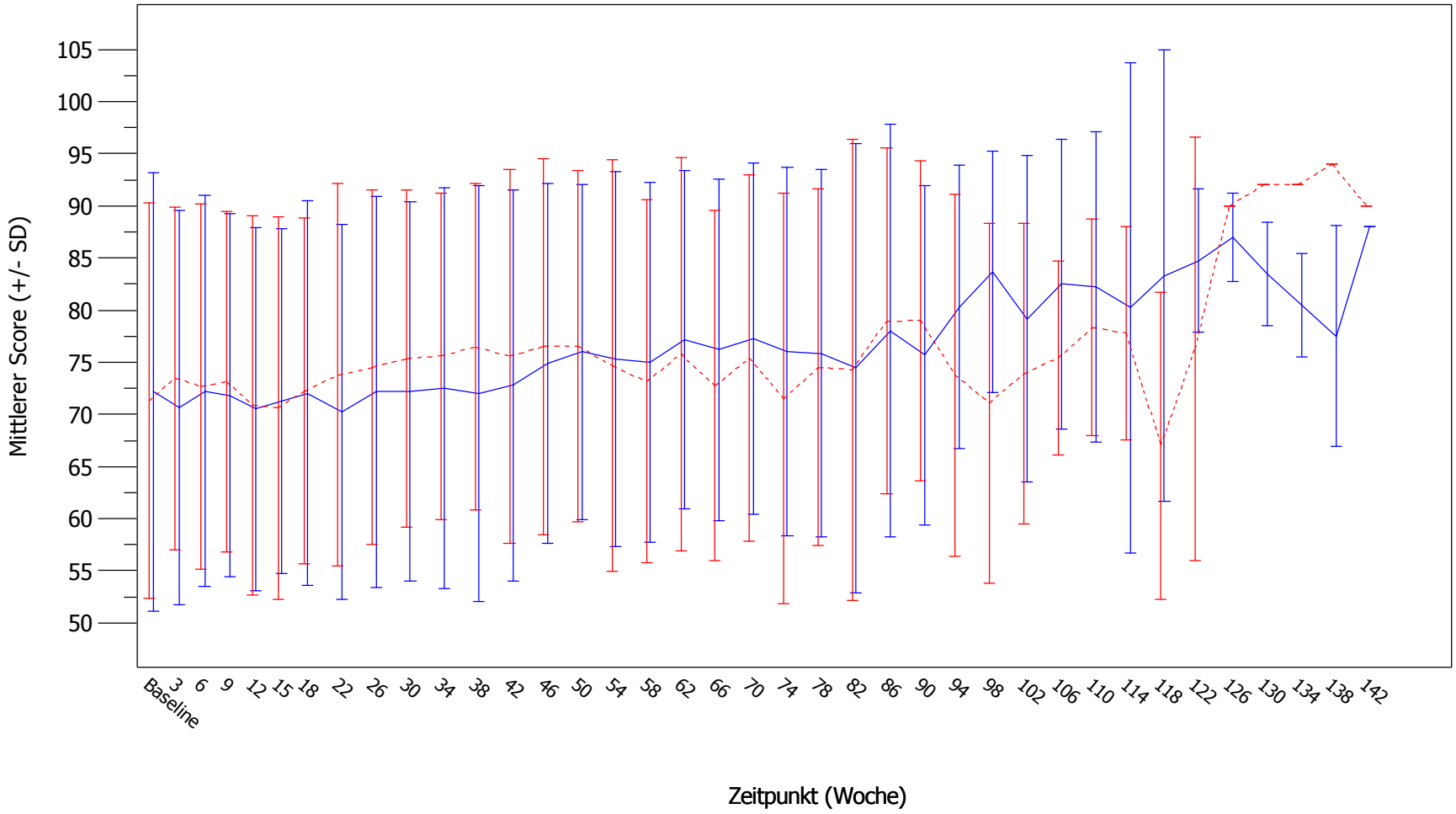
Figure 2.5.3.2.1 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of EQ-5D-5L Visuelle Analogskala across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

161	162	146	136	133	125	121	128	127	113	111	108	110	103	91	85	78	68	58	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
154	145	139	132	132	131	109	120	117	107	100	96	95	83	81	73	60	53	49	32	35	30	23	20	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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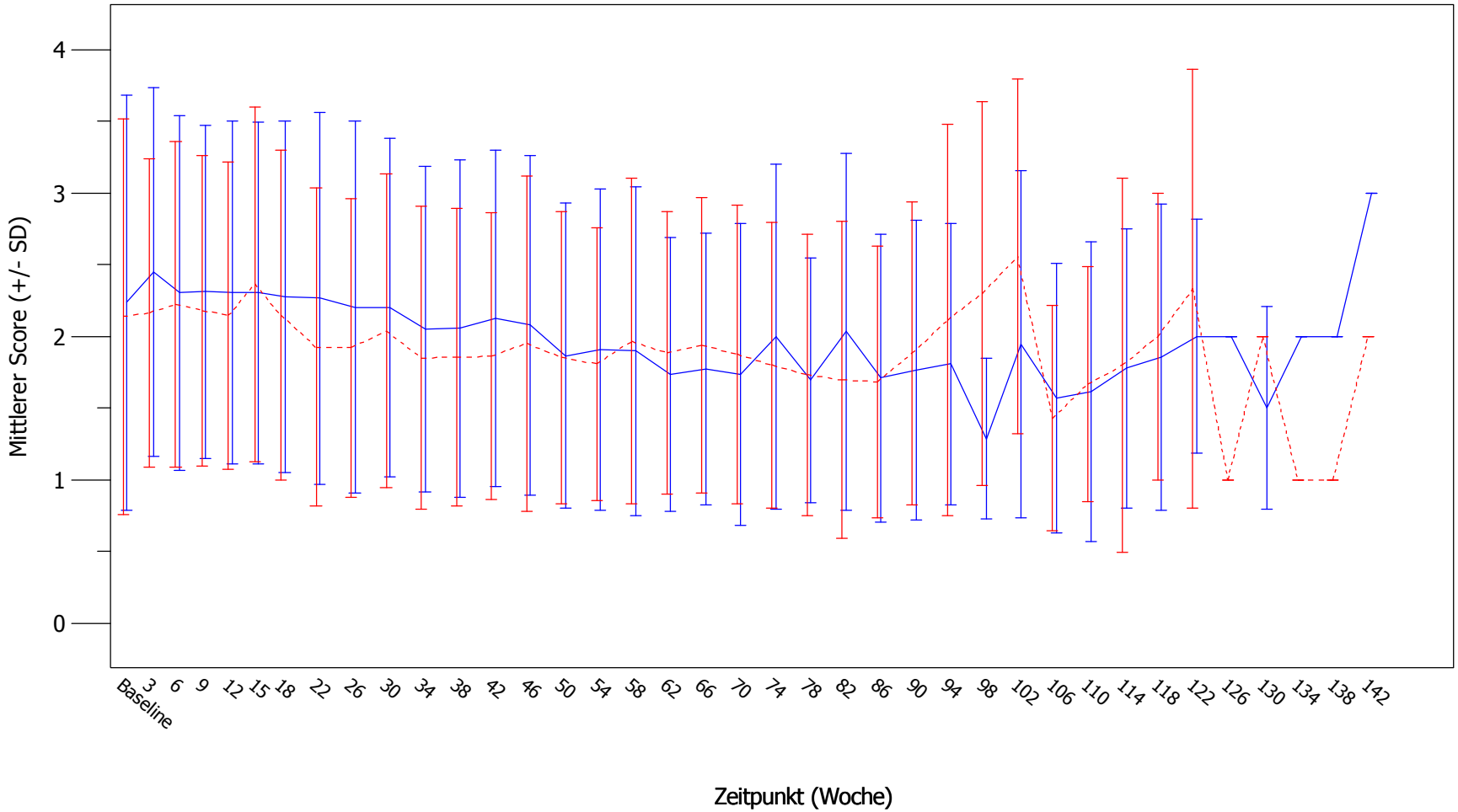
Figure 2.5.4.2.1 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of PGIS across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

161	161	145	135	133	125	119	128	127	113	111	108	109	103	90	85	78	68	57	45	44	36	30	31	34	26	21	18	14	13	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
152	145	138	132	131	129	108	120	114	106	100	96	94	83	82	73	60	52	49	32	35	30	23	19	17	9	10	9	7	6	5	3	3	1	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

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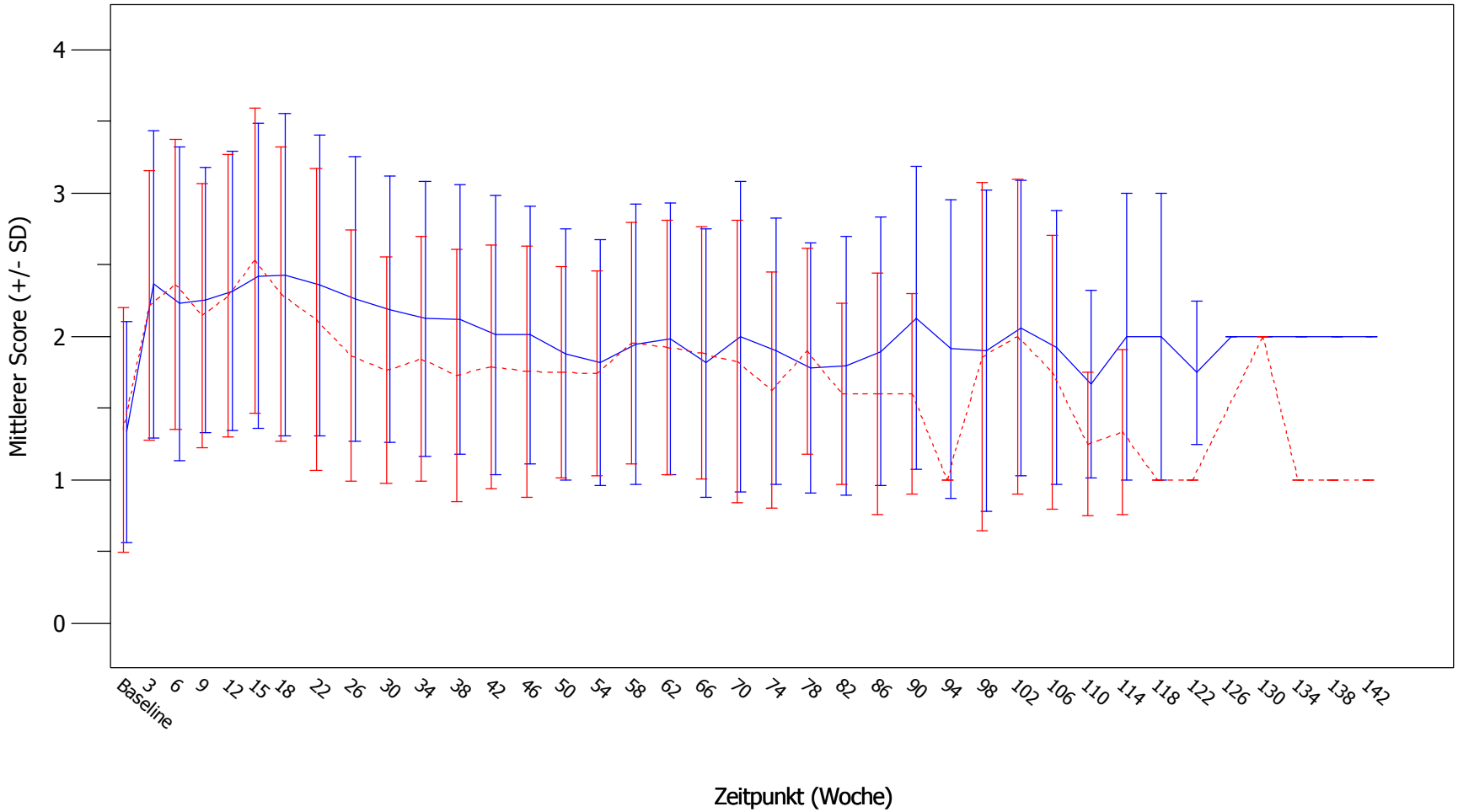
Figure 2.5.5.2.1 DUO-E (pMMR Durva/Ola): Mean (+/- SD) plot of PGI-TT across timepoints, by treatment group
Patients with pMMR tumour status, DCO 12APR2023



Anzahl Patienten:

159	159	145	134	130	121	117	123	122	106	105	101	99	94	80	77	70	62	54	42	40	32	29	29	31	23	20	17	13	12	9	7	4	2	2	2	2	1	CTx+Dur.+Ola.
150	144	138	131	131	126	108	119	112	101	95	85	85	70	64	58	46	40	34	23	24	20	15	10	10	3	7	6	4	4	3	1	1	0	1	1	1	1	CTx

CTx = Carboplatin + Paclitaxel.

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Allgemeine Lebensqualität/ Gesundheitsszustand	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	68,31	21,592	0,0	66,67	100,0
		Tag 22 (Woche 3)	169	66,91	19,679	8,3	66,67	100,0
		Tag 43 (Woche 6)	150	66,50	20,740	0,0	66,67	100,0
		Tag 64 (Woche 9)	139	67,33	18,254	16,7	66,67	100,0
		Tag 85 (Woche 12)	138	65,70	18,595	16,7	66,67	100,0
		Tag 106 (Woche 15)	130	66,86	17,096	16,7	66,67	100,0
		Tag 127 (Woche 18)	122	65,23	19,036	16,7	66,67	100,0
		Tag 155 (Woche 22)	130	64,36	20,174	0,0	66,67	100,0
		Tag 183 (Woche 26)	127	65,75	19,108	0,0	66,67	100,0
		Tag 211 (Woche 30)	115	67,03	19,352	0,0	66,67	100,0
		Tag 239 (Woche 34)	111	68,32	19,392	0,0	66,67	100,0
		Tag 267 (Woche 38)	108	68,98	18,116	16,7	66,67	100,0
		Tag 295 (Woche 42)	111	67,49	19,363	0,0	66,67	100,0
		Tag 323 (Woche 46)	105	70,24	17,748	0,0	75,00	100,0
		Tag 351 (Woche 50)	91	71,52	16,623	16,7	75,00	100,0
		Tag 379 (Woche 54)	86	71,03	19,248	8,3	66,67	100,0
		Tag 407 (Woche 58)	78	70,73	20,882	0,0	75,00	100,0
		Tag 435 (Woche 62)	68	71,20	17,001	16,7	75,00	100,0
		Tag 463 (Woche 66)	58	73,28	18,388	33,3	83,33	100,0
		Tag 491 (Woche 70)	45	70,37	19,263	16,7	75,00	100,0
		Tag 519 (Woche 74)	45	72,04	18,132	33,3	83,33	100,0
		Tag 547 (Woche 78)	37	75,45	14,822	33,3	83,33	100,0
		Tag 575 (Woche 82)	31	68,28	19,769	25,0	75,00	100,0
		Tag 603 (Woche 86)	31	71,51	17,048	33,3	83,33	100,0
		Tag 631 (Woche 90)	34	69,12	16,859	33,3	70,83	100,0
		Tag 659 (Woche 94)	26	74,36	11,767	50,0	75,00	100,0
		Tag 687 (Woche 98)	21	75,79	14,885	25,0	83,33	100,0
		Tag 715 (Woche 102)	18	72,69	13,038	41,7	79,17	83,3
		Tag 743 (Woche 106)	14	76,19	9,162	58,3	83,33	83,3
		Tag 771 (Woche 110)	13	76,28	13,108	50,0	83,33	91,7
		Tag 799 (Woche 114)	9	75,00	16,667	33,3	83,33	83,3

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Allgemeine Lebensqualität/ Gesundheitsszustand	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	77,38	14,203	50,0	83,33	91,7
		Tag 855 (Woche 122)	4	83,33	6,804	75,0	83,33	91,7
		Tag 883 (Woche 126)	2	75,00	0,000	75,0	75,00	75,0
		Tag 911 (Woche 130)	2	70,83	5,893	66,7	70,83	75,0
		Tag 939 (Woche 134)	2	75,00	11,785	66,7	75,00	83,3
		Tag 967 (Woche 138)	2	83,33	0,000	83,3	83,33	83,3
		Tag 995 (Woche 142)	1	75,00	NC	75,0	75,00	75,0
	CTx (N=192)	Baseline	158	67,93	20,546	16,7	66,67	100,0
		Tag 22 (Woche 3)	153	67,70	18,044	0,0	66,67	100,0
		Tag 43 (Woche 6)	146	66,89	17,396	16,7	66,67	100,0
		Tag 64 (Woche 9)	138	68,48	15,912	16,7	66,67	100,0
		Tag 85 (Woche 12)	134	66,54	16,666	16,7	66,67	100,0
		Tag 106 (Woche 15)	131	64,82	17,792	0,0	66,67	100,0
		Tag 127 (Woche 18)	111	64,79	17,433	8,3	66,67	100,0
		Tag 155 (Woche 22)	120	71,39	17,478	16,7	75,00	100,0
		Tag 183 (Woche 26)	117	70,73	16,973	8,3	66,67	100,0
		Tag 211 (Woche 30)	108	71,37	18,060	0,0	75,00	100,0
		Tag 239 (Woche 34)	100	72,92	15,369	16,7	70,83	100,0
		Tag 267 (Woche 38)	96	72,92	15,811	16,7	75,00	100,0
		Tag 295 (Woche 42)	95	70,53	19,135	0,0	66,67	100,0
		Tag 323 (Woche 46)	83	73,69	16,538	0,0	75,00	100,0
		Tag 351 (Woche 50)	83	69,88	16,709	16,7	75,00	100,0
		Tag 379 (Woche 54)	74	69,48	18,104	16,7	70,83	100,0
		Tag 407 (Woche 58)	61	69,95	16,547	33,3	66,67	100,0
		Tag 435 (Woche 62)	53	70,13	17,635	16,7	75,00	100,0
		Tag 463 (Woche 66)	49	65,65	16,283	16,7	66,67	91,7
		Tag 491 (Woche 70)	32	66,93	15,334	33,3	66,67	91,7
		Tag 519 (Woche 74)	35	68,10	18,019	33,3	66,67	100,0
		Tag 547 (Woche 78)	30	70,00	14,939	41,7	70,83	100,0
		Tag 575 (Woche 82)	23	76,09	11,866	58,3	83,33	100,0
		Tag 603 (Woche 86)	20	76,67	13,680	41,7	83,33	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Allgemeine Lebensqualität/ Gesundheitsszustand	CTx (N=192)	Tag 631 (Woche 90)	17	69,61	17,165	33,3	75,00	91,7
		Tag 659 (Woche 94)	9	75,00	11,785	50,0	83,33	83,3
		Tag 687 (Woche 98)	10	68,33	17,480	41,7	70,83	91,7
		Tag 715 (Woche 102)	9	68,52	14,894	50,0	66,67	83,3
		Tag 743 (Woche 106)	7	71,43	11,644	50,0	75,00	83,3
		Tag 771 (Woche 110)	6	79,17	10,206	58,3	83,33	83,3
		Tag 799 (Woche 114)	5	76,67	6,972	66,7	75,00	83,3
		Tag 827 (Woche 118)	3	77,78	9,623	66,7	83,33	83,3
		Tag 855 (Woche 122)	3	75,00	8,333	66,7	75,00	83,3
		Tag 883 (Woche 126)	1	83,33	NC	83,3	83,33	83,3
		Tag 911 (Woche 130)	1	83,33	NC	83,3	83,33	83,3
		Tag 939 (Woche 134)	1	83,33	NC	83,3	83,33	83,3
		Tag 967 (Woche 138)	1	83,33	NC	83,3	83,33	83,3
		Tag 995 (Woche 142)	1	83,33	NC	83,3	83,33	83,3
EORTC QLQ-C30 Funktionsskala: Körper	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	79,48	21,571	13,3	86,67	100,0
		Tag 22 (Woche 3)	169	75,94	20,882	0,0	80,00	100,0
		Tag 43 (Woche 6)	150	75,69	20,799	0,0	80,00	100,0
		Tag 64 (Woche 9)	139	75,35	20,139	20,0	80,00	100,0
		Tag 85 (Woche 12)	138	74,30	19,475	20,0	80,00	100,0
		Tag 106 (Woche 15)	130	73,38	20,694	6,7	80,00	100,0
		Tag 127 (Woche 18)	122	73,28	22,210	6,7	80,00	100,0
		Tag 155 (Woche 22)	130	74,10	22,484	0,0	80,00	100,0
		Tag 183 (Woche 26)	127	74,38	22,513	0,0	80,00	100,0
		Tag 211 (Woche 30)	115	77,68	20,253	0,0	80,00	100,0
		Tag 239 (Woche 34)	111	79,28	18,713	20,0	80,00	100,0
		Tag 267 (Woche 38)	108	78,77	19,144	20,0	80,00	100,0
		Tag 295 (Woche 42)	111	78,74	19,848	0,0	80,00	100,0
		Tag 323 (Woche 46)	105	79,94	18,822	6,7	86,67	100,0
		Tag 351 (Woche 50)	91	82,05	17,204	33,3	86,67	100,0
		Tag 379 (Woche 54)	86	81,78	16,692	33,3	86,67	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Körper	CTx + Durvalumab + Olaparib (N=191)	Tag 407 (Woche 58)	78	81,03	19,132	0,0	86,67	100,0
		Tag 435 (Woche 62)	68	84,02	16,007	40,0	86,67	100,0
		Tag 463 (Woche 66)	58	80,11	16,870	40,0	80,00	100,0
		Tag 491 (Woche 70)	45	80,00	19,280	26,7	80,00	100,0
		Tag 519 (Woche 74)	45	80,00	19,016	20,0	86,67	100,0
		Tag 547 (Woche 78)	37	81,98	15,859	46,7	80,00	100,0
		Tag 575 (Woche 82)	31	76,56	21,352	26,7	80,00	100,0
		Tag 603 (Woche 86)	31	79,35	20,895	33,3	80,00	100,0
		Tag 631 (Woche 90)	34	82,35	17,437	26,7	83,33	100,0
		Tag 659 (Woche 94)	26	79,49	18,754	20,0	80,00	100,0
		Tag 687 (Woche 98)	21	85,08	13,317	60,0	86,67	100,0
		Tag 715 (Woche 102)	18	80,37	18,361	33,3	86,67	100,0
		Tag 743 (Woche 106)	14	83,81	18,622	33,3	86,67	100,0
		Tag 771 (Woche 110)	13	82,05	22,175	20,0	86,67	100,0
		Tag 799 (Woche 114)	9	77,04	27,911	13,3	86,67	100,0
		Tag 827 (Woche 118)	7	77,14	27,178	20,0	86,67	100,0
		Tag 855 (Woche 122)	4	90,00	6,667	86,7	86,67	100,0
		Tag 883 (Woche 126)	2	83,33	4,714	80,0	83,33	86,7
		Tag 911 (Woche 130)	2	90,00	4,714	86,7	90,00	93,3
		Tag 939 (Woche 134)	2	80,00	9,428	73,3	80,00	86,7
		Tag 967 (Woche 138)	2	86,67	0,000	86,7	86,67	86,7
		Tag 995 (Woche 142)	1	86,67	NC	86,7	86,67	86,7
	CTx (N=192)	Baseline	158	78,69	20,980	0,0	86,67	100,0
		Tag 22 (Woche 3)	153	79,22	17,320	13,3	86,67	100,0
		Tag 43 (Woche 6)	146	77,72	17,862	6,7	80,00	100,0
		Tag 64 (Woche 9)	138	77,34	18,710	6,7	80,00	100,0
		Tag 85 (Woche 12)	134	75,62	19,069	0,0	80,00	100,0
		Tag 106 (Woche 15)	131	74,61	20,905	0,0	80,00	100,0
		Tag 127 (Woche 18)	111	74,83	19,147	20,0	80,00	100,0
		Tag 155 (Woche 22)	120	79,11	19,631	0,0	86,67	100,0
		Tag 183 (Woche 26)	117	80,80	19,499	6,7	86,67	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Körper	CTx (N=192)	Tag 211 (Woche 30)	108	80,62	19,325	0,0	86,67	100,0
		Tag 239 (Woche 34)	100	81,00	18,187	6,7	86,67	100,0
		Tag 267 (Woche 38)	96	81,60	18,219	26,7	86,67	100,0
		Tag 295 (Woche 42)	95	82,39	17,555	13,3	86,67	100,0
		Tag 323 (Woche 46)	83	81,85	16,831	13,3	86,67	100,0
		Tag 351 (Woche 50)	83	81,20	17,704	13,3	86,67	100,0
		Tag 379 (Woche 54)	74	81,71	17,795	26,7	86,67	100,0
		Tag 407 (Woche 58)	61	80,55	18,670	6,7	80,00	100,0
		Tag 435 (Woche 62)	53	82,14	18,106	0,0	80,00	100,0
		Tag 463 (Woche 66)	49	80,14	15,604	40,0	80,00	100,0
		Tag 491 (Woche 70)	32	84,17	15,027	40,0	86,67	100,0
		Tag 519 (Woche 74)	35	80,95	15,180	46,7	80,00	100,0
		Tag 547 (Woche 78)	30	84,67	11,500	66,7	80,00	100,0
		Tag 575 (Woche 82)	23	84,35	12,966	66,7	80,00	100,0
		Tag 603 (Woche 86)	20	85,67	13,896	60,0	83,33	100,0
		Tag 631 (Woche 90)	17	83,53	14,552	53,3	86,67	100,0
		Tag 659 (Woche 94)	9	83,70	11,600	66,7	86,67	100,0
		Tag 687 (Woche 98)	10	83,33	16,405	53,3	83,33	100,0
		Tag 715 (Woche 102)	9	73,33	12,472	53,3	80,00	86,7
		Tag 743 (Woche 106)	7	88,57	9,974	73,3	86,67	100,0
		Tag 771 (Woche 110)	6	87,78	8,861	73,3	86,67	100,0
		Tag 799 (Woche 114)	5	85,33	8,692	80,0	80,00	100,0
		Tag 827 (Woche 118)	3	86,67	13,333	73,3	86,67	100,0
		Tag 855 (Woche 122)	3	86,67	13,333	73,3	86,67	100,0
		Tag 883 (Woche 126)	1	86,67	NC	86,7	86,67	86,7
		Tag 911 (Woche 130)	1	100,00	NC	100,0	100,00	100,0
		Tag 939 (Woche 134)	1	100,00	NC	100,0	100,00	100,0
		Tag 967 (Woche 138)	1	100,00	NC	100,0	100,00	100,0
		Tag 995 (Woche 142)	1	100,00	NC	100,0	100,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Rolle	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	76,85	29,828	0,0	100,00	100,0
		Tag 22 (Woche 3)	169	75,25	26,671	0,0	83,33	100,0
		Tag 43 (Woche 6)	150	75,67	26,660	0,0	83,33	100,0
		Tag 64 (Woche 9)	139	73,14	25,341	0,0	66,67	100,0
		Tag 85 (Woche 12)	138	70,77	27,153	0,0	66,67	100,0
		Tag 106 (Woche 15)	130	72,44	26,471	0,0	66,67	100,0
		Tag 127 (Woche 18)	122	70,36	27,063	0,0	66,67	100,0
		Tag 155 (Woche 22)	130	72,18	27,717	0,0	66,67	100,0
		Tag 183 (Woche 26)	127	71,65	28,196	0,0	66,67	100,0
		Tag 211 (Woche 30)	115	74,35	25,677	0,0	83,33	100,0
		Tag 239 (Woche 34)	111	76,43	24,357	0,0	66,67	100,0
		Tag 267 (Woche 38)	108	77,31	24,271	0,0	83,33	100,0
		Tag 295 (Woche 42)	111	78,23	24,391	0,0	83,33	100,0
		Tag 323 (Woche 46)	105	78,73	23,513	0,0	83,33	100,0
		Tag 351 (Woche 50)	91	82,42	22,684	0,0	100,00	100,0
		Tag 379 (Woche 54)	86	81,78	21,179	0,0	83,33	100,0
		Tag 407 (Woche 58)	78	81,84	24,351	0,0	100,00	100,0
		Tag 435 (Woche 62)	68	81,37	21,264	16,7	83,33	100,0
		Tag 463 (Woche 66)	58	81,32	21,192	33,3	83,33	100,0
		Tag 491 (Woche 70)	45	81,85	21,562	16,7	83,33	100,0
		Tag 519 (Woche 74)	45	81,11	21,789	33,3	83,33	100,0
		Tag 547 (Woche 78)	37	81,53	17,909	33,3	83,33	100,0
		Tag 575 (Woche 82)	31	79,03	23,161	16,7	83,33	100,0
		Tag 603 (Woche 86)	31	82,26	23,935	0,0	100,00	100,0
		Tag 631 (Woche 90)	34	78,92	22,589	0,0	83,33	100,0
		Tag 659 (Woche 94)	26	78,85	21,887	16,7	75,00	100,0
		Tag 687 (Woche 98)	21	84,92	15,728	66,7	83,33	100,0
		Tag 715 (Woche 102)	18	78,70	25,441	0,0	75,00	100,0
		Tag 743 (Woche 106)	14	83,33	20,672	33,3	91,67	100,0
		Tag 771 (Woche 110)	13	75,64	27,735	0,0	66,67	100,0
		Tag 799 (Woche 114)	9	81,48	24,216	33,3	100,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Rolle	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	83,33	25,459	33,3	100,00	100,0
		Tag 855 (Woche 122)	4	91,67	16,667	66,7	100,00	100,0
		Tag 883 (Woche 126)	2	91,67	11,785	83,3	91,67	100,0
		Tag 911 (Woche 130)	2	100,00	0,000	100,0	100,00	100,0
		Tag 939 (Woche 134)	2	83,33	23,570	66,7	83,33	100,0
		Tag 967 (Woche 138)	2	91,67	11,785	83,3	91,67	100,0
		Tag 995 (Woche 142)	1	100,00	NC	100,0	100,00	100,0
	CTx (N=192)	Baseline	158	78,80	23,768	0,0	83,33	100,0
		Tag 22 (Woche 3)	153	76,58	22,494	0,0	83,33	100,0
		Tag 43 (Woche 6)	146	78,54	22,142	0,0	83,33	100,0
		Tag 64 (Woche 9)	138	74,88	23,332	0,0	66,67	100,0
		Tag 85 (Woche 12)	134	71,64	25,200	0,0	66,67	100,0
		Tag 106 (Woche 15)	131	69,21	24,934	0,0	66,67	100,0
		Tag 127 (Woche 18)	111	69,07	27,140	0,0	66,67	100,0
		Tag 155 (Woche 22)	120	76,39	24,501	0,0	83,33	100,0
		Tag 183 (Woche 26)	117	81,62	25,275	0,0	100,00	100,0
		Tag 211 (Woche 30)	108	80,56	23,515	0,0	91,67	100,0
		Tag 239 (Woche 34)	100	81,17	21,796	0,0	83,33	100,0
		Tag 267 (Woche 38)	96	81,42	23,179	0,0	100,00	100,0
		Tag 295 (Woche 42)	95	82,11	21,088	16,7	83,33	100,0
		Tag 323 (Woche 46)	83	81,33	23,339	0,0	83,33	100,0
		Tag 351 (Woche 50)	83	80,92	22,562	0,0	83,33	100,0
		Tag 379 (Woche 54)	74	80,86	21,312	33,3	83,33	100,0
		Tag 407 (Woche 58)	61	76,50	24,033	0,0	66,67	100,0
		Tag 435 (Woche 62)	53	80,82	23,433	0,0	83,33	100,0
		Tag 463 (Woche 66)	49	75,85	22,064	33,3	66,67	100,0
		Tag 491 (Woche 70)	32	77,08	22,699	16,7	66,67	100,0
		Tag 519 (Woche 74)	35	76,67	20,691	33,3	66,67	100,0
		Tag 547 (Woche 78)	30	82,78	16,072	50,0	83,33	100,0
		Tag 575 (Woche 82)	23	81,88	20,046	33,3	83,33	100,0
		Tag 603 (Woche 86)	20	85,00	16,132	66,7	91,67	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Rolle	CTx (N=192)	Tag 631 (Woche 90)	17	84,31	19,067	50,0	100,00	100,0
		Tag 659 (Woche 94)	9	85,19	19,444	50,0	100,00	100,0
		Tag 687 (Woche 98)	10	73,33	31,623	0,0	75,00	100,0
		Tag 715 (Woche 102)	9	68,52	25,610	16,7	66,67	100,0
		Tag 743 (Woche 106)	7	83,33	16,667	66,7	83,33	100,0
		Tag 771 (Woche 110)	6	91,67	13,944	66,7	100,00	100,0
		Tag 799 (Woche 114)	5	80,00	18,257	66,7	66,67	100,0
		Tag 827 (Woche 118)	3	88,89	19,245	66,7	100,00	100,0
		Tag 855 (Woche 122)	3	88,89	19,245	66,7	100,00	100,0
		Tag 883 (Woche 126)	1	100,00	NC	100,0	100,00	100,0
		Tag 911 (Woche 130)	1	83,33	NC	83,3	83,33	83,3
		Tag 939 (Woche 134)	1	83,33	NC	83,3	83,33	83,3
		Tag 967 (Woche 138)	1	100,00	NC	100,0	100,00	100,0
		Tag 995 (Woche 142)	1	83,33	NC	83,3	83,33	83,3
EORTC QLQ-C30 Funktionsskala: Emotionalität	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	75,45	20,984	16,7	75,00	100,0
		Tag 22 (Woche 3)	169	78,99	19,074	0,0	83,33	100,0
		Tag 43 (Woche 6)	150	80,22	19,657	8,3	83,33	100,0
		Tag 64 (Woche 9)	139	79,20	17,788	16,7	83,33	100,0
		Tag 85 (Woche 12)	138	77,29	22,532	0,0	83,33	100,0
		Tag 106 (Woche 15)	130	77,69	20,286	0,0	83,33	100,0
		Tag 127 (Woche 18)	122	77,87	20,906	0,0	83,33	100,0
		Tag 155 (Woche 22)	130	77,05	22,232	0,0	83,33	100,0
		Tag 183 (Woche 26)	127	77,76	21,156	0,0	83,33	100,0
		Tag 211 (Woche 30)	115	80,43	20,294	0,0	83,33	100,0
		Tag 239 (Woche 34)	111	79,58	21,074	8,3	83,33	100,0
		Tag 267 (Woche 38)	108	81,71	20,395	8,3	91,67	100,0
		Tag 295 (Woche 42)	111	80,63	20,967	0,0	83,33	100,0
		Tag 323 (Woche 46)	105	83,33	18,954	8,3	91,67	100,0
		Tag 351 (Woche 50)	91	85,44	17,769	8,3	91,67	100,0
		Tag 379 (Woche 54)	86	84,79	18,752	0,0	91,67	100,0
		Tag 407 (Woche 58)	78	81,62	20,206	0,0	91,67	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Emotionalität	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	84,93	15,591	50,0	91,67	100,0
		Tag 463 (Woche 66)	58	84,63	17,921	33,3	91,67	100,0
		Tag 491 (Woche 70)	45	83,70	21,317	8,3	91,67	100,0
		Tag 519 (Woche 74)	45	83,70	16,376	41,7	83,33	100,0
		Tag 547 (Woche 78)	37	85,59	19,109	33,3	91,67	100,0
		Tag 575 (Woche 82)	31	81,45	20,940	8,3	91,67	100,0
		Tag 603 (Woche 86)	31	82,80	22,663	0,0	83,33	100,0
		Tag 631 (Woche 90)	34	79,66	22,954	0,0	83,33	100,0
		Tag 659 (Woche 94)	26	80,77	21,444	8,3	83,33	100,0
		Tag 687 (Woche 98)	21	89,29	13,729	58,3	100,00	100,0
		Tag 715 (Woche 102)	18	81,02	25,050	0,0	91,67	100,0
		Tag 743 (Woche 106)	14	80,36	25,023	8,3	87,50	100,0
		Tag 771 (Woche 110)	13	80,77	27,927	0,0	91,67	100,0
		Tag 799 (Woche 114)	9	87,04	32,838	0,0	100,00	100,0
		Tag 827 (Woche 118)	7	84,52	34,166	8,3	100,00	100,0
		Tag 855 (Woche 122)	4	93,75	7,979	83,3	95,83	100,0
		Tag 883 (Woche 126)	2	95,83	5,893	91,7	95,83	100,0
		Tag 911 (Woche 130)	2	95,83	5,893	91,7	95,83	100,0
		Tag 939 (Woche 134)	2	87,50	5,893	83,3	87,50	91,7
		Tag 967 (Woche 138)	2	91,67	11,785	83,3	91,67	100,0
		Tag 995 (Woche 142)	1	83,33	NC	83,3	83,33	83,3
	CTx (N=192)	Baseline	158	73,58	19,188	0,0	75,00	100,0
		Tag 22 (Woche 3)	153	80,88	17,649	25,0	83,33	100,0
		Tag 43 (Woche 6)	146	78,54	19,861	8,3	83,33	100,0
		Tag 64 (Woche 9)	138	78,02	19,780	0,0	83,33	100,0
		Tag 85 (Woche 12)	134	79,04	18,696	0,0	83,33	100,0
		Tag 106 (Woche 15)	131	76,53	19,137	0,0	75,00	100,0
		Tag 127 (Woche 18)	111	75,45	22,072	0,0	75,00	100,0
		Tag 155 (Woche 22)	120	78,96	22,479	0,0	83,33	100,0
		Tag 183 (Woche 26)	117	80,48	21,641	0,0	83,33	100,0
		Tag 211 (Woche 30)	108	79,63	20,518	8,3	83,33	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Emotionalität	CTx (N=192)	Tag 239 (Woche 34)	100	80,25	21,538	0,0	83,33	100,0
		Tag 267 (Woche 38)	96	80,90	19,343	0,0	83,33	100,0
		Tag 295 (Woche 42)	95	79,39	20,659	0,0	83,33	100,0
		Tag 323 (Woche 46)	83	80,32	20,060	16,7	83,33	100,0
		Tag 351 (Woche 50)	83	80,92	18,476	25,0	83,33	100,0
		Tag 379 (Woche 54)	74	78,94	20,608	0,0	83,33	100,0
		Tag 407 (Woche 58)	61	78,83	20,782	16,7	83,33	100,0
		Tag 435 (Woche 62)	53	79,72	18,813	0,0	83,33	100,0
		Tag 463 (Woche 66)	49	77,89	19,060	0,0	75,00	100,0
		Tag 491 (Woche 70)	32	81,51	15,802	33,3	83,33	100,0
		Tag 519 (Woche 74)	35	81,67	19,575	25,0	83,33	100,0
		Tag 547 (Woche 78)	30	83,61	14,095	50,0	83,33	100,0
		Tag 575 (Woche 82)	23	80,07	13,931	58,3	75,00	100,0
		Tag 603 (Woche 86)	20	84,17	13,491	66,7	87,50	100,0
		Tag 631 (Woche 90)	17	81,86	15,376	50,0	83,33	100,0
		Tag 659 (Woche 94)	9	88,89	13,819	58,3	91,67	100,0
		Tag 687 (Woche 98)	10	81,67	15,615	58,3	79,17	100,0
		Tag 715 (Woche 102)	9	79,63	17,732	58,3	66,67	100,0
		Tag 743 (Woche 106)	7	80,95	13,363	58,3	83,33	100,0
		Tag 771 (Woche 110)	6	87,50	11,487	75,0	87,50	100,0
		Tag 799 (Woche 114)	5	71,67	9,501	58,3	75,00	83,3
		Tag 827 (Woche 118)	3	69,44	9,623	58,3	75,00	75,0
		Tag 855 (Woche 122)	3	77,78	25,459	50,0	83,33	100,0
		Tag 883 (Woche 126)	1	100,00	NC	100,0	100,00	100,0
		Tag 911 (Woche 130)	1	83,33	NC	83,3	83,33	83,3
		Tag 939 (Woche 134)	1	75,00	NC	75,0	75,00	75,0
		Tag 967 (Woche 138)	1	75,00	NC	75,0	75,00	75,0
		Tag 995 (Woche 142)	1	75,00	NC	75,0	75,00	75,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Kognition	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	87,33	16,384	16,7	100,00	100,0
		Tag 22 (Woche 3)	169	86,49	16,363	33,3	83,33	100,0
		Tag 43 (Woche 6)	150	83,89	19,156	0,0	83,33	100,0
		Tag 64 (Woche 9)	139	82,61	19,021	0,0	83,33	100,0
		Tag 85 (Woche 12)	138	81,04	21,613	0,0	83,33	100,0
		Tag 106 (Woche 15)	130	81,92	18,681	16,7	83,33	100,0
		Tag 127 (Woche 18)	122	81,28	18,751	33,3	83,33	100,0
		Tag 155 (Woche 22)	130	81,92	19,800	16,7	83,33	100,0
		Tag 183 (Woche 26)	127	79,53	23,588	0,0	83,33	100,0
		Tag 211 (Woche 30)	115	82,32	19,532	16,7	83,33	100,0
		Tag 239 (Woche 34)	111	81,38	19,429	16,7	83,33	100,0
		Tag 267 (Woche 38)	108	81,64	18,919	16,7	83,33	100,0
		Tag 295 (Woche 42)	111	80,78	19,358	0,0	83,33	100,0
		Tag 323 (Woche 46)	105	84,92	16,750	33,3	83,33	100,0
		Tag 351 (Woche 50)	91	84,25	19,777	0,0	83,33	100,0
		Tag 379 (Woche 54)	86	83,14	21,617	0,0	83,33	100,0
		Tag 407 (Woche 58)	78	83,55	17,715	16,7	83,33	100,0
		Tag 435 (Woche 62)	68	84,07	15,886	50,0	83,33	100,0
		Tag 463 (Woche 66)	58	83,91	15,599	50,0	83,33	100,0
		Tag 491 (Woche 70)	45	83,70	15,687	50,0	83,33	100,0
		Tag 519 (Woche 74)	45	80,00	17,624	50,0	83,33	100,0
		Tag 547 (Woche 78)	37	85,59	14,252	66,7	83,33	100,0
		Tag 575 (Woche 82)	31	80,65	21,558	0,0	83,33	100,0
		Tag 603 (Woche 86)	31	84,95	21,237	0,0	83,33	100,0
		Tag 631 (Woche 90)	34	81,86	21,069	16,7	83,33	100,0
		Tag 659 (Woche 94)	26	76,92	23,606	0,0	83,33	100,0
		Tag 687 (Woche 98)	21	81,75	17,404	50,0	83,33	100,0
		Tag 715 (Woche 102)	18	77,78	25,565	0,0	83,33	100,0
		Tag 743 (Woche 106)	14	77,38	24,985	16,7	83,33	100,0
		Tag 771 (Woche 110)	13	76,92	23,113	33,3	83,33	100,0
		Tag 799 (Woche 114)	9	83,33	22,048	33,3	83,33	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Kognition	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	69,05	24,398	16,7	83,33	83,3
		Tag 855 (Woche 122)	4	83,33	13,608	66,7	83,33	100,0
		Tag 883 (Woche 126)	2	75,00	11,785	66,7	75,00	83,3
		Tag 911 (Woche 130)	2	91,67	11,785	83,3	91,67	100,0
		Tag 939 (Woche 134)	2	75,00	11,785	66,7	75,00	83,3
		Tag 967 (Woche 138)	2	83,33	0,000	83,3	83,33	83,3
		Tag 995 (Woche 142)	1	83,33	NC	83,3	83,33	83,3
	CTx (N=192)	Baseline	158	86,29	16,455	33,3	83,33	100,0
		Tag 22 (Woche 3)	153	87,25	17,074	0,0	100,00	100,0
		Tag 43 (Woche 6)	146	85,05	17,257	16,7	83,33	100,0
		Tag 64 (Woche 9)	138	84,18	18,048	0,0	83,33	100,0
		Tag 85 (Woche 12)	134	83,46	19,118	16,7	83,33	100,0
		Tag 106 (Woche 15)	131	80,03	22,209	0,0	83,33	100,0
		Tag 127 (Woche 18)	111	82,88	18,594	0,0	83,33	100,0
		Tag 155 (Woche 22)	120	83,33	18,206	0,0	83,33	100,0
		Tag 183 (Woche 26)	117	83,62	19,326	16,7	83,33	100,0
		Tag 211 (Woche 30)	108	83,95	18,075	0,0	83,33	100,0
		Tag 239 (Woche 34)	100	85,00	16,834	16,7	83,33	100,0
		Tag 267 (Woche 38)	96	81,77	19,358	0,0	83,33	100,0
		Tag 295 (Woche 42)	95	82,63	22,137	0,0	83,33	100,0
		Tag 323 (Woche 46)	83	82,33	19,365	16,7	83,33	100,0
		Tag 351 (Woche 50)	83	81,93	20,856	0,0	83,33	100,0
		Tag 379 (Woche 54)	74	84,91	19,540	0,0	83,33	100,0
		Tag 407 (Woche 58)	61	83,06	22,046	0,0	83,33	100,0
		Tag 435 (Woche 62)	53	81,45	22,801	0,0	83,33	100,0
		Tag 463 (Woche 66)	49	78,91	24,715	0,0	83,33	100,0
		Tag 491 (Woche 70)	32	84,38	21,560	33,3	100,00	100,0
		Tag 519 (Woche 74)	35	83,81	22,682	16,7	100,00	100,0
		Tag 547 (Woche 78)	30	86,11	17,553	33,3	91,67	100,0
		Tag 575 (Woche 82)	23	84,06	17,025	50,0	83,33	100,0
		Tag 603 (Woche 86)	20	87,50	18,634	33,3	100,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Kognition	CTx (N=192)	Tag 631 (Woche 90)	17	87,25	18,190	33,3	100,00	100,0
		Tag 659 (Woche 94)	9	85,19	19,444	50,0	100,00	100,0
		Tag 687 (Woche 98)	10	75,00	11,785	66,7	66,67	100,0
		Tag 715 (Woche 102)	9	74,07	22,222	33,3	83,33	100,0
		Tag 743 (Woche 106)	7	78,57	18,545	50,0	83,33	100,0
		Tag 771 (Woche 110)	6	83,33	21,082	50,0	91,67	100,0
		Tag 799 (Woche 114)	5	66,67	23,570	33,3	66,67	100,0
		Tag 827 (Woche 118)	3	55,56	34,694	16,7	66,67	83,3
		Tag 855 (Woche 122)	3	55,56	34,694	16,7	66,67	83,3
		Tag 883 (Woche 126)	1	83,33	NC	83,3	83,33	83,3
		Tag 911 (Woche 130)	1	66,67	NC	66,7	66,67	66,7
		Tag 939 (Woche 134)	1	66,67	NC	66,7	66,67	66,7
		Tag 967 (Woche 138)	1	66,67	NC	66,7	66,67	66,7
		Tag 995 (Woche 142)	1	66,67	NC	66,7	66,67	66,7
EORTC QLQ-C30 Funktionsskala: Sozial	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	78,84	24,437	0,0	83,33	100,0
		Tag 22 (Woche 3)	169	76,63	25,021	0,0	83,33	100,0
		Tag 43 (Woche 6)	150	75,89	24,082	0,0	83,33	100,0
		Tag 64 (Woche 9)	139	76,86	22,478	0,0	83,33	100,0
		Tag 85 (Woche 12)	138	73,19	23,779	0,0	66,67	100,0
		Tag 106 (Woche 15)	130	74,62	25,435	0,0	83,33	100,0
		Tag 127 (Woche 18)	122	74,86	24,827	0,0	66,67	100,0
		Tag 155 (Woche 22)	130	74,36	26,098	0,0	75,00	100,0
		Tag 183 (Woche 26)	127	76,77	24,859	0,0	83,33	100,0
		Tag 211 (Woche 30)	115	79,28	21,356	0,0	83,33	100,0
		Tag 239 (Woche 34)	111	80,63	22,309	0,0	83,33	100,0
		Tag 267 (Woche 38)	108	79,94	22,759	0,0	83,33	100,0
		Tag 295 (Woche 42)	111	80,03	24,600	0,0	83,33	100,0
		Tag 323 (Woche 46)	105	80,79	22,501	0,0	83,33	100,0
		Tag 351 (Woche 50)	91	80,22	21,930	16,7	83,33	100,0
		Tag 379 (Woche 54)	86	80,81	24,188	0,0	91,67	100,0
		Tag 407 (Woche 58)	78	79,91	23,777	0,0	83,33	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Sozial	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	80,15	20,816	0,0	83,33	100,0
		Tag 463 (Woche 66)	58	83,05	20,589	33,3	91,67	100,0
		Tag 491 (Woche 70)	45	81,85	21,267	33,3	83,33	100,0
		Tag 519 (Woche 74)	45	80,74	22,461	33,3	83,33	100,0
		Tag 547 (Woche 78)	37	85,14	17,909	33,3	100,00	100,0
		Tag 575 (Woche 82)	31	82,26	23,148	0,0	100,00	100,0
		Tag 603 (Woche 86)	31	85,48	20,968	33,3	100,00	100,0
		Tag 631 (Woche 90)	34	76,47	19,296	16,7	66,67	100,0
		Tag 659 (Woche 94)	26	78,85	21,887	16,7	83,33	100,0
		Tag 687 (Woche 98)	21	81,75	21,019	33,3	83,33	100,0
		Tag 715 (Woche 102)	18	82,41	19,363	50,0	91,67	100,0
		Tag 743 (Woche 106)	14	76,19	21,398	33,3	66,67	100,0
		Tag 771 (Woche 110)	13	79,49	31,294	0,0	100,00	100,0
		Tag 799 (Woche 114)	9	83,33	28,868	16,7	100,00	100,0
		Tag 827 (Woche 118)	7	80,95	26,227	33,3	100,00	100,0
		Tag 855 (Woche 122)	4	83,33	13,608	66,7	83,33	100,0
		Tag 883 (Woche 126)	2	83,33	0,000	83,3	83,33	83,3
		Tag 911 (Woche 130)	2	75,00	11,785	66,7	75,00	83,3
		Tag 939 (Woche 134)	2	91,67	11,785	83,3	91,67	100,0
		Tag 967 (Woche 138)	2	83,33	23,570	66,7	83,33	100,0
		Tag 995 (Woche 142)	1	66,67	NC	66,7	66,67	66,7
	CTx (N=192)	Baseline	158	77,95	25,116	0,0	83,33	100,0
		Tag 22 (Woche 3)	153	82,57	19,435	33,3	83,33	100,0
		Tag 43 (Woche 6)	146	77,63	24,560	0,0	83,33	100,0
		Tag 64 (Woche 9)	138	76,21	23,732	0,0	83,33	100,0
		Tag 85 (Woche 12)	134	74,25	23,976	0,0	75,00	100,0
		Tag 106 (Woche 15)	131	75,45	23,418	0,0	66,67	100,0
		Tag 127 (Woche 18)	111	75,83	25,100	16,7	83,33	100,0
		Tag 155 (Woche 22)	120	78,89	24,324	0,0	83,33	100,0
		Tag 183 (Woche 26)	117	82,19	23,745	0,0	100,00	100,0
		Tag 211 (Woche 30)	108	81,33	22,754	16,7	100,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Sozial	CTx (N=192)	Tag 239 (Woche 34)	100	81,00	21,058	0,0	83,33	100,0
		Tag 267 (Woche 38)	96	82,47	20,430	16,7	83,33	100,0
		Tag 295 (Woche 42)	95	83,33	20,340	0,0	100,00	100,0
		Tag 323 (Woche 46)	83	83,94	20,237	16,7	100,00	100,0
		Tag 351 (Woche 50)	83	82,13	20,624	16,7	100,00	100,0
		Tag 379 (Woche 54)	74	83,56	22,325	0,0	100,00	100,0
		Tag 407 (Woche 58)	61	81,42	19,976	33,3	83,33	100,0
		Tag 435 (Woche 62)	53	82,08	22,610	0,0	83,33	100,0
		Tag 463 (Woche 66)	49	80,95	20,412	16,7	83,33	100,0
		Tag 491 (Woche 70)	32	83,33	17,961	33,3	83,33	100,0
		Tag 519 (Woche 74)	35	84,76	20,361	33,3	100,00	100,0
		Tag 547 (Woche 78)	30	83,89	18,817	33,3	91,67	100,0
		Tag 575 (Woche 82)	23	88,41	14,595	66,7	100,00	100,0
		Tag 603 (Woche 86)	20	83,33	16,222	50,0	83,33	100,0
		Tag 631 (Woche 90)	17	83,33	22,048	33,3	100,00	100,0
		Tag 659 (Woche 94)	9	81,48	19,444	50,0	83,33	100,0
		Tag 687 (Woche 98)	10	75,00	23,895	33,3	66,67	100,0
		Tag 715 (Woche 102)	9	72,22	20,412	33,3	66,67	100,0
		Tag 743 (Woche 106)	7	78,57	18,545	50,0	83,33	100,0
		Tag 771 (Woche 110)	6	86,11	16,387	66,7	91,67	100,0
		Tag 799 (Woche 114)	5	80,00	13,944	66,7	83,33	100,0
		Tag 827 (Woche 118)	3	83,33	16,667	66,7	83,33	100,0
		Tag 855 (Woche 122)	3	83,33	16,667	66,7	83,33	100,0
		Tag 883 (Woche 126)	1	100,00	NC	100,0	100,00	100,0
		Tag 911 (Woche 130)	1	100,00	NC	100,0	100,00	100,0
		Tag 939 (Woche 134)	1	83,33	NC	83,3	83,33	83,3
		Tag 967 (Woche 138)	1	83,33	NC	83,3	83,33	83,3
		Tag 995 (Woche 142)	1	66,67	NC	66,7	66,67	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Fatigue	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	28,81	23,654	0,0	22,22	100,0
		Tag 22 (Woche 3)	169	35,50	21,797	0,0	33,33	100,0
		Tag 43 (Woche 6)	150	34,89	22,223	0,0	33,33	100,0
		Tag 64 (Woche 9)	139	36,69	20,271	0,0	33,33	100,0
		Tag 85 (Woche 12)	138	39,53	21,312	0,0	33,33	100,0
		Tag 106 (Woche 15)	130	39,15	23,283	0,0	33,33	100,0
		Tag 127 (Woche 18)	122	38,80	21,676	0,0	33,33	100,0
		Tag 155 (Woche 22)	130	38,12	22,477	0,0	33,33	100,0
		Tag 183 (Woche 26)	127	35,70	23,199	0,0	33,33	100,0
		Tag 211 (Woche 30)	115	33,82	20,833	0,0	33,33	100,0
		Tag 239 (Woche 34)	111	33,03	19,789	0,0	33,33	88,9
		Tag 267 (Woche 38)	108	32,30	21,725	0,0	33,33	100,0
		Tag 295 (Woche 42)	111	31,13	20,858	0,0	33,33	100,0
		Tag 323 (Woche 46)	105	30,16	22,153	0,0	33,33	100,0
		Tag 351 (Woche 50)	91	28,33	21,099	0,0	33,33	88,9
		Tag 379 (Woche 54)	86	26,49	19,961	0,0	33,33	100,0
		Tag 407 (Woche 58)	78	30,77	20,877	0,0	33,33	88,9
		Tag 435 (Woche 62)	68	25,00	16,777	0,0	22,22	77,8
		Tag 463 (Woche 66)	58	28,74	19,858	0,0	33,33	100,0
		Tag 491 (Woche 70)	45	27,90	23,763	0,0	22,22	100,0
		Tag 519 (Woche 74)	45	27,90	19,480	0,0	33,33	77,8
		Tag 547 (Woche 78)	37	25,23	18,638	0,0	33,33	66,7
		Tag 575 (Woche 82)	31	29,03	23,947	0,0	33,33	100,0
		Tag 603 (Woche 86)	31	25,09	23,477	0,0	22,22	77,8
		Tag 631 (Woche 90)	34	28,43	20,321	0,0	33,33	100,0
		Tag 659 (Woche 94)	26	28,21	23,982	0,0	33,33	88,9
		Tag 687 (Woche 98)	21	25,40	18,968	0,0	22,22	66,7
		Tag 715 (Woche 102)	18	25,93	26,678	0,0	22,22	100,0
		Tag 743 (Woche 106)	14	29,37	21,175	0,0	33,33	88,9
		Tag 771 (Woche 110)	13	28,21	25,099	0,0	22,22	88,9
		Tag 799 (Woche 114)	9	29,63	24,845	0,0	22,22	88,9

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Fatigue	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	33,33	25,660	11,1	22,22	88,9
		Tag 855 (Woche 122)	4	22,22	9,072	11,1	22,22	33,3
		Tag 883 (Woche 126)	2	27,78	7,857	22,2	27,78	33,3
		Tag 911 (Woche 130)	2	22,22	15,713	11,1	22,22	33,3
		Tag 939 (Woche 134)	2	27,78	7,857	22,2	27,78	33,3
		Tag 967 (Woche 138)	2	27,78	7,857	22,2	27,78	33,3
		Tag 995 (Woche 142)	1	22,22	NC	22,2	22,22	22,2
	CTx (N=192)	Baseline	158	29,68	20,161	0,0	27,78	88,9
		Tag 22 (Woche 3)	153	31,81	20,195	0,0	33,33	88,9
		Tag 43 (Woche 6)	146	34,25	18,199	0,0	33,33	88,9
		Tag 64 (Woche 9)	138	35,27	19,635	0,0	33,33	77,8
		Tag 85 (Woche 12)	134	37,56	21,919	0,0	33,33	100,0
		Tag 106 (Woche 15)	131	38,68	22,365	0,0	33,33	100,0
		Tag 127 (Woche 18)	111	39,14	23,964	0,0	33,33	100,0
		Tag 155 (Woche 22)	120	30,09	20,135	0,0	33,33	100,0
		Tag 183 (Woche 26)	117	26,69	20,272	0,0	22,22	88,9
		Tag 211 (Woche 30)	108	28,40	21,231	0,0	22,22	100,0
		Tag 239 (Woche 34)	100	26,67	17,937	0,0	27,78	77,8
		Tag 267 (Woche 38)	96	28,47	21,976	0,0	33,33	100,0
		Tag 295 (Woche 42)	95	28,77	22,014	0,0	33,33	100,0
		Tag 323 (Woche 46)	83	27,31	19,959	0,0	22,22	88,9
		Tag 351 (Woche 50)	83	27,84	20,632	0,0	33,33	100,0
		Tag 379 (Woche 54)	74	27,18	17,266	0,0	27,78	66,7
		Tag 407 (Woche 58)	61	29,87	19,725	0,0	33,33	88,9
		Tag 435 (Woche 62)	53	27,46	19,564	0,0	22,22	77,8
		Tag 463 (Woche 66)	49	32,65	20,083	0,0	33,33	88,9
		Tag 491 (Woche 70)	32	29,51	19,268	0,0	33,33	66,7
		Tag 519 (Woche 74)	35	27,94	19,126	0,0	33,33	66,7
		Tag 547 (Woche 78)	30	25,56	18,489	0,0	22,22	55,6
		Tag 575 (Woche 82)	23	25,12	17,478	0,0	22,22	66,7
		Tag 603 (Woche 86)	20	25,56	18,061	0,0	27,78	55,6

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Fatigue	CTx (N=192)	Tag 631 (Woche 90)	17	30,07	19,940	0,0	33,33	66,7
		Tag 659 (Woche 94)	9	23,46	23,204	0,0	22,22	66,7
		Tag 687 (Woche 98)	10	32,22	18,481	0,0	33,33	55,6
		Tag 715 (Woche 102)	9	34,57	21,114	0,0	33,33	66,7
		Tag 743 (Woche 106)	7	25,40	17,817	0,0	22,22	55,6
		Tag 771 (Woche 110)	6	24,07	16,355	0,0	27,78	44,4
		Tag 799 (Woche 114)	5	35,56	14,487	22,2	33,33	55,6
		Tag 827 (Woche 118)	3	33,33	19,245	22,2	22,22	55,6
		Tag 855 (Woche 122)	3	37,04	25,660	22,2	22,22	66,7
		Tag 883 (Woche 126)	1	11,11	NC	11,1	11,11	11,1
		Tag 911 (Woche 130)	1	22,22	NC	22,2	22,22	22,2
		Tag 939 (Woche 134)	1	22,22	NC	22,2	22,22	22,2
		Tag 967 (Woche 138)	1	22,22	NC	22,2	22,22	22,2
		Tag 995 (Woche 142)	1	22,22	NC	22,2	22,22	22,2
EORTC QLQ-C30 Übelkeit und Erbrechen	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	4,79	11,728	0,0	0,00	83,3
		Tag 22 (Woche 3)	169	8,19	14,217	0,0	0,00	100,0
		Tag 43 (Woche 6)	150	7,89	15,044	0,0	0,00	100,0
		Tag 64 (Woche 9)	139	9,11	15,045	0,0	0,00	83,3
		Tag 85 (Woche 12)	138	9,18	14,944	0,0	0,00	66,7
		Tag 106 (Woche 15)	130	8,72	13,799	0,0	0,00	66,7
		Tag 127 (Woche 18)	122	8,47	14,413	0,0	0,00	83,3
		Tag 155 (Woche 22)	130	12,95	17,396	0,0	0,00	83,3
		Tag 183 (Woche 26)	127	11,42	16,088	0,0	0,00	66,7
		Tag 211 (Woche 30)	115	10,00	14,776	0,0	0,00	83,3
		Tag 239 (Woche 34)	111	9,46	14,146	0,0	0,00	66,7
		Tag 267 (Woche 38)	108	8,18	12,583	0,0	0,00	50,0
		Tag 295 (Woche 42)	111	8,11	12,074	0,0	0,00	50,0
		Tag 323 (Woche 46)	105	6,98	13,030	0,0	0,00	83,3
		Tag 351 (Woche 50)	91	5,31	8,916	0,0	0,00	33,3
		Tag 379 (Woche 54)	86	7,56	16,100	0,0	0,00	100,0
		Tag 407 (Woche 58)	78	6,20	12,045	0,0	0,00	50,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Übelkeit und Erbrechen	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	5,39	9,740	0,0	0,00	33,3
		Tag 463 (Woche 66)	58	5,17	11,346	0,0	0,00	66,7
		Tag 491 (Woche 70)	45	6,30	14,775	0,0	0,00	66,7
		Tag 519 (Woche 74)	45	8,15	15,334	0,0	0,00	66,7
		Tag 547 (Woche 78)	37	7,21	11,480	0,0	0,00	50,0
		Tag 575 (Woche 82)	31	6,99	14,125	0,0	0,00	66,7
		Tag 603 (Woche 86)	31	9,14	19,167	0,0	0,00	83,3
		Tag 631 (Woche 90)	34	5,88	13,535	0,0	0,00	66,7
		Tag 659 (Woche 94)	26	9,62	15,036	0,0	0,00	50,0
		Tag 687 (Woche 98)	21	3,17	6,706	0,0	0,00	16,7
		Tag 715 (Woche 102)	18	6,48	16,309	0,0	0,00	66,7
		Tag 743 (Woche 106)	14	4,76	10,187	0,0	0,00	33,3
		Tag 771 (Woche 110)	13	10,26	17,398	0,0	0,00	50,0
		Tag 799 (Woche 114)	9	7,41	16,897	0,0	0,00	50,0
		Tag 827 (Woche 118)	7	7,14	18,898	0,0	0,00	50,0
		Tag 855 (Woche 122)	4	4,17	8,333	0,0	0,00	16,7
		Tag 883 (Woche 126)	2	0,00	0,000	0,0	0,00	0,0
		Tag 911 (Woche 130)	2	0,00	0,000	0,0	0,00	0,0
		Tag 939 (Woche 134)	2	0,00	0,000	0,0	0,00	0,0
		Tag 967 (Woche 138)	2	0,00	0,000	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	16,67	NC	16,7	16,67	16,7
	CTx (N=192)	Baseline	158	7,91	15,592	0,0	0,00	83,3
		Tag 22 (Woche 3)	153	7,19	13,350	0,0	0,00	83,3
		Tag 43 (Woche 6)	146	8,11	13,595	0,0	0,00	66,7
		Tag 64 (Woche 9)	138	8,09	13,693	0,0	0,00	66,7
		Tag 85 (Woche 12)	134	7,84	14,694	0,0	0,00	66,7
		Tag 106 (Woche 15)	131	8,52	15,382	0,0	0,00	66,7
		Tag 127 (Woche 18)	111	6,01	11,190	0,0	0,00	50,0
		Tag 155 (Woche 22)	120	5,00	10,497	0,0	0,00	50,0
		Tag 183 (Woche 26)	117	5,41	11,952	0,0	0,00	83,3
		Tag 211 (Woche 30)	108	4,63	13,448	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Übelkeit und Erbrechen	CTx (N=192)	Tag 239 (Woche 34)	100	3,33	9,476	0,0	0,00	66,7
		Tag 267 (Woche 38)	96	4,86	11,577	0,0	0,00	50,0
		Tag 295 (Woche 42)	95	6,84	17,275	0,0	0,00	100,0
		Tag 323 (Woche 46)	83	5,02	14,430	0,0	0,00	100,0
		Tag 351 (Woche 50)	83	3,82	13,099	0,0	0,00	100,0
		Tag 379 (Woche 54)	74	5,63	10,052	0,0	0,00	33,3
		Tag 407 (Woche 58)	61	4,37	10,047	0,0	0,00	50,0
		Tag 435 (Woche 62)	53	4,09	9,190	0,0	0,00	33,3
		Tag 463 (Woche 66)	49	4,76	10,758	0,0	0,00	33,3
		Tag 491 (Woche 70)	32	2,60	7,465	0,0	0,00	33,3
		Tag 519 (Woche 74)	35	2,86	7,547	0,0	0,00	33,3
		Tag 547 (Woche 78)	30	1,11	4,228	0,0	0,00	16,7
		Tag 575 (Woche 82)	23	2,90	6,459	0,0	0,00	16,7
		Tag 603 (Woche 86)	20	2,50	8,156	0,0	0,00	33,3
		Tag 631 (Woche 90)	17	1,96	5,535	0,0	0,00	16,7
		Tag 659 (Woche 94)	9	1,85	5,556	0,0	0,00	16,7
		Tag 687 (Woche 98)	10	1,67	5,270	0,0	0,00	16,7
		Tag 715 (Woche 102)	9	1,85	5,556	0,0	0,00	16,7
		Tag 743 (Woche 106)	7	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	6	2,78	6,804	0,0	0,00	16,7
		Tag 799 (Woche 114)	5	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	3	0,00	0,000	0,0	0,00	0,0
		Tag 855 (Woche 122)	3	0,00	0,000	0,0	0,00	0,0
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Schmerzen	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	26,25	27,587	0,0	16,67	100,0
		Tag 22 (Woche 3)	169	24,06	26,028	0,0	16,67	100,0
		Tag 43 (Woche 6)	150	21,22	24,110	0,0	16,67	100,0
		Tag 64 (Woche 9)	139	20,38	24,903	0,0	16,67	83,3
		Tag 85 (Woche 12)	138	22,71	25,547	0,0	16,67	100,0
		Tag 106 (Woche 15)	130	20,64	22,524	0,0	16,67	83,3
		Tag 127 (Woche 18)	122	21,31	27,211	0,0	16,67	100,0
		Tag 155 (Woche 22)	130	21,54	25,790	0,0	16,67	100,0
		Tag 183 (Woche 26)	127	23,23	26,156	0,0	16,67	100,0
		Tag 211 (Woche 30)	115	21,88	24,618	0,0	16,67	100,0
		Tag 239 (Woche 34)	111	18,62	20,688	0,0	16,67	100,0
		Tag 267 (Woche 38)	108	17,13	23,730	0,0	0,00	100,0
		Tag 295 (Woche 42)	111	21,17	23,457	0,0	16,67	100,0
		Tag 323 (Woche 46)	105	17,94	22,011	0,0	16,67	83,3
		Tag 351 (Woche 50)	91	15,93	21,215	0,0	16,67	100,0
		Tag 379 (Woche 54)	86	17,05	21,690	0,0	16,67	100,0
		Tag 407 (Woche 58)	78	17,95	23,990	0,0	8,33	100,0
		Tag 435 (Woche 62)	68	13,73	19,304	0,0	0,00	66,7
		Tag 463 (Woche 66)	58	18,10	21,239	0,0	16,67	66,7
		Tag 491 (Woche 70)	45	16,67	27,979	0,0	0,00	100,0
		Tag 519 (Woche 74)	45	21,11	23,138	0,0	16,67	66,7
		Tag 547 (Woche 78)	37	16,22	18,209	0,0	16,67	50,0
		Tag 575 (Woche 82)	31	18,82	24,245	0,0	0,00	83,3
		Tag 603 (Woche 86)	31	15,05	19,886	0,0	0,00	66,7
		Tag 631 (Woche 90)	34	17,65	19,652	0,0	16,67	83,3
		Tag 659 (Woche 94)	26	20,51	24,179	0,0	16,67	83,3
		Tag 687 (Woche 98)	21	12,70	17,404	0,0	0,00	50,0
		Tag 715 (Woche 102)	18	14,81	30,726	0,0	0,00	100,0
		Tag 743 (Woche 106)	14	14,29	20,524	0,0	0,00	66,7
		Tag 771 (Woche 110)	13	20,51	25,598	0,0	16,67	83,3
		Tag 799 (Woche 114)	9	20,37	33,101	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Schmerzen	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	21,43	36,911	0,0	0,00	100,0
		Tag 855 (Woche 122)	4	12,50	15,957	0,0	8,33	33,3
		Tag 883 (Woche 126)	2	8,33	11,785	0,0	8,33	16,7
		Tag 911 (Woche 130)	2	8,33	11,785	0,0	8,33	16,7
		Tag 939 (Woche 134)	2	25,00	35,355	0,0	25,00	50,0
		Tag 967 (Woche 138)	2	16,67	23,570	0,0	16,67	33,3
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
	CTx (N=192)	Baseline	158	23,95	26,698	0,0	16,67	100,0
		Tag 22 (Woche 3)	153	21,57	22,852	0,0	16,67	100,0
		Tag 43 (Woche 6)	146	21,69	22,177	0,0	16,67	100,0
		Tag 64 (Woche 9)	138	21,62	22,461	0,0	16,67	100,0
		Tag 85 (Woche 12)	134	24,50	25,255	0,0	16,67	100,0
		Tag 106 (Woche 15)	131	22,01	24,308	0,0	16,67	100,0
		Tag 127 (Woche 18)	111	23,42	24,861	0,0	16,67	100,0
		Tag 155 (Woche 22)	120	18,33	23,807	0,0	16,67	100,0
		Tag 183 (Woche 26)	117	16,81	22,156	0,0	16,67	100,0
		Tag 211 (Woche 30)	108	23,30	23,006	0,0	16,67	100,0
		Tag 239 (Woche 34)	100	20,33	23,280	0,0	16,67	83,3
		Tag 267 (Woche 38)	96	21,53	23,560	0,0	16,67	83,3
		Tag 295 (Woche 42)	95	19,12	23,059	0,0	16,67	100,0
		Tag 323 (Woche 46)	83	19,68	23,876	0,0	16,67	83,3
		Tag 351 (Woche 50)	83	20,48	22,591	0,0	16,67	100,0
		Tag 379 (Woche 54)	74	20,27	23,452	0,0	16,67	100,0
		Tag 407 (Woche 58)	61	20,77	22,496	0,0	16,67	100,0
		Tag 435 (Woche 62)	53	16,67	23,113	0,0	0,00	83,3
		Tag 463 (Woche 66)	49	20,75	22,956	0,0	16,67	100,0
		Tag 491 (Woche 70)	32	21,35	24,405	0,0	16,67	83,3
		Tag 519 (Woche 74)	35	18,10	22,999	0,0	0,00	83,3
		Tag 547 (Woche 78)	30	20,56	23,029	0,0	16,67	66,7
		Tag 575 (Woche 82)	23	17,39	19,770	0,0	16,67	50,0
		Tag 603 (Woche 86)	20	19,17	21,815	0,0	16,67	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Schmerzen	CTx (N=192)	Tag 631 (Woche 90)	17	20,59	25,365	0,0	16,67	83,3
		Tag 659 (Woche 94)	9	12,96	13,889	0,0	16,67	33,3
		Tag 687 (Woche 98)	10	18,33	22,839	0,0	16,67	66,7
		Tag 715 (Woche 102)	9	24,07	20,601	0,0	33,33	50,0
		Tag 743 (Woche 106)	7	19,05	14,996	0,0	16,67	33,3
		Tag 771 (Woche 110)	6	11,11	13,608	0,0	8,33	33,3
		Tag 799 (Woche 114)	5	3,33	7,454	0,0	0,00	16,7
		Tag 827 (Woche 118)	3	0,00	0,000	0,0	0,00	0,0
		Tag 855 (Woche 122)	3	5,56	9,623	0,0	0,00	16,7
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0
EORTC QLQ-C30 Dyspnoe	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	12,77	21,872	0,0	0,00	100,0
		Tag 22 (Woche 3)	169	15,38	21,207	0,0	0,00	100,0
		Tag 43 (Woche 6)	150	18,00	22,060	0,0	0,00	100,0
		Tag 64 (Woche 9)	139	18,23	20,549	0,0	0,00	66,7
		Tag 85 (Woche 12)	138	19,32	23,763	0,0	0,00	100,0
		Tag 106 (Woche 15)	130	20,26	22,541	0,0	33,33	100,0
		Tag 127 (Woche 18)	122	19,67	22,980	0,0	0,00	100,0
		Tag 155 (Woche 22)	130	14,62	18,563	0,0	0,00	66,7
		Tag 183 (Woche 26)	127	13,39	21,107	0,0	0,00	100,0
		Tag 211 (Woche 30)	115	13,33	19,646	0,0	0,00	66,7
		Tag 239 (Woche 34)	111	13,21	19,735	0,0	0,00	100,0
		Tag 267 (Woche 38)	108	13,89	20,946	0,0	0,00	100,0
		Tag 295 (Woche 42)	111	13,51	20,782	0,0	0,00	100,0
		Tag 323 (Woche 46)	105	12,06	20,215	0,0	0,00	100,0
		Tag 351 (Woche 50)	91	10,99	18,629	0,0	0,00	66,7
		Tag 379 (Woche 54)	86	10,08	18,485	0,0	0,00	66,7
		Tag 407 (Woche 58)	78	9,40	16,024	0,0	0,00	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Dyspnoe	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	10,78	16,732	0,0	0,00	66,7
		Tag 463 (Woche 66)	58	10,34	18,946	0,0	0,00	66,7
		Tag 491 (Woche 70)	45	3,70	10,594	0,0	0,00	33,3
		Tag 519 (Woche 74)	45	8,15	17,632	0,0	0,00	66,7
		Tag 547 (Woche 78)	37	7,21	15,977	0,0	0,00	66,7
		Tag 575 (Woche 82)	31	11,83	23,646	0,0	0,00	100,0
		Tag 603 (Woche 86)	31	4,30	14,252	0,0	0,00	66,7
		Tag 631 (Woche 90)	34	8,82	18,908	0,0	0,00	66,7
		Tag 659 (Woche 94)	26	17,95	23,534	0,0	0,00	66,7
		Tag 687 (Woche 98)	21	11,11	16,102	0,0	0,00	33,3
		Tag 715 (Woche 102)	18	12,96	28,328	0,0	0,00	100,0
		Tag 743 (Woche 106)	14	9,52	20,375	0,0	0,00	66,7
		Tag 771 (Woche 110)	13	15,38	32,247	0,0	0,00	100,0
		Tag 799 (Woche 114)	9	14,81	24,216	0,0	0,00	66,7
		Tag 827 (Woche 118)	7	9,52	25,198	0,0	0,00	66,7
		Tag 855 (Woche 122)	4	0,00	0,000	0,0	0,00	0,0
		Tag 883 (Woche 126)	2	0,00	0,000	0,0	0,00	0,0
		Tag 911 (Woche 130)	2	0,00	0,000	0,0	0,00	0,0
		Tag 939 (Woche 134)	2	0,00	0,000	0,0	0,00	0,0
		Tag 967 (Woche 138)	2	0,00	0,000	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0
	CTx (N=192)	Baseline	158	13,29	21,593	0,0	0,00	100,0
		Tag 22 (Woche 3)	153	14,38	20,507	0,0	0,00	100,0
		Tag 43 (Woche 6)	146	17,81	22,202	0,0	0,00	100,0
		Tag 64 (Woche 9)	138	19,08	22,743	0,0	0,00	100,0
		Tag 85 (Woche 12)	134	19,90	22,058	0,0	33,33	100,0
		Tag 106 (Woche 15)	131	20,87	24,227	0,0	33,33	100,0
		Tag 127 (Woche 18)	111	19,82	23,085	0,0	33,33	100,0
		Tag 155 (Woche 22)	120	14,72	19,227	0,0	0,00	66,7
		Tag 183 (Woche 26)	117	10,54	18,388	0,0	0,00	100,0
		Tag 211 (Woche 30)	108	13,27	20,854	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Dyspnoe	CTx (N=192)	Tag 239 (Woche 34)	100	12,33	16,854	0,0	0,00	66,7
		Tag 267 (Woche 38)	96	13,54	21,940	0,0	0,00	100,0
		Tag 295 (Woche 42)	95	14,04	20,958	0,0	0,00	100,0
		Tag 323 (Woche 46)	83	12,45	17,815	0,0	0,00	66,7
		Tag 351 (Woche 50)	83	14,46	20,948	0,0	0,00	66,7
		Tag 379 (Woche 54)	74	13,51	19,831	0,0	0,00	100,0
		Tag 407 (Woche 58)	61	14,21	20,601	0,0	0,00	66,7
		Tag 435 (Woche 62)	53	15,72	19,175	0,0	0,00	66,7
		Tag 463 (Woche 66)	49	21,77	26,832	0,0	0,00	100,0
		Tag 491 (Woche 70)	32	13,54	16,633	0,0	0,00	33,3
		Tag 519 (Woche 74)	35	15,24	16,848	0,0	0,00	33,3
		Tag 547 (Woche 78)	30	18,89	20,869	0,0	16,67	66,7
		Tag 575 (Woche 82)	23	17,39	19,770	0,0	0,00	66,7
		Tag 603 (Woche 86)	20	11,67	16,312	0,0	0,00	33,3
		Tag 631 (Woche 90)	17	9,80	15,656	0,0	0,00	33,3
		Tag 659 (Woche 94)	9	14,81	17,568	0,0	0,00	33,3
		Tag 687 (Woche 98)	10	13,33	17,213	0,0	0,00	33,3
		Tag 715 (Woche 102)	9	22,22	23,570	0,0	33,33	66,7
		Tag 743 (Woche 106)	7	23,81	25,198	0,0	33,33	66,7
		Tag 771 (Woche 110)	6	11,11	17,213	0,0	0,00	33,3
		Tag 799 (Woche 114)	5	20,00	18,257	0,0	33,33	33,3
		Tag 827 (Woche 118)	3	22,22	19,245	0,0	33,33	33,3
		Tag 855 (Woche 122)	3	22,22	19,245	0,0	33,33	33,3
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Schlaflosigkeit	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	27,94	28,883	0,0	33,33	100,0
		Tag 22 (Woche 3)	169	26,23	25,502	0,0	33,33	100,0
		Tag 43 (Woche 6)	150	23,11	26,461	0,0	33,33	100,0
		Tag 64 (Woche 9)	139	25,66	25,794	0,0	33,33	100,0
		Tag 85 (Woche 12)	138	24,64	27,700	0,0	33,33	100,0
		Tag 106 (Woche 15)	130	23,85	24,984	0,0	33,33	100,0
		Tag 127 (Woche 18)	122	25,96	26,247	0,0	33,33	100,0
		Tag 155 (Woche 22)	130	24,10	24,908	0,0	33,33	100,0
		Tag 183 (Woche 26)	127	27,82	30,215	0,0	33,33	100,0
		Tag 211 (Woche 30)	115	24,64	27,954	0,0	33,33	100,0
		Tag 239 (Woche 34)	111	23,72	26,738	0,0	33,33	100,0
		Tag 267 (Woche 38)	108	22,22	28,093	0,0	0,00	100,0
		Tag 295 (Woche 42)	111	21,92	24,410	0,0	33,33	100,0
		Tag 323 (Woche 46)	105	21,27	24,514	0,0	33,33	100,0
		Tag 351 (Woche 50)	91	20,15	24,785	0,0	0,00	100,0
		Tag 379 (Woche 54)	86	15,89	22,710	0,0	0,00	100,0
		Tag 407 (Woche 58)	78	17,95	24,437	0,0	0,00	100,0
		Tag 435 (Woche 62)	68	17,16	21,925	0,0	0,00	100,0
		Tag 463 (Woche 66)	58	18,39	23,506	0,0	0,00	100,0
		Tag 491 (Woche 70)	45	20,74	27,788	0,0	0,00	100,0
		Tag 519 (Woche 74)	45	20,74	24,913	0,0	0,00	100,0
		Tag 547 (Woche 78)	37	21,62	23,852	0,0	33,33	100,0
		Tag 575 (Woche 82)	31	21,51	27,953	0,0	0,00	100,0
		Tag 603 (Woche 86)	31	16,13	24,146	0,0	0,00	100,0
		Tag 631 (Woche 90)	34	24,51	28,790	0,0	33,33	100,0
		Tag 659 (Woche 94)	26	21,79	24,841	0,0	33,33	100,0
		Tag 687 (Woche 98)	21	17,46	20,053	0,0	0,00	66,7
		Tag 715 (Woche 102)	18	22,22	25,565	0,0	33,33	100,0
		Tag 743 (Woche 106)	14	30,95	27,625	0,0	33,33	100,0
		Tag 771 (Woche 110)	13	35,90	25,318	0,0	33,33	100,0
		Tag 799 (Woche 114)	9	25,93	32,394	0,0	33,33	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Schlaflosigkeit	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	38,10	29,991	0,0	33,33	100,0
		Tag 855 (Woche 122)	4	25,00	16,667	0,0	33,33	33,3
		Tag 883 (Woche 126)	2	16,67	23,570	0,0	16,67	33,3
		Tag 911 (Woche 130)	2	16,67	23,570	0,0	16,67	33,3
		Tag 939 (Woche 134)	2	33,33	0,000	33,3	33,33	33,3
		Tag 967 (Woche 138)	2	33,33	0,000	33,3	33,33	33,3
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
	CTx (N=192)	Baseline	158	29,11	27,578	0,0	33,33	100,0
		Tag 22 (Woche 3)	153	26,80	26,781	0,0	33,33	100,0
		Tag 43 (Woche 6)	146	25,57	26,563	0,0	33,33	100,0
		Tag 64 (Woche 9)	138	23,67	25,852	0,0	33,33	100,0
		Tag 85 (Woche 12)	134	21,14	24,709	0,0	0,00	100,0
		Tag 106 (Woche 15)	131	24,43	23,688	0,0	33,33	100,0
		Tag 127 (Woche 18)	111	26,43	28,111	0,0	33,33	100,0
		Tag 155 (Woche 22)	120	20,28	24,558	0,0	0,00	100,0
		Tag 183 (Woche 26)	117	19,94	25,166	0,0	0,00	100,0
		Tag 211 (Woche 30)	108	18,83	24,232	0,0	0,00	100,0
		Tag 239 (Woche 34)	100	21,00	24,461	0,0	33,33	100,0
		Tag 267 (Woche 38)	96	19,79	24,934	0,0	0,00	100,0
		Tag 295 (Woche 42)	95	19,30	23,104	0,0	0,00	100,0
		Tag 323 (Woche 46)	83	22,09	25,116	0,0	33,33	100,0
		Tag 351 (Woche 50)	83	23,29	26,917	0,0	33,33	100,0
		Tag 379 (Woche 54)	74	20,72	25,104	0,0	0,00	100,0
		Tag 407 (Woche 58)	61	22,40	24,886	0,0	33,33	100,0
		Tag 435 (Woche 62)	53	22,64	24,261	0,0	33,33	100,0
		Tag 463 (Woche 66)	49	25,17	27,664	0,0	33,33	100,0
		Tag 491 (Woche 70)	32	21,87	30,065	0,0	0,00	100,0
		Tag 519 (Woche 74)	35	20,95	31,401	0,0	0,00	100,0
		Tag 547 (Woche 78)	30	18,89	27,240	0,0	0,00	100,0
		Tag 575 (Woche 82)	23	20,29	27,959	0,0	0,00	100,0
		Tag 603 (Woche 86)	20	25,00	28,357	0,0	33,33	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Schlaflosigkeit	CTx (N=192)	Tag 631 (Woche 90)	17	21,57	31,049	0,0	0,00	100,0
		Tag 659 (Woche 94)	9	14,81	17,568	0,0	0,00	33,3
		Tag 687 (Woche 98)	10	16,67	23,570	0,0	0,00	66,7
		Tag 715 (Woche 102)	9	14,81	24,216	0,0	0,00	66,7
		Tag 743 (Woche 106)	7	14,29	17,817	0,0	0,00	33,3
		Tag 771 (Woche 110)	6	16,67	18,257	0,0	16,67	33,3
		Tag 799 (Woche 114)	5	20,00	18,257	0,0	33,33	33,3
		Tag 827 (Woche 118)	3	22,22	19,245	0,0	33,33	33,3
		Tag 855 (Woche 122)	3	11,11	19,245	0,0	0,00	33,3
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	33,33	NC	33,3	33,33	33,3
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
EORTC QLQ-C30 Appetitverlust	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	15,37	24,747	0,0	0,00	100,0
		Tag 22 (Woche 3)	169	17,55	24,415	0,0	0,00	100,0
		Tag 43 (Woche 6)	150	16,44	24,039	0,0	0,00	100,0
		Tag 64 (Woche 9)	139	17,51	23,167	0,0	0,00	100,0
		Tag 85 (Woche 12)	138	20,53	24,605	0,0	0,00	100,0
		Tag 106 (Woche 15)	130	18,46	24,223	0,0	0,00	100,0
		Tag 127 (Woche 18)	122	18,03	22,329	0,0	0,00	100,0
		Tag 155 (Woche 22)	130	24,62	26,755	0,0	33,33	100,0
		Tag 183 (Woche 26)	127	22,31	28,808	0,0	0,00	100,0
		Tag 211 (Woche 30)	115	23,19	26,555	0,0	33,33	100,0
		Tag 239 (Woche 34)	111	22,22	26,336	0,0	0,00	100,0
		Tag 267 (Woche 38)	108	17,28	23,452	0,0	0,00	100,0
		Tag 295 (Woche 42)	111	15,02	22,356	0,0	0,00	100,0
		Tag 323 (Woche 46)	105	14,60	23,077	0,0	0,00	100,0
		Tag 351 (Woche 50)	91	13,19	22,155	0,0	0,00	100,0
		Tag 379 (Woche 54)	86	12,79	22,963	0,0	0,00	100,0
		Tag 407 (Woche 58)	78	12,82	18,003	0,0	0,00	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Appetitverlust	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	12,75	18,239	0,0	0,00	66,7
		Tag 463 (Woche 66)	58	12,07	17,324	0,0	0,00	66,7
		Tag 491 (Woche 70)	45	11,11	21,320	0,0	0,00	100,0
		Tag 519 (Woche 74)	45	8,15	16,136	0,0	0,00	66,7
		Tag 547 (Woche 78)	37	11,71	17,944	0,0	0,00	66,7
		Tag 575 (Woche 82)	31	15,05	22,507	0,0	0,00	66,7
		Tag 603 (Woche 86)	31	15,05	28,335	0,0	0,00	100,0
		Tag 631 (Woche 90)	34	11,76	19,903	0,0	0,00	66,7
		Tag 659 (Woche 94)	26	11,54	20,960	0,0	0,00	66,7
		Tag 687 (Woche 98)	21	1,59	7,274	0,0	0,00	33,3
		Tag 715 (Woche 102)	18	7,41	18,277	0,0	0,00	66,7
		Tag 743 (Woche 106)	14	4,76	12,105	0,0	0,00	33,3
		Tag 771 (Woche 110)	13	5,13	12,518	0,0	0,00	33,3
		Tag 799 (Woche 114)	9	11,11	23,570	0,0	0,00	66,7
		Tag 827 (Woche 118)	7	9,52	25,198	0,0	0,00	66,7
		Tag 855 (Woche 122)	4	8,33	16,667	0,0	0,00	33,3
		Tag 883 (Woche 126)	2	16,67	23,570	0,0	16,67	33,3
		Tag 911 (Woche 130)	2	0,00	0,000	0,0	0,00	0,0
		Tag 939 (Woche 134)	2	0,00	0,000	0,0	0,00	0,0
		Tag 967 (Woche 138)	2	0,00	0,000	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0
	CTx (N=192)	Baseline	158	21,94	28,097	0,0	0,00	100,0
		Tag 22 (Woche 3)	153	16,12	20,270	0,0	0,00	66,7
		Tag 43 (Woche 6)	146	14,38	23,130	0,0	0,00	100,0
		Tag 64 (Woche 9)	138	16,91	23,911	0,0	0,00	100,0
		Tag 85 (Woche 12)	134	16,67	23,032	0,0	0,00	100,0
		Tag 106 (Woche 15)	131	17,05	22,783	0,0	0,00	100,0
		Tag 127 (Woche 18)	111	16,82	21,961	0,0	0,00	100,0
		Tag 155 (Woche 22)	120	10,56	20,261	0,0	0,00	100,0
		Tag 183 (Woche 26)	117	9,12	17,301	0,0	0,00	100,0
		Tag 211 (Woche 30)	108	8,64	18,994	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Appetitverlust	CTx (N=192)	Tag 239 (Woche 34)	100	7,67	15,610	0,0	0,00	66,7
		Tag 267 (Woche 38)	96	9,72	19,892	0,0	0,00	100,0
		Tag 295 (Woche 42)	95	10,18	19,493	0,0	0,00	100,0
		Tag 323 (Woche 46)	83	8,84	19,537	0,0	0,00	100,0
		Tag 351 (Woche 50)	83	10,04	21,923	0,0	0,00	100,0
		Tag 379 (Woche 54)	74	9,46	17,896	0,0	0,00	66,7
		Tag 407 (Woche 58)	61	9,84	16,493	0,0	0,00	66,7
		Tag 435 (Woche 62)	53	9,43	18,921	0,0	0,00	66,7
		Tag 463 (Woche 66)	49	9,52	16,667	0,0	0,00	66,7
		Tag 491 (Woche 70)	32	9,38	19,371	0,0	0,00	66,7
		Tag 519 (Woche 74)	35	6,67	15,760	0,0	0,00	66,7
		Tag 547 (Woche 78)	30	10,00	15,536	0,0	0,00	33,3
		Tag 575 (Woche 82)	23	5,80	12,918	0,0	0,00	33,3
		Tag 603 (Woche 86)	20	6,67	13,680	0,0	0,00	33,3
		Tag 631 (Woche 90)	17	9,80	19,596	0,0	0,00	66,7
		Tag 659 (Woche 94)	9	3,70	11,111	0,0	0,00	33,3
		Tag 687 (Woche 98)	10	6,67	14,055	0,0	0,00	33,3
		Tag 715 (Woche 102)	9	11,11	16,667	0,0	0,00	33,3
		Tag 743 (Woche 106)	7	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	6	5,56	13,608	0,0	0,00	33,3
		Tag 799 (Woche 114)	5	6,67	14,907	0,0	0,00	33,3
		Tag 827 (Woche 118)	3	0,00	0,000	0,0	0,00	0,0
		Tag 855 (Woche 122)	3	0,00	0,000	0,0	0,00	0,0
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Verstopfung	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	15,57	24,210	0,0	0,00	100,0
		Tag 22 (Woche 3)	169	23,67	27,069	0,0	33,33	100,0
		Tag 43 (Woche 6)	150	20,67	24,628	0,0	0,00	100,0
		Tag 64 (Woche 9)	139	22,78	26,325	0,0	33,33	100,0
		Tag 85 (Woche 12)	138	22,46	24,880	0,0	33,33	100,0
		Tag 106 (Woche 15)	130	19,49	24,479	0,0	0,00	100,0
		Tag 127 (Woche 18)	122	17,21	25,074	0,0	0,00	100,0
		Tag 155 (Woche 22)	130	18,46	23,501	0,0	0,00	100,0
		Tag 183 (Woche 26)	127	15,75	23,317	0,0	0,00	100,0
		Tag 211 (Woche 30)	115	15,07	23,464	0,0	0,00	100,0
		Tag 239 (Woche 34)	111	15,32	25,340	0,0	0,00	100,0
		Tag 267 (Woche 38)	108	16,67	24,752	0,0	0,00	100,0
		Tag 295 (Woche 42)	111	14,71	24,073	0,0	0,00	100,0
		Tag 323 (Woche 46)	105	14,60	23,077	0,0	0,00	100,0
		Tag 351 (Woche 50)	91	13,92	24,377	0,0	0,00	100,0
		Tag 379 (Woche 54)	86	13,57	22,508	0,0	0,00	100,0
		Tag 407 (Woche 58)	78	14,10	21,835	0,0	0,00	100,0
		Tag 435 (Woche 62)	68	15,20	21,880	0,0	0,00	100,0
		Tag 463 (Woche 66)	58	16,09	24,376	0,0	0,00	100,0
		Tag 491 (Woche 70)	45	13,33	22,918	0,0	0,00	100,0
		Tag 519 (Woche 74)	45	10,37	22,273	0,0	0,00	100,0
		Tag 547 (Woche 78)	37	13,51	19,968	0,0	0,00	66,7
		Tag 575 (Woche 82)	31	10,75	21,751	0,0	0,00	100,0
		Tag 603 (Woche 86)	31	12,90	25,353	0,0	0,00	100,0
		Tag 631 (Woche 90)	34	12,75	21,734	0,0	0,00	66,7
		Tag 659 (Woche 94)	26	11,54	18,720	0,0	0,00	66,7
		Tag 687 (Woche 98)	21	12,70	16,587	0,0	0,00	33,3
		Tag 715 (Woche 102)	18	14,81	23,493	0,0	0,00	66,7
		Tag 743 (Woche 106)	14	11,90	21,111	0,0	0,00	66,7
		Tag 771 (Woche 110)	13	10,26	21,014	0,0	0,00	66,7
		Tag 799 (Woche 114)	9	22,22	33,333	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Verstopfung	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	28,57	35,635	0,0	33,33	100,0
		Tag 855 (Woche 122)	4	16,67	19,245	0,0	16,67	33,3
		Tag 883 (Woche 126)	2	16,67	23,570	0,0	16,67	33,3
		Tag 911 (Woche 130)	2	16,67	23,570	0,0	16,67	33,3
		Tag 939 (Woche 134)	2	16,67	23,570	0,0	16,67	33,3
		Tag 967 (Woche 138)	2	33,33	0,000	33,3	33,33	33,3
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
	CTx (N=192)	Baseline	158	25,11	27,822	0,0	33,33	100,0
		Tag 22 (Woche 3)	153	22,66	24,972	0,0	33,33	100,0
		Tag 43 (Woche 6)	146	17,35	22,563	0,0	0,00	100,0
		Tag 64 (Woche 9)	138	18,84	23,121	0,0	0,00	100,0
		Tag 85 (Woche 12)	134	20,15	27,120	0,0	0,00	100,0
		Tag 106 (Woche 15)	131	19,59	21,432	0,0	33,33	100,0
		Tag 127 (Woche 18)	111	18,02	23,692	0,0	0,00	100,0
		Tag 155 (Woche 22)	120	13,61	20,035	0,0	0,00	100,0
		Tag 183 (Woche 26)	117	9,69	15,817	0,0	0,00	66,7
		Tag 211 (Woche 30)	108	11,42	20,463	0,0	0,00	100,0
		Tag 239 (Woche 34)	100	12,00	19,831	0,0	0,00	100,0
		Tag 267 (Woche 38)	96	12,85	18,334	0,0	0,00	66,7
		Tag 295 (Woche 42)	95	12,28	22,309	0,0	0,00	100,0
		Tag 323 (Woche 46)	83	15,26	21,653	0,0	0,00	100,0
		Tag 351 (Woche 50)	83	14,06	20,243	0,0	0,00	66,7
		Tag 379 (Woche 54)	74	17,57	24,190	0,0	0,00	100,0
		Tag 407 (Woche 58)	61	14,21	22,327	0,0	0,00	100,0
		Tag 435 (Woche 62)	53	16,98	25,839	0,0	0,00	100,0
		Tag 463 (Woche 66)	49	14,97	22,629	0,0	0,00	66,7
		Tag 491 (Woche 70)	32	18,75	26,690	0,0	0,00	100,0
		Tag 519 (Woche 74)	35	16,19	24,749	0,0	0,00	100,0
		Tag 547 (Woche 78)	30	14,44	22,630	0,0	0,00	66,7
		Tag 575 (Woche 82)	23	15,94	22,178	0,0	0,00	66,7
		Tag 603 (Woche 86)	20	15,00	29,568	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Verstopfung	CTx (N=192)	Tag 631 (Woche 90)	17	15,69	29,149	0,0	0,00	100,0
		Tag 659 (Woche 94)	9	14,81	33,793	0,0	0,00	100,0
		Tag 687 (Woche 98)	10	13,33	23,307	0,0	0,00	66,7
		Tag 715 (Woche 102)	9	18,52	37,680	0,0	0,00	100,0
		Tag 743 (Woche 106)	7	23,81	37,090	0,0	0,00	100,0
		Tag 771 (Woche 110)	6	22,22	40,369	0,0	0,00	100,0
		Tag 799 (Woche 114)	5	33,33	40,825	0,0	33,33	100,0
		Tag 827 (Woche 118)	3	33,33	57,735	0,0	0,00	100,0
		Tag 855 (Woche 122)	3	33,33	57,735	0,0	0,00	100,0
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	33,33	NC	33,3	33,33	33,3
		Tag 967 (Woche 138)	1	33,33	NC	33,3	33,33	33,3
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
EORTC QLQ-C30 Diarrhö	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	6,59	17,638	0,0	0,00	100,0
		Tag 22 (Woche 3)	169	7,30	16,844	0,0	0,00	66,7
		Tag 43 (Woche 6)	150	9,56	16,537	0,0	0,00	66,7
		Tag 64 (Woche 9)	139	10,79	16,650	0,0	0,00	66,7
		Tag 85 (Woche 12)	138	7,97	15,884	0,0	0,00	66,7
		Tag 106 (Woche 15)	130	11,79	22,681	0,0	0,00	100,0
		Tag 127 (Woche 18)	122	11,75	20,518	0,0	0,00	100,0
		Tag 155 (Woche 22)	130	8,97	17,991	0,0	0,00	100,0
		Tag 183 (Woche 26)	127	8,66	19,793	0,0	0,00	100,0
		Tag 211 (Woche 30)	115	7,54	15,333	0,0	0,00	66,7
		Tag 239 (Woche 34)	111	6,01	15,041	0,0	0,00	66,7
		Tag 267 (Woche 38)	108	6,79	16,279	0,0	0,00	100,0
		Tag 295 (Woche 42)	111	5,71	13,389	0,0	0,00	66,7
		Tag 323 (Woche 46)	105	4,76	11,720	0,0	0,00	33,3
		Tag 351 (Woche 50)	91	5,13	13,074	0,0	0,00	66,7
		Tag 379 (Woche 54)	86	7,75	14,165	0,0	0,00	33,3
		Tag 407 (Woche 58)	78	4,70	11,677	0,0	0,00	33,3

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Diarrhö	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	4,90	11,893	0,0	0,00	33,3
		Tag 463 (Woche 66)	58	6,32	14,586	0,0	0,00	66,7
		Tag 491 (Woche 70)	45	8,15	17,632	0,0	0,00	66,7
		Tag 519 (Woche 74)	45	9,63	20,868	0,0	0,00	66,7
		Tag 547 (Woche 78)	37	3,60	10,493	0,0	0,00	33,3
		Tag 575 (Woche 82)	31	11,83	22,024	0,0	0,00	66,7
		Tag 603 (Woche 86)	31	6,45	15,915	0,0	0,00	66,7
		Tag 631 (Woche 90)	34	5,88	12,898	0,0	0,00	33,3
		Tag 659 (Woche 94)	26	10,26	22,646	0,0	0,00	100,0
		Tag 687 (Woche 98)	21	1,59	7,274	0,0	0,00	33,3
		Tag 715 (Woche 102)	18	3,70	10,779	0,0	0,00	33,3
		Tag 743 (Woche 106)	14	4,76	12,105	0,0	0,00	33,3
		Tag 771 (Woche 110)	13	5,13	12,518	0,0	0,00	33,3
		Tag 799 (Woche 114)	9	14,81	17,568	0,0	0,00	33,3
		Tag 827 (Woche 118)	7	14,29	26,227	0,0	0,00	66,7
		Tag 855 (Woche 122)	4	0,00	0,000	0,0	0,00	0,0
		Tag 883 (Woche 126)	2	0,00	0,000	0,0	0,00	0,0
		Tag 911 (Woche 130)	2	16,67	23,570	0,0	16,67	33,3
		Tag 939 (Woche 134)	2	16,67	23,570	0,0	16,67	33,3
		Tag 967 (Woche 138)	2	16,67	23,570	0,0	16,67	33,3
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0
	CTx (N=192)	Baseline	158	5,49	15,448	0,0	0,00	100,0
		Tag 22 (Woche 3)	153	7,19	15,738	0,0	0,00	100,0
		Tag 43 (Woche 6)	146	10,27	20,923	0,0	0,00	100,0
		Tag 64 (Woche 9)	138	7,73	15,748	0,0	0,00	66,7
		Tag 85 (Woche 12)	134	9,95	17,831	0,0	0,00	100,0
		Tag 106 (Woche 15)	131	10,43	19,864	0,0	0,00	100,0
		Tag 127 (Woche 18)	111	9,31	18,075	0,0	0,00	100,0
		Tag 155 (Woche 22)	120	5,83	14,758	0,0	0,00	100,0
		Tag 183 (Woche 26)	117	7,41	15,848	0,0	0,00	66,7
		Tag 211 (Woche 30)	108	6,79	17,508	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Diarrhö	CTx (N=192)	Tag 239 (Woche 34)	100	6,67	17,082	0,0	0,00	100,0
		Tag 267 (Woche 38)	96	6,25	13,944	0,0	0,00	66,7
		Tag 295 (Woche 42)	95	6,32	15,600	0,0	0,00	66,7
		Tag 323 (Woche 46)	83	6,02	15,742	0,0	0,00	100,0
		Tag 351 (Woche 50)	83	7,63	17,519	0,0	0,00	100,0
		Tag 379 (Woche 54)	74	5,86	12,771	0,0	0,00	33,3
		Tag 407 (Woche 58)	61	7,65	14,134	0,0	0,00	33,3
		Tag 435 (Woche 62)	53	10,06	16,775	0,0	0,00	66,7
		Tag 463 (Woche 66)	49	6,80	13,574	0,0	0,00	33,3
		Tag 491 (Woche 70)	32	1,04	5,893	0,0	0,00	33,3
		Tag 519 (Woche 74)	35	9,52	20,725	0,0	0,00	100,0
		Tag 547 (Woche 78)	30	7,78	16,800	0,0	0,00	66,7
		Tag 575 (Woche 82)	23	4,35	11,478	0,0	0,00	33,3
		Tag 603 (Woche 86)	20	11,67	24,839	0,0	0,00	100,0
		Tag 631 (Woche 90)	17	1,96	8,085	0,0	0,00	33,3
		Tag 659 (Woche 94)	9	11,11	33,333	0,0	0,00	100,0
		Tag 687 (Woche 98)	10	3,33	10,541	0,0	0,00	33,3
		Tag 715 (Woche 102)	9	3,70	11,111	0,0	0,00	33,3
		Tag 743 (Woche 106)	7	4,76	12,599	0,0	0,00	33,3
		Tag 771 (Woche 110)	6	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	5	6,67	14,907	0,0	0,00	33,3
		Tag 827 (Woche 118)	3	0,00	0,000	0,0	0,00	0,0
		Tag 855 (Woche 122)	3	0,00	0,000	0,0	0,00	0,0
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Finanzielle Schwierigkeiten	CTx + Durvalumab + Olaparib (N=191)	Baseline	167	20,96	28,457	0,0	0,00	100,0
		Tag 22 (Woche 3)	169	21,89	28,878	0,0	0,00	100,0
		Tag 43 (Woche 6)	150	20,00	27,579	0,0	0,00	100,0
		Tag 64 (Woche 9)	139	20,62	27,626	0,0	0,00	100,0
		Tag 85 (Woche 12)	138	24,40	30,550	0,0	0,00	100,0
		Tag 106 (Woche 15)	130	23,85	28,525	0,0	33,33	100,0
		Tag 127 (Woche 18)	122	22,95	30,328	0,0	0,00	100,0
		Tag 155 (Woche 22)	130	22,05	28,319	0,0	0,00	100,0
		Tag 183 (Woche 26)	127	22,83	30,197	0,0	0,00	100,0
		Tag 211 (Woche 30)	115	21,16	30,052	0,0	0,00	100,0
		Tag 239 (Woche 34)	111	18,62	27,592	0,0	0,00	100,0
		Tag 267 (Woche 38)	108	18,21	25,934	0,0	0,00	100,0
		Tag 295 (Woche 42)	111	16,52	26,543	0,0	0,00	100,0
		Tag 323 (Woche 46)	105	16,51	25,371	0,0	0,00	100,0
		Tag 351 (Woche 50)	91	16,85	26,469	0,0	0,00	100,0
		Tag 379 (Woche 54)	86	15,89	25,934	0,0	0,00	100,0
		Tag 407 (Woche 58)	78	19,66	29,637	0,0	0,00	100,0
		Tag 435 (Woche 62)	68	15,20	25,388	0,0	0,00	100,0
		Tag 463 (Woche 66)	58	13,79	20,741	0,0	0,00	100,0
		Tag 491 (Woche 70)	45	17,04	27,175	0,0	0,00	100,0
		Tag 519 (Woche 74)	45	15,56	19,592	0,0	0,00	66,7
		Tag 547 (Woche 78)	37	16,22	24,371	0,0	0,00	100,0
		Tag 575 (Woche 82)	31	17,20	24,146	0,0	0,00	100,0
		Tag 603 (Woche 86)	31	13,98	23,997	0,0	0,00	100,0
		Tag 631 (Woche 90)	34	23,53	26,628	0,0	33,33	100,0
		Tag 659 (Woche 94)	26	24,36	32,052	0,0	0,00	100,0
		Tag 687 (Woche 98)	21	19,05	27,021	0,0	0,00	100,0
		Tag 715 (Woche 102)	18	25,93	33,442	0,0	16,67	100,0
		Tag 743 (Woche 106)	14	33,33	29,235	0,0	33,33	100,0
		Tag 771 (Woche 110)	13	28,21	35,606	0,0	33,33	100,0
		Tag 799 (Woche 114)	9	18,52	24,216	0,0	0,00	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Finanzielle Schwierigkeiten	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	19,05	26,227	0,0	0,00	66,7
		Tag 855 (Woche 122)	4	25,00	16,667	0,0	33,33	33,3
		Tag 883 (Woche 126)	2	33,33	0,000	33,3	33,33	33,3
		Tag 911 (Woche 130)	2	33,33	0,000	33,3	33,33	33,3
		Tag 939 (Woche 134)	2	16,67	23,570	0,0	16,67	33,3
		Tag 967 (Woche 138)	2	16,67	23,570	0,0	16,67	33,3
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
	CTx (N=192)	Baseline	158	18,35	25,391	0,0	0,00	100,0
		Tag 22 (Woche 3)	153	14,38	23,806	0,0	0,00	100,0
		Tag 43 (Woche 6)	146	16,44	25,445	0,0	0,00	100,0
		Tag 64 (Woche 9)	138	16,67	24,909	0,0	0,00	100,0
		Tag 85 (Woche 12)	134	15,92	25,434	0,0	0,00	100,0
		Tag 106 (Woche 15)	131	17,56	26,256	0,0	0,00	100,0
		Tag 127 (Woche 18)	111	14,71	24,489	0,0	0,00	100,0
		Tag 155 (Woche 22)	120	15,83	25,915	0,0	0,00	100,0
		Tag 183 (Woche 26)	117	14,53	25,665	0,0	0,00	100,0
		Tag 211 (Woche 30)	108	14,81	25,099	0,0	0,00	100,0
		Tag 239 (Woche 34)	100	15,33	23,887	0,0	0,00	100,0
		Tag 267 (Woche 38)	96	17,71	25,571	0,0	0,00	100,0
		Tag 295 (Woche 42)	95	17,89	27,851	0,0	0,00	100,0
		Tag 323 (Woche 46)	83	18,47	25,637	0,0	0,00	100,0
		Tag 351 (Woche 50)	83	19,28	24,484	0,0	0,00	100,0
		Tag 379 (Woche 54)	74	19,82	29,153	0,0	0,00	100,0
		Tag 407 (Woche 58)	61	16,39	25,548	0,0	0,00	100,0
		Tag 435 (Woche 62)	53	16,35	21,306	0,0	0,00	66,7
		Tag 463 (Woche 66)	49	16,33	24,648	0,0	0,00	100,0
		Tag 491 (Woche 70)	32	22,92	31,036	0,0	0,00	100,0
		Tag 519 (Woche 74)	35	17,14	26,036	0,0	0,00	100,0
		Tag 547 (Woche 78)	30	13,33	18,775	0,0	0,00	66,7
		Tag 575 (Woche 82)	23	18,84	24,259	0,0	0,00	100,0
		Tag 603 (Woche 86)	20	13,33	16,754	0,0	0,00	33,3

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.1.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Finanzielle Schwierigkeiten	CTx (N=192)	Tag 631 (Woche 90)	17	15,69	26,661	0,0	0,00	100,0
		Tag 659 (Woche 94)	9	18,52	17,568	0,0	33,33	33,3
		Tag 687 (Woche 98)	10	13,33	17,213	0,0	0,00	33,3
		Tag 715 (Woche 102)	9	11,11	16,667	0,0	0,00	33,3
		Tag 743 (Woche 106)	7	19,05	17,817	0,0	33,33	33,3
		Tag 771 (Woche 110)	6	16,67	18,257	0,0	16,67	33,3
		Tag 799 (Woche 114)	5	20,00	18,257	0,0	33,33	33,3
		Tag 827 (Woche 118)	3	22,22	19,245	0,0	33,33	33,3
		Tag 855 (Woche 122)	3	22,22	19,245	0,0	33,33	33,3
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	33,33	NC	33,3	33,33	33,3
		Tag 939 (Woche 134)	1	33,33	NC	33,3	33,33	33,3
		Tag 967 (Woche 138)	1	33,33	NC	33,3	33,33	33,3
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprba 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelles Interesse	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	90,48	19,518	0,0	100,00	100,0
		Tag 22 (Woche 3)	163	89,16	23,390	0,0	100,00	100,0
		Tag 43 (Woche 6)	148	91,67	18,596	0,0	100,00	100,0
		Tag 64 (Woche 9)	137	91,00	19,176	0,0	100,00	100,0
		Tag 85 (Woche 12)	134	92,54	19,016	0,0	100,00	100,0
		Tag 106 (Woche 15)	126	92,06	18,585	0,0	100,00	100,0
		Tag 127 (Woche 18)	121	93,11	17,700	0,0	100,00	100,0
		Tag 155 (Woche 22)	129	93,02	18,006	0,0	100,00	100,0
		Tag 183 (Woche 26)	127	91,60	19,684	0,0	100,00	100,0
		Tag 211 (Woche 30)	114	92,69	18,688	0,0	100,00	100,0
		Tag 239 (Woche 34)	111	90,99	20,074	0,0	100,00	100,0
		Tag 267 (Woche 38)	108	92,28	16,810	33,3	100,00	100,0
		Tag 295 (Woche 42)	110	93,33	17,948	0,0	100,00	100,0
		Tag 323 (Woche 46)	103	93,53	16,208	33,3	100,00	100,0
		Tag 351 (Woche 50)	91	93,04	16,863	33,3	100,00	100,0
		Tag 379 (Woche 54)	86	94,57	16,056	0,0	100,00	100,0
		Tag 407 (Woche 58)	77	95,24	11,741	66,7	100,00	100,0
		Tag 435 (Woche 62)	68	90,69	22,925	0,0	100,00	100,0
		Tag 463 (Woche 66)	58	90,23	21,637	0,0	100,00	100,0
		Tag 491 (Woche 70)	45	88,89	21,320	33,3	100,00	100,0
		Tag 519 (Woche 74)	44	90,91	20,790	33,3	100,00	100,0
		Tag 547 (Woche 78)	36	91,67	16,667	33,3	100,00	100,0
		Tag 575 (Woche 82)	30	93,33	16,141	33,3	100,00	100,0
		Tag 603 (Woche 86)	31	94,62	15,146	33,3	100,00	100,0
		Tag 631 (Woche 90)	34	98,04	7,961	66,7	100,00	100,0
		Tag 659 (Woche 94)	26	93,59	21,122	0,0	100,00	100,0
		Tag 687 (Woche 98)	21	92,06	17,965	33,3	100,00	100,0
		Tag 715 (Woche 102)	18	94,44	17,150	33,3	100,00	100,0
		Tag 743 (Woche 106)	14	95,24	12,105	66,7	100,00	100,0
		Tag 771 (Woche 110)	13	87,18	28,991	0,0	100,00	100,0
		Tag 799 (Woche 114)	9	77,78	23,570	33,3	66,67	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelles Interesse	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	71,43	35,635	0,0	66,67	100,0
		Tag 855 (Woche 122)	4	83,33	19,245	66,7	83,33	100,0
		Tag 883 (Woche 126)	2	83,33	23,570	66,7	83,33	100,0
		Tag 911 (Woche 130)	2	100,00	0,000	100,0	100,00	100,0
		Tag 939 (Woche 134)	2	83,33	23,570	66,7	83,33	100,0
		Tag 967 (Woche 138)	2	83,33	23,570	66,7	83,33	100,0
		Tag 995 (Woche 142)	1	66,67	NC	66,7	66,67	66,7
	CTx (N=192)	Baseline	156	89,53	19,603	0,0	100,00	100,0
		Tag 22 (Woche 3)	146	92,92	16,240	0,0	100,00	100,0
		Tag 43 (Woche 6)	141	91,49	16,621	33,3	100,00	100,0
		Tag 64 (Woche 9)	134	92,29	16,306	33,3	100,00	100,0
		Tag 85 (Woche 12)	132	93,18	14,700	33,3	100,00	100,0
		Tag 106 (Woche 15)	131	91,60	19,101	0,0	100,00	100,0
		Tag 127 (Woche 18)	110	92,12	15,594	33,3	100,00	100,0
		Tag 155 (Woche 22)	120	93,06	14,905	33,3	100,00	100,0
		Tag 183 (Woche 26)	117	89,46	19,402	33,3	100,00	100,0
		Tag 211 (Woche 30)	108	89,20	18,695	33,3	100,00	100,0
		Tag 239 (Woche 34)	100	90,00	16,751	33,3	100,00	100,0
		Tag 267 (Woche 38)	96	90,63	15,823	33,3	100,00	100,0
		Tag 295 (Woche 42)	95	88,42	17,374	33,3	100,00	100,0
		Tag 323 (Woche 46)	83	91,97	15,258	33,3	100,00	100,0
		Tag 351 (Woche 50)	83	92,37	15,021	33,3	100,00	100,0
		Tag 379 (Woche 54)	73	92,69	16,893	0,0	100,00	100,0
		Tag 407 (Woche 58)	60	91,11	14,865	66,7	100,00	100,0
		Tag 435 (Woche 62)	53	93,08	15,133	33,3	100,00	100,0
		Tag 463 (Woche 66)	49	93,20	15,183	33,3	100,00	100,0
		Tag 491 (Woche 70)	32	91,67	16,933	33,3	100,00	100,0
		Tag 519 (Woche 74)	35	93,33	15,760	33,3	100,00	100,0
		Tag 547 (Woche 78)	30	92,22	16,800	33,3	100,00	100,0
		Tag 575 (Woche 82)	23	98,55	6,950	66,7	100,00	100,0
		Tag 603 (Woche 86)	20	96,67	10,260	66,7	100,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelles Interesse	CTx (N=192)	Tag 631 (Woche 90)	17	98,04	8,085	66,7	100,00	100,0
		Tag 659 (Woche 94)	9	96,30	11,111	66,7	100,00	100,0
		Tag 687 (Woche 98)	10	100,00	0,000	100,0	100,00	100,0
		Tag 715 (Woche 102)	9	100,00	0,000	100,0	100,00	100,0
		Tag 743 (Woche 106)	7	100,00	0,000	100,0	100,00	100,0
		Tag 771 (Woche 110)	6	100,00	0,000	100,0	100,00	100,0
		Tag 799 (Woche 114)	5	100,00	0,000	100,0	100,00	100,0
		Tag 827 (Woche 118)	3	100,00	0,000	100,0	100,00	100,0
		Tag 855 (Woche 122)	3	100,00	0,000	100,0	100,00	100,0
		Tag 883 (Woche 126)	1	100,00	NC	100,0	100,00	100,0
		Tag 911 (Woche 130)	1	100,00	NC	100,0	100,00	100,0
		Tag 939 (Woche 134)	1	100,00	NC	100,0	100,00	100,0
		Tag 967 (Woche 138)	1	100,00	NC	100,0	100,00	100,0
		Tag 995 (Woche 142)	1	100,00	NC	100,0	100,00	100,0
EORTC QLQ-EN24 Sexuelle Aktivität	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	92,96	16,419	0,0	100,00	100,0
		Tag 22 (Woche 3)	163	95,09	12,413	33,3	100,00	100,0
		Tag 43 (Woche 6)	148	95,27	12,301	33,3	100,00	100,0
		Tag 64 (Woche 9)	137	94,65	14,705	33,3	100,00	100,0
		Tag 85 (Woche 12)	134	95,02	14,456	0,0	100,00	100,0
		Tag 106 (Woche 15)	126	94,44	15,055	0,0	100,00	100,0
		Tag 127 (Woche 18)	121	96,14	13,046	0,0	100,00	100,0
		Tag 155 (Woche 22)	129	95,09	13,242	33,3	100,00	100,0
		Tag 183 (Woche 26)	127	94,75	15,388	0,0	100,00	100,0
		Tag 211 (Woche 30)	114	94,44	14,652	33,3	100,00	100,0
		Tag 239 (Woche 34)	111	94,59	15,917	0,0	100,00	100,0
		Tag 267 (Woche 38)	108	92,28	17,417	33,3	100,00	100,0
		Tag 295 (Woche 42)	110	95,15	12,640	33,3	100,00	100,0
		Tag 323 (Woche 46)	103	95,47	13,242	33,3	100,00	100,0
		Tag 351 (Woche 50)	91	94,87	13,987	33,3	100,00	100,0
		Tag 379 (Woche 54)	86	94,19	14,634	33,3	100,00	100,0
		Tag 407 (Woche 58)	77	96,97	9,645	66,7	100,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelle Aktivität	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	93,14	16,849	33,3	100,00	100,0
		Tag 463 (Woche 66)	58	94,25	17,812	0,0	100,00	100,0
		Tag 491 (Woche 70)	45	93,33	16,817	33,3	100,00	100,0
		Tag 519 (Woche 74)	44	93,94	16,507	33,3	100,00	100,0
		Tag 547 (Woche 78)	36	95,37	14,148	33,3	100,00	100,0
		Tag 575 (Woche 82)	30	95,56	11,525	66,7	100,00	100,0
		Tag 603 (Woche 86)	31	97,85	8,324	66,7	100,00	100,0
		Tag 631 (Woche 90)	34	99,02	5,717	66,7	100,00	100,0
		Tag 659 (Woche 94)	26	97,44	9,058	66,7	100,00	100,0
		Tag 687 (Woche 98)	21	98,41	7,274	66,7	100,00	100,0
		Tag 715 (Woche 102)	18	92,59	24,403	0,0	100,00	100,0
		Tag 743 (Woche 106)	14	95,24	12,105	66,7	100,00	100,0
		Tag 771 (Woche 110)	13	89,74	16,013	66,7	100,00	100,0
		Tag 799 (Woche 114)	9	88,89	16,667	66,7	100,00	100,0
		Tag 827 (Woche 118)	7	85,71	17,817	66,7	100,00	100,0
		Tag 855 (Woche 122)	4	83,33	19,245	66,7	83,33	100,0
		Tag 883 (Woche 126)	2	100,00	0,000	100,0	100,00	100,0
		Tag 911 (Woche 130)	2	100,00	0,000	100,0	100,00	100,0
		Tag 939 (Woche 134)	2	100,00	0,000	100,0	100,00	100,0
		Tag 967 (Woche 138)	2	100,00	0,000	100,0	100,00	100,0
		Tag 995 (Woche 142)	1	100,00	NC	100,0	100,00	100,0
	CTx (N=192)	Baseline	156	93,38	17,110	0,0	100,00	100,0
		Tag 22 (Woche 3)	146	95,66	11,915	33,3	100,00	100,0
		Tag 43 (Woche 6)	141	93,38	16,045	0,0	100,00	100,0
		Tag 64 (Woche 9)	134	94,53	15,400	0,0	100,00	100,0
		Tag 85 (Woche 12)	132	95,45	13,518	33,3	100,00	100,0
		Tag 106 (Woche 15)	131	95,17	13,788	33,3	100,00	100,0
		Tag 127 (Woche 18)	110	96,36	10,439	66,7	100,00	100,0
		Tag 155 (Woche 22)	120	96,67	10,042	66,7	100,00	100,0
		Tag 183 (Woche 26)	117	93,45	15,926	33,3	100,00	100,0
		Tag 211 (Woche 30)	108	92,90	15,150	33,3	100,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelle Aktivität	CTx (N=192)	Tag 239 (Woche 34)	100	92,33	15,610	33,3	100,00	100,0
		Tag 267 (Woche 38)	96	93,40	13,351	66,7	100,00	100,0
		Tag 295 (Woche 42)	95	91,93	15,155	33,3	100,00	100,0
		Tag 323 (Woche 46)	83	93,57	13,229	66,7	100,00	100,0
		Tag 351 (Woche 50)	83	95,58	11,371	66,7	100,00	100,0
		Tag 379 (Woche 54)	73	94,98	12,007	66,7	100,00	100,0
		Tag 407 (Woche 58)	60	93,33	13,446	66,7	100,00	100,0
		Tag 435 (Woche 62)	53	94,97	12,047	66,7	100,00	100,0
		Tag 463 (Woche 66)	49	94,56	12,448	66,7	100,00	100,0
		Tag 491 (Woche 70)	32	93,75	13,219	66,7	100,00	100,0
		Tag 519 (Woche 74)	35	95,24	11,835	66,7	100,00	100,0
		Tag 547 (Woche 78)	30	96,67	10,171	66,7	100,00	100,0
		Tag 575 (Woche 82)	23	98,55	6,950	66,7	100,00	100,0
		Tag 603 (Woche 86)	20	96,67	10,260	66,7	100,00	100,0
		Tag 631 (Woche 90)	17	100,00	0,000	100,0	100,00	100,0
		Tag 659 (Woche 94)	9	96,30	11,111	66,7	100,00	100,0
		Tag 687 (Woche 98)	10	100,00	0,000	100,0	100,00	100,0
		Tag 715 (Woche 102)	9	100,00	0,000	100,0	100,00	100,0
		Tag 743 (Woche 106)	7	100,00	0,000	100,0	100,00	100,0
		Tag 771 (Woche 110)	6	100,00	0,000	100,0	100,00	100,0
		Tag 799 (Woche 114)	5	100,00	0,000	100,0	100,00	100,0
		Tag 827 (Woche 118)	3	100,00	0,000	100,0	100,00	100,0
		Tag 855 (Woche 122)	3	100,00	0,000	100,0	100,00	100,0
		Tag 883 (Woche 126)	1	100,00	NC	100,0	100,00	100,0
		Tag 911 (Woche 130)	1	100,00	NC	100,0	100,00	100,0
		Tag 939 (Woche 134)	1	100,00	NC	100,0	100,00	100,0
		Tag 967 (Woche 138)	1	100,00	NC	100,0	100,00	100,0
		Tag 995 (Woche 142)	1	100,00	NC	100,0	100,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelles Vergnügen	CTx + Durvalumab + Olaparib (N=191)	Baseline	29	60,92	29,639	0,0	66,67	100,0
		Tag 22 (Woche 3)	24	62,50	35,864	0,0	66,67	100,0
		Tag 43 (Woche 6)	20	60,00	27,784	0,0	66,67	100,0
		Tag 64 (Woche 9)	18	59,26	33,442	0,0	66,67	100,0
		Tag 85 (Woche 12)	17	54,90	26,197	0,0	66,67	100,0
		Tag 106 (Woche 15)	18	55,56	34,300	0,0	66,67	100,0
		Tag 127 (Woche 18)	12	47,22	26,432	0,0	66,67	66,7
		Tag 155 (Woche 22)	17	62,75	28,583	0,0	66,67	100,0
		Tag 183 (Woche 26)	17	54,90	28,726	0,0	66,67	100,0
		Tag 211 (Woche 30)	16	56,25	23,472	0,0	66,67	100,0
		Tag 239 (Woche 34)	14	52,38	25,198	0,0	66,67	66,7
		Tag 267 (Woche 38)	20	70,00	30,397	0,0	66,67	100,0
		Tag 295 (Woche 42)	15	71,11	17,213	33,3	66,67	100,0
		Tag 323 (Woche 46)	12	61,11	31,248	0,0	66,67	100,0
		Tag 351 (Woche 50)	12	63,89	26,432	33,3	66,67	100,0
		Tag 379 (Woche 54)	13	66,67	27,217	0,0	66,67	100,0
		Tag 407 (Woche 58)	7	66,67	0,000	66,7	66,67	66,7
		Tag 435 (Woche 62)	11	54,55	34,230	0,0	66,67	100,0
		Tag 463 (Woche 66)	7	52,38	42,414	0,0	66,67	100,0
		Tag 491 (Woche 70)	7	52,38	32,530	0,0	66,67	100,0
		Tag 519 (Woche 74)	6	38,89	32,773	0,0	50,00	66,7
		Tag 547 (Woche 78)	4	50,00	19,245	33,3	50,00	66,7
		Tag 575 (Woche 82)	4	41,67	31,914	0,0	50,00	66,7
		Tag 603 (Woche 86)	2	33,33	47,140	0,0	33,33	66,7
		Tag 631 (Woche 90)	1	66,67	NC	66,7	66,67	66,7
		Tag 659 (Woche 94)	2	33,33	47,140	0,0	33,33	66,7
		Tag 687 (Woche 98)	1	66,67	NC	66,7	66,67	66,7
		Tag 715 (Woche 102)	2	33,33	47,140	0,0	33,33	66,7
		Tag 743 (Woche 106)	2	50,00	23,570	33,3	50,00	66,7
		Tag 771 (Woche 110)	4	75,00	16,667	66,7	66,67	100,0
		Tag 799 (Woche 114)	3	44,44	38,490	0,0	66,67	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelles Vergnügen	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	3	44,44	38,490	0,0	66,67	66,7
		Tag 855 (Woche 122)	2	66,67	0,000	66,7	66,67	66,7
	CTx (N=192)	Baseline	25	53,33	28,868	0,0	66,67	100,0
		Tag 22 (Woche 3)	18	55,56	30,250	0,0	66,67	100,0
		Tag 43 (Woche 6)	24	55,56	23,399	0,0	66,67	100,0
		Tag 64 (Woche 9)	18	55,56	28,006	0,0	66,67	100,0
		Tag 85 (Woche 12)	15	60,00	18,687	33,3	66,67	100,0
		Tag 106 (Woche 15)	16	60,42	25,000	33,3	66,67	100,0
		Tag 127 (Woche 18)	12	61,11	19,245	0,0	66,67	66,7
		Tag 155 (Woche 22)	12	47,22	30,011	0,0	66,67	66,7
		Tag 183 (Woche 26)	19	56,14	27,336	0,0	66,67	100,0
		Tag 211 (Woche 30)	21	55,56	21,943	0,0	66,67	100,0
		Tag 239 (Woche 34)	21	50,79	20,053	0,0	66,67	66,7
		Tag 267 (Woche 38)	19	59,65	23,776	0,0	66,67	100,0
		Tag 295 (Woche 42)	22	53,03	24,471	0,0	66,67	100,0
		Tag 323 (Woche 46)	16	62,50	23,960	33,3	66,67	100,0
		Tag 351 (Woche 50)	11	60,61	20,101	33,3	66,67	100,0
		Tag 379 (Woche 54)	11	60,61	25,025	33,3	66,67	100,0
		Tag 407 (Woche 58)	12	66,67	24,618	33,3	66,67	100,0
		Tag 435 (Woche 62)	8	62,50	11,785	33,3	66,67	66,7
		Tag 463 (Woche 66)	8	62,50	21,362	33,3	66,67	100,0
		Tag 491 (Woche 70)	6	77,78	17,213	66,7	66,67	100,0
		Tag 519 (Woche 74)	5	73,33	14,907	66,7	66,67	100,0
		Tag 547 (Woche 78)	3	66,67	0,000	66,7	66,67	66,7
		Tag 575 (Woche 82)	1	66,67	NC	66,7	66,67	66,7
		Tag 603 (Woche 86)	2	50,00	23,570	33,3	50,00	66,7
		Tag 659 (Woche 94)	1	66,67	NC	66,7	66,67	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Lymphödem	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	10,97	18,737	0,0	0,00	100,0
		Tag 22 (Woche 3)	163	15,03	19,617	0,0	0,00	100,0
		Tag 43 (Woche 6)	148	18,58	22,881	0,0	16,67	100,0
		Tag 64 (Woche 9)	137	16,67	18,413	0,0	16,67	83,3
		Tag 85 (Woche 12)	134	19,53	22,898	0,0	16,67	100,0
		Tag 106 (Woche 15)	126	21,96	23,252	0,0	16,67	100,0
		Tag 127 (Woche 18)	121	23,42	24,398	0,0	16,67	100,0
		Tag 155 (Woche 22)	129	19,25	19,923	0,0	16,67	100,0
		Tag 183 (Woche 26)	127	21,52	21,732	0,0	16,67	100,0
		Tag 211 (Woche 30)	114	18,42	21,310	0,0	16,67	100,0
		Tag 239 (Woche 34)	111	13,81	18,786	0,0	0,00	83,3
		Tag 267 (Woche 38)	108	14,97	17,933	0,0	16,67	66,7
		Tag 295 (Woche 42)	110	15,76	19,267	0,0	16,67	83,3
		Tag 323 (Woche 46)	103	15,05	18,745	0,0	0,00	66,7
		Tag 351 (Woche 50)	91	17,03	21,079	0,0	0,00	66,7
		Tag 379 (Woche 54)	86	15,70	19,361	0,0	8,33	66,7
		Tag 407 (Woche 58)	77	17,32	20,669	0,0	16,67	66,7
		Tag 435 (Woche 62)	68	13,97	18,797	0,0	0,00	66,7
		Tag 463 (Woche 66)	58	13,51	18,058	0,0	0,00	66,7
		Tag 491 (Woche 70)	45	12,59	19,187	0,0	0,00	66,7
		Tag 519 (Woche 74)	44	22,73	26,436	0,0	16,67	100,0
		Tag 547 (Woche 78)	36	25,46	28,027	0,0	16,67	100,0
		Tag 575 (Woche 82)	30	21,11	25,118	0,0	16,67	100,0
		Tag 603 (Woche 86)	31	18,82	27,129	0,0	0,00	100,0
		Tag 631 (Woche 90)	34	20,10	24,543	0,0	16,67	83,3
		Tag 659 (Woche 94)	26	21,15	20,847	0,0	16,67	66,7
		Tag 687 (Woche 98)	21	19,84	25,614	0,0	16,67	100,0
		Tag 715 (Woche 102)	18	19,44	23,044	0,0	16,67	66,7
		Tag 743 (Woche 106)	14	16,67	29,957	0,0	0,00	100,0
		Tag 771 (Woche 110)	13	19,23	28,744	0,0	0,00	100,0
		Tag 799 (Woche 114)	9	20,37	23,241	0,0	16,67	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Lymphödem	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	30,95	27,936	0,0	33,33	83,3
		Tag 855 (Woche 122)	4	8,33	16,667	0,0	0,00	33,3
		Tag 883 (Woche 126)	2	16,67	23,570	0,0	16,67	33,3
		Tag 911 (Woche 130)	2	16,67	23,570	0,0	16,67	33,3
		Tag 939 (Woche 134)	2	16,67	23,570	0,0	16,67	33,3
		Tag 967 (Woche 138)	2	33,33	47,140	0,0	33,33	66,7
		Tag 995 (Woche 142)	1	16,67	NC	16,7	16,67	16,7
	CTx (N=192)	Baseline	156	12,50	22,846	0,0	0,00	100,0
		Tag 22 (Woche 3)	146	12,44	20,882	0,0	0,00	100,0
		Tag 43 (Woche 6)	141	15,72	20,776	0,0	0,00	100,0
		Tag 64 (Woche 9)	134	17,04	20,383	0,0	16,67	100,0
		Tag 85 (Woche 12)	132	17,68	22,724	0,0	16,67	100,0
		Tag 106 (Woche 15)	131	17,18	21,277	0,0	16,67	100,0
		Tag 127 (Woche 18)	110	20,00	24,084	0,0	16,67	100,0
		Tag 155 (Woche 22)	120	17,92	24,076	0,0	16,67	100,0
		Tag 183 (Woche 26)	117	14,25	20,089	0,0	0,00	100,0
		Tag 211 (Woche 30)	108	17,13	23,065	0,0	8,33	100,0
		Tag 239 (Woche 34)	100	14,83	19,663	0,0	0,00	66,7
		Tag 267 (Woche 38)	96	12,85	19,568	0,0	0,00	100,0
		Tag 295 (Woche 42)	95	15,79	21,245	0,0	0,00	100,0
		Tag 323 (Woche 46)	83	16,47	22,765	0,0	0,00	100,0
		Tag 351 (Woche 50)	83	18,27	25,318	0,0	0,00	100,0
		Tag 379 (Woche 54)	73	16,67	20,223	0,0	16,67	100,0
		Tag 407 (Woche 58)	60	16,94	24,063	0,0	0,00	100,0
		Tag 435 (Woche 62)	53	18,24	24,518	0,0	0,00	100,0
		Tag 463 (Woche 66)	49	19,05	20,127	0,0	16,67	66,7
		Tag 491 (Woche 70)	32	15,63	24,296	0,0	0,00	100,0
		Tag 519 (Woche 74)	35	15,71	22,846	0,0	0,00	100,0
		Tag 547 (Woche 78)	30	17,22	19,320	0,0	16,67	66,7
		Tag 575 (Woche 82)	23	15,22	20,046	0,0	0,00	66,7
		Tag 603 (Woche 86)	20	17,50	25,058	0,0	0,00	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Lymphödem	CTx (N=192)	Tag 631 (Woche 90)	17	16,67	22,048	0,0	16,67	66,7
		Tag 659 (Woche 94)	9	18,52	25,610	0,0	0,00	66,7
		Tag 687 (Woche 98)	10	10,00	14,055	0,0	0,00	33,3
		Tag 715 (Woche 102)	9	12,96	21,695	0,0	0,00	66,7
		Tag 743 (Woche 106)	7	9,52	18,898	0,0	0,00	50,0
		Tag 771 (Woche 110)	6	11,11	27,217	0,0	0,00	66,7
		Tag 799 (Woche 114)	5	20,00	27,386	0,0	16,67	66,7
		Tag 827 (Woche 118)	3	33,33	33,333	0,0	33,33	66,7
		Tag 855 (Woche 122)	3	33,33	33,333	0,0	33,33	66,7
		Tag 883 (Woche 126)	1	16,67	NC	16,7	16,67	16,7
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0
EORTC QLQ-EN24 Urologische Symptome	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	16,56	15,756	0,0	16,67	75,0
		Tag 22 (Woche 3)	163	16,31	14,969	0,0	16,67	66,7
		Tag 43 (Woche 6)	148	16,78	15,733	0,0	16,67	75,0
		Tag 64 (Woche 9)	137	18,92	16,955	0,0	16,67	66,7
		Tag 85 (Woche 12)	134	18,41	18,052	0,0	16,67	75,0
		Tag 106 (Woche 15)	126	18,39	16,341	0,0	16,67	100,0
		Tag 127 (Woche 18)	121	18,18	17,938	0,0	16,67	75,0
		Tag 155 (Woche 22)	129	15,96	17,181	0,0	8,33	75,0
		Tag 183 (Woche 26)	127	15,35	16,246	0,0	8,33	75,0
		Tag 211 (Woche 30)	114	14,69	16,230	0,0	8,33	75,0
		Tag 239 (Woche 34)	111	12,84	15,763	0,0	8,33	75,0
		Tag 267 (Woche 38)	108	12,35	13,456	0,0	8,33	58,3
		Tag 295 (Woche 42)	110	13,64	16,541	0,0	8,33	75,0
		Tag 323 (Woche 46)	103	11,89	14,368	0,0	8,33	75,0
		Tag 351 (Woche 50)	91	11,45	14,361	0,0	8,33	66,7
		Tag 379 (Woche 54)	86	14,34	15,106	0,0	8,33	58,3
		Tag 407 (Woche 58)	77	12,66	14,282	0,0	8,33	58,3

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Urologische Symptome	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	12,50	13,697	0,0	8,33	50,0
		Tag 463 (Woche 66)	58	14,37	16,056	0,0	8,33	58,3
		Tag 491 (Woche 70)	45	13,70	14,987	0,0	16,67	66,7
		Tag 519 (Woche 74)	44	15,34	20,169	0,0	8,33	83,3
		Tag 547 (Woche 78)	36	11,57	18,610	0,0	0,00	91,7
		Tag 575 (Woche 82)	30	11,11	17,416	0,0	0,00	58,3
		Tag 603 (Woche 86)	31	8,33	13,944	0,0	0,00	58,3
		Tag 631 (Woche 90)	34	8,82	12,299	0,0	0,00	50,0
		Tag 659 (Woche 94)	26	10,58	13,241	0,0	0,00	41,7
		Tag 687 (Woche 98)	21	9,13	12,884	0,0	0,00	41,7
		Tag 715 (Woche 102)	18	10,19	13,271	0,0	4,17	41,7
		Tag 743 (Woche 106)	14	5,95	8,909	0,0	0,00	25,0
		Tag 771 (Woche 110)	13	9,62	11,204	0,0	8,33	33,3
		Tag 799 (Woche 114)	9	11,11	8,333	0,0	8,33	25,0
		Tag 827 (Woche 118)	7	11,90	11,644	0,0	8,33	33,3
		Tag 855 (Woche 122)	4	4,17	8,333	0,0	0,00	16,7
		Tag 883 (Woche 126)	2	12,50	5,893	8,3	12,50	16,7
		Tag 911 (Woche 130)	2	0,00	0,000	0,0	0,00	0,0
		Tag 939 (Woche 134)	2	12,50	17,678	0,0	12,50	25,0
		Tag 967 (Woche 138)	2	8,33	11,785	0,0	8,33	16,7
		Tag 995 (Woche 142)	1	16,67	NC	16,7	16,67	16,7
	CTx (N=192)	Baseline	156	16,29	18,217	0,0	8,33	83,3
		Tag 22 (Woche 3)	146	16,32	17,559	0,0	8,33	91,7
		Tag 43 (Woche 6)	141	16,19	17,530	0,0	8,33	83,3
		Tag 64 (Woche 9)	134	17,23	17,706	0,0	16,67	66,7
		Tag 85 (Woche 12)	132	16,10	17,631	0,0	16,67	91,7
		Tag 106 (Woche 15)	131	18,00	19,138	0,0	16,67	83,3
		Tag 127 (Woche 18)	110	14,85	17,059	0,0	8,33	83,3
		Tag 155 (Woche 22)	120	12,64	13,834	0,0	8,33	50,0
		Tag 183 (Woche 26)	117	13,75	16,461	0,0	8,33	75,0
		Tag 211 (Woche 30)	108	14,27	16,314	0,0	8,33	91,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Urologische Symptome	CTx (N=192)	Tag 239 (Woche 34)	100	13,00	15,817	0,0	8,33	91,7
		Tag 267 (Woche 38)	96	12,67	14,906	0,0	8,33	50,0
		Tag 295 (Woche 42)	95	10,70	15,359	0,0	0,00	66,7
		Tag 323 (Woche 46)	83	12,35	15,198	0,0	8,33	83,3
		Tag 351 (Woche 50)	83	12,05	15,522	0,0	8,33	66,7
		Tag 379 (Woche 54)	73	12,10	16,080	0,0	8,33	66,7
		Tag 407 (Woche 58)	60	12,22	15,682	0,0	8,33	75,0
		Tag 435 (Woche 62)	53	11,01	14,505	0,0	8,33	66,7
		Tag 463 (Woche 66)	49	13,44	15,940	0,0	8,33	83,3
		Tag 491 (Woche 70)	32	12,50	16,396	0,0	8,33	75,0
		Tag 519 (Woche 74)	35	11,90	16,944	0,0	8,33	83,3
		Tag 547 (Woche 78)	30	10,28	15,884	0,0	4,17	75,0
		Tag 575 (Woche 82)	23	13,04	20,230	0,0	8,33	91,7
		Tag 603 (Woche 86)	20	8,75	13,646	0,0	0,00	50,0
		Tag 631 (Woche 90)	17	10,29	17,060	0,0	0,00	66,7
		Tag 659 (Woche 94)	9	5,56	9,317	0,0	0,00	25,0
		Tag 687 (Woche 98)	10	13,33	31,230	0,0	0,00	100,0
		Tag 715 (Woche 102)	9	17,59	24,096	0,0	0,00	66,7
		Tag 743 (Woche 106)	7	15,48	31,339	0,0	0,00	83,3
		Tag 771 (Woche 110)	6	2,78	6,804	0,0	0,00	16,7
		Tag 799 (Woche 114)	5	10,00	10,865	0,0	8,33	25,0
		Tag 827 (Woche 118)	3	11,11	19,245	0,0	0,00	33,3
		Tag 855 (Woche 122)	3	11,11	19,245	0,0	0,00	33,3
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	8,33	NC	8,3	8,33	8,3
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Gastrointestinale Symptome	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	11,51	11,949	0,0	6,67	53,3
		Tag 22 (Woche 3)	163	11,21	11,178	0,0	6,67	53,3
		Tag 43 (Woche 6)	148	10,99	10,544	0,0	6,67	46,7
		Tag 64 (Woche 9)	137	13,58	11,559	0,0	13,33	46,7
		Tag 85 (Woche 12)	134	11,79	12,898	0,0	6,67	60,0
		Tag 106 (Woche 15)	126	12,54	12,525	0,0	6,67	60,0
		Tag 127 (Woche 18)	121	12,78	12,783	0,0	13,33	60,0
		Tag 155 (Woche 22)	129	11,68	12,305	0,0	6,67	53,3
		Tag 183 (Woche 26)	127	12,65	13,720	0,0	6,67	53,3
		Tag 211 (Woche 30)	114	12,11	12,623	0,0	6,67	66,7
		Tag 239 (Woche 34)	111	11,17	11,089	0,0	6,67	53,3
		Tag 267 (Woche 38)	108	11,98	12,687	0,0	6,67	73,3
		Tag 295 (Woche 42)	110	12,30	12,256	0,0	13,33	53,3
		Tag 323 (Woche 46)	103	10,10	10,760	0,0	6,67	40,0
		Tag 351 (Woche 50)	91	11,43	11,079	0,0	6,67	46,7
		Tag 379 (Woche 54)	86	11,24	11,937	0,0	13,33	66,7
		Tag 407 (Woche 58)	77	11,43	12,181	0,0	6,67	53,3
		Tag 435 (Woche 62)	68	9,22	9,430	0,0	6,67	33,3
		Tag 463 (Woche 66)	58	10,23	11,184	0,0	6,67	40,0
		Tag 491 (Woche 70)	45	9,04	10,839	0,0	6,67	40,0
		Tag 519 (Woche 74)	44	13,03	11,408	0,0	13,33	40,0
		Tag 547 (Woche 78)	36	9,26	12,270	0,0	0,00	40,0
		Tag 575 (Woche 82)	30	9,11	13,949	0,0	0,00	53,3
		Tag 603 (Woche 86)	31	9,03	13,283	0,0	0,00	46,7
		Tag 631 (Woche 90)	34	10,00	14,047	0,0	6,67	60,0
		Tag 659 (Woche 94)	26	10,51	14,132	0,0	6,67	60,0
		Tag 687 (Woche 98)	21	8,57	8,729	0,0	6,67	20,0
		Tag 715 (Woche 102)	18	13,70	17,634	0,0	6,67	66,7
		Tag 743 (Woche 106)	14	10,95	16,457	0,0	3,33	60,0
		Tag 771 (Woche 110)	13	11,79	16,137	0,0	6,67	60,0
		Tag 799 (Woche 114)	9	17,78	25,166	0,0	13,33	80,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Gastrointestinale Symptome	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	15,24	20,625	0,0	13,33	60,0
		Tag 855 (Woche 122)	4	6,67	5,443	0,0	6,67	13,3
		Tag 883 (Woche 126)	2	10,00	14,142	0,0	10,00	20,0
		Tag 911 (Woche 130)	2	6,67	9,428	0,0	6,67	13,3
		Tag 939 (Woche 134)	2	13,33	18,856	0,0	13,33	26,7
		Tag 967 (Woche 138)	2	6,67	9,428	0,0	6,67	13,3
		Tag 995 (Woche 142)	1	20,00	NC	20,0	20,00	20,0
	CTx (N=192)	Baseline	156	13,89	14,065	0,0	10,00	73,3
		Tag 22 (Woche 3)	146	11,14	11,825	0,0	6,67	53,3
		Tag 43 (Woche 6)	141	11,06	12,237	0,0	6,67	53,3
		Tag 64 (Woche 9)	134	10,80	12,230	0,0	6,67	73,3
		Tag 85 (Woche 12)	132	11,21	12,059	0,0	6,67	53,3
		Tag 106 (Woche 15)	131	11,30	12,037	0,0	6,67	66,7
		Tag 127 (Woche 18)	110	10,36	12,948	0,0	6,67	80,0
		Tag 155 (Woche 22)	120	8,83	9,630	0,0	6,67	53,3
		Tag 183 (Woche 26)	117	9,52	12,140	0,0	6,67	66,7
		Tag 211 (Woche 30)	108	11,17	11,737	0,0	6,67	53,3
		Tag 239 (Woche 34)	100	10,67	13,027	0,0	6,67	66,7
		Tag 267 (Woche 38)	96	10,76	14,261	0,0	6,67	60,0
		Tag 295 (Woche 42)	95	8,56	10,857	0,0	6,67	60,0
		Tag 323 (Woche 46)	83	10,60	13,853	0,0	6,67	93,3
		Tag 351 (Woche 50)	83	9,72	13,547	0,0	6,67	80,0
		Tag 379 (Woche 54)	73	8,95	9,637	0,0	6,67	40,0
		Tag 407 (Woche 58)	60	8,56	9,193	0,0	6,67	33,3
		Tag 435 (Woche 62)	53	9,06	10,219	0,0	6,67	40,0
		Tag 463 (Woche 66)	49	9,52	11,467	0,0	6,67	46,7
		Tag 491 (Woche 70)	32	8,33	10,018	0,0	6,67	33,3
		Tag 519 (Woche 74)	35	7,24	9,751	0,0	6,67	40,0
		Tag 547 (Woche 78)	30	10,67	12,818	0,0	6,67	46,7
		Tag 575 (Woche 82)	23	7,25	8,742	0,0	6,67	26,7
		Tag 603 (Woche 86)	20	7,00	8,779	0,0	6,67	26,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Gastrointestinale Symptome	CTx (N=192)	Tag 631 (Woche 90)	17	7,84	10,065	0,0	6,67	33,3
		Tag 659 (Woche 94)	9	4,44	6,667	0,0	0,00	20,0
		Tag 687 (Woche 98)	10	10,00	14,142	0,0	6,67	46,7
		Tag 715 (Woche 102)	9	7,41	7,778	0,0	6,67	20,0
		Tag 743 (Woche 106)	7	7,62	11,174	0,0	0,00	26,7
		Tag 771 (Woche 110)	6	5,56	8,861	0,0	0,00	20,0
		Tag 799 (Woche 114)	5	6,67	8,165	0,0	6,67	20,0
		Tag 827 (Woche 118)	3	2,22	3,849	0,0	0,00	6,7
		Tag 855 (Woche 122)	3	2,22	3,849	0,0	0,00	6,7
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0
EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	17,60	26,631	0,0	0,00	100,0
		Tag 22 (Woche 3)	163	27,61	26,345	0,0	33,33	100,0
		Tag 43 (Woche 6)	148	32,32	29,752	0,0	33,33	100,0
		Tag 64 (Woche 9)	137	32,24	30,128	0,0	33,33	100,0
		Tag 85 (Woche 12)	134	35,45	31,225	0,0	33,33	100,0
		Tag 106 (Woche 15)	126	34,39	32,024	0,0	33,33	100,0
		Tag 127 (Woche 18)	121	35,12	31,754	0,0	33,33	100,0
		Tag 155 (Woche 22)	129	35,14	32,089	0,0	33,33	100,0
		Tag 183 (Woche 26)	127	31,36	32,707	0,0	33,33	100,0
		Tag 211 (Woche 30)	114	28,07	28,423	0,0	33,33	100,0
		Tag 239 (Woche 34)	111	27,18	28,861	0,0	33,33	100,0
		Tag 267 (Woche 38)	108	28,09	28,971	0,0	33,33	100,0
		Tag 295 (Woche 42)	110	26,06	28,155	0,0	25,00	100,0
		Tag 323 (Woche 46)	103	23,79	27,575	0,0	16,67	100,0
		Tag 351 (Woche 50)	91	23,63	26,767	0,0	16,67	100,0
		Tag 379 (Woche 54)	86	23,26	25,473	0,0	25,00	100,0
		Tag 407 (Woche 58)	77	25,97	26,968	0,0	33,33	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	19,61	22,845	0,0	16,67	100,0
		Tag 463 (Woche 66)	58	16,38	21,287	0,0	8,33	100,0
		Tag 491 (Woche 70)	45	22,96	27,590	0,0	16,67	100,0
		Tag 519 (Woche 74)	44	24,62	25,540	0,0	16,67	100,0
		Tag 547 (Woche 78)	36	20,83	27,710	0,0	0,00	100,0
		Tag 575 (Woche 82)	30	21,67	28,077	0,0	8,33	100,0
		Tag 603 (Woche 86)	31	24,19	33,289	0,0	0,00	100,0
		Tag 631 (Woche 90)	34	25,49	29,937	0,0	16,67	100,0
		Tag 659 (Woche 94)	26	25,00	30,641	0,0	16,67	100,0
		Tag 687 (Woche 98)	21	18,25	23,514	0,0	16,67	66,7
		Tag 715 (Woche 102)	18	23,15	27,499	0,0	16,67	100,0
		Tag 743 (Woche 106)	14	28,57	30,959	0,0	25,00	100,0
		Tag 771 (Woche 110)	13	25,64	33,065	0,0	16,67	100,0
		Tag 799 (Woche 114)	9	20,37	33,101	0,0	0,00	100,0
		Tag 827 (Woche 118)	7	26,19	28,637	0,0	16,67	83,3
		Tag 855 (Woche 122)	4	25,00	16,667	0,0	33,33	33,3
		Tag 883 (Woche 126)	2	8,33	11,785	0,0	8,33	16,7
		Tag 911 (Woche 130)	2	16,67	23,570	0,0	16,67	33,3
		Tag 939 (Woche 134)	2	16,67	23,570	0,0	16,67	33,3
		Tag 967 (Woche 138)	2	8,33	11,785	0,0	8,33	16,7
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
	CTx (N=192)	Baseline	156	15,81	23,402	0,0	0,00	100,0
		Tag 22 (Woche 3)	146	23,06	27,492	0,0	16,67	100,0
		Tag 43 (Woche 6)	141	29,79	28,508	0,0	33,33	100,0
		Tag 64 (Woche 9)	134	30,35	29,395	0,0	33,33	100,0
		Tag 85 (Woche 12)	132	30,05	29,803	0,0	33,33	100,0
		Tag 106 (Woche 15)	131	33,46	30,974	0,0	33,33	100,0
		Tag 127 (Woche 18)	110	30,45	30,778	0,0	33,33	100,0
		Tag 155 (Woche 22)	120	28,47	28,534	0,0	33,33	100,0
		Tag 183 (Woche 26)	117	25,21	25,673	0,0	33,33	100,0
		Tag 211 (Woche 30)	108	20,68	21,959	0,0	16,67	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung	CTx (N=192)	Tag 239 (Woche 34)	100	20,67	23,939	0,0	16,67	100,0
		Tag 267 (Woche 38)	96	21,70	25,833	0,0	16,67	100,0
		Tag 295 (Woche 42)	95	19,65	24,186	0,0	16,67	100,0
		Tag 323 (Woche 46)	83	22,49	27,353	0,0	16,67	100,0
		Tag 351 (Woche 50)	83	22,89	27,634	0,0	16,67	100,0
		Tag 379 (Woche 54)	73	21,46	27,000	0,0	16,67	100,0
		Tag 407 (Woche 58)	60	23,33	27,990	0,0	16,67	100,0
		Tag 435 (Woche 62)	53	20,44	23,489	0,0	16,67	100,0
		Tag 463 (Woche 66)	49	23,81	28,666	0,0	16,67	100,0
		Tag 491 (Woche 70)	32	21,88	26,585	0,0	25,00	100,0
		Tag 519 (Woche 74)	35	23,81	26,595	0,0	16,67	100,0
		Tag 547 (Woche 78)	30	21,67	26,677	0,0	8,33	100,0
		Tag 575 (Woche 82)	23	20,29	25,602	0,0	16,67	100,0
		Tag 603 (Woche 86)	20	20,00	24,543	0,0	16,67	100,0
		Tag 631 (Woche 90)	17	20,59	29,773	0,0	0,00	100,0
		Tag 659 (Woche 94)	9	24,07	32,394	0,0	16,67	100,0
		Tag 687 (Woche 98)	10	16,67	23,570	0,0	0,00	66,7
		Tag 715 (Woche 102)	9	35,19	29,397	0,0	33,33	100,0
		Tag 743 (Woche 106)	7	23,81	37,090	0,0	0,00	100,0
		Tag 771 (Woche 110)	6	27,78	38,968	0,0	16,67	100,0
		Tag 799 (Woche 114)	5	33,33	40,825	0,0	33,33	100,0
		Tag 827 (Woche 118)	3	44,44	50,918	0,0	33,33	100,0
		Tag 855 (Woche 122)	3	44,44	50,918	0,0	33,33	100,0
		Tag 883 (Woche 126)	1	33,33	NC	33,3	33,33	33,3
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	16,67	NC	16,7	16,67	16,7
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelle/vaginale Probleme	CTx + Durvalumab + Olaparib (N=191)	Baseline	29	22,22	22,810	0,0	22,22	88,9
		Tag 22 (Woche 3)	24	25,46	23,508	0,0	22,22	88,9
		Tag 43 (Woche 6)	20	27,22	23,769	0,0	22,22	77,8
		Tag 64 (Woche 9)	18	22,22	33,224	0,0	5,56	100,0
		Tag 85 (Woche 12)	17	24,18	28,662	0,0	22,22	100,0
		Tag 106 (Woche 15)	18	24,07	23,260	0,0	22,22	66,7
		Tag 127 (Woche 18)	12	18,52	14,474	0,0	22,22	44,4
		Tag 155 (Woche 22)	17	29,41	29,902	0,0	22,22	100,0
		Tag 183 (Woche 26)	17	28,76	26,661	0,0	33,33	88,9
		Tag 211 (Woche 30)	16	30,56	31,817	0,0	27,78	88,9
		Tag 239 (Woche 34)	14	34,13	30,340	0,0	33,33	88,9
		Tag 267 (Woche 38)	20	26,11	25,047	0,0	22,22	88,9
		Tag 295 (Woche 42)	15	44,44	26,561	0,0	44,44	100,0
		Tag 323 (Woche 46)	12	33,33	29,206	0,0	27,78	88,9
		Tag 351 (Woche 50)	12	20,37	18,852	0,0	22,22	55,6
		Tag 379 (Woche 54)	13	26,50	24,653	0,0	33,33	66,7
		Tag 407 (Woche 58)	7	41,27	15,335	22,2	33,33	66,7
		Tag 435 (Woche 62)	11	32,32	22,473	0,0	33,33	66,7
		Tag 463 (Woche 66)	7	25,40	25,430	0,0	33,33	55,6
		Tag 491 (Woche 70)	7	36,51	26,227	0,0	55,56	55,6
		Tag 519 (Woche 74)	6	31,48	28,473	0,0	33,33	66,7
		Tag 547 (Woche 78)	4	22,22	27,217	0,0	16,67	55,6
		Tag 575 (Woche 82)	4	50,00	33,333	0,0	66,67	66,7
		Tag 603 (Woche 86)	2	27,78	39,284	0,0	27,78	55,6
		Tag 631 (Woche 90)	1	55,56	NC	55,6	55,56	55,6
		Tag 659 (Woche 94)	2	27,78	39,284	0,0	27,78	55,6
		Tag 687 (Woche 98)	1	55,56	NC	55,6	55,56	55,6
		Tag 715 (Woche 102)	2	33,33	47,140	0,0	33,33	66,7
		Tag 743 (Woche 106)	2	55,56	15,713	44,4	55,56	66,7
		Tag 771 (Woche 110)	4	66,67	24,003	44,4	61,11	100,0
		Tag 799 (Woche 114)	3	37,04	33,945	0,0	44,44	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelle/vaginale Probleme	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	3	40,74	35,717	0,0	55,56	66,7
		Tag 855 (Woche 122)	2	50,00	7,857	44,4	50,00	55,6
	CTx (N=192)	Baseline	25	14,67	13,878	0,0	11,11	44,4
		Tag 22 (Woche 3)	18	21,60	18,853	0,0	22,22	55,6
		Tag 43 (Woche 6)	24	23,61	24,147	0,0	22,22	100,0
		Tag 64 (Woche 9)	18	21,60	22,698	0,0	16,67	77,8
		Tag 85 (Woche 12)	15	25,19	17,042	0,0	22,22	55,6
		Tag 106 (Woche 15)	16	25,00	26,759	0,0	16,67	88,9
		Tag 127 (Woche 18)	12	20,37	14,081	0,0	22,22	44,4
		Tag 155 (Woche 22)	12	21,30	20,899	0,0	16,67	77,8
		Tag 183 (Woche 26)	19	21,64	18,693	0,0	22,22	66,7
		Tag 211 (Woche 30)	21	21,69	18,750	0,0	22,22	66,7
		Tag 239 (Woche 34)	21	24,87	20,459	0,0	22,22	77,8
		Tag 267 (Woche 38)	19	18,71	14,839	0,0	22,22	55,6
		Tag 295 (Woche 42)	22	20,71	18,873	0,0	22,22	66,7
		Tag 323 (Woche 46)	16	21,53	23,820	0,0	11,11	77,8
		Tag 351 (Woche 50)	11	17,17	26,926	0,0	0,00	77,8
		Tag 379 (Woche 54)	11	30,30	23,878	0,0	33,33	66,7
		Tag 407 (Woche 58)	12	23,15	24,370	0,0	16,67	66,7
		Tag 435 (Woche 62)	8	26,39	31,392	0,0	22,22	88,9
		Tag 463 (Woche 66)	8	30,56	32,934	0,0	27,78	88,9
		Tag 491 (Woche 70)	6	29,63	19,458	0,0	27,78	55,6
		Tag 519 (Woche 74)	5	31,11	24,088	0,0	33,33	66,7
		Tag 547 (Woche 78)	3	18,52	16,973	0,0	22,22	33,3
		Tag 575 (Woche 82)	1	22,22	NC	22,2	22,22	22,2
		Tag 603 (Woche 86)	2	33,33	0,000	33,3	33,33	33,3
		Tag 659 (Woche 94)	1	22,22	NC	22,2	22,22	22,2

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Rücken- und Beckenschmerzen	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	26,29	27,236	0,0	33,33	100,0
		Tag 22 (Woche 3)	163	19,22	22,800	0,0	0,00	100,0
		Tag 43 (Woche 6)	148	19,14	23,996	0,0	0,00	100,0
		Tag 64 (Woche 9)	137	18,73	21,716	0,0	0,00	100,0
		Tag 85 (Woche 12)	134	19,65	24,598	0,0	0,00	100,0
		Tag 106 (Woche 15)	126	19,31	22,844	0,0	0,00	100,0
		Tag 127 (Woche 18)	121	19,28	25,731	0,0	0,00	100,0
		Tag 155 (Woche 22)	129	23,00	25,617	0,0	33,33	100,0
		Tag 183 (Woche 26)	127	23,88	28,760	0,0	33,33	100,0
		Tag 211 (Woche 30)	114	19,30	26,196	0,0	0,00	100,0
		Tag 239 (Woche 34)	111	18,92	24,463	0,0	0,00	100,0
		Tag 267 (Woche 38)	108	17,28	23,005	0,0	0,00	66,7
		Tag 295 (Woche 42)	110	21,21	23,776	0,0	33,33	100,0
		Tag 323 (Woche 46)	103	22,01	24,052	0,0	33,33	100,0
		Tag 351 (Woche 50)	91	20,15	23,768	0,0	0,00	100,0
		Tag 379 (Woche 54)	86	20,16	24,670	0,0	0,00	100,0
		Tag 407 (Woche 58)	77	20,78	23,594	0,0	33,33	100,0
		Tag 435 (Woche 62)	68	17,65	21,137	0,0	0,00	66,7
		Tag 463 (Woche 66)	58	21,84	26,159	0,0	16,67	100,0
		Tag 491 (Woche 70)	45	20,00	25,025	0,0	0,00	100,0
		Tag 519 (Woche 74)	44	20,45	21,824	0,0	33,33	66,7
		Tag 547 (Woche 78)	36	16,67	20,315	0,0	0,00	66,7
		Tag 575 (Woche 82)	30	15,56	20,960	0,0	0,00	66,7
		Tag 603 (Woche 86)	31	10,75	15,840	0,0	0,00	33,3
		Tag 631 (Woche 90)	34	17,65	23,549	0,0	0,00	100,0
		Tag 659 (Woche 94)	26	24,36	24,143	0,0	33,33	66,7
		Tag 687 (Woche 98)	21	17,46	20,053	0,0	0,00	66,7
		Tag 715 (Woche 102)	18	14,81	20,523	0,0	0,00	66,7
		Tag 743 (Woche 106)	14	16,67	17,296	0,0	16,67	33,3
		Tag 771 (Woche 110)	13	17,95	22,008	0,0	0,00	66,7
		Tag 799 (Woche 114)	9	22,22	16,667	0,0	33,33	33,3

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Rücken- und Beckenschmerzen	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	28,57	23,002	0,0	33,33	66,7
		Tag 855 (Woche 122)	4	25,00	16,667	0,0	33,33	33,3
		Tag 883 (Woche 126)	2	33,33	0,000	33,3	33,33	33,3
		Tag 911 (Woche 130)	2	16,67	23,570	0,0	16,67	33,3
		Tag 939 (Woche 134)	2	16,67	23,570	0,0	16,67	33,3
		Tag 967 (Woche 138)	2	33,33	0,000	33,3	33,33	33,3
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
	CTx (N=192)	Baseline	156	26,92	27,071	0,0	33,33	100,0
		Tag 22 (Woche 3)	146	16,21	22,227	0,0	0,00	100,0
		Tag 43 (Woche 6)	141	17,97	23,744	0,0	0,00	100,0
		Tag 64 (Woche 9)	134	15,42	21,104	0,0	0,00	66,7
		Tag 85 (Woche 12)	132	19,44	24,031	0,0	0,00	100,0
		Tag 106 (Woche 15)	131	17,56	23,869	0,0	0,00	100,0
		Tag 127 (Woche 18)	110	17,58	26,601	0,0	0,00	100,0
		Tag 155 (Woche 22)	120	18,61	25,855	0,0	0,00	100,0
		Tag 183 (Woche 26)	117	19,37	25,611	0,0	0,00	100,0
		Tag 211 (Woche 30)	108	24,07	27,658	0,0	33,33	100,0
		Tag 239 (Woche 34)	100	20,00	25,950	0,0	0,00	100,0
		Tag 267 (Woche 38)	96	19,44	26,783	0,0	0,00	100,0
		Tag 295 (Woche 42)	95	18,95	25,102	0,0	0,00	100,0
		Tag 323 (Woche 46)	83	24,50	29,024	0,0	33,33	100,0
		Tag 351 (Woche 50)	83	20,08	25,471	0,0	0,00	100,0
		Tag 379 (Woche 54)	73	20,09	22,041	0,0	33,33	100,0
		Tag 407 (Woche 58)	60	19,44	17,672	0,0	33,33	66,7
		Tag 435 (Woche 62)	53	17,61	19,175	0,0	0,00	66,7
		Tag 463 (Woche 66)	49	17,69	20,528	0,0	0,00	66,7
		Tag 491 (Woche 70)	32	20,83	21,997	0,0	33,33	66,7
		Tag 519 (Woche 74)	35	18,10	20,361	0,0	0,00	66,7
		Tag 547 (Woche 78)	30	17,78	19,045	0,0	16,67	66,7
		Tag 575 (Woche 82)	23	17,39	19,770	0,0	0,00	66,7
		Tag 603 (Woche 86)	20	20,00	29,419	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Rücken- und Beckenschmerzen	CTx (N=192)	Tag 631 (Woche 90)	17	17,65	17,150	0,0	33,33	33,3
		Tag 659 (Woche 94)	9	14,81	17,568	0,0	0,00	33,3
		Tag 687 (Woche 98)	10	20,00	17,213	0,0	33,33	33,3
		Tag 715 (Woche 102)	9	18,52	24,216	0,0	0,00	66,7
		Tag 743 (Woche 106)	7	14,29	17,817	0,0	0,00	33,3
		Tag 771 (Woche 110)	6	11,11	17,213	0,0	0,00	33,3
		Tag 799 (Woche 114)	5	13,33	18,257	0,0	0,00	33,3
		Tag 827 (Woche 118)	3	22,22	19,245	0,0	33,33	33,3
		Tag 855 (Woche 122)	3	22,22	38,490	0,0	0,00	66,7
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0
EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	15,53	24,729	0,0	0,00	100,0
		Tag 22 (Woche 3)	163	29,04	27,752	0,0	33,33	100,0
		Tag 43 (Woche 6)	148	36,49	29,183	0,0	33,33	100,0
		Tag 64 (Woche 9)	137	40,15	28,907	0,0	33,33	100,0
		Tag 85 (Woche 12)	134	43,78	29,594	0,0	33,33	100,0
		Tag 106 (Woche 15)	126	49,74	30,036	0,0	33,33	100,0
		Tag 127 (Woche 18)	121	48,48	32,203	0,0	33,33	100,0
		Tag 155 (Woche 22)	129	45,48	29,445	0,0	33,33	100,0
		Tag 183 (Woche 26)	127	46,98	29,203	0,0	33,33	100,0
		Tag 211 (Woche 30)	114	42,40	28,837	0,0	33,33	100,0
		Tag 239 (Woche 34)	111	40,24	28,468	0,0	33,33	100,0
		Tag 267 (Woche 38)	108	38,27	28,392	0,0	33,33	100,0
		Tag 295 (Woche 42)	110	37,88	29,772	0,0	33,33	100,0
		Tag 323 (Woche 46)	103	37,54	29,770	0,0	33,33	100,0
		Tag 351 (Woche 50)	91	35,53	30,953	0,0	33,33	100,0
		Tag 379 (Woche 54)	86	36,43	28,297	0,0	33,33	100,0
		Tag 407 (Woche 58)	77	33,77	30,824	0,0	33,33	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	34,31	29,909	0,0	33,33	100,0
		Tag 463 (Woche 66)	58	41,38	29,492	0,0	33,33	100,0
		Tag 491 (Woche 70)	45	39,26	30,392	0,0	33,33	100,0
		Tag 519 (Woche 74)	44	40,91	29,521	0,0	33,33	100,0
		Tag 547 (Woche 78)	36	43,52	32,679	0,0	33,33	100,0
		Tag 575 (Woche 82)	30	45,56	28,343	0,0	33,33	100,0
		Tag 603 (Woche 86)	31	37,63	33,045	0,0	33,33	100,0
		Tag 631 (Woche 90)	34	41,18	30,769	0,0	33,33	100,0
		Tag 659 (Woche 94)	26	43,59	24,530	0,0	33,33	100,0
		Tag 687 (Woche 98)	21	39,68	35,931	0,0	33,33	100,0
		Tag 715 (Woche 102)	18	35,19	29,087	0,0	33,33	100,0
		Tag 743 (Woche 106)	14	35,71	24,335	0,0	33,33	66,7
		Tag 771 (Woche 110)	13	28,21	22,958	0,0	33,33	66,7
		Tag 799 (Woche 114)	9	37,04	20,031	0,0	33,33	66,7
		Tag 827 (Woche 118)	7	38,10	23,002	0,0	33,33	66,7
		Tag 855 (Woche 122)	4	33,33	27,217	0,0	33,33	66,7
		Tag 883 (Woche 126)	2	50,00	23,570	33,3	50,00	66,7
		Tag 911 (Woche 130)	2	33,33	47,140	0,0	33,33	66,7
		Tag 939 (Woche 134)	2	50,00	23,570	33,3	50,00	66,7
		Tag 967 (Woche 138)	2	50,00	23,570	33,3	50,00	66,7
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
	CTx (N=192)	Baseline	156	12,39	21,156	0,0	0,00	100,0
		Tag 22 (Woche 3)	146	29,22	28,200	0,0	33,33	100,0
		Tag 43 (Woche 6)	141	38,06	31,010	0,0	33,33	100,0
		Tag 64 (Woche 9)	134	39,30	32,917	0,0	33,33	100,0
		Tag 85 (Woche 12)	132	46,97	29,972	0,0	33,33	100,0
		Tag 106 (Woche 15)	131	52,16	32,052	0,0	66,67	100,0
		Tag 127 (Woche 18)	110	52,12	29,097	0,0	66,67	100,0
		Tag 155 (Woche 22)	120	43,89	30,856	0,0	33,33	100,0
		Tag 183 (Woche 26)	117	44,73	30,689	0,0	33,33	100,0
		Tag 211 (Woche 30)	108	41,05	26,419	0,0	33,33	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl	CTx (N=192)	Tag 239 (Woche 34)	100	41,67	26,958	0,0	33,33	100,0
		Tag 267 (Woche 38)	96	39,24	26,488	0,0	33,33	100,0
		Tag 295 (Woche 42)	95	38,25	26,169	0,0	33,33	100,0
		Tag 323 (Woche 46)	83	36,55	27,847	0,0	33,33	100,0
		Tag 351 (Woche 50)	83	37,35	26,747	0,0	33,33	100,0
		Tag 379 (Woche 54)	73	33,33	22,906	0,0	33,33	100,0
		Tag 407 (Woche 58)	60	37,22	20,439	0,0	33,33	100,0
		Tag 435 (Woche 62)	53	38,36	23,016	0,0	33,33	100,0
		Tag 463 (Woche 66)	49	36,05	27,077	0,0	33,33	100,0
		Tag 491 (Woche 70)	32	33,33	25,400	0,0	33,33	100,0
		Tag 519 (Woche 74)	35	35,24	22,785	0,0	33,33	66,7
		Tag 547 (Woche 78)	30	37,78	24,343	0,0	33,33	100,0
		Tag 575 (Woche 82)	23	33,33	22,473	0,0	33,33	66,7
		Tag 603 (Woche 86)	20	38,33	24,839	0,0	33,33	100,0
		Tag 631 (Woche 90)	17	35,29	27,565	0,0	33,33	100,0
		Tag 659 (Woche 94)	9	29,63	20,031	0,0	33,33	66,7
		Tag 687 (Woche 98)	10	36,67	29,187	0,0	33,33	100,0
		Tag 715 (Woche 102)	9	44,44	28,868	0,0	33,33	100,0
		Tag 743 (Woche 106)	7	47,62	26,227	33,3	33,33	100,0
		Tag 771 (Woche 110)	6	33,33	21,082	0,0	33,33	66,7
		Tag 799 (Woche 114)	5	20,00	18,257	0,0	33,33	33,3
		Tag 827 (Woche 118)	3	44,44	19,245	33,3	33,33	66,7
		Tag 855 (Woche 122)	3	44,44	19,245	33,3	33,33	66,7
		Tag 883 (Woche 126)	1	33,33	NC	33,3	33,33	33,3
		Tag 911 (Woche 130)	1	33,33	NC	33,3	33,33	33,3
		Tag 939 (Woche 134)	1	33,33	NC	33,3	33,33	33,3
		Tag 967 (Woche 138)	1	33,33	NC	33,3	33,33	33,3
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Muskulärer Schmerz	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	15,11	22,958	0,0	0,00	100,0
		Tag 22 (Woche 3)	163	22,09	24,906	0,0	33,33	100,0
		Tag 43 (Woche 6)	148	22,30	25,904	0,0	33,33	100,0
		Tag 64 (Woche 9)	137	23,11	25,102	0,0	33,33	100,0
		Tag 85 (Woche 12)	134	25,87	26,377	0,0	33,33	100,0
		Tag 106 (Woche 15)	126	25,40	26,138	0,0	33,33	100,0
		Tag 127 (Woche 18)	121	25,62	26,791	0,0	33,33	100,0
		Tag 155 (Woche 22)	129	22,74	26,016	0,0	33,33	100,0
		Tag 183 (Woche 26)	127	23,36	24,957	0,0	33,33	100,0
		Tag 211 (Woche 30)	114	22,51	26,046	0,0	33,33	100,0
		Tag 239 (Woche 34)	111	23,72	25,579	0,0	33,33	100,0
		Tag 267 (Woche 38)	108	23,15	22,538	0,0	33,33	66,7
		Tag 295 (Woche 42)	110	20,00	23,112	0,0	0,00	100,0
		Tag 323 (Woche 46)	103	22,98	22,880	0,0	33,33	66,7
		Tag 351 (Woche 50)	91	23,44	25,577	0,0	33,33	100,0
		Tag 379 (Woche 54)	86	20,93	22,893	0,0	33,33	100,0
		Tag 407 (Woche 58)	77	19,91	24,339	0,0	0,00	66,7
		Tag 435 (Woche 62)	68	21,08	25,694	0,0	0,00	100,0
		Tag 463 (Woche 66)	58	24,14	24,814	0,0	33,33	100,0
		Tag 491 (Woche 70)	45	16,30	26,230	0,0	0,00	100,0
		Tag 519 (Woche 74)	44	25,00	23,978	0,0	33,33	66,7
		Tag 547 (Woche 78)	36	26,85	22,282	0,0	33,33	66,7
		Tag 575 (Woche 82)	30	20,00	22,489	0,0	16,67	66,7
		Tag 603 (Woche 86)	31	24,73	24,294	0,0	33,33	66,7
		Tag 631 (Woche 90)	34	21,57	24,457	0,0	16,67	66,7
		Tag 659 (Woche 94)	26	33,33	26,667	0,0	33,33	100,0
		Tag 687 (Woche 98)	21	25,40	25,614	0,0	33,33	66,7
		Tag 715 (Woche 102)	18	20,37	23,260	0,0	16,67	66,7
		Tag 743 (Woche 106)	14	26,19	23,310	0,0	33,33	66,7
		Tag 771 (Woche 110)	13	23,08	21,014	0,0	33,33	66,7
		Tag 799 (Woche 114)	9	25,93	22,222	0,0	33,33	66,7

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Muskulärer Schmerz	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	19,05	17,817	0,0	33,33	33,3
		Tag 855 (Woche 122)	4	25,00	16,667	0,0	33,33	33,3
		Tag 883 (Woche 126)	2	33,33	0,000	33,3	33,33	33,3
		Tag 911 (Woche 130)	2	16,67	23,570	0,0	16,67	33,3
		Tag 939 (Woche 134)	2	33,33	47,140	0,0	33,33	66,7
		Tag 967 (Woche 138)	2	16,67	23,570	0,0	16,67	33,3
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
	CTx (N=192)	Baseline	156	14,96	21,848	0,0	0,00	100,0
		Tag 22 (Woche 3)	146	19,41	24,684	0,0	0,00	100,0
		Tag 43 (Woche 6)	141	26,00	25,848	0,0	33,33	100,0
		Tag 64 (Woche 9)	134	24,13	28,140	0,0	33,33	100,0
		Tag 85 (Woche 12)	132	26,26	27,018	0,0	33,33	100,0
		Tag 106 (Woche 15)	131	27,48	26,306	0,0	33,33	100,0
		Tag 127 (Woche 18)	110	24,24	25,103	0,0	33,33	100,0
		Tag 155 (Woche 22)	120	19,44	23,504	0,0	0,00	100,0
		Tag 183 (Woche 26)	117	21,37	27,144	0,0	0,00	100,0
		Tag 211 (Woche 30)	108	26,54	26,479	0,0	33,33	100,0
		Tag 239 (Woche 34)	100	25,00	26,958	0,0	33,33	100,0
		Tag 267 (Woche 38)	96	26,74	29,268	0,0	33,33	100,0
		Tag 295 (Woche 42)	95	25,61	25,007	0,0	33,33	100,0
		Tag 323 (Woche 46)	83	26,10	28,536	0,0	33,33	100,0
		Tag 351 (Woche 50)	83	31,33	26,210	0,0	33,33	100,0
		Tag 379 (Woche 54)	73	30,14	26,155	0,0	33,33	100,0
		Tag 407 (Woche 58)	60	30,56	26,248	0,0	33,33	100,0
		Tag 435 (Woche 62)	53	27,04	24,509	0,0	33,33	100,0
		Tag 463 (Woche 66)	49	25,17	27,664	0,0	33,33	100,0
		Tag 491 (Woche 70)	32	31,25	30,454	0,0	33,33	100,0
		Tag 519 (Woche 74)	35	27,62	23,550	0,0	33,33	66,7
		Tag 547 (Woche 78)	30	27,78	27,797	0,0	33,33	100,0
		Tag 575 (Woche 82)	23	28,99	30,657	0,0	33,33	100,0
		Tag 603 (Woche 86)	20	36,67	34,028	0,0	33,33	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Muskulärer Schmerz	CTx (N=192)	Tag 631 (Woche 90)	17	33,33	33,333	0,0	33,33	100,0
		Tag 659 (Woche 94)	9	22,22	16,667	0,0	33,33	33,3
		Tag 687 (Woche 98)	10	33,33	22,222	0,0	33,33	66,7
		Tag 715 (Woche 102)	9	40,74	32,394	0,0	33,33	100,0
		Tag 743 (Woche 106)	7	23,81	16,265	0,0	33,33	33,3
		Tag 771 (Woche 110)	6	22,22	17,213	0,0	33,33	33,3
		Tag 799 (Woche 114)	5	20,00	18,257	0,0	33,33	33,3
		Tag 827 (Woche 118)	3	33,33	0,000	33,3	33,33	33,3
		Tag 855 (Woche 122)	3	11,11	19,245	0,0	0,00	33,3
		Tag 883 (Woche 126)	1	33,33	NC	33,3	33,33	33,3
		Tag 911 (Woche 130)	1	33,33	NC	33,3	33,33	33,3
		Tag 939 (Woche 134)	1	33,33	NC	33,3	33,33	33,3
		Tag 967 (Woche 138)	1	33,33	NC	33,3	33,33	33,3
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
EORTC QLQ-EN24 Haarausfall	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	6,00	16,197	0,0	0,00	100,0
		Tag 22 (Woche 3)	163	77,10	27,348	0,0	100,00	100,0
		Tag 43 (Woche 6)	148	70,05	33,161	0,0	66,67	100,0
		Tag 64 (Woche 9)	137	61,31	37,754	0,0	66,67	100,0
		Tag 85 (Woche 12)	134	53,98	39,163	0,0	66,67	100,0
		Tag 106 (Woche 15)	126	62,43	40,658	0,0	66,67	100,0
		Tag 127 (Woche 18)	121	56,75	43,172	0,0	66,67	100,0
		Tag 155 (Woche 22)	129	42,12	43,003	0,0	33,33	100,0
		Tag 183 (Woche 26)	127	28,35	40,298	0,0	0,00	100,0
		Tag 211 (Woche 30)	114	18,13	34,390	0,0	0,00	100,0
		Tag 239 (Woche 34)	111	12,61	29,492	0,0	0,00	100,0
		Tag 267 (Woche 38)	108	8,64	25,525	0,0	0,00	100,0
		Tag 295 (Woche 42)	110	9,70	24,460	0,0	0,00	100,0
		Tag 323 (Woche 46)	103	9,71	25,833	0,0	0,00	100,0
		Tag 351 (Woche 50)	91	8,42	24,136	0,0	0,00	100,0
		Tag 379 (Woche 54)	86	7,75	22,096	0,0	0,00	100,0
		Tag 407 (Woche 58)	77	9,52	24,695	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Haarausfall	CTx + Durvalumab + Olaparib (N=191)	Tag 435 (Woche 62)	68	7,84	20,859	0,0	0,00	100,0
		Tag 463 (Woche 66)	58	13,79	25,770	0,0	0,00	100,0
		Tag 491 (Woche 70)	45	11,85	24,777	0,0	0,00	100,0
		Tag 519 (Woche 74)	44	18,18	32,513	0,0	0,00	100,0
		Tag 547 (Woche 78)	36	12,04	26,610	0,0	0,00	100,0
		Tag 575 (Woche 82)	30	12,22	25,496	0,0	0,00	100,0
		Tag 603 (Woche 86)	31	16,13	28,377	0,0	0,00	100,0
		Tag 631 (Woche 90)	34	10,78	19,627	0,0	0,00	66,7
		Tag 659 (Woche 94)	26	19,23	31,514	0,0	0,00	100,0
		Tag 687 (Woche 98)	21	14,29	22,537	0,0	0,00	66,7
		Tag 715 (Woche 102)	18	16,67	23,570	0,0	0,00	66,7
		Tag 743 (Woche 106)	14	14,29	21,540	0,0	0,00	66,7
		Tag 771 (Woche 110)	13	17,95	22,008	0,0	0,00	66,7
		Tag 799 (Woche 114)	9	14,81	24,216	0,0	0,00	66,7
		Tag 827 (Woche 118)	7	19,05	26,227	0,0	0,00	66,7
		Tag 855 (Woche 122)	4	0,00	0,000	0,0	0,00	0,0
		Tag 883 (Woche 126)	2	16,67	23,570	0,0	16,67	33,3
		Tag 911 (Woche 130)	2	0,00	0,000	0,0	0,00	0,0
		Tag 939 (Woche 134)	2	16,67	23,570	0,0	16,67	33,3
		Tag 967 (Woche 138)	2	0,00	0,000	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	33,33	NC	33,3	33,33	33,3
	CTx (N=192)	Baseline	156	4,70	15,816	0,0	0,00	100,0
		Tag 22 (Woche 3)	146	71,46	29,030	0,0	66,67	100,0
		Tag 43 (Woche 6)	141	71,39	32,264	0,0	66,67	100,0
		Tag 64 (Woche 9)	134	55,22	38,801	0,0	66,67	100,0
		Tag 85 (Woche 12)	132	59,60	39,296	0,0	66,67	100,0
		Tag 106 (Woche 15)	131	53,18	40,038	0,0	33,33	100,0
		Tag 127 (Woche 18)	110	46,97	38,656	0,0	33,33	100,0
		Tag 155 (Woche 22)	120	38,61	42,340	0,0	33,33	100,0
		Tag 183 (Woche 26)	117	14,81	31,393	0,0	0,00	100,0
		Tag 211 (Woche 30)	108	12,96	30,514	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Haarausfall	CTx (N=192)	Tag 239 (Woche 34)	100	11,33	27,307	0,0	0,00	100,0
		Tag 267 (Woche 38)	96	11,46	28,130	0,0	0,00	100,0
		Tag 295 (Woche 42)	95	9,12	26,382	0,0	0,00	100,0
		Tag 323 (Woche 46)	83	3,61	11,655	0,0	0,00	66,7
		Tag 351 (Woche 50)	83	6,83	18,595	0,0	0,00	100,0
		Tag 379 (Woche 54)	73	7,76	22,581	0,0	0,00	100,0
		Tag 407 (Woche 58)	60	3,33	11,805	0,0	0,00	66,7
		Tag 435 (Woche 62)	53	3,77	12,507	0,0	0,00	66,7
		Tag 463 (Woche 66)	49	5,44	17,142	0,0	0,00	100,0
		Tag 491 (Woche 70)	32	5,21	14,930	0,0	0,00	66,7
		Tag 519 (Woche 74)	35	5,71	15,094	0,0	0,00	66,7
		Tag 547 (Woche 78)	30	3,33	10,171	0,0	0,00	33,3
		Tag 575 (Woche 82)	23	7,25	14,058	0,0	0,00	33,3
		Tag 603 (Woche 86)	20	5,00	12,212	0,0	0,00	33,3
		Tag 631 (Woche 90)	17	1,96	8,085	0,0	0,00	33,3
		Tag 659 (Woche 94)	9	7,41	14,699	0,0	0,00	33,3
		Tag 687 (Woche 98)	10	13,33	23,307	0,0	0,00	66,7
		Tag 715 (Woche 102)	9	14,81	24,216	0,0	0,00	66,7
		Tag 743 (Woche 106)	7	9,52	25,198	0,0	0,00	66,7
		Tag 771 (Woche 110)	6	11,11	27,217	0,0	0,00	66,7
		Tag 799 (Woche 114)	5	6,67	14,907	0,0	0,00	33,3
		Tag 827 (Woche 118)	3	22,22	38,490	0,0	0,00	66,7
		Tag 855 (Woche 122)	3	22,22	38,490	0,0	0,00	66,7
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Geschmacksveränderung	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	7,45	17,470	0,0	0,00	100,0
		Tag 22 (Woche 3)	163	21,27	27,423	0,0	0,00	100,0
		Tag 43 (Woche 6)	148	23,65	30,430	0,0	0,00	100,0
		Tag 64 (Woche 9)	137	22,87	27,933	0,0	0,00	100,0
		Tag 85 (Woche 12)	134	29,35	28,917	0,0	33,33	100,0
		Tag 106 (Woche 15)	126	27,51	29,538	0,0	33,33	100,0
		Tag 127 (Woche 18)	121	24,79	27,732	0,0	33,33	100,0
		Tag 155 (Woche 22)	129	25,06	27,960	0,0	33,33	100,0
		Tag 183 (Woche 26)	127	27,30	30,980	0,0	33,33	100,0
		Tag 211 (Woche 30)	114	26,02	30,647	0,0	33,33	100,0
		Tag 239 (Woche 34)	111	22,22	28,897	0,0	0,00	100,0
		Tag 267 (Woche 38)	108	17,90	25,138	0,0	0,00	100,0
		Tag 295 (Woche 42)	110	18,79	24,947	0,0	0,00	100,0
		Tag 323 (Woche 46)	103	14,89	22,737	0,0	0,00	100,0
		Tag 351 (Woche 50)	91	17,58	25,503	0,0	0,00	100,0
		Tag 379 (Woche 54)	86	17,83	24,360	0,0	0,00	100,0
		Tag 407 (Woche 58)	77	16,02	23,946	0,0	0,00	100,0
		Tag 435 (Woche 62)	68	14,22	21,016	0,0	0,00	100,0
		Tag 463 (Woche 66)	58	13,79	19,779	0,0	0,00	66,7
		Tag 491 (Woche 70)	45	14,07	20,706	0,0	0,00	66,7
		Tag 519 (Woche 74)	44	13,64	20,734	0,0	0,00	66,7
		Tag 547 (Woche 78)	36	16,67	21,822	0,0	0,00	66,7
		Tag 575 (Woche 82)	30	16,67	20,991	0,0	0,00	66,7
		Tag 603 (Woche 86)	31	10,75	21,751	0,0	0,00	66,7
		Tag 631 (Woche 90)	34	13,73	26,102	0,0	0,00	100,0
		Tag 659 (Woche 94)	26	17,95	31,596	0,0	0,00	100,0
		Tag 687 (Woche 98)	21	12,70	24,667	0,0	0,00	66,7
		Tag 715 (Woche 102)	18	20,37	30,548	0,0	0,00	100,0
		Tag 743 (Woche 106)	14	16,67	31,351	0,0	0,00	100,0
		Tag 771 (Woche 110)	13	12,82	21,681	0,0	0,00	66,7
		Tag 799 (Woche 114)	9	22,22	33,333	0,0	0,00	100,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Geschmacksveränderung	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	23,81	25,198	0,0	33,33	66,7
		Tag 855 (Woche 122)	4	16,67	33,333	0,0	0,00	66,7
		Tag 883 (Woche 126)	2	16,67	23,570	0,0	16,67	33,3
		Tag 911 (Woche 130)	2	0,00	0,000	0,0	0,00	0,0
		Tag 939 (Woche 134)	2	33,33	47,140	0,0	33,33	66,7
		Tag 967 (Woche 138)	2	16,67	23,570	0,0	16,67	33,3
		Tag 995 (Woche 142)	1	66,67	NC	66,7	66,67	66,7
	CTx (N=192)	Baseline	156	8,97	21,199	0,0	0,00	100,0
		Tag 22 (Woche 3)	146	19,18	25,622	0,0	0,00	100,0
		Tag 43 (Woche 6)	141	22,22	28,078	0,0	0,00	100,0
		Tag 64 (Woche 9)	134	25,37	31,178	0,0	33,33	100,0
		Tag 85 (Woche 12)	132	27,02	34,245	0,0	0,00	100,0
		Tag 106 (Woche 15)	131	27,48	32,418	0,0	33,33	100,0
		Tag 127 (Woche 18)	110	22,73	27,809	0,0	0,00	100,0
		Tag 155 (Woche 22)	120	15,56	22,427	0,0	0,00	100,0
		Tag 183 (Woche 26)	117	8,26	18,521	0,0	0,00	100,0
		Tag 211 (Woche 30)	108	8,95	18,571	0,0	0,00	100,0
		Tag 239 (Woche 34)	100	7,33	17,459	0,0	0,00	100,0
		Tag 267 (Woche 38)	96	5,56	13,392	0,0	0,00	66,7
		Tag 295 (Woche 42)	95	6,67	18,578	0,0	0,00	100,0
		Tag 323 (Woche 46)	83	9,24	18,267	0,0	0,00	100,0
		Tag 351 (Woche 50)	83	11,65	21,736	0,0	0,00	100,0
		Tag 379 (Woche 54)	73	9,59	17,984	0,0	0,00	66,7
		Tag 407 (Woche 58)	60	7,22	16,343	0,0	0,00	66,7
		Tag 435 (Woche 62)	53	7,55	18,071	0,0	0,00	66,7
		Tag 463 (Woche 66)	49	11,56	21,028	0,0	0,00	100,0
		Tag 491 (Woche 70)	32	11,46	23,355	0,0	0,00	100,0
		Tag 519 (Woche 74)	35	5,71	15,094	0,0	0,00	66,7
		Tag 547 (Woche 78)	30	7,78	16,800	0,0	0,00	66,7
		Tag 575 (Woche 82)	23	7,25	17,281	0,0	0,00	66,7
		Tag 603 (Woche 86)	20	3,33	10,260	0,0	0,00	33,3

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

Table 2.6.2.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Geschmacksveränderung	CTx (N=192)	Tag 631 (Woche 90)	17	5,88	17,620	0,0	0,00	66,7
		Tag 659 (Woche 94)	9	3,70	11,111	0,0	0,00	33,3
		Tag 687 (Woche 98)	10	20,00	42,164	0,0	0,00	100,0
		Tag 715 (Woche 102)	9	14,81	29,397	0,0	0,00	66,7
		Tag 743 (Woche 106)	7	9,52	25,198	0,0	0,00	66,7
		Tag 771 (Woche 110)	6	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	5	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	3	0,00	0,000	0,0	0,00	0,0
		Tag 855 (Woche 122)	3	0,00	0,000	0,0	0,00	0,0
		Tag 883 (Woche 126)	1	0,00	NC	0,0	0,00	0,0
		Tag 911 (Woche 130)	1	0,00	NC	0,0	0,00	0,0
		Tag 939 (Woche 134)	1	0,00	NC	0,0	0,00	0,0
		Tag 967 (Woche 138)	1	0,00	NC	0,0	0,00	0,0
		Tag 995 (Woche 142)	1	0,00	NC	0,0	0,00	0,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbb 13MAR2024:16:01

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Table 2.6.3.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EQ-5D-5L VAS scores over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EQ-5D-5L Visuelle Analogskala	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	72,20	21,030	0,0	79,00	100,0
		Tag 22 (Woche 3)	162	70,66	18,950	0,0	75,50	100,0
		Tag 43 (Woche 6)	146	72,24	18,788	10,0	76,00	100,0
		Tag 64 (Woche 9)	136	71,82	17,427	0,0	75,00	100,0
		Tag 85 (Woche 12)	133	70,53	17,432	20,0	72,00	100,0
		Tag 106 (Woche 15)	125	71,25	16,552	20,0	74,00	100,0
		Tag 127 (Woche 18)	121	72,04	18,425	17,0	75,00	100,0
		Tag 155 (Woche 22)	128	70,20	17,995	25,0	72,00	100,0
		Tag 183 (Woche 26)	127	72,16	18,741	10,0	78,00	100,0
		Tag 211 (Woche 30)	113	72,20	18,160	8,0	77,00	100,0
		Tag 239 (Woche 34)	111	72,52	19,246	10,0	78,00	100,0
		Tag 267 (Woche 38)	108	72,04	19,938	9,0	79,00	100,0
		Tag 295 (Woche 42)	110	72,81	18,754	21,0	79,00	100,0
		Tag 323 (Woche 46)	103	74,87	17,244	9,0	79,00	100,0
		Tag 351 (Woche 50)	91	76,00	16,080	38,0	79,00	100,0
		Tag 379 (Woche 54)	85	75,32	17,953	24,0	81,00	100,0
		Tag 407 (Woche 58)	78	74,99	17,240	31,0	80,00	100,0
		Tag 435 (Woche 62)	68	77,19	16,244	18,0	80,00	99,0
		Tag 463 (Woche 66)	58	76,21	16,394	29,0	80,00	100,0
		Tag 491 (Woche 70)	45	77,29	16,861	40,0	80,00	98,0
		Tag 519 (Woche 74)	44	76,00	17,653	29,0	80,50	100,0
		Tag 547 (Woche 78)	36	75,86	17,597	39,0	80,00	100,0
		Tag 575 (Woche 82)	30	74,43	21,545	18,0	84,00	100,0
		Tag 603 (Woche 86)	31	78,03	19,810	7,0	82,00	100,0
		Tag 631 (Woche 90)	34	75,68	16,266	37,0	79,50	96,0
		Tag 659 (Woche 94)	26	80,31	13,626	40,0	82,50	97,0
		Tag 687 (Woche 98)	21	83,67	11,616	60,0	90,00	96,0
		Tag 715 (Woche 102)	18	79,17	15,663	40,0	79,50	96,0
		Tag 743 (Woche 106)	14	82,50	13,899	47,0	87,50	97,0
		Tag 771 (Woche 110)	13	82,23	14,884	50,0	90,00	96,0
		Tag 799 (Woche 114)	9	80,22	23,509	20,0	88,00	95,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbc 13MAR2024:16:01

Table 2.6.3.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EQ-5D-5L VAS scores over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EQ-5D-5L Visuelle Analogskala	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	83,29	21,670	35,0	88,00	96,0
		Tag 855 (Woche 122)	4	84,75	6,850	81,0	81,50	95,0
		Tag 883 (Woche 126)	2	87,00	4,243	84,0	87,00	90,0
		Tag 911 (Woche 130)	2	83,50	4,950	80,0	83,50	87,0
		Tag 939 (Woche 134)	2	80,50	4,950	77,0	80,50	84,0
		Tag 967 (Woche 138)	2	77,50	10,607	70,0	77,50	85,0
		Tag 995 (Woche 142)	1	88,00	NC	88,0	88,00	88,0
	CTx (N=192)	Baseline	154	71,30	18,942	13,0	76,00	100,0
		Tag 22 (Woche 3)	145	73,49	16,438	27,0	75,00	100,0
		Tag 43 (Woche 6)	139	72,68	17,523	21,0	79,00	100,0
		Tag 64 (Woche 9)	132	73,14	16,374	9,0	78,00	100,0
		Tag 85 (Woche 12)	132	70,89	18,208	9,0	73,50	99,0
		Tag 106 (Woche 15)	131	70,61	18,339	10,0	75,00	100,0
		Tag 127 (Woche 18)	109	72,23	16,585	35,0	75,00	99,0
		Tag 155 (Woche 22)	120	73,78	18,344	0,0	80,00	100,0
		Tag 183 (Woche 26)	117	74,52	17,020	15,0	80,00	99,0
		Tag 211 (Woche 30)	107	75,36	16,164	13,0	80,00	98,0
		Tag 239 (Woche 34)	100	75,60	15,651	22,0	80,00	99,0
		Tag 267 (Woche 38)	96	76,47	15,672	31,0	80,00	100,0
		Tag 295 (Woche 42)	95	75,58	17,936	17,0	80,00	98,0
		Tag 323 (Woche 46)	83	76,52	18,029	2,0	80,00	98,0
		Tag 351 (Woche 50)	81	76,54	16,833	15,0	80,00	99,0
		Tag 379 (Woche 54)	73	74,66	19,722	11,0	80,00	100,0
		Tag 407 (Woche 58)	60	73,15	17,406	34,0	78,00	100,0
		Tag 435 (Woche 62)	53	75,79	18,833	21,0	80,00	97,0
		Tag 463 (Woche 66)	49	72,73	16,795	42,0	73,00	97,0
		Tag 491 (Woche 70)	32	75,41	17,526	21,0	80,00	97,0
		Tag 519 (Woche 74)	35	71,51	19,715	24,0	75,00	97,0
		Tag 547 (Woche 78)	30	74,50	17,116	40,0	80,00	98,0
		Tag 575 (Woche 82)	23	74,30	22,127	20,0	81,00	97,0
		Tag 603 (Woche 86)	20	78,95	16,564	47,0	87,00	96,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbc 13MAR2024:16:01

Table 2.6.3.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of EQ-5D-5L VAS scores over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EQ-5D-5L Visuelle Analogskala	CTx (N=192)	Tag 631 (Woche 90)	17	79,00	15,350	45,0	80,00	97,0
		Tag 659 (Woche 94)	9	73,78	17,391	39,0	80,00	91,0
		Tag 687 (Woche 98)	10	71,10	17,272	46,0	75,50	95,0
		Tag 715 (Woche 102)	9	73,89	14,400	52,0	79,00	89,0
		Tag 743 (Woche 106)	7	75,43	9,289	62,0	72,00	86,0
		Tag 771 (Woche 110)	6	78,33	10,405	61,0	84,00	87,0
		Tag 799 (Woche 114)	5	77,80	10,208	60,0	81,00	86,0
		Tag 827 (Woche 118)	3	67,00	14,731	51,0	70,00	80,0
		Tag 855 (Woche 122)	3	76,33	20,306	53,0	86,00	90,0
		Tag 883 (Woche 126)	1	90,00	NC	90,0	90,00	90,0
		Tag 911 (Woche 130)	1	92,00	NC	92,0	92,00	92,0
		Tag 939 (Woche 134)	1	92,00	NC	92,0	92,00	92,0
		Tag 967 (Woche 138)	1	94,00	NC	94,0	94,00	94,0
		Tag 995 (Woche 142)	1	90,00	NC	90,0	90,00	90,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbc 13MAR2024:16:01

Table 2.6.4.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of PGIS questionnaire results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGIS	CTx + Durvalumab + Olaparib (N=191)	Baseline	161	2,24	1,447	1,0	2,00	6,0
		Tag 22 (Woche 3)	161	2,45	1,284	1,0	2,00	6,0
		Tag 43 (Woche 6)	145	2,30	1,238	1,0	2,00	5,0
		Tag 64 (Woche 9)	135	2,31	1,162	1,0	2,00	5,0
		Tag 85 (Woche 12)	133	2,31	1,195	1,0	2,00	5,0
		Tag 106 (Woche 15)	125	2,30	1,193	1,0	2,00	5,0
		Tag 127 (Woche 18)	119	2,28	1,228	1,0	2,00	6,0
		Tag 155 (Woche 22)	128	2,27	1,295	1,0	2,00	6,0
		Tag 183 (Woche 26)	127	2,20	1,299	1,0	2,00	6,0
		Tag 211 (Woche 30)	113	2,20	1,181	1,0	2,00	6,0
		Tag 239 (Woche 34)	111	2,05	1,135	1,0	2,00	5,0
		Tag 267 (Woche 38)	108	2,06	1,175	1,0	2,00	5,0
		Tag 295 (Woche 42)	109	2,13	1,171	1,0	2,00	6,0
		Tag 323 (Woche 46)	103	2,08	1,186	1,0	2,00	6,0
		Tag 351 (Woche 50)	90	1,87	1,062	1,0	2,00	5,0
		Tag 379 (Woche 54)	85	1,91	1,119	1,0	2,00	5,0
		Tag 407 (Woche 58)	78	1,90	1,146	1,0	1,00	5,0
		Tag 435 (Woche 62)	68	1,74	0,956	1,0	1,00	5,0
		Tag 463 (Woche 66)	57	1,77	0,945	1,0	2,00	5,0
		Tag 491 (Woche 70)	45	1,73	1,053	1,0	1,00	5,0
		Tag 519 (Woche 74)	44	2,00	1,201	1,0	2,00	5,0
		Tag 547 (Woche 78)	36	1,69	0,856	1,0	1,50	4,0
		Tag 575 (Woche 82)	30	2,03	1,245	1,0	2,00	5,0
		Tag 603 (Woche 86)	31	1,71	1,006	1,0	1,00	4,0
		Tag 631 (Woche 90)	34	1,76	1,046	1,0	1,00	4,0
		Tag 659 (Woche 94)	26	1,81	0,981	1,0	1,50	4,0
		Tag 687 (Woche 98)	21	1,29	0,561	1,0	1,00	3,0
		Tag 715 (Woche 102)	18	1,94	1,211	1,0	1,50	5,0
		Tag 743 (Woche 106)	14	1,57	0,938	1,0	1,00	4,0
		Tag 771 (Woche 110)	13	1,62	1,044	1,0	1,00	4,0
		Tag 799 (Woche 114)	9	1,78	0,972	1,0	2,00	4,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbd 13MAR2024:16:01

Table 2.6.4.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of PGIS questionnaire results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGIS	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	1,86	1,069	1,0	2,00	4,0
		Tag 855 (Woche 122)	4	2,00	0,816	1,0	2,00	3,0
		Tag 883 (Woche 126)	2	2,00	0,000	2,0	2,00	2,0
		Tag 911 (Woche 130)	2	1,50	0,707	1,0	1,50	2,0
		Tag 939 (Woche 134)	2	2,00	0,000	2,0	2,00	2,0
		Tag 967 (Woche 138)	2	2,00	0,000	2,0	2,00	2,0
		Tag 995 (Woche 142)	1	3,00	NC	3,0	3,00	3,0
	CTx (N=192)	Baseline	152	2,14	1,381	1,0	1,00	6,0
		Tag 22 (Woche 3)	145	2,17	1,074	1,0	2,00	5,0
		Tag 43 (Woche 6)	138	2,22	1,134	1,0	2,00	5,0
		Tag 64 (Woche 9)	132	2,18	1,083	1,0	2,00	5,0
		Tag 85 (Woche 12)	131	2,15	1,068	1,0	2,00	5,0
		Tag 106 (Woche 15)	129	2,36	1,237	1,0	2,00	6,0
		Tag 127 (Woche 18)	108	2,15	1,150	1,0	2,00	6,0
		Tag 155 (Woche 22)	120	1,93	1,109	1,0	2,00	6,0
		Tag 183 (Woche 26)	114	1,92	1,040	1,0	2,00	5,0
		Tag 211 (Woche 30)	106	2,04	1,095	1,0	2,00	5,0
		Tag 239 (Woche 34)	100	1,85	1,058	1,0	1,50	5,0
		Tag 267 (Woche 38)	96	1,85	1,036	1,0	2,00	5,0
		Tag 295 (Woche 42)	94	1,86	1,001	1,0	2,00	5,0
		Tag 323 (Woche 46)	83	1,95	1,168	1,0	2,00	6,0
		Tag 351 (Woche 50)	82	1,85	1,020	1,0	2,00	4,0
		Tag 379 (Woche 54)	73	1,81	0,952	1,0	2,00	4,0
		Tag 407 (Woche 58)	60	1,97	1,134	1,0	2,00	5,0
		Tag 435 (Woche 62)	52	1,88	0,983	1,0	2,00	4,0
		Tag 463 (Woche 66)	49	1,94	1,029	1,0	2,00	4,0
		Tag 491 (Woche 70)	32	1,88	1,040	1,0	2,00	4,0
		Tag 519 (Woche 74)	35	1,80	0,994	1,0	1,00	4,0
		Tag 547 (Woche 78)	30	1,73	0,980	1,0	1,50	5,0
		Tag 575 (Woche 82)	23	1,70	1,105	1,0	1,00	5,0
		Tag 603 (Woche 86)	19	1,68	0,946	1,0	1,00	4,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbd 13MAR2024:16:01

Table 2.6.4.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of PGIS questionnaire results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGIS	CTx (N=192)	Tag 631 (Woche 90)	17	1,88	1,054	1,0	2,00	5,0
		Tag 659 (Woche 94)	9	2,11	1,364	1,0	2,00	5,0
		Tag 687 (Woche 98)	10	2,30	1,337	1,0	2,00	5,0
		Tag 715 (Woche 102)	9	2,56	1,236	1,0	2,00	4,0
		Tag 743 (Woche 106)	7	1,43	0,787	1,0	1,00	3,0
		Tag 771 (Woche 110)	6	1,67	0,816	1,0	1,50	3,0
		Tag 799 (Woche 114)	5	1,80	1,304	1,0	1,00	4,0
		Tag 827 (Woche 118)	3	2,00	1,000	1,0	2,00	3,0
		Tag 855 (Woche 122)	3	2,33	1,528	1,0	2,00	4,0
		Tag 883 (Woche 126)	1	1,00	NC	1,0	1,00	1,0
		Tag 911 (Woche 130)	1	2,00	NC	2,0	2,00	2,0
		Tag 939 (Woche 134)	1	1,00	NC	1,0	1,00	1,0
		Tag 967 (Woche 138)	1	1,00	NC	1,0	1,00	1,0
		Tag 995 (Woche 142)	1	2,00	NC	2,0	2,00	2,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbd 13MAR2024:16:01

Table 2.6.5.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of PGI-TT questionnaire results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGI-TT	CTx + Durvalumab + Olaparib (N=191)	Baseline	159	1,33	0,769	1,0	1,00	5,0
		Tag 22 (Woche 3)	159	2,36	1,070	1,0	2,00	5,0
		Tag 43 (Woche 6)	145	2,23	1,091	1,0	2,00	5,0
		Tag 64 (Woche 9)	134	2,25	0,923	1,0	2,00	4,0
		Tag 85 (Woche 12)	130	2,32	0,973	1,0	2,00	5,0
		Tag 106 (Woche 15)	121	2,42	1,063	1,0	2,00	5,0
		Tag 127 (Woche 18)	117	2,43	1,124	1,0	2,00	5,0
		Tag 155 (Woche 22)	123	2,36	1,049	1,0	2,00	5,0
		Tag 183 (Woche 26)	122	2,26	0,994	1,0	2,00	5,0
		Tag 211 (Woche 30)	106	2,19	0,927	1,0	2,00	5,0
		Tag 239 (Woche 34)	105	2,12	0,958	1,0	2,00	4,0
		Tag 267 (Woche 38)	101	2,12	0,941	1,0	2,00	5,0
		Tag 295 (Woche 42)	99	2,01	0,974	1,0	2,00	4,0
		Tag 323 (Woche 46)	94	2,01	0,898	1,0	2,00	4,0
		Tag 351 (Woche 50)	80	1,88	0,877	1,0	2,00	5,0
		Tag 379 (Woche 54)	77	1,82	0,854	1,0	2,00	4,0
		Tag 407 (Woche 58)	70	1,94	0,976	1,0	2,00	5,0
		Tag 435 (Woche 62)	62	1,98	0,949	1,0	2,00	5,0
		Tag 463 (Woche 66)	54	1,81	0,933	1,0	2,00	4,0
		Tag 491 (Woche 70)	42	2,00	1,082	1,0	2,00	5,0
		Tag 519 (Woche 74)	40	1,90	0,928	1,0	2,00	4,0
		Tag 547 (Woche 78)	32	1,78	0,870	1,0	2,00	4,0
		Tag 575 (Woche 82)	29	1,79	0,902	1,0	2,00	4,0
		Tag 603 (Woche 86)	29	1,90	0,939	1,0	2,00	4,0
		Tag 631 (Woche 90)	31	2,13	1,056	1,0	2,00	4,0
		Tag 659 (Woche 94)	23	1,91	1,041	1,0	2,00	5,0
		Tag 687 (Woche 98)	20	1,90	1,119	1,0	2,00	5,0
		Tag 715 (Woche 102)	17	2,06	1,029	1,0	2,00	4,0
		Tag 743 (Woche 106)	13	1,92	0,954	1,0	2,00	4,0
		Tag 771 (Woche 110)	12	1,67	0,651	1,0	2,00	3,0
		Tag 799 (Woche 114)	9	2,00	1,000	1,0	2,00	4,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbe 13MAR2024:16:01

Table 2.6.5.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of PGI-TT questionnaire results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGI-TT	CTx + Durvalumab + Olaparib (N=191)	Tag 827 (Woche 118)	7	2,00	1,000	1,0	2,00	4,0
		Tag 855 (Woche 122)	4	1,75	0,500	1,0	2,00	2,0
		Tag 883 (Woche 126)	2	2,00	0,000	2,0	2,00	2,0
		Tag 911 (Woche 130)	2	2,00	0,000	2,0	2,00	2,0
		Tag 939 (Woche 134)	2	2,00	0,000	2,0	2,00	2,0
		Tag 967 (Woche 138)	2	2,00	0,000	2,0	2,00	2,0
		Tag 995 (Woche 142)	1	2,00	NC	2,0	2,00	2,0
	CTx (N=192)	Baseline	150	1,35	0,851	1,0	1,00	5,0
		Tag 22 (Woche 3)	144	2,22	0,940	1,0	2,00	5,0
		Tag 43 (Woche 6)	138	2,36	1,010	1,0	2,00	5,0
		Tag 64 (Woche 9)	131	2,15	0,921	1,0	2,00	4,0
		Tag 85 (Woche 12)	131	2,28	0,987	1,0	2,00	5,0
		Tag 106 (Woche 15)	126	2,53	1,063	1,0	2,00	5,0
		Tag 127 (Woche 18)	108	2,30	1,025	1,0	2,00	5,0
		Tag 155 (Woche 22)	119	2,12	1,051	1,0	2,00	5,0
		Tag 183 (Woche 26)	112	1,87	0,875	1,0	2,00	4,0
		Tag 211 (Woche 30)	101	1,76	0,789	1,0	2,00	5,0
		Tag 239 (Woche 34)	95	1,84	0,854	1,0	2,00	4,0
		Tag 267 (Woche 38)	85	1,73	0,878	1,0	2,00	5,0
		Tag 295 (Woche 42)	85	1,79	0,846	1,0	2,00	5,0
		Tag 323 (Woche 46)	70	1,76	0,875	1,0	2,00	5,0
		Tag 351 (Woche 50)	64	1,75	0,735	1,0	2,00	4,0
		Tag 379 (Woche 54)	58	1,74	0,715	1,0	2,00	4,0
		Tag 407 (Woche 58)	46	1,96	0,842	1,0	2,00	4,0
		Tag 435 (Woche 62)	40	1,93	0,888	1,0	2,00	4,0
		Tag 463 (Woche 66)	34	1,88	0,880	1,0	2,00	4,0
		Tag 491 (Woche 70)	23	1,83	0,984	1,0	2,00	4,0
		Tag 519 (Woche 74)	24	1,63	0,824	1,0	1,00	4,0
		Tag 547 (Woche 78)	20	1,90	0,718	1,0	2,00	3,0
		Tag 575 (Woche 82)	15	1,60	0,632	1,0	2,00	3,0
		Tag 603 (Woche 86)	10	1,60	0,843	1,0	1,00	3,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbe 13MAR2024:16:01

Table 2.6.5.2 DUO-E (pMMR Durva/Ola): Summary of absolute values of PGI-TT questionnaire results over time by treatment group
Patients with pMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGI-TT	CTx (N=192)	Tag 631 (Woche 90)	10	1,60	0,699	1,0	1,50	3,0
		Tag 659 (Woche 94)	3	1,00	0,000	1,0	1,00	1,0
		Tag 687 (Woche 98)	7	1,86	1,215	1,0	1,00	4,0
		Tag 715 (Woche 102)	6	2,00	1,095	1,0	2,00	3,0
		Tag 743 (Woche 106)	4	1,75	0,957	1,0	1,50	3,0
		Tag 771 (Woche 110)	4	1,25	0,500	1,0	1,00	2,0
		Tag 799 (Woche 114)	3	1,33	0,577	1,0	1,00	2,0
		Tag 827 (Woche 118)	1	1,00	NC	1,0	1,00	1,0
		Tag 855 (Woche 122)	1	1,00	NC	1,0	1,00	1,0
		Tag 911 (Woche 130)	1	2,00	NC	2,0	2,00	2,0
		Tag 939 (Woche 134)	1	1,00	NC	1,0	1,00	1,0
		Tag 967 (Woche 138)	1	1,00	NC	1,0	1,00	1,0
		Tag 995 (Woche 142)	1	1,00	NC	1,0	1,00	1,0

CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/smeanpr.sas gsmeanprbe 13MAR2024:16:01

Nutzenbewertung nach AMNOG

Table 3.2.1.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event
(total, and by SOC and PT occurring with frequency >=10 patients and at least 1% in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE	191	190 (99,5)	0,1 [0,1; 0,1]	190	190 (100)	0,1 [0,1; 0,1]	0,95	[0,78; 1,17]	0,7272
SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	191	135 (70,7)	2,3 [1,4; 4,3]	190	119 (62,6)	2,2 [1,6; 4,4]	1,13	[0,88; 1,44]	0,3526
PT: Asthenie	191	37 (19,4)	NE [NE; NE]	190	18 (9,5)	NE [NE; NE]	2,07	[1,20; 3,72]	0,0097*
PT: Ermuedung	191	77 (40,3)	21,4 [13,3; NE]	190	66 (34,7)	NE [NE; NE]	1,13	[0,82; 1,58]	0,4607
PT: Fieber	191	18 (9,4)	NE [NE; NE]	190	12 (6,3)	NE [NE; NE]	1,33	[0,64; 2,85]	0,4424
PT: Oedem peripher	191	22 (11,5)	NE [NE; NE]	190	15 (7,9)	NE [NE; NE]	1,48	[0,77; 2,91]	0,2421
PT: Schmerz	191	10 (5,2)	NE [NE; NE]	190	7 (3,7)	NE [NE; NE]	1,35	[0,52; 3,73]	0,5394
PT: Unwohlsein	191	11 (5,8)	NE [NE; NE]	190	14 (7,4)	NE [NE; NE]	0,74	[0,33; 1,62]	0,4444
SOC: Augenerkrankungen	191	24 (12,6)	NE [NE; NE]	190	25 (13,2)	NE [NE; NE]	0,89	[0,50; 1,56]	0,6837
SOC: Endokrine Erkrankungen	191	38 (19,9)	NE [NE; NE]	190	9 (4,7)	NE [NE; NE]	4,45	[2,25; 9,82]	<0,0001*
PT: Hypothyreose	191	29 (15,2)	NE [NE; NE]	190	6 (3,2)	NE [NE; NE]	4,98	[2,22; 13,30]	<0,0001*

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1ba 17APR2024:11:32

Table 3.2.1.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event
(total, and by SOC and PT occurring with frequency >=10 patients and at least 1% in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums	191	63 (33,0)	NE [NE; NE]	190	69 (36,3)	NE [NE; NE]	0,81	[0,57; 1,14]	0,2181
PT: Dyspnoe	191	24 (12,6)	NE [NE; NE]	190	22 (11,6)	NE [NE; NE]	1,00	[0,56; 1,80]	0,9932
PT: Husten	191	28 (14,7)	NE [NE; NE]	190	18 (9,5)	NE [NE; NE]	1,43	[0,80; 2,64]	0,2333
SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese	191	31 (16,2)	NE [NE; NE]	190	27 (14,2)	NE [NE; NE]	1,07	[0,64; 1,80]	0,8101
PT: Vaginale Blutung	191	6 (3,1)	NE [NE; NE]	190	12 (6,3)	NE [NE; NE]	0,46	[0,16; 1,19]	0,1129
PT: Vaginaler Ausfluss	191	12 (6,3)	NE [NE; NE]	190	2 (1,1)	NE [NE; NE]	5,79	[1,58; 37,27]	0,0092*
SOC: Erkrankungen der Haut und des Unterhautgewebes	191	142 (74,3)	0,7 [0,6; 0,9]	190	126 (66,3)	0,8 [0,7; 1,5]	1,18	[0,93; 1,50]	0,1721
PT: Alopezie	191	102 (53,4)	2,1 [0,7; NE]	190	99 (52,1)	1,6 [0,7; NE]	1,03	[0,78; 1,37]	0,7965
PT: Ausschlag	191	22 (11,5)	NE [NE; NE]	190	21 (11,1)	NE [NE; NE]	1,04	[0,57; 1,90]	0,9043
PT: Ausschlag makulo-papuloes	191	11 (5,8)	NE [NE; NE]	190	6 (3,2)	NE [NE; NE]	1,70	[0,64; 4,94]	0,2936
PT: Pruritus	191	30 (15,7)	NE [NE; NE]	190	24 (12,6)	NE [NE; NE]	1,21	[0,71; 2,09]	0,4900

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.1.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event
(total, and by SOC and PT occurring with frequency >=10 patients and at least 1% in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
SOC: Erkrankungen der Nieren und Harnwege	191	40 (20,9)	NE [NE; NE]	190	48 (25,3)	NE [NE; NE]	0,75	[0,49; 1,14]	0,1749
PT: Pollakisurie	191	7 (3,7)	NE [NE; NE]	190	11 (5,8)	NE [NE; NE]	0,57	[0,21; 1,45]	0,2394
SOC: Erkrankungen des Blutes und des Lymphsystems	191	132 (69,1)	3,4 [2,1; 3,8]	190	114 (60,0)	3,5 [2,8; 4,2]	1,20	[0,94; 1,55]	0,1444
PT: Anaemie	191	120 (62,8)	3,7 [2,8; 4,8]	190	103 (54,2)	4,2 [3,4; NE]	1,23	[0,95; 1,60]	0,1230
PT: Leukopenie	191	11 (5,8)	NE [NE; NE]	190	8 (4,2)	NE [NE; NE]	1,33	[0,54; 3,44]	0,5396
PT: Neutropenie	191	38 (19,9)	NE [NE; NE]	190	23 (12,1)	NE [NE; NE]	1,66	[0,9995; 2,83]	0,0513
PT: Thrombozytopenie	191	31 (16,2)	NE [NE; NE]	190	14 (7,4)	NE [NE; NE]	2,26	[1,23; 4,39]	0,0092*
SOC: Erkrankungen des Gastrointestinaltrakts	191	157 (82,2)	0,8 [0,4; 1,1]	190	143 (75,3)	0,6 [0,2; 0,9]	1,09	[0,87; 1,37]	0,4198
PT: Abdominalschmerz	191	34 (17,8)	NE [NE; NE]	190	32 (16,8)	NE [NE; NE]	1,00	[0,61; 1,62]	0,9839
PT: Bauch aufgetrieben	191	12 (6,3)	NE [NE; NE]	190	9 (4,7)	NE [NE; NE]	1,19	[0,50; 2,95]	0,6919
PT: Diarrhoe	191	59 (30,9)	NE [NE; NE]	190	55 (28,9)	NE [NE; NE]	1,04	[0,72; 1,50]	0,8434

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.1.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event
(total, and by SOC and PT occurring with frequency >=10 patients and at least 1% in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
PT: Dyspepsie	191	19 (9,9)	NE [NE; NE]	190	12 (6,3)	NE [NE; NE]	1,49	[0,73; 3,16]	0,2782
PT: Erbrechen	191	49 (25,7)	NE [NE; NE]	190	33 (17,4)	NE [NE; NE]	1,46	[0,94; 2,29]	0,0920
PT: Obstipation	191	64 (33,5)	NE [NE; NE]	190	65 (34,2)	NE [NE; NE]	0,95	[0,67; 1,34]	0,7773
PT: Schmerzen Oberbauch	191	12 (6,3)	NE [NE; NE]	190	6 (3,2)	NE [NE; NE]	1,89	[0,73; 5,43]	0,1990
PT: Schmerzen Unterbauch	191	4 (2,1)	NE [NE; NE]	190	10 (5,3)	NE [NE; NE]	0,37	[0,10; 1,12]	0,0833
PT: Stomatitis	191	20 (10,5)	NE [NE; NE]	190	16 (8,4)	NE [NE; NE]	1,21	[0,63; 2,38]	0,5623
PT: Uebelkeit	191	108 (56,5)	5,3 [4,4; 6,9]	190	83 (43,7)	NE [NE; NE]	1,31	[0,98; 1,75]	0,0634
SOC: Erkrankungen des Immunsystems	191	15 (7,9)	NE [NE; NE]	190	11 (5,8)	NE [NE; NE]	1,17	[0,53; 2,64]	0,6973
SOC: Erkrankungen des Nervensystems	191	145 (75,9)	1,5 [1,3; 2,3]	190	140 (73,7)	1,1 [0,8; 1,4]	0,92	[0,73; 1,16]	0,4783
PT: Dysgeusie	191	24 (12,6)	NE [NE; NE]	190	22 (11,6)	NE [NE; NE]	1,00	[0,56; 1,80]	0,9994
PT: Hypoaesthesie	191	12 (6,3)	NE [NE; NE]	190	11 (5,8)	NE [NE; NE]	1,04	[0,45; 2,40]	0,9262
PT: Kopfschmerzen	191	30 (15,7)	NE [NE; NE]	190	27 (14,2)	NE [NE; NE]	1,06	[0,63; 1,79]	0,8352

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.1.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event
(total, and by SOC and PT occurring with frequency >=10 patients and at least 1% in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
PT: Periphere Neuropathie	191	45 (23,6)	NE [NE; NE]	190	57 (30,0)	NE [NE; NE]	0,72	[0,48; 1,06]	0,1000
PT: Periphere sensorische Neuropathie	191	49 (25,7)	NE [NE; NE]	190	49 (25,8)	NE [NE; NE]	0,96	[0,64; 1,43]	0,8428
PT: Schwindelgefuehl	191	33 (17,3)	NE [NE; NE]	190	26 (13,7)	NE [NE; NE]	1,19	[0,71; 2,01]	0,5038
SOC: Erkrankungen des Ohrs und des Labyrinths	191	8 (4,2)	NE [NE; NE]	190	14 (7,4)	NE [NE; NE]	0,51	[0,20; 1,19]	0,1194
SOC: Gefaesserkrankungen	191	43 (22,5)	NE [NE; NE]	190	32 (16,8)	NE [NE; NE]	1,35	[0,86; 2,15]	0,1982
PT: Hypertonie	191	11 (5,8)	NE [NE; NE]	190	6 (3,2)	NE [NE; NE]	1,85	[0,70; 5,37]	0,2192
PT: Hypotonie	191	10 (5,2)	NE [NE; NE]	190	2 (1,1)	NE [NE; NE]	4,74	[1,25; 30,87]	0,0270*
SOC: Herzerkrankungen	191	16 (8,4)	NE [NE; NE]	190	14 (7,4)	NE [NE; NE]	1,10	[0,54; 2,29]	0,7916
SOC: Infektionen und parasitaere Erkrankungen	191	101 (52,9)	10,7 [8,3;14,0]	190	96 (50,5)	8,9 [6,5;13,6]	0,97	[0,73; 1,28]	0,8046
PT: COVID-19	191	39 (20,4)	26,5 [20,1; NE]	190	25 (13,2)	25,0 [20,5; NE]	1,22	[0,74; 2,05]	0,4434
PT: Harnwegsinfektion	191	41 (21,5)	NE [NE; NE]	190	45 (23,7)	NE [NE; NE]	0,83	[0,54; 1,26]	0,3766
SOC: Leber- und Gallenerkrankungen	191	10 (5,2)	NE [NE; NE]	190	2 (1,1)	NE [NE; NE]	4,92	[1,30; 31,98]	0,0227*

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.1.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event
(total, and by SOC and PT occurring with frequency >=10 patients and at least 1% in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
SOC: Psychiatrische Erkrankungen	191	41 (21,5)	NE [NE; NE]	190	41 (21,6)	NE [NE; NE]	0,95	[0,61; 1,46]	0,8036
PT: Angst	191	7 (3,7)	NE [NE; NE]	190	10 (5,3)	NE [NE; NE]	0,62	[0,22; 1,62]	0,3297
PT: Depression	191	10 (5,2)	NE [NE; NE]	190	9 (4,7)	NE [NE; NE]	1,03	[0,41; 2,60]	0,9499
PT: Schlaflosigkeit	191	26 (13,6)	NE [NE; NE]	190	28 (14,7)	NE [NE; NE]	0,91	[0,53; 1,56]	0,7328
SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen	191	105 (55,0)	9,7 [3,5;15,1]	190	111 (58,4)	4,7 [2,1; 8,3]	0,84	[0,64; 1,09]	0,1937
PT: Arthralgie	191	41 (21,5)	NE [NE; NE]	190	45 (23,7)	NE [NE; NE]	0,82	[0,53; 1,25]	0,3476
PT: Knochenschmerzen	191	10 (5,2)	NE [NE; NE]	190	18 (9,5)	NE [NE; NE]	0,54	[0,24; 1,14]	0,1106
PT: Muskulaere Schwaeche	191	12 (6,3)	NE [NE; NE]	190	13 (6,8)	NE [NE; NE]	0,87	[0,39; 1,92]	0,7252
PT: Myalgie	191	25 (13,1)	NE [NE; NE]	190	35 (18,4)	NE [NE; NE]	0,69	[0,41; 1,15]	0,1575
PT: Rueckenschmerzen	191	30 (15,7)	NE [NE; NE]	190	20 (10,5)	NE [NE; NE]	1,35	[0,77; 2,42]	0,2951
PT: Schmerz in einer Extremitaet	191	26 (13,6)	NE [NE; NE]	190	27 (14,2)	NE [NE; NE]	0,90	[0,52; 1,55]	0,7120

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.1.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event
(total, and by SOC and PT occurring with frequency >=10 patients and at least 1% in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
SOC: Stoffwechsel- und Ernaehrungsstoerungen	191	94 (49,2)	12,6 [5,8; NE]	190	94 (49,5)	10,4 [3,5; NE]	0,92	[0,69; 1,23]	0,5971
PT: Appetit vermindert	191	39 (20,4)	NE [NE; NE]	190	35 (18,4)	NE [NE; NE]	1,05	[0,67; 1,67]	0,8256
PT: Hypalbuminaemie	191	10 (5,2)	NE [NE; NE]	190	4 (2,1)	NE [NE; NE]	2,38	[0,79; 8,68]	0,1320
PT: Hyperglykaemie	191	13 (6,8)	NE [NE; NE]	190	16 (8,4)	NE [NE; NE]	0,72	[0,34; 1,51]	0,3908
PT: Hypokaliaemie	191	27 (14,1)	NE [NE; NE]	190	15 (7,9)	NE [NE; NE]	1,83	[0,99; 3,53]	0,0569
PT: Hypomagnesiaemie	191	32 (16,8)	NE [NE; NE]	190	32 (16,8)	NE [NE; NE]	0,98	[0,60; 1,60]	0,9202
PT: Hyponatriaemie	191	10 (5,2)	NE [NE; NE]	190	8 (4,2)	NE [NE; NE]	1,22	[0,48; 3,19]	0,6801
SOC: Untersuchungen	191	111 (58,1)	6,0 [3,7; 8,5]	190	109 (57,4)	3,9 [3,0; 9,9]	0,95	[0,73; 1,24]	0,7201
PT: Alaninaminotransferase erhoeht	191	23 (12,0)	NE [NE; NE]	190	15 (7,9)	NE [NE; NE]	1,49	[0,78; 2,92]	0,2308
PT: Aspartataminotransferase erhoeht	191	16 (8,4)	NE [NE; NE]	190	15 (7,9)	NE [NE; NE]	0,98	[0,48; 2,01]	0,9560
PT: Gamma-Glutamyltransferase erhoeht	191	13 (6,8)	NE [NE; NE]	190	10 (5,3)	NE [NE; NE]	1,27	[0,56; 2,98]	0,5688

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.1.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event
(total, and by SOC and PT occurring with frequency >=10 patients and at least 1% in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
PT: Gewicht erniedrigt	191	14 (7,3)	NE [NE; NE]	190	16 (8,4)	NE [NE; NE]	0,80	[0,39; 1,65]	0,5538
PT: Kreatinin im Blut erhoeht	191	19 (9,9)	NE [NE; NE]	190	10 (5,3)	NE [NE; NE]	1,70	[0,80; 3,82]	0,1733
PT: Laktatdehydrogenase im Blut erhoeht	191	7 (3,7)	NE [NE; NE]	190	12 (6,3)	NE [NE; NE]	0,48	[0,18; 1,21]	0,1228
PT: Leukozytenzahl erniedrigt	191	33 (17,3)	NE [NE; NE]	190	34 (17,9)	NE [NE; NE]	0,93	[0,57; 1,50]	0,7556
PT: Lipase erhoeht	191	3 (1,6)	NE [NE; NE]	190	10 (5,3)	NE [NE; NE]	0,27	[0,06; 0,88]	0,0319*
PT: Lymphozytenzahl erniedrigt	191	10 (5,2)	NE [NE; NE]	190	11 (5,8)	NE [NE; NE]	0,80	[0,33; 1,91]	0,6180
PT: Neutrophilenzahl erniedrigt	191	43 (22,5)	NE [NE; NE]	190	53 (27,9)	NE [NE; NE]	0,77	[0,51; 1,15]	0,1991
PT: Thrombozytenzahl vermindert	191	32 (16,8)	NE [NE; NE]	190	31 (16,3)	NE [NE; NE]	0,98	[0,60; 1,61]	0,9352
SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	191	49 (25,7)	NE [NE; NE]	190	45 (23,7)	NE [NE; NE]	0,94	[0,63; 1,42]	0,7936

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.1.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event
(total, and by SOC and PT occurring with frequency >=10 patients and at least 1% in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
PT: Reaktion im Zusammenhang mit einer Infusion	191	13 (6,8)	NE [NE; NE]	190	22 (11,6)	NE [NE; NE]	0,56	[0,27; 1,09]	0,0971
PT: Sturz	191	16 (8,4)	NE [NE; NE]	190	12 (6,3)	NE [NE; NE]	1,07	[0,50; 2,32]	0,8691

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Nutzenbewertung nach AMNOG

Table 3.2.2.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first serious adverse event (total, and by SOC and PT occurring with frequency >=5% of patients in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
SUE	191	69 (36,1)	24,7 [24,7; NE]	190	58 (30,5)	NE [NE; NE]	1,14	[0,80; 1,62]	0,4699
SUE SOC: Erkrankungen des Blutes und des Lymphsystems	191	28 (14,7)	NE [NE; NE]	190	14 (7,4)	NE [NE; NE]	1,92	[1,03; 3,76]	0,0424*
SUE PT: Anaemie	191	13 (6,8)	NE [NE; NE]	190	7 (3,7)	NE [NE; NE]	1,80	[0,74; 4,79]	0,2038
SUE SOC: Erkrankungen des Gastrointestinaltrakts	191	8 (4,2)	NE [NE; NE]	190	15 (7,9)	NE [NE; NE]	0,50	[0,20; 1,15]	0,1080
SUE SOC: Infektionen und parasitaere Erkrankungen	191	19 (9,9)	NE [NE; NE]	190	16 (8,4)	NE [NE; NE]	1,11	[0,57; 2,19]	0,7576

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.3.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event leading to discontinuation of study treatment
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
Therapieabbruch aufgrund von UE	191	47 (24,6)	NE [NE; NE]	190	37 (19,5)	NE [NE; NE]	1,19	[0,78; 1,85]	0,4184

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.4.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event with max. CTCAE grade 3 or higher (total, and by SOC and PT occurring with frequency >=5% of patients in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UE mit CTCAE Grad >=3	191	129 (67,5)	3,4 [2,3; 6,2]	190	104 (54,7)	5,3 [3,1;12,2]	1,28	[0,99; 1,66]	0,0630
G>=3 SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	191	13 (6,8)	NE [NE; NE]	190	7 (3,7)	NE [NE; NE]	1,78	[0,73; 4,73]	0,2156
G>=3 SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums	191	11 (5,8)	NE [NE; NE]	190	7 (3,7)	NE [NE; NE]	1,47	[0,58; 4,00]	0,4214
G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems	191	62 (32,5)	NE [NE; NE]	190	39 (20,5)	NE [NE; NE]	1,64	[1,11; 2,47]	0,0142*
G>=3 PT: Anaemie	191	46 (24,1)	NE [NE; NE]	190	24 (12,6)	NE [NE; NE]	1,96	[1,21; 3,26]	0,0065*
G>=3 PT: Neutropenie	191	20 (10,5)	NE [NE; NE]	190	10 (5,3)	NE [NE; NE]	2,00	[0,96; 4,45]	0,0685
G>=3 SOC: Erkrankungen des Gastrointestinaltrakts	191	16 (8,4)	NE [NE; NE]	190	18 (9,5)	NE [NE; NE]	0,84	[0,43; 1,66]	0,6206
G>=3 SOC: Erkrankungen des Nervensystems	191	17 (8,9)	NE [NE; NE]	190	12 (6,3)	NE [NE; NE]	1,36	[0,66; 2,93]	0,4083

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.4.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event with max. CTCAE grade 3 or higher (total, and by SOC and PT occurring with frequency >=5% of patients in either treatment arm)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
G>=3 SOC: Gefaesserkrankungen	191	12 (6,3)	NE [NE; NE]	190	4 (2,1)	NE [NE; NE]	2,91	[1,01; 10,42]	0,0531
G>=3 SOC: Infektionen und parasitaere Erkrankungen	191	23 (12,0)	NE [NE; NE]	190	17 (8,9)	NE [NE; NE]	1,26	[0,67; 2,40]	0,4727
G>=3 SOC: Stoffwechsel- und Ernaehrungsstoerungen	191	16 (8,4)	NE [NE; NE]	190	8 (4,2)	NE [NE; NE]	1,96	[0,86; 4,83]	0,1135
G>=3 SOC: Untersuchungen	191	43 (22,5)	NE [NE; NE]	190	39 (20,5)	NE [NE; NE]	1,06	[0,68; 1,63]	0,8069
G>=3 PT: Leukozytenzahl erniedrigt	191	8 (4,2)	NE [NE; NE]	190	10 (5,3)	NE [NE; NE]	0,79	[0,30; 2,01]	0,6244
G>=3 PT: Neutrophilenzahl erniedrigt	191	28 (14,7)	NE [NE; NE]	190	28 (14,7)	NE [NE; NE]	0,98	[0,58; 1,66]	0,9325

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Nutzenbewertung nach AMNOG

Table 3.2.5.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event of special interest (total and by grouped term)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UESI	191	124 (64,9)	3,7 [2,1; 5,5]	190	99 (52,1)	5,8 [3,5; NE]	1,32	[1,01; 1,72]	0,0392*
UESI GT: Andere seltene/sonstige Ereignisse	191	4 (2,1)	NE [NE; NE]	190	1 (0,5)	NE [NE; NE]	3,36	[0,49; 65,94]	0,2528
UESI GT: Dermatitis/Hautausschlag	191	47 (24,6)	NE [NE; NE]	190	40 (21,1)	NE [NE; NE]	1,15	[0,75; 1,76]	0,5266
UESI GT: Diarrhö/Kolitis	191	60 (31,4)	NE [NE; NE]	190	55 (28,9)	NE [NE; NE]	1,06	[0,73; 1,53]	0,7668
UESI GT: Hepatische Ereignisse	191	2 (1,0)	NE [NE; NE]	190	1 (0,5)	NE [NE; NE]	1,65	[0,15; 35,77]	0,6837
UESI GT: Hyperthyreose Ereignisse	191	8 (4,2)	NE [NE; NE]	190	1 (0,5)	NE [NE; NE]	8,06	[1,48;149,48]	0,0191*
UESI GT: Hypothyreose Ereignisse	191	29 (15,2)	NE [NE; NE]	190	6 (3,2)	NE [NE; NE]	4,98	[2,22; 13,30]	<0,0001*
UESI GT: Infusions- und Überempfindlichkeitsreaktionen	191	26 (13,6)	NE [NE; NE]	190	27 (14,2)	NE [NE; NE]	0,89	[0,52; 1,54]	0,7055
UESI GT: Myositis	191	1 (0,5)	NE [NE; NE]	190	0	NE [NE; NE]	NC	NC	0,3485

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only. Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.5.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event of special interest (total and by grouped term)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UESI GT: Neue primäre Malignität	191	2 (1,0)	NE [NE; NE]	190	2 (1,1)	NE [NE; NE]	0,96	[0,12; 8,02]	0,9693
UESI GT: Pneumonitis	191	8 (4,2)	NE [NE; NE]	190	1 (0,5)	NE [NE; NE]	7,11	[1,30;132,06]	0,0314*
UESI GT: Renale Ereignisse	191	0	NE [NE; NE]	190	1 (0,5)	NE [NE; NE]	NC	NC	0,3203
UESI GT: Thyreoiditis	191	6 (3,1)	NE [NE; NE]	190	0	NE [NE; NE]	NC	NC	0,0157*

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.6.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first adverse event of special interest with max. CTCAE grad
(total and by grouped term)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
UESI G>=3	191	17 (8,9)	NE [NE; NE]	190	14 (7,4)	NE [NE; NE]	1,17	[0,58; 2,42]	0,6561
UESI G>=3 GT: Andere seltene/sonstige Ereignisse	191	2 (1,0)	NE [NE; NE]	190	0	NE [NE; NE]	NC	NC	0,2670
UESI G>=3 GT: Dermatitis/Hautausschlag	191	1 (0,5)	NE [NE; NE]	190	2 (1,1)	NE [NE; NE]	0,50	[0,02; 5,21]	0,5627
UESI G>=3 GT: Diarrhö/Kolitis	191	4 (2,1)	NE [NE; NE]	190	5 (2,6)	NE [NE; NE]	0,75	[0,18; 2,84]	0,6650
UESI G>=3 GT: Infusions- und Überempfindlichkeitsreaktionen	191	6 (3,1)	NE [NE; NE]	190	6 (3,2)	NE [NE; NE]	0,95	[0,30; 3,03]	0,9249
UESI G>=3 GT: Myositis	191	1 (0,5)	NE [NE; NE]	190	0	NE [NE; NE]	NC	NC	0,3485
UESI G>=3 GT: Neue primäre Malignität	191	0	NE [NE; NE]	190	1 (0,5)	NE [NE; NE]	NC	NC	0,3065
UESI G>=3 GT: Pneumonitis	191	3 (1,6)	NE [NE; NE]	190	0	NE [NE; NE]	NC	NC	0,1121

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.7.2.1D DUO-E (pMMR Durva/Ola): Summary of analysis of time to first serious adverse event of special interest (total and by grouped term)
Patients with pMMR tumour status, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [c]
SUESI	191	12 (6,3)	NE [NE; NE]	190	8 (4,2)	NE [NE; NE]	1,45	[0,60; 3,71]	0,4106
SUESI GT: Andere seltene/sonstige Ereignisse	191	1 (0,5)	NE [NE; NE]	190	0	NE [NE; NE]	NC	NC	0,4635
SUESI GT: Dermatitis/Hautausschlag	191	0	NE [NE; NE]	190	1 (0,5)	NE [NE; NE]	NC	NC	0,3147
SUESI GT: Diarrhö/Kolitis	191	3 (1,6)	NE [NE; NE]	190	4 (2,1)	NE [NE; NE]	0,74	[0,14; 3,34]	0,6863
SUESI GT: Hepatische Ereignisse	191	1 (0,5)	NE [NE; NE]	190	0	NE [NE; NE]	NC	NC	0,3199
SUESI GT: Infusions- und Überempfindlichkeitsreaktionen	191	2 (1,0)	NE [NE; NE]	190	3 (1,6)	NE [NE; NE]	0,66	[0,09; 3,96]	0,6427
SUESI GT: Myositis	191	1 (0,5)	NE [NE; NE]	190	0	NE [NE; NE]	NC	NC	0,3485
SUESI GT: Neue primäre Malignität	191	1 (0,5)	NE [NE; NE]	190	1 (0,5)	NE [NE; NE]	0,97	[0,04; 24,45]	0,9815
SUESI GT: Pneumonitis	191	3 (1,6)	NE [NE; NE]	190	0	NE [NE; NE]	NC	NC	0,1121

The time to event endpoint is defined as the time from first dose of study treatment to first onset of the respective AE during the observation period as defined in Table 3.1.2. Any patient that has not experienced the AE will be censored at the end of observation period. All AEs are coded using MedDRA version 25.1.
[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated using unstratified Cox proportional hazard model including treatment only.
Efron method for handling ties. 95% CI from profile likelihood estimation.
[c] Determined using unstratified log-rank test.
Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.5.2.1D DUO-E (pMMR Durva/Ola): Summary of adverse events leading to discontinuation of study treatment (total, and by SOC and PT)
Patients with pMMR tumour status, DCO 12APR2023

System organ class / MedDRA Preferred term	Number (%) of patients CTx + Durvalumab + Olaparib (N=191)	 CTx (N=190)
Patienten mit Abbruch wegen UE	47 (24,6)	37 (19,5)
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	2 (1,0)	4 (2,1)
Asthenie	0 (0,0)	1 (0,5)
Brustkorbschmerz	1 (0,5)	0 (0,0)
Ermuedung	1 (0,5)	0 (0,0)
Gefuehl anomal	1 (0,5)	0 (0,0)
Leistung vermindert	0 (0,0)	2 (1,1)
Thoraxschmerz nicht kardialen Ursprungs	0 (0,0)	1 (0,5)
Erkrankungen der Atemwege, des Brustraums und Mediastinums	6 (3,1)	0 (0,0)
Interstitielle Lungenerkrankung	2 (1,0)	0 (0,0)
Pneumonitis	4 (2,1)	0 (0,0)
Erkrankungen der Geschlechtsorgane und der Brustdruese	1 (0,5)	0 (0,0)
Fistel des weiblichen Geschlechtstrakts	1 (0,5)	0 (0,0)
Erkrankungen der Haut und des Unterhautgewebes	3 (1,6)	1 (0,5)
Ausschlag	0 (0,0)	1 (0,5)
Ausschlag makulo-papuloes	1 (0,5)	0 (0,0)
Dermatomyositis	1 (0,5)	0 (0,0)
Urtikaria	1 (0,5)	0 (0,0)
Erkrankungen der Nieren und Harnwege	2 (1,0)	2 (1,1)
Akute Nierenschaedigung	0 (0,0)	1 (0,5)
Hydronephrose	1 (0,5)	0 (0,0)
Nephrolithiasis	0 (0,0)	1 (0,5)

Includes adverse events with an onset date or that worsen on or after the date of first dose of study treatment up until the initiation of the first subsequent anti-cancer therapy following discontinuation of study treatment or until the end of safety follow-up period (latest of either 30 days following discontinuation of olaparib/placebo or 90 days following discontinuation of durvalumab/placebo), whichever occurs first.
Number (%) of patients with an adverse event leading to discontinuation of any study treatment or Carboplatin + Paclitaxel.
Patients with multiple events in the same category are counted only once in that category.
Patients with events in more than one category are counted once in each of those categories. MedDRA version 25.1.
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Table 3.5.2.1D DUO-E (pMMR Durva/Ola): Summary of adverse events leading to discontinuation of study treatment (total, and by SOC and PT)
Patients with pMMR tumour status, DCO 12APR2023

System organ class / MedDRA Preferred term	Number (%) of patients CTx + Durvalumab + Olaparib (N=191)	CTx (N=190)
Nierenversagen	1 (0,5)	0 (0,0)
Erkrankungen des Blutes und des Lymphsystems	14 (7,3)	6 (3,2)
Anaemie	9 (4,7)	4 (2,1)
Febrile Neutropenie	1 (0,5)	0 (0,0)
Myelosuppression	1 (0,5)	0 (0,0)
Neutropenie	3 (1,6)	1 (0,5)
Pure red cell aplasia	1 (0,5)	0 (0,0)
Thrombozytopenie	1 (0,5)	1 (0,5)
Erkrankungen des Gastrointestinaltrakts	3 (1,6)	5 (2,6)
Darmobstruktion	0 (0,0)	1 (0,5)
Diarrhoe	0 (0,0)	1 (0,5)
Dyspepsie	0 (0,0)	1 (0,5)
Magenperforation	0 (0,0)	1 (0,5)
Obstipation	0 (0,0)	1 (0,5)
Subileus	1 (0,5)	0 (0,0)
Uebelkeit	2 (1,0)	0 (0,0)
Erkrankungen des Immunsystems	4 (2,1)	0 (0,0)
Anaphylaktischer Schock	1 (0,5)	0 (0,0)
Arzneimittelueberempfindlichkeit	3 (1,6)	0 (0,0)
Erkrankungen des Nervensystems	10 (5,2)	8 (4,2)
Ischialgie	0 (0,0)	1 (0,5)
Periphere Neuropathie	6 (3,1)	4 (2,1)
Periphere sensorische Neuropathie	1 (0,5)	2 (1,1)

Includes adverse events with an onset date or that worsen on or after the date of first dose of study treatment up until the initiation of the first subsequent anti-cancer therapy following discontinuation of study treatment or until the end of safety follow-up period (latest of either 30 days following discontinuation of olaparib/placebo or 90 days following discontinuation of durvalumab/placebo), whichever occurs first.
Number (%) of patients with an adverse event leading to discontinuation of any study treatment or Carboplatin + Paclitaxel.
Patients with multiple events in the same category are counted only once in that category.
Patients with events in more than one category are counted once in each of those categories. MedDRA version 25.1.
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Table 3.5.2.1D DUO-E (pMMR Durva/Ola): Summary of adverse events leading to discontinuation of study treatment (total, and by SOC and PT)
Patients with pMMR tumour status, DCO 12APR2023

System organ class / MedDRA Preferred term	Number (%) of patients CTx + Durvalumab + Olaparib (N=191)	CTx (N=190)
Polyneuropathie	2 (1,0)	0 (0,0)
Sekundaere zerebellaere Degeneration	1 (0,5)	0 (0,0)
Tremor	0 (0,0)	1 (0,5)
Infektionen und parasitaere Erkrankungen	5 (2,6)	3 (1,6)
COVID-19	0 (0,0)	1 (0,5)
COVID-19-Lungenentzuendung	1 (0,5)	0 (0,0)
Diszitis	1 (0,5)	0 (0,0)
Harnwegsinfektion	1 (0,5)	1 (0,5)
Hepatitis C	1 (0,5)	0 (0,0)
Lungenabszess	1 (0,5)	0 (0,0)
Pneumonie	1 (0,5)	0 (0,0)
Postoperative Wundinfektion	1 (0,5)	0 (0,0)
Urosepsis	0 (0,0)	1 (0,5)
Leber- und Gallenerkrankungen	1 (0,5)	0 (0,0)
Leberfunktion anomal	1 (0,5)	0 (0,0)
Psychiatrische Erkrankungen	0 (0,0)	1 (0,5)
Angst	0 (0,0)	1 (0,5)
Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen	2 (1,0)	2 (1,1)
Arthralgie	1 (0,5)	0 (0,0)
Myalgie	1 (0,5)	0 (0,0)
Rueckenschmerzen	0 (0,0)	2 (1,1)
Stoffwechsel- und Ernaehrungsstoerungen	1 (0,5)	0 (0,0)

Includes adverse events with an onset date or that worsen on or after the date of first dose of study treatment up until the initiation of the first subsequent anti-cancer therapy following discontinuation of study treatment or until the end of safety follow-up period (latest of either 30 days following discontinuation of olaparib/placebo or 90 days following discontinuation of durvalumab/placebo), whichever occurs first.
Number (%) of patients with an adverse event leading to discontinuation of any study treatment or Carboplatin + Paclitaxel.
Patients with multiple events in the same category are counted only once in that category.
Patients with events in more than one category are counted once in each of those categories. MedDRA version 25.1.
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Table 3.5.2.1D DUO-E (pMMR Durva/Ola): Summary of adverse events leading to discontinuation of study treatment (total, and by SOC and PT)
Patients with pMMR tumour status, DCO 12APR2023

System organ class / MedDRA Preferred term	Number (%) of patients CTx + Durvalumab + Olaparib (N=191)	CTx (N=190)
Hypalbuminaemie	1 (0,5)	0 (0,0)
Untersuchungen	3 (1,6)	4 (2,1)
Alaninaminotransferase erhoeht	1 (0,5)	1 (0,5)
Aspartataminotransferase erhoeht	1 (0,5)	1 (0,5)
Erythroblastenzahl erhoeht	1 (0,5)	0 (0,0)
Kreatinin im Blut erhoeht	0 (0,0)	2 (1,1)
Leukozytenzahl erniedrigt	1 (0,5)	0 (0,0)
Monozytenzahl erhoeht	1 (0,5)	0 (0,0)
Neutrophilenzahl erniedrigt	1 (0,5)	0 (0,0)
Thrombozytenzahl vermindert	0 (0,0)	1 (0,5)
Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	5 (2,6)	10 (5,3)
Reaktion im Zusammenhang mit einer Infusion	5 (2,6)	10 (5,3)

Includes adverse events with an onset date or that worsen on or after the date of first dose of study treatment up until the initiation of the first subsequent anti-cancer therapy following discontinuation of study treatment or until the end of safety follow-up period (latest of either 30 days following discontinuation of olaparib/placebo or 90 days following discontinuation of durvalumab/placebo), whichever occurs first.
Number (%) of patients with an adverse event leading to discontinuation of any study treatment or Carboplatin + Paclitaxel.
Patients with multiple events in the same category are counted only once in that category.
Patients with events in more than one category are counted once in each of those categories. MedDRA version 25.1.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/aediscsumdc1.sas gaediscsumdc1b 18APR2024:12:50

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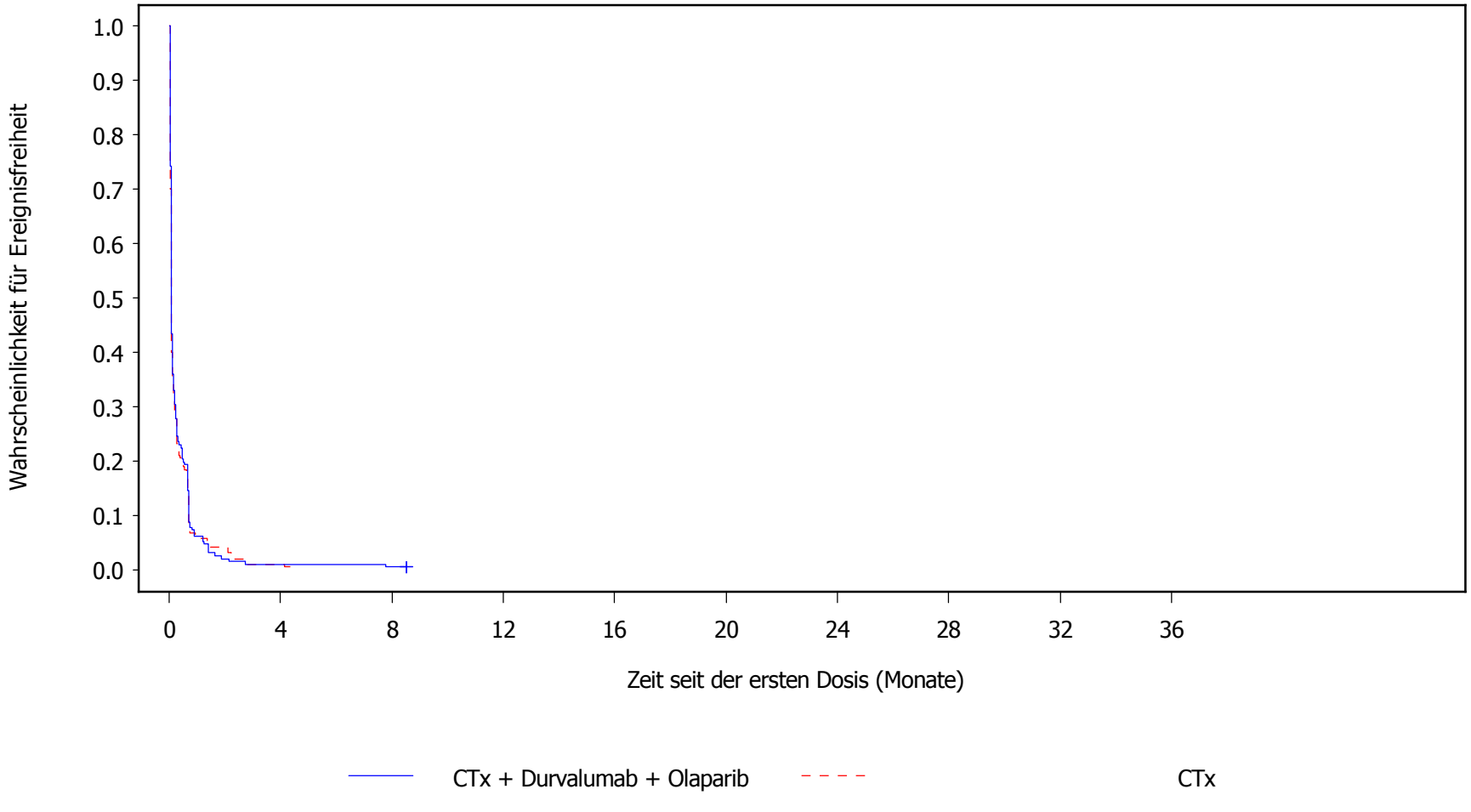
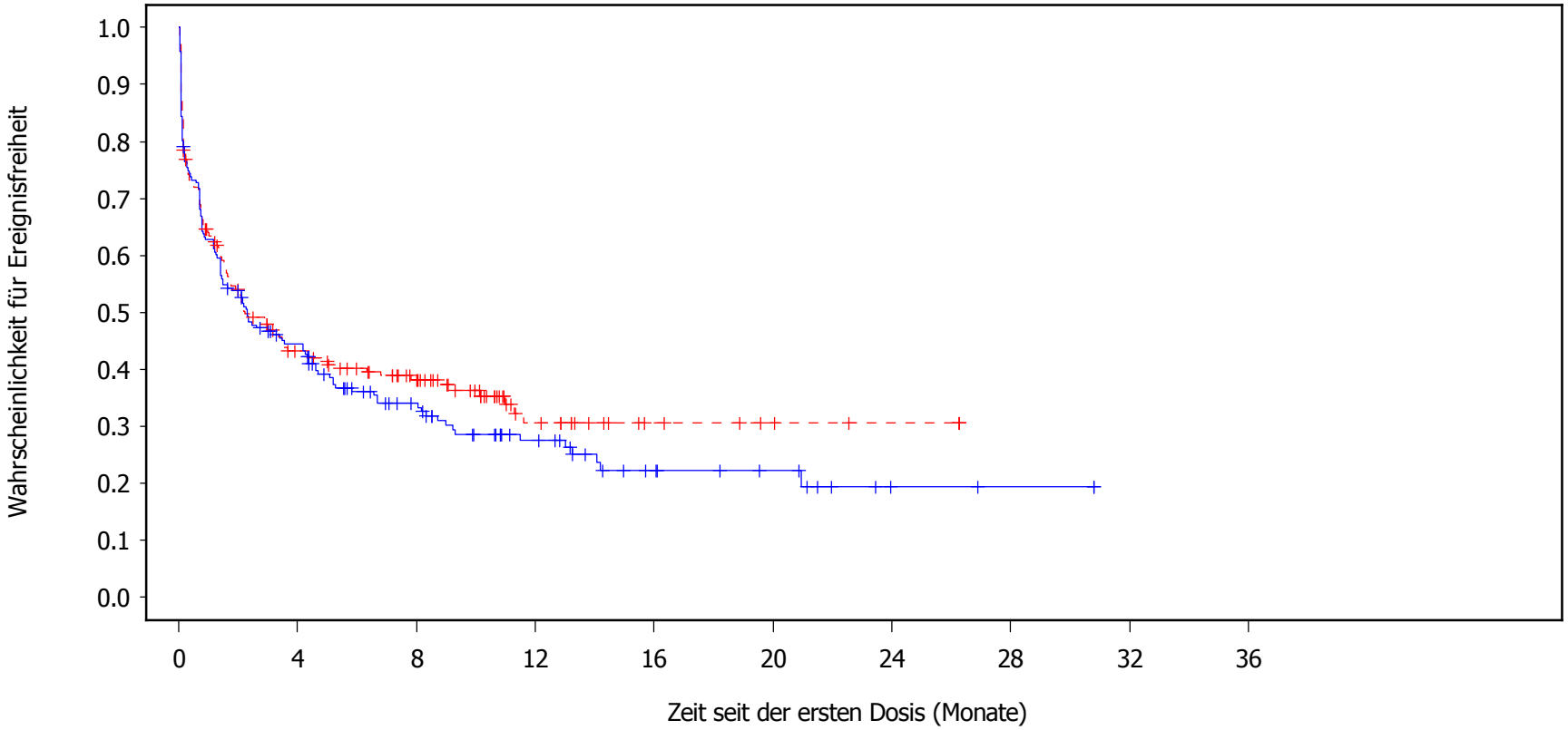
Figure 3.3.2.1D.1 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UE
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	2	1	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
190	2	0	0	0	0	0	0	0	0	CTx

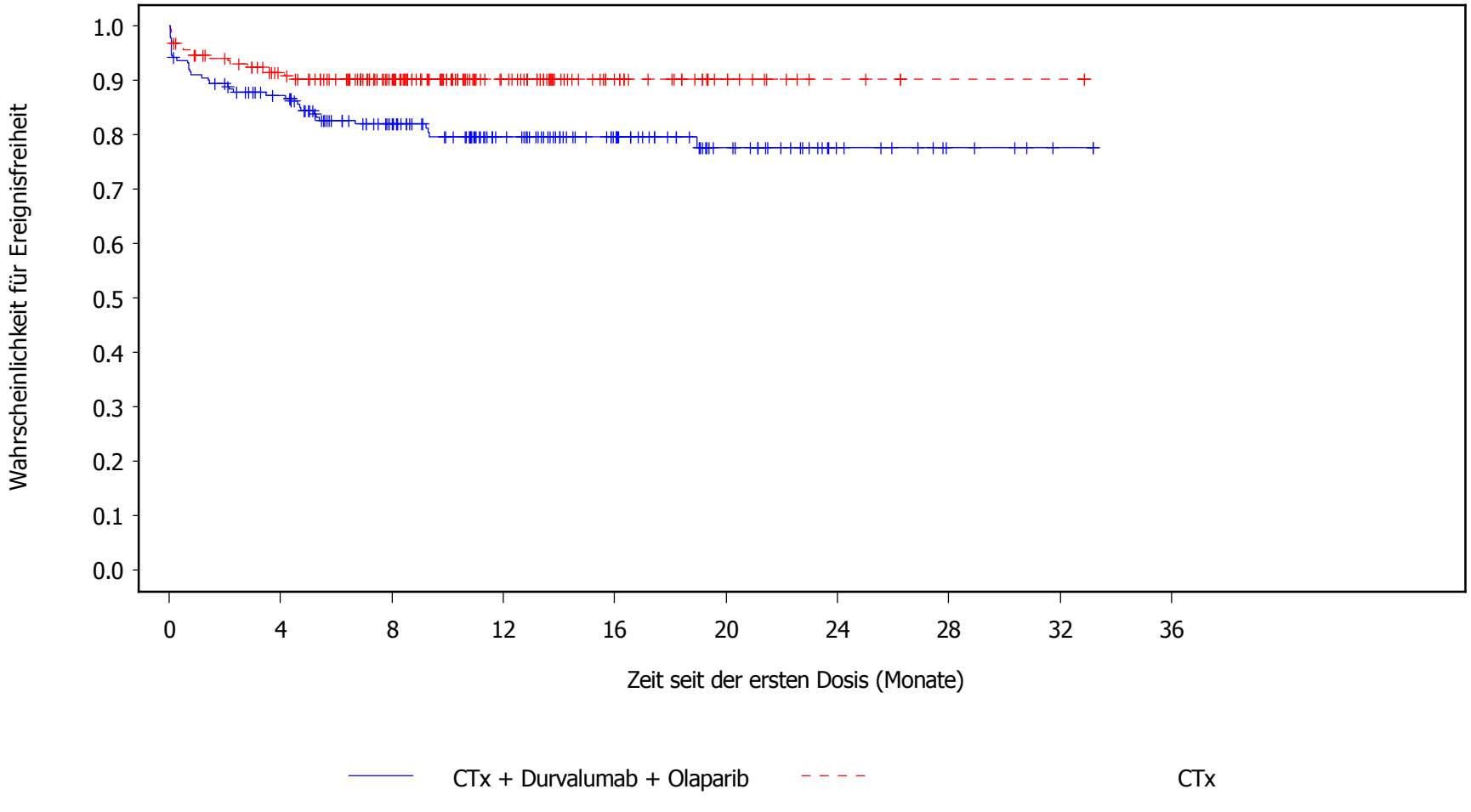
Figure 3.3.2.1D.2 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	78	46	26	13	9	2	1	0	0	CTx + Durvalumab + Olaparib
190	72	50	18	7	4	2	0	0	0	CTx

Figure 3.3.2.1D.3 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Asthenie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	156	117	80	54	30	12	5	1	0	CTx + Durvalumab + Olaparib
190	158	117	63	31	13	4	1	1	0	CTx

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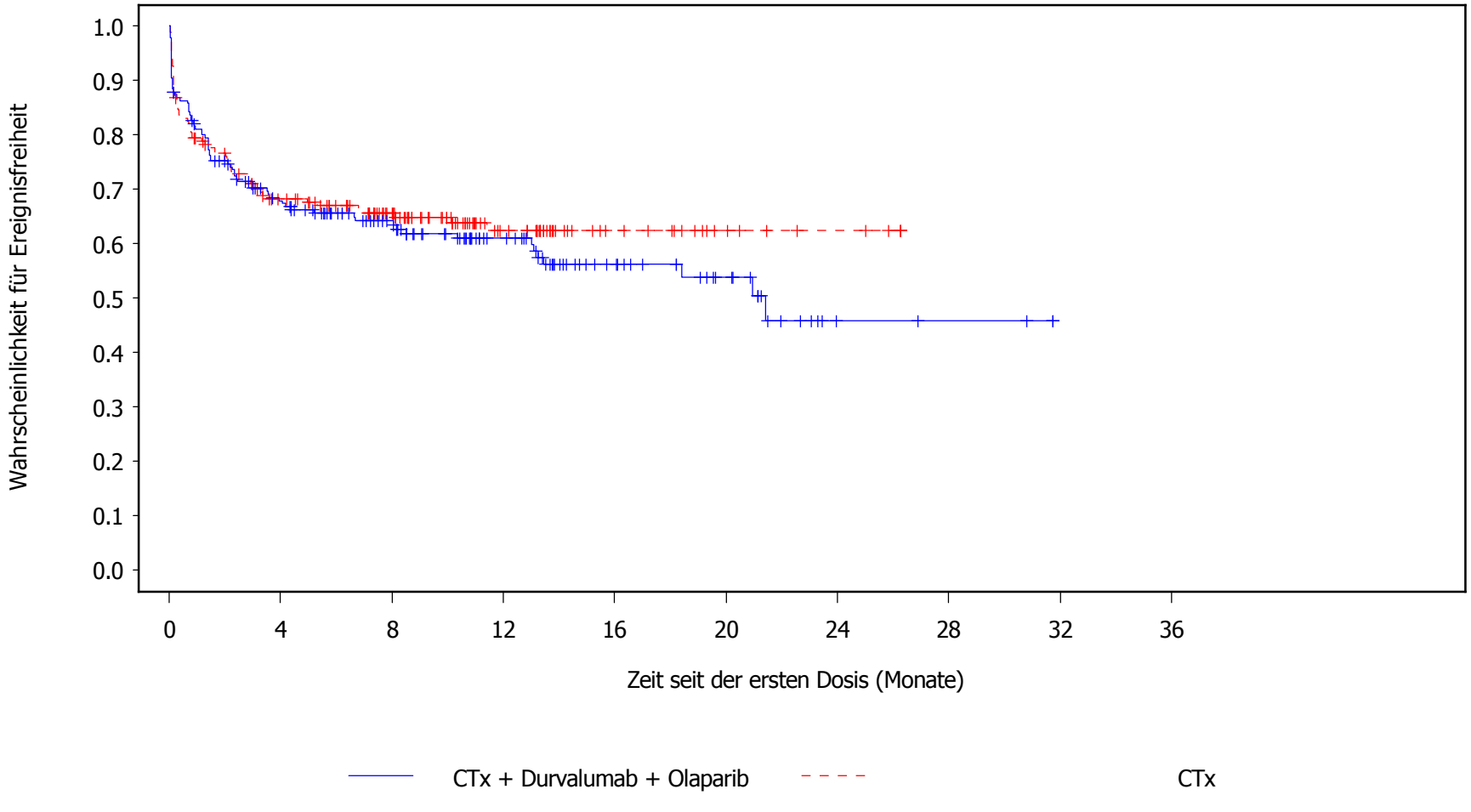
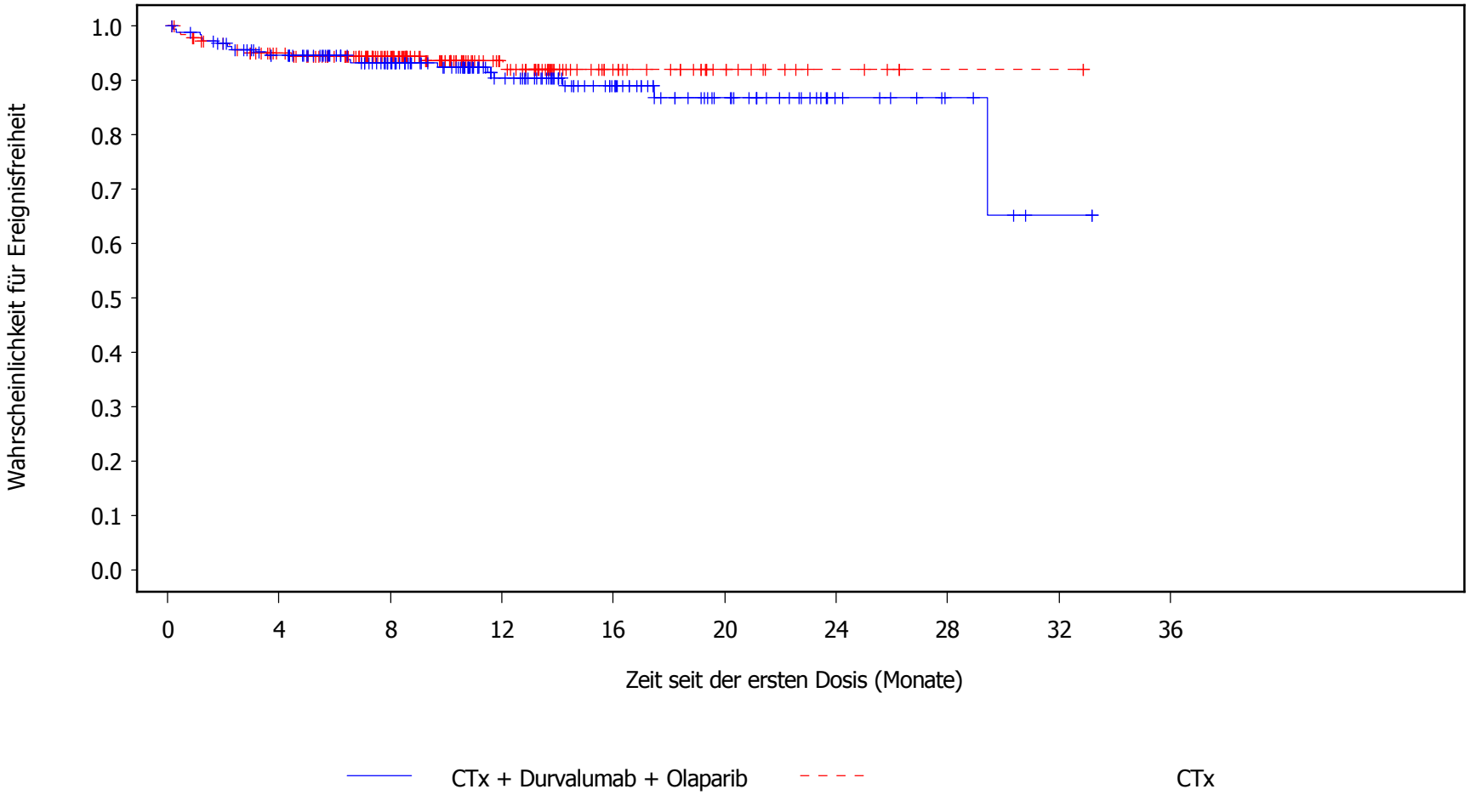
Figure 3.3.2.1D.4 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Ermuedung
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	117	87	56	31	19	3	2	0	0	CTx + Durvalumab + Olaparib
190	116	84	40	17	8	4	0	0	0	CTx

Figure 3.3.2.1D.5 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Fieber
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	167	131	87	54	30	11	5	1	0	CTx + Durvalumab + Olaparib
190	165	121	65	30	14	5	1	1	0	CTx

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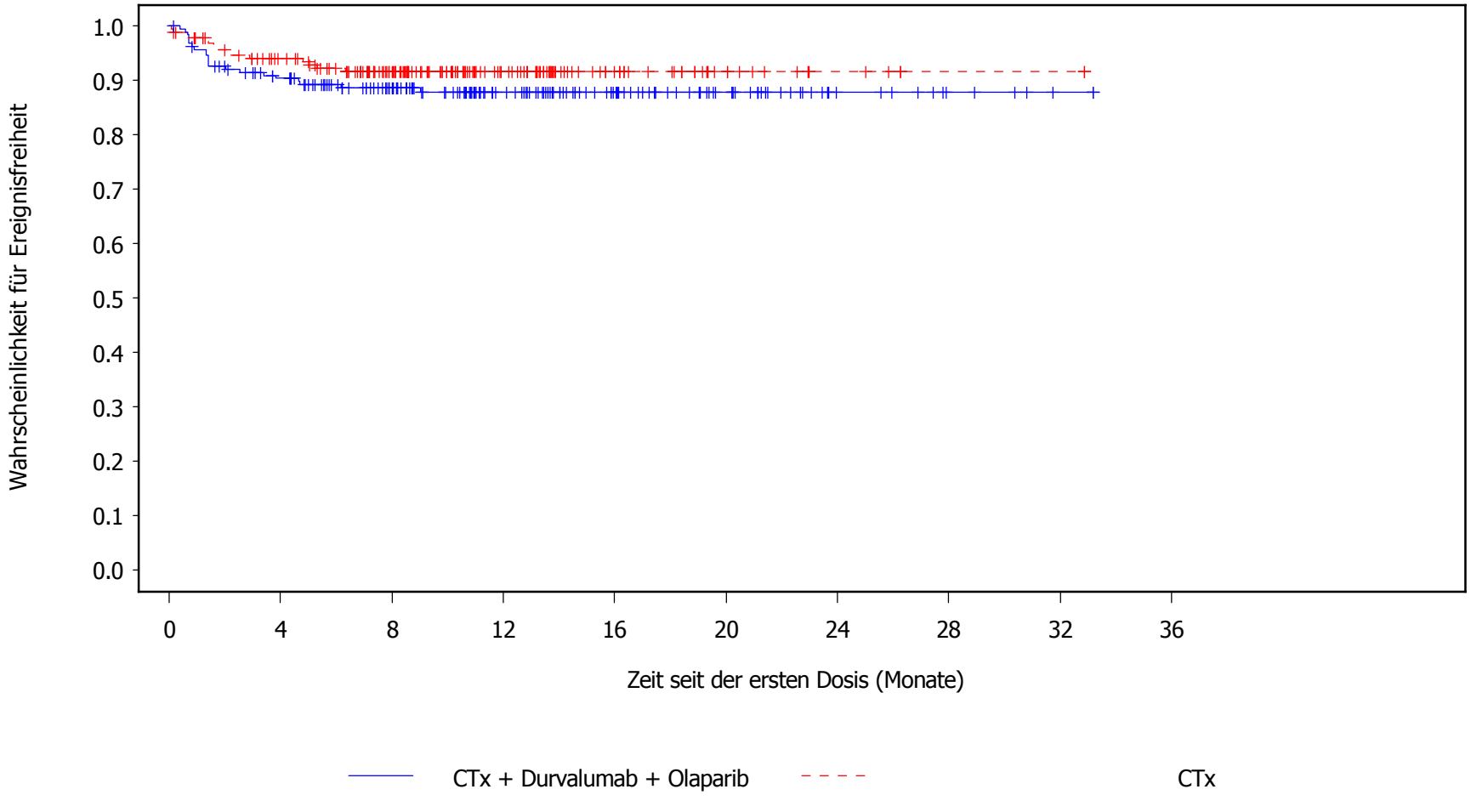
Figure 3.3.2.1D.6 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Oedem peripher
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	161	125	84	54	32	11	5	1	0	CTx + Durvalumab + Olaparib
190	163	119	65	31	13	5	1	1	0	CTx

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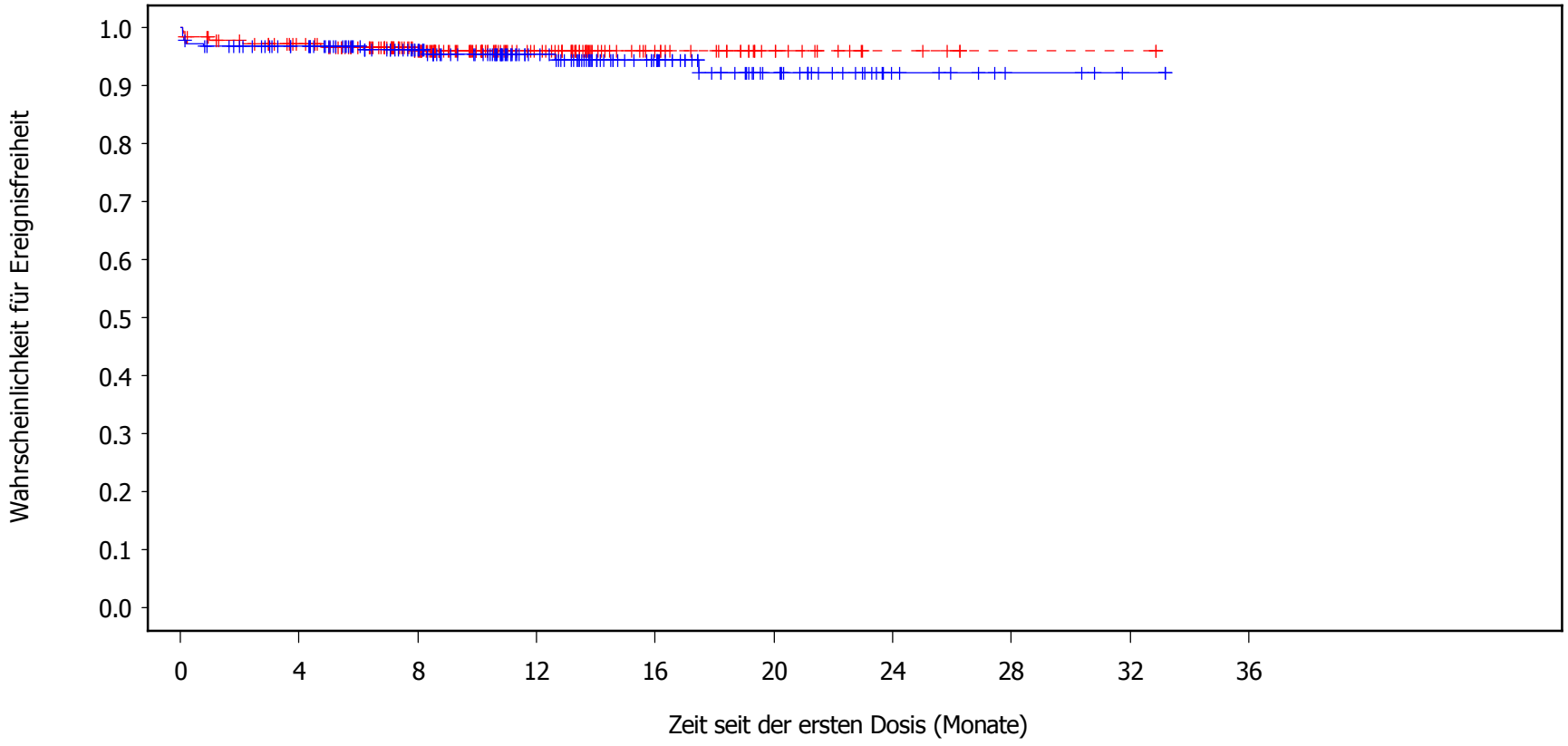
Figure 3.3.2.1D.7 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schmerz
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	170	134	92	58	31	10	4	1	0	CTx + Durvalumab + Olaparib
190	170	124	68	33	15	5	1	1	0	CTx

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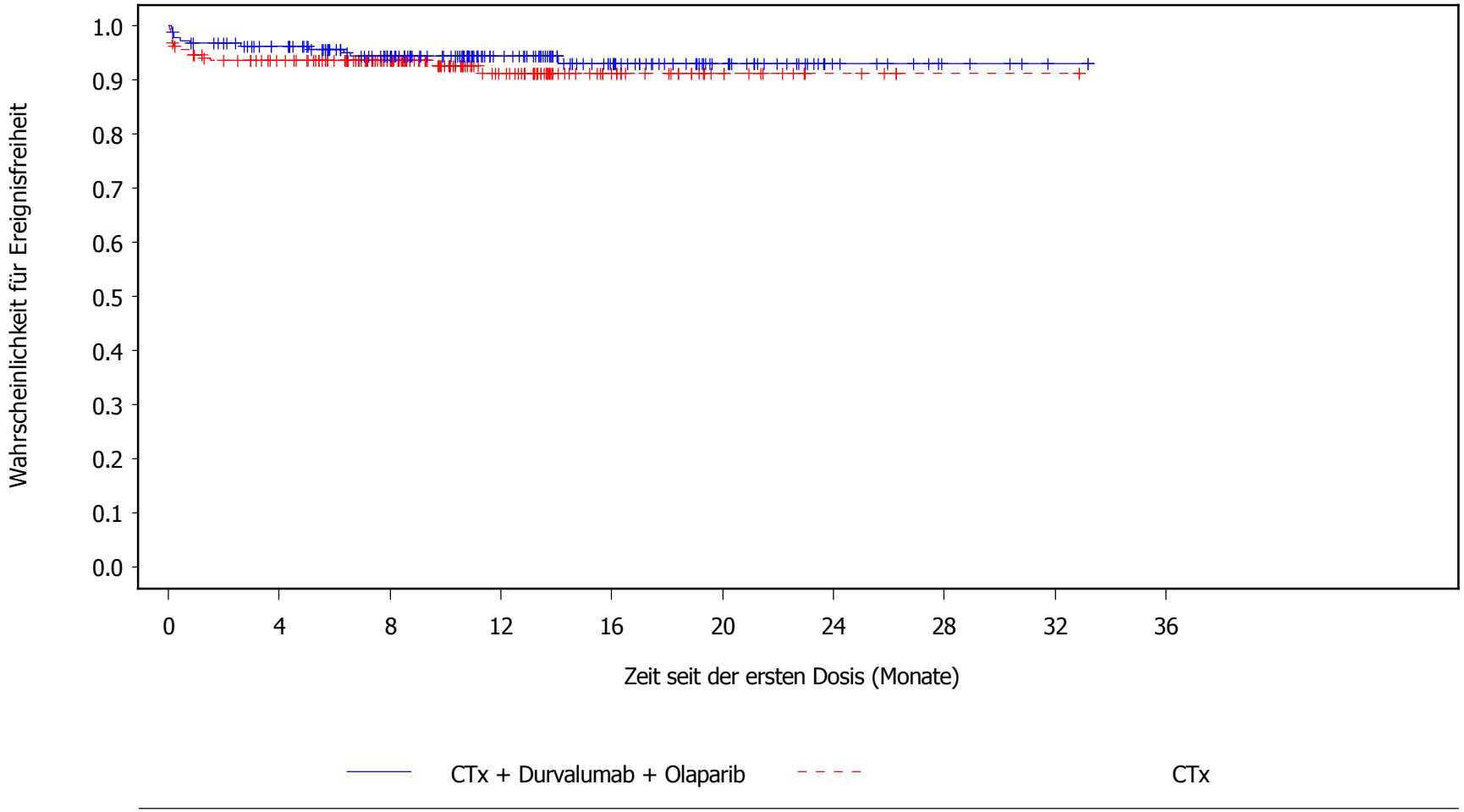
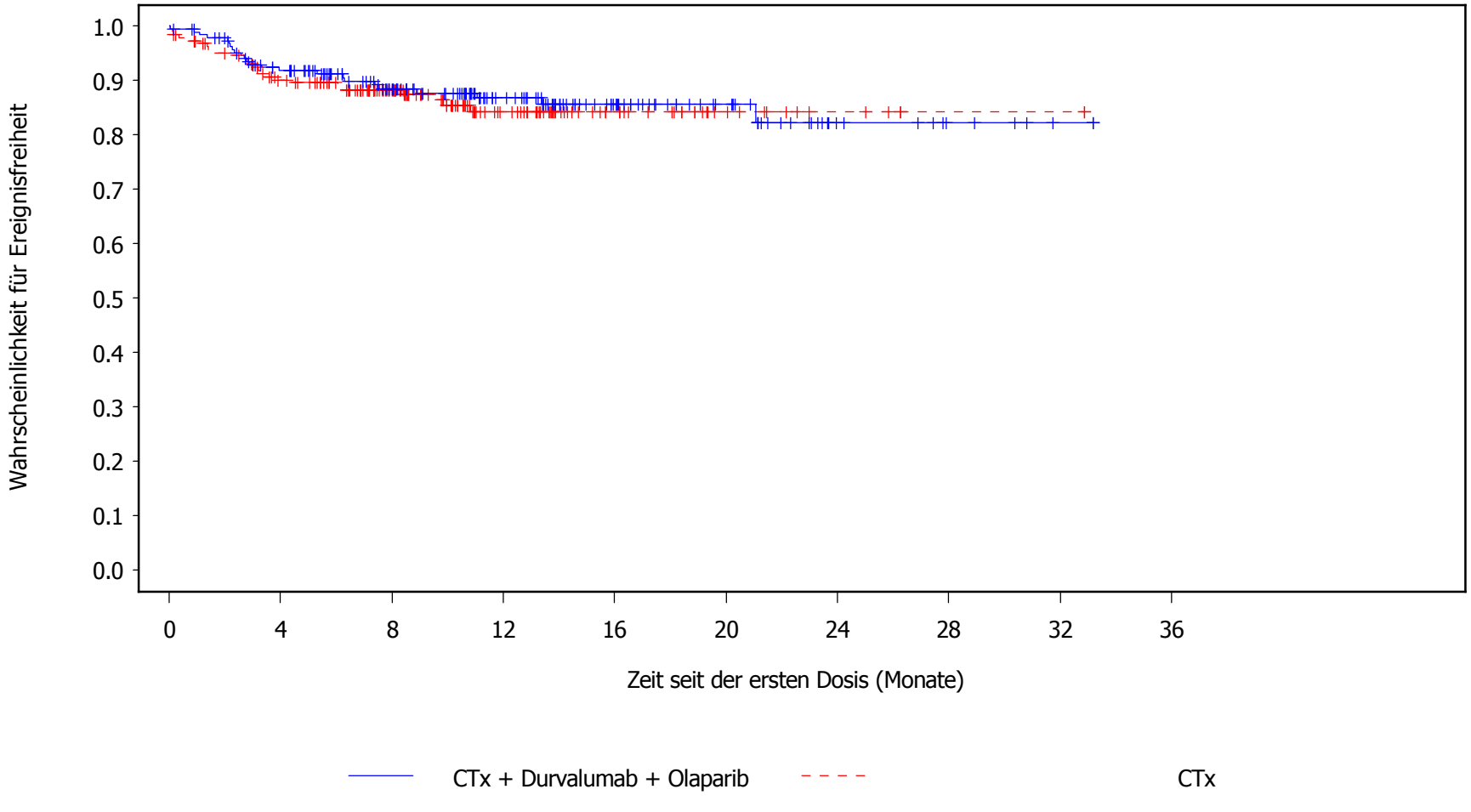
Figure 3.3.2.1D.8 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Unwohlsein
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	169	135	93	60	34	12	5	1	0	CTx + Durvalumab + Olaparib
190	163	120	66	31	14	5	1	1	0	CTx

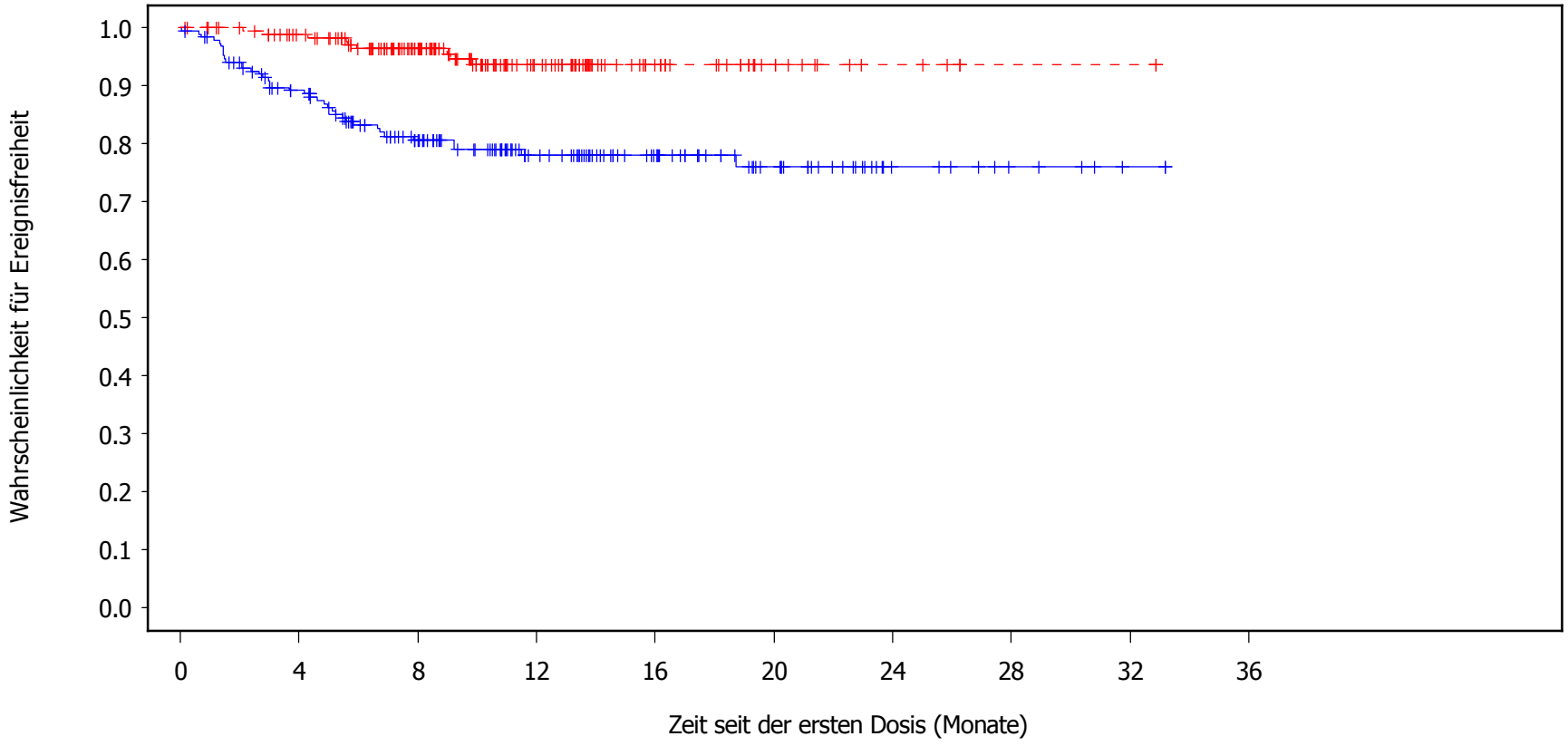
Figure 3.3.2.1D.9 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Augenerkrankungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	161	123	83	50	31	10	5	1	0	CTx + Durvalumab + Olaparib
190	156	111	57	27	12	5	1	1	0	CTx

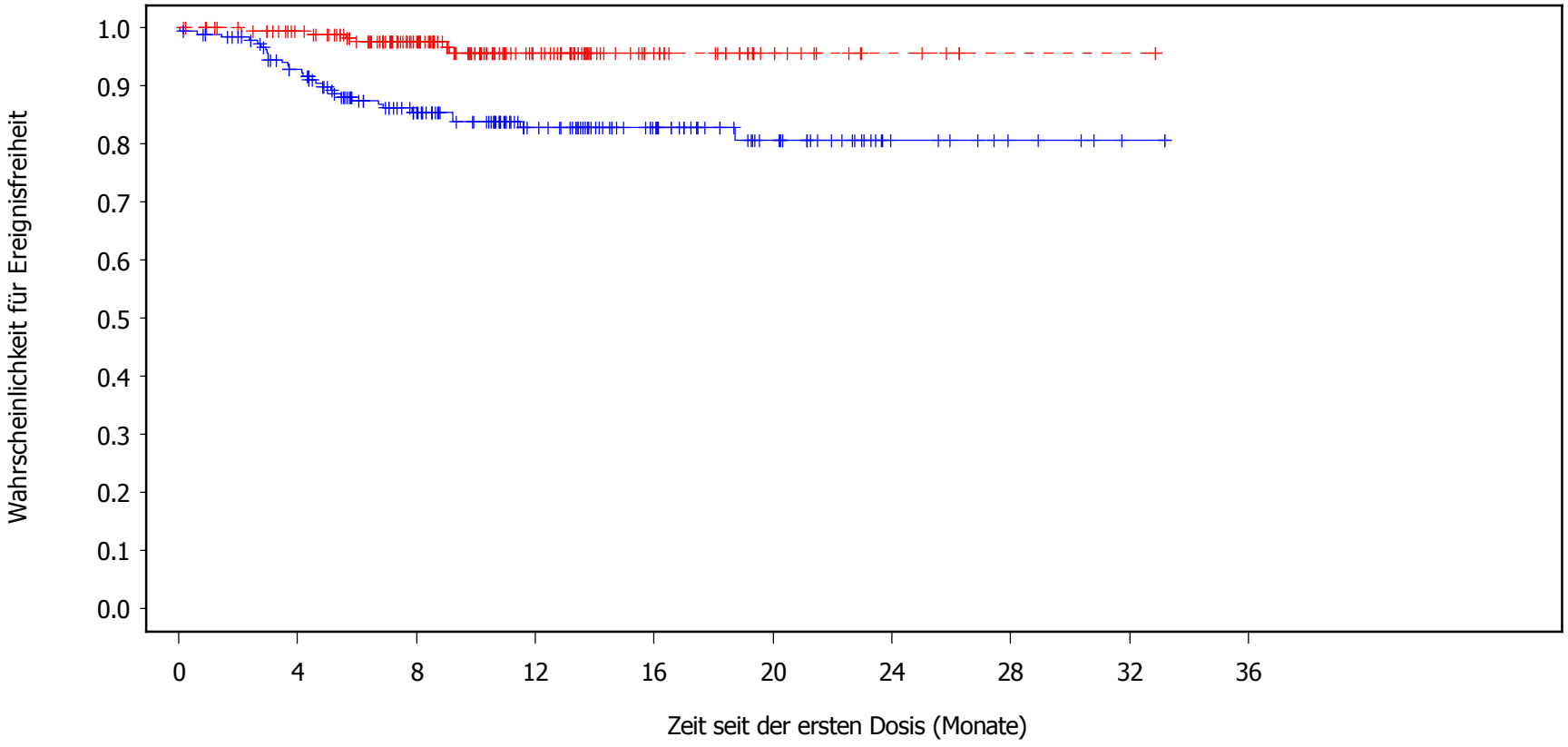
Figure 3.3.2.1D.10 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Endokrine Erkrankungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	156	116	76	51	30	10	5	1	0	CTx + Durvalumab + Olaparib
190	172	122	64	30	13	5	1	1	0	CTx

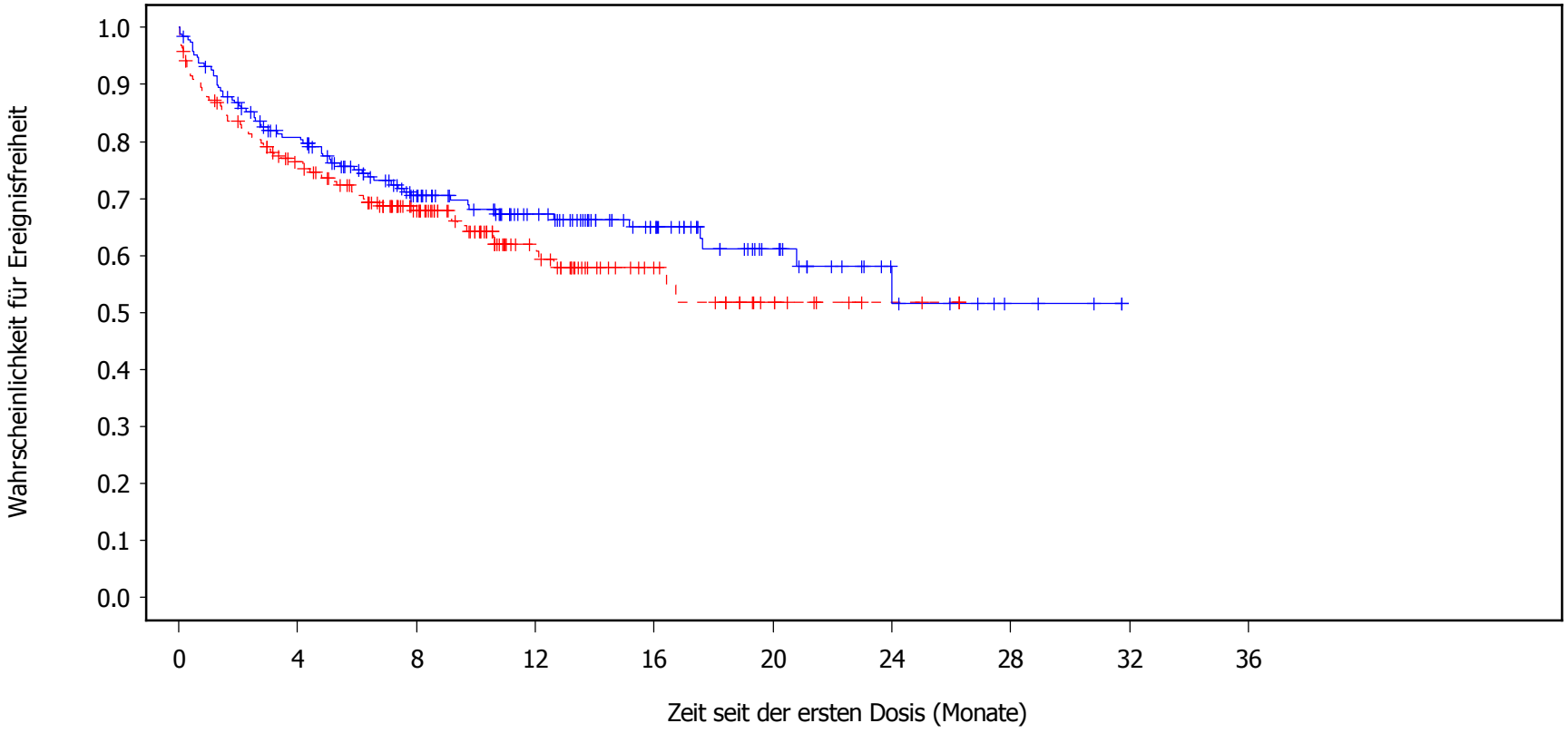
Figure 3.3.2.1D.11 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypothyreose
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	163	121	79	53	30	10	5	1	0	CTx + Durvalumab + Olaparib
190	173	124	67	32	14	5	1	1	0	CTx

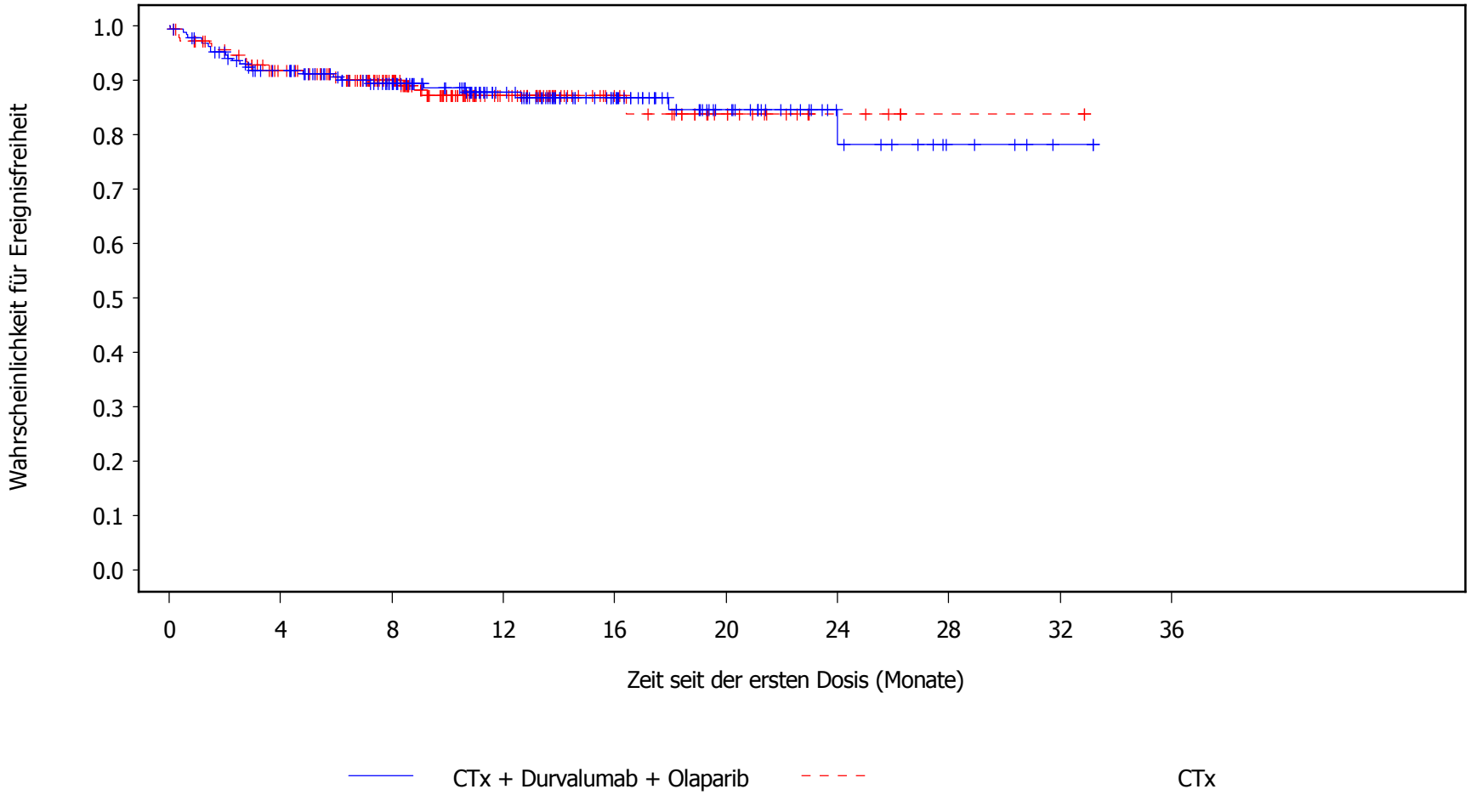
Figure 3.3.2.1D.12 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	144	102	72	45	23	8	3	0	0	CTx + Durvalumab + Olaparib
190	134	91	45	21	9	2	0	0	0	CTx

Figure 3.3.2.1D.13 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Dyspnoe
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	162	128	89	57	31	12	5	1	0	CTx + Durvalumab + Olaparib
190	159	115	60	29	15	5	1	1	0	CTx

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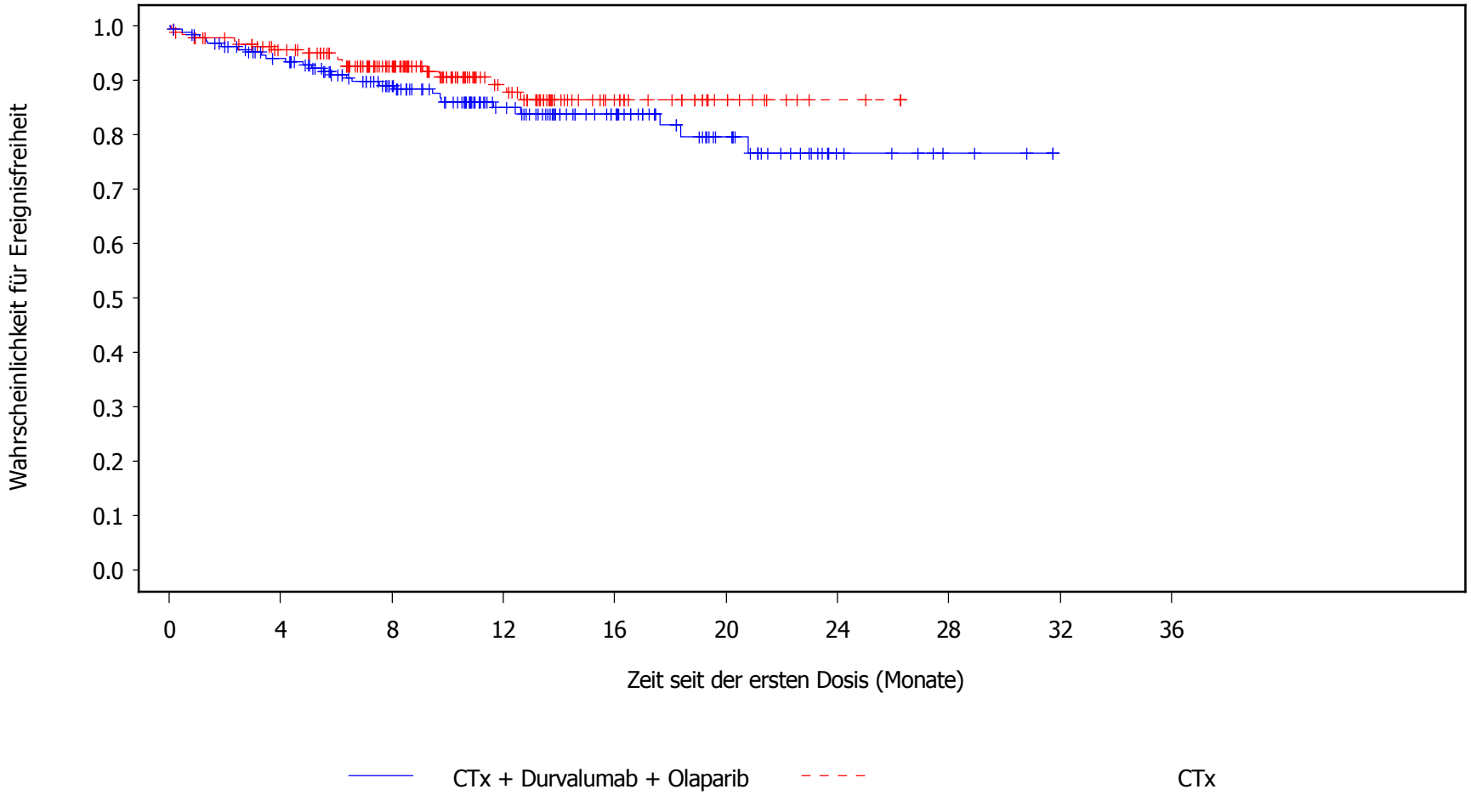
Figure 3.3.2.1D.14 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Husten
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	166	126	83	55	30	8	3	0	0	CTx + Durvalumab + Olaparib
190	166	119	64	30	12	3	0	0	0	CTx

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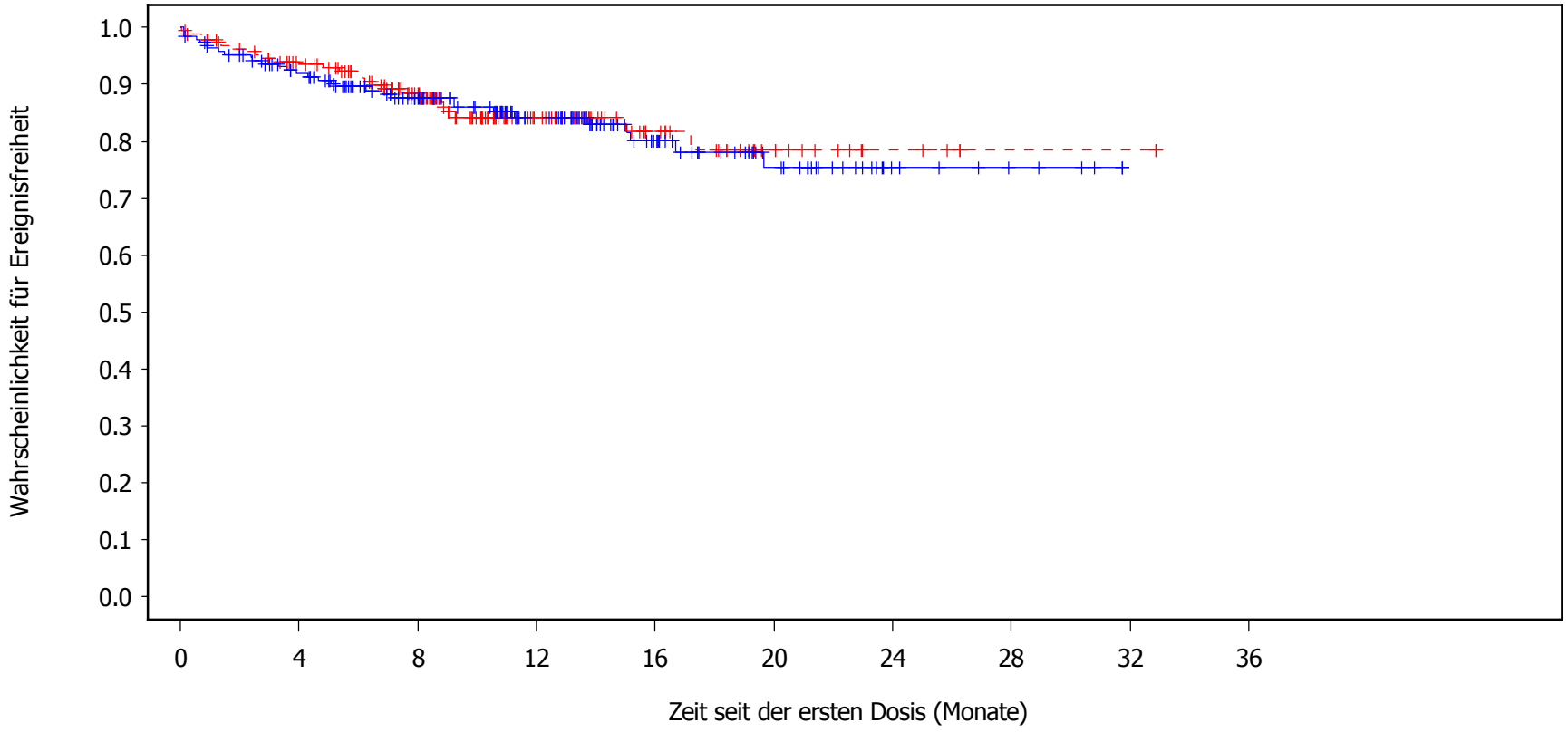
Figure 3.3.2.1D.15 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	162	123	82	49	27	8	4	0	0	CTx + Durvalumab + Olaparib
190	163	120	62	29	14	5	1	1	0	CTx

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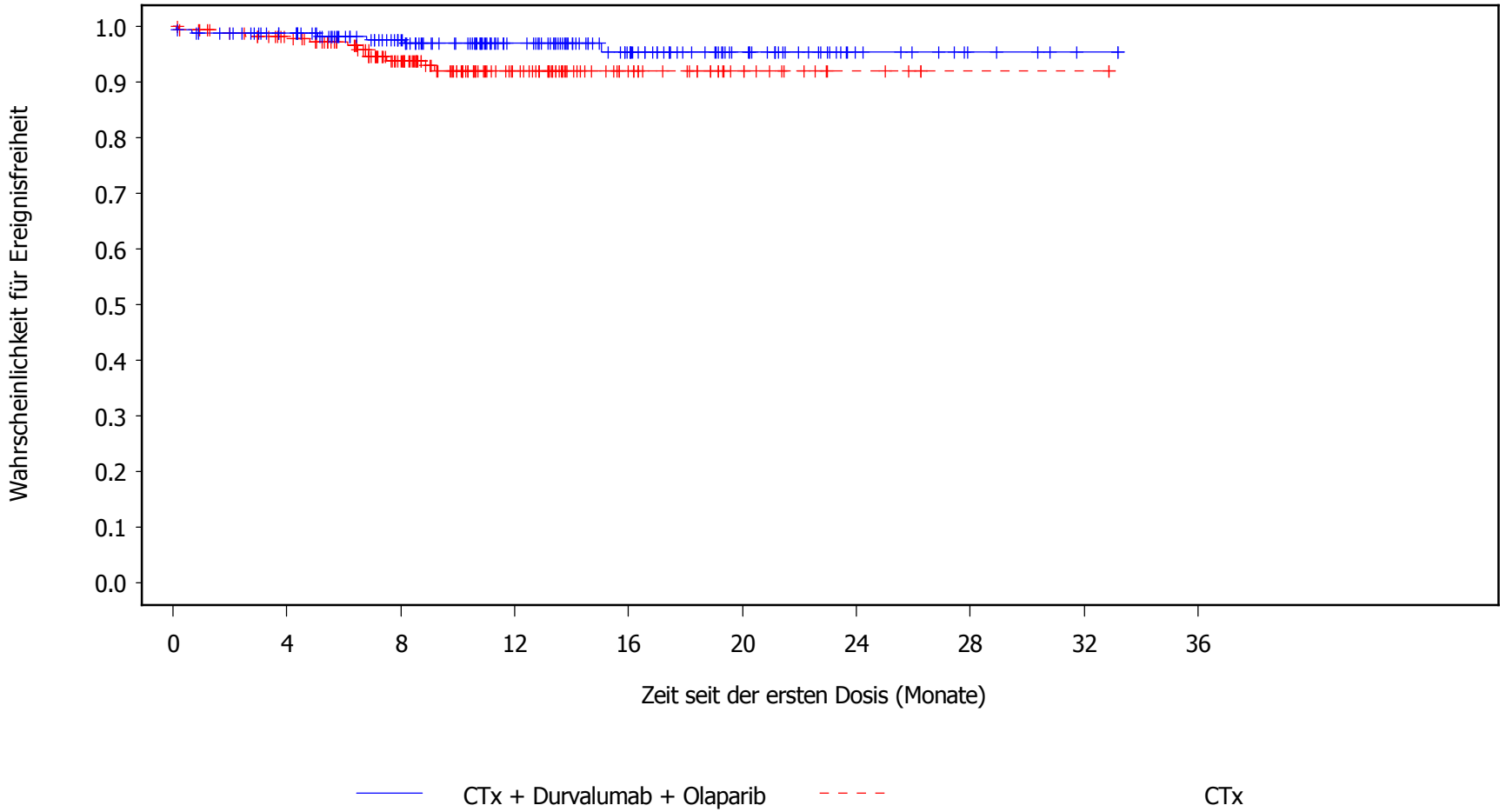
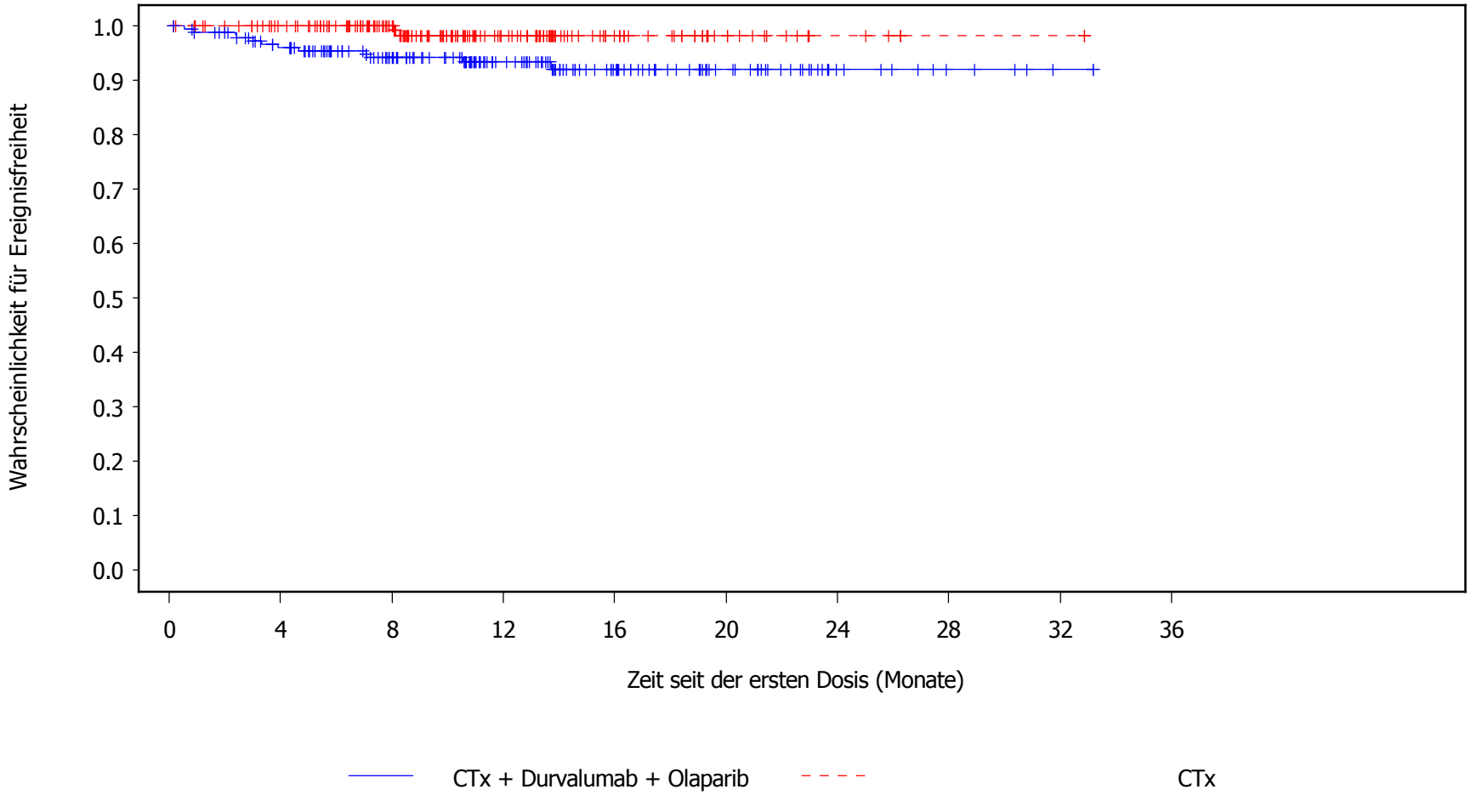
Figure 3.3.2.1D.16 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Vaginale Blutung
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	175	140	96	62	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	171	123	67	33	15	5	1	1	0	CTx

Figure 3.3.2.1D.17 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Vaginaler Ausfluss
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	169	131	89	55	32	11	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	69	34	15	5	1	1	0	CTx

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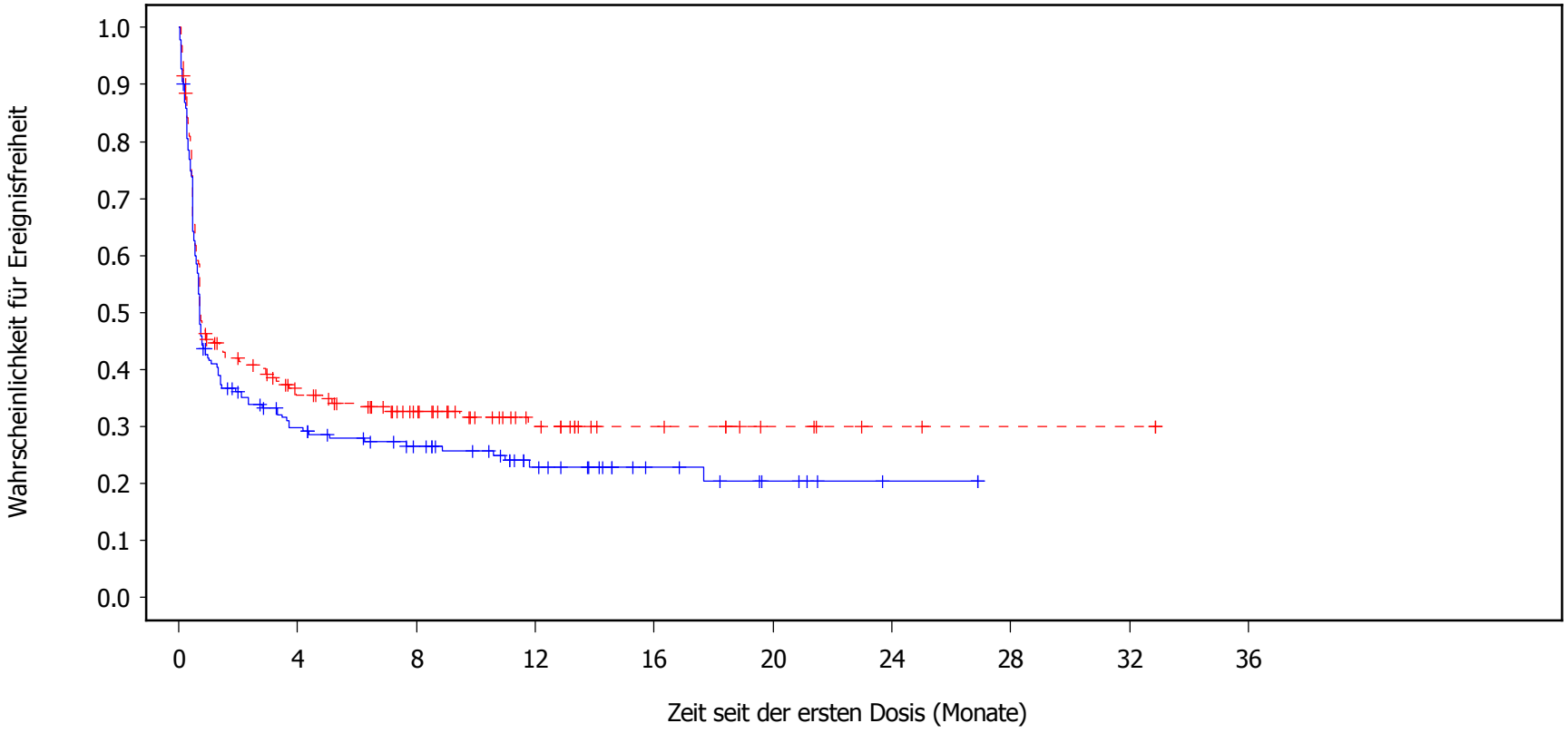
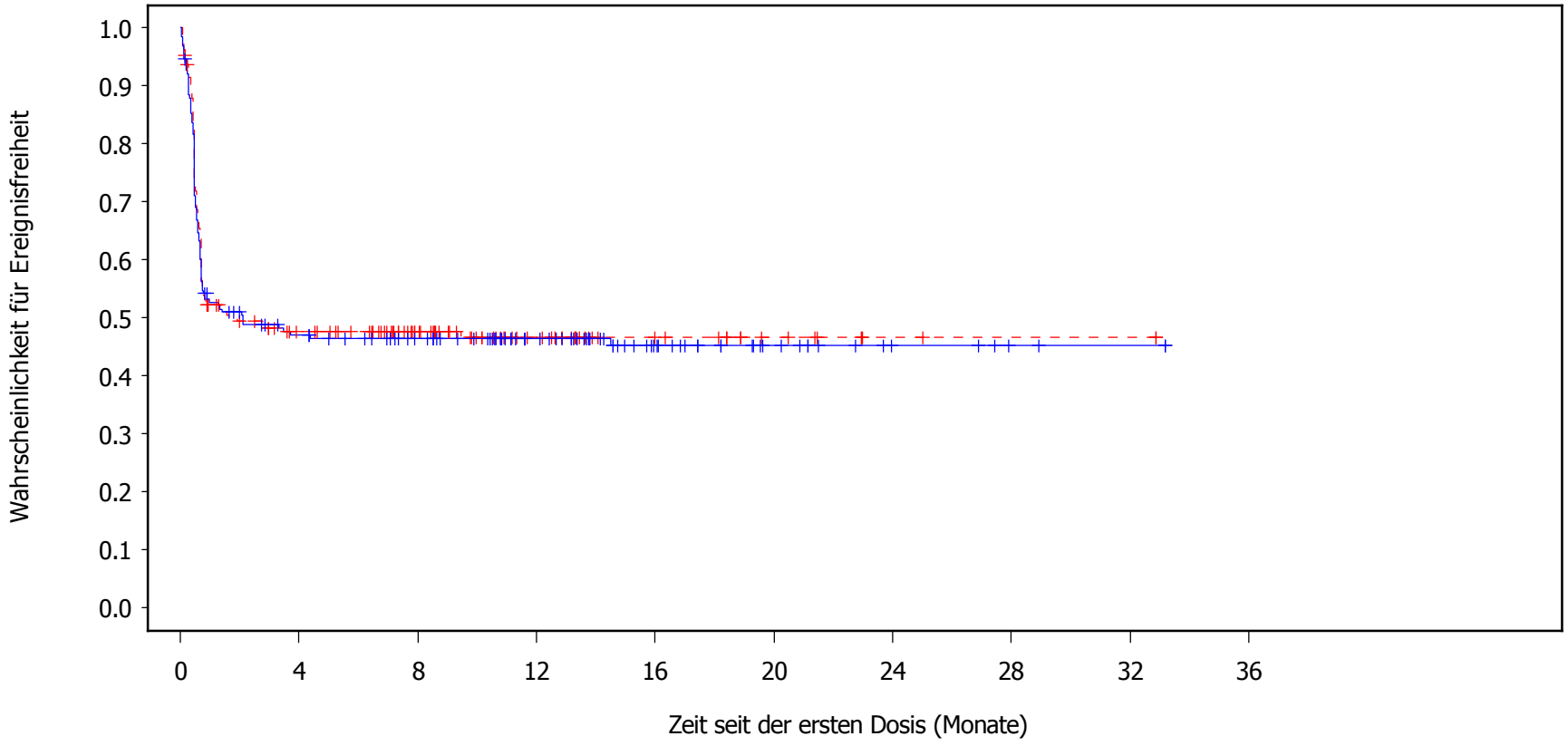
Figure 3.3.2.1D.18 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Haut und des Unterhautgewebes
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	50	37	21	10	5	1	0	0	0	CTx + Durvalumab + Olaparib
190	57	38	19	10	5	2	1	1	0	CTx

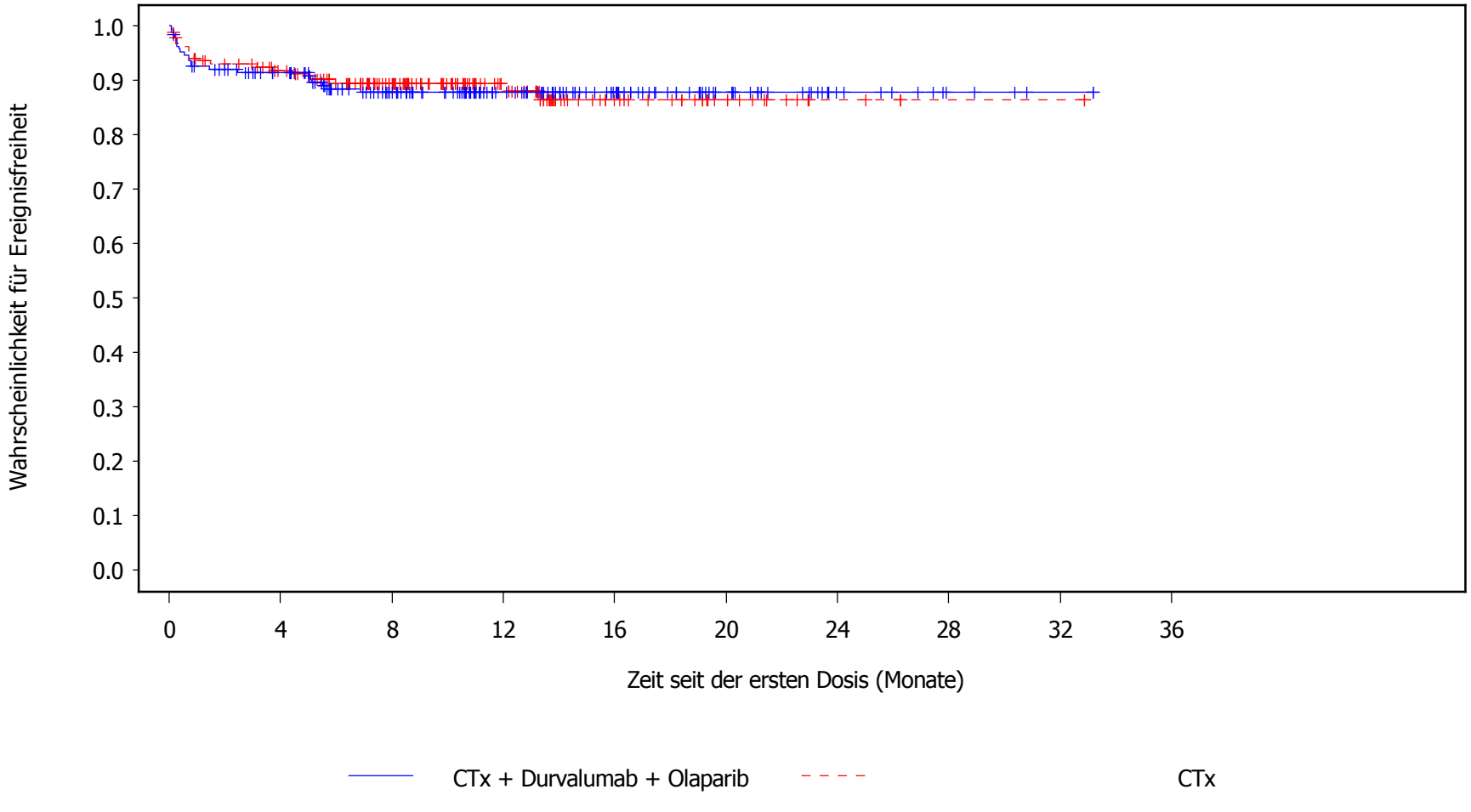
Figure 3.3.2.1D.19 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Alopezie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	82	69	48	26	13	5	2	1	0	CTx + Durvalumab + Olaparib
190	78	54	29	15	7	2	1	1	0	CTx

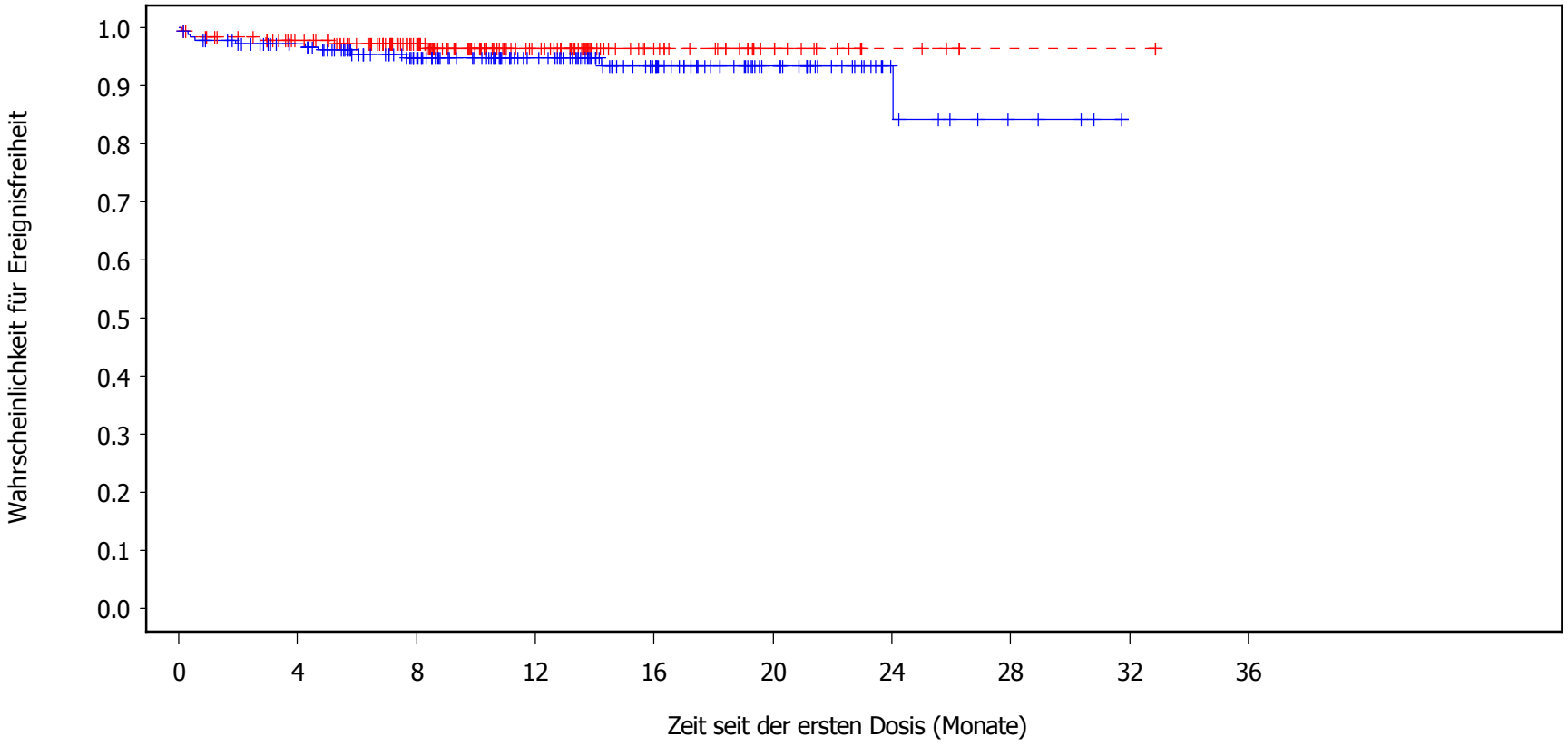
Figure 3.3.2.1D.20 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Ausschlag
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	160	121	83	54	30	11	4	1	0	CTx + Durvalumab + Olaparib
190	160	115	63	28	14	4	1	1	0	CTx

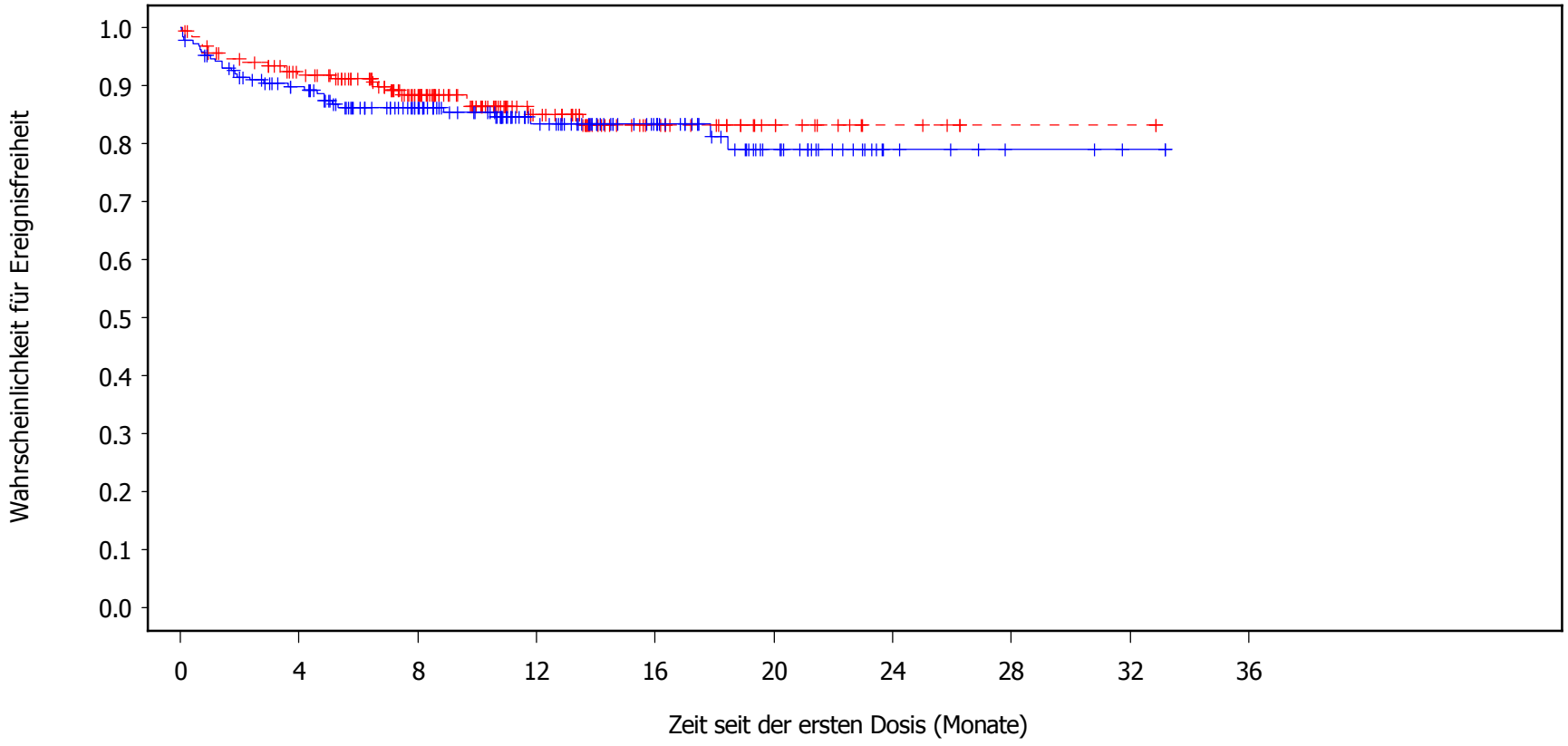
Figure 3.3.2.1D.21 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Ausschlag makulo-papuloes
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	171	134	95	60	33	10	4	0	0	CTx + Durvalumab + Olaparib
190	170	125	68	33	15	5	1	1	0	CTx

Figure 3.3.2.1D.22 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Pruritus
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	157	118	78	50	26	7	3	1	0	CTx + Durvalumab + Olaparib
190	159	112	59	28	14	5	1	1	0	CTx

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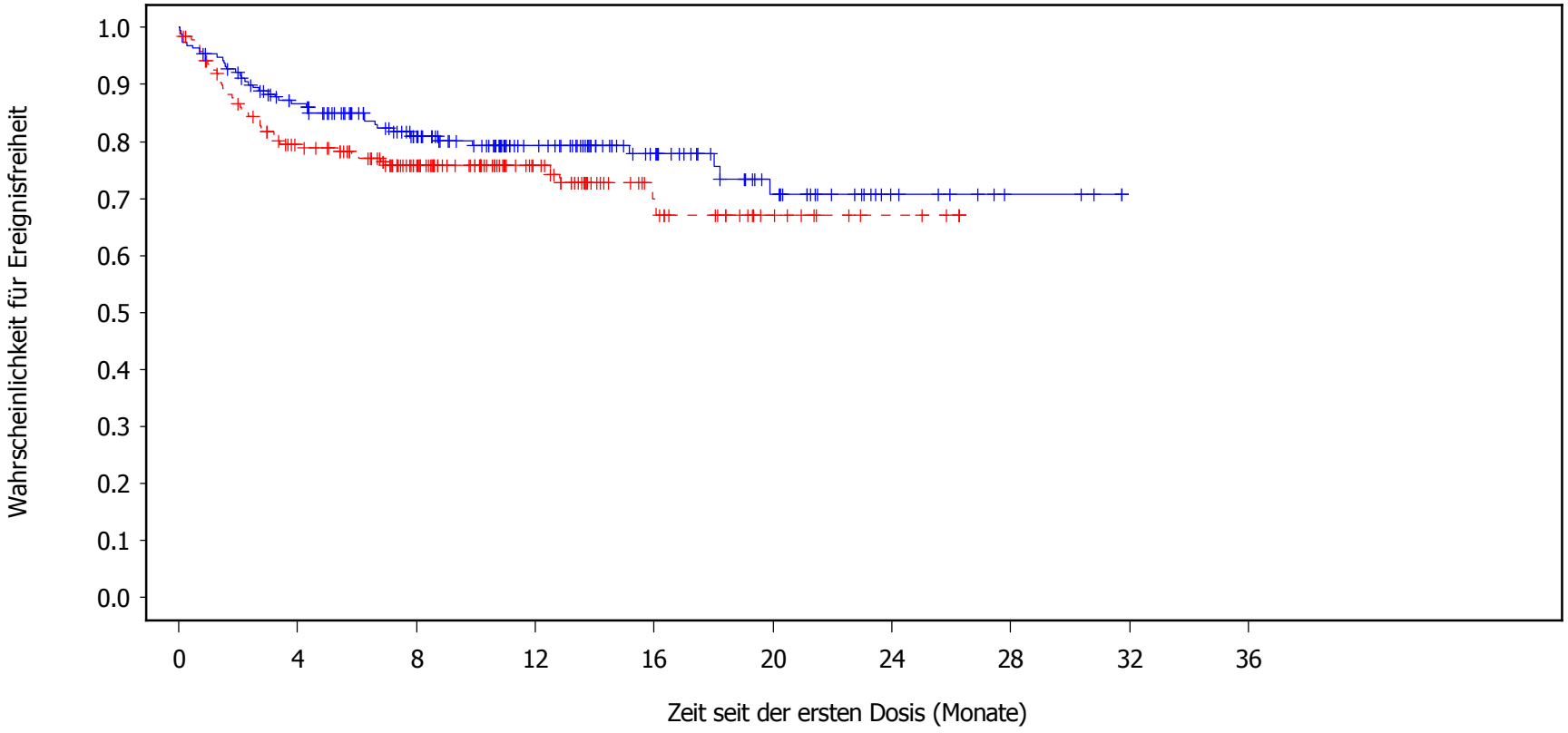
Figure 3.3.2.1D.23 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Nieren und Harnwege
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	153	114	76	47	26	9	3	0	0	CTx + Durvalumab + Olaparib
190	138	98	54	25	11	4	0	0	0	CTx

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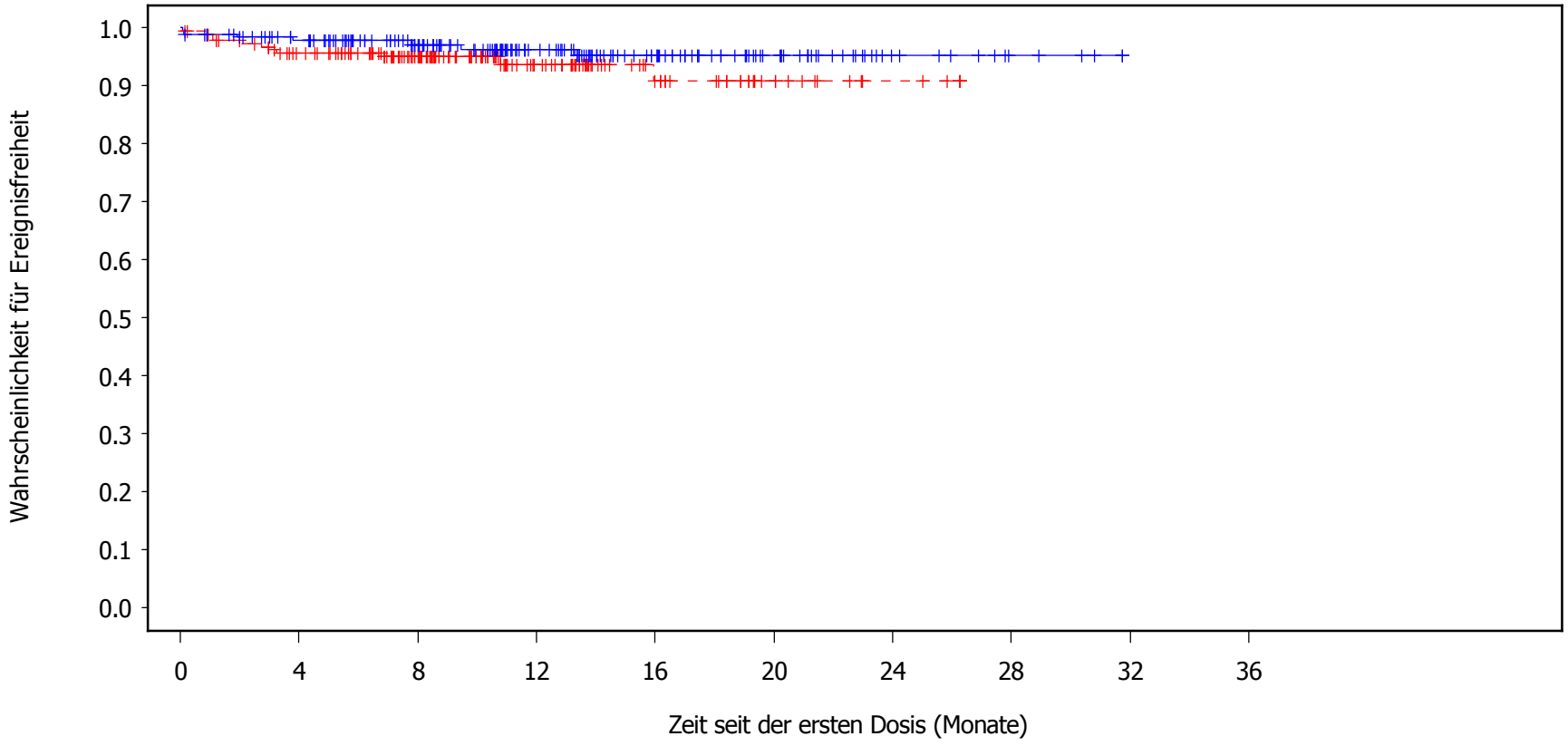
Figure 3.3.2.1D.24 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Pollakisurie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	172	137	92	58	33	11	4	0	0	CTx + Durvalumab + Olaparib
190	166	120	64	31	13	4	0	0	0	CTx

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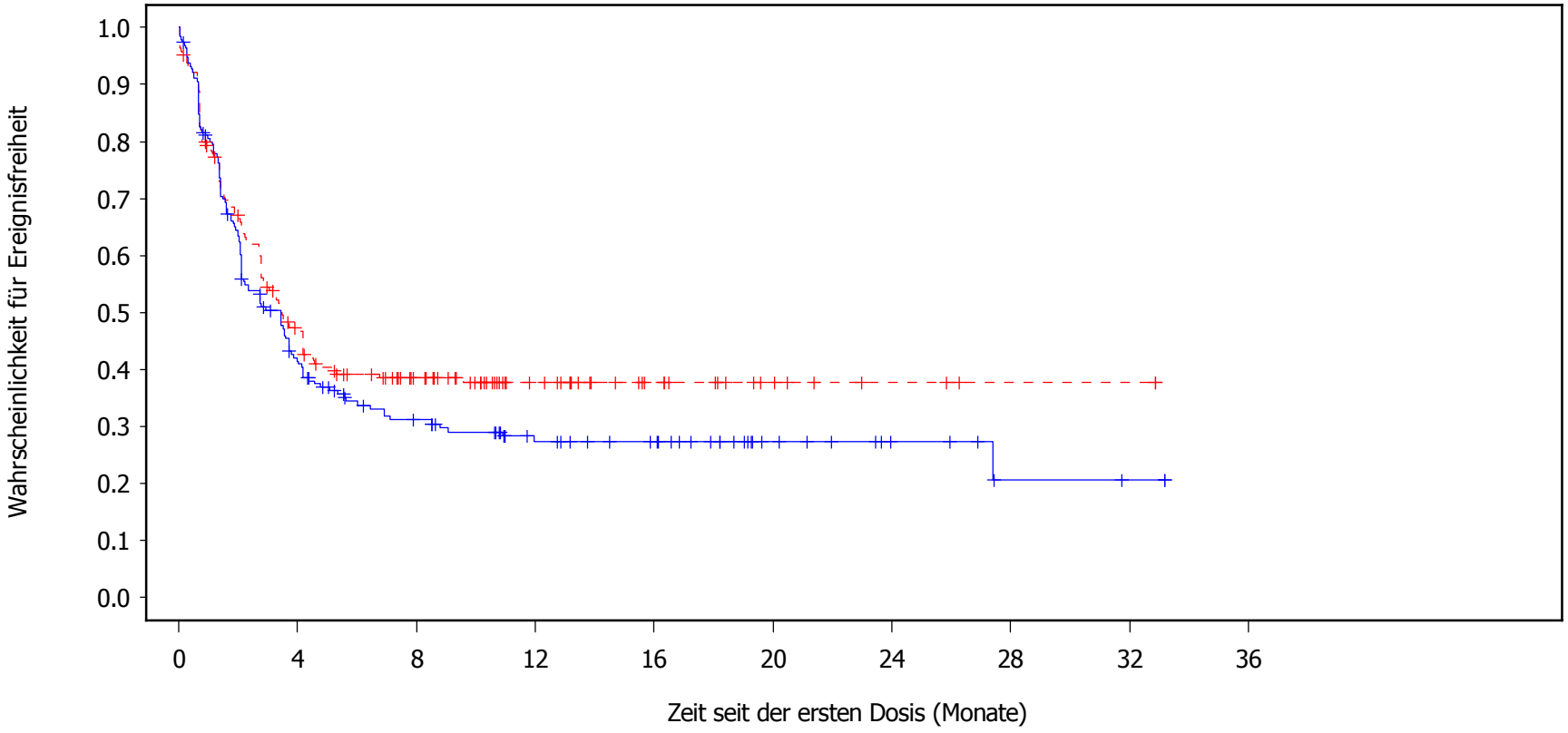
Figure 3.3.2.1D.25 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with pMMR tumour status, DCO 12APR2023

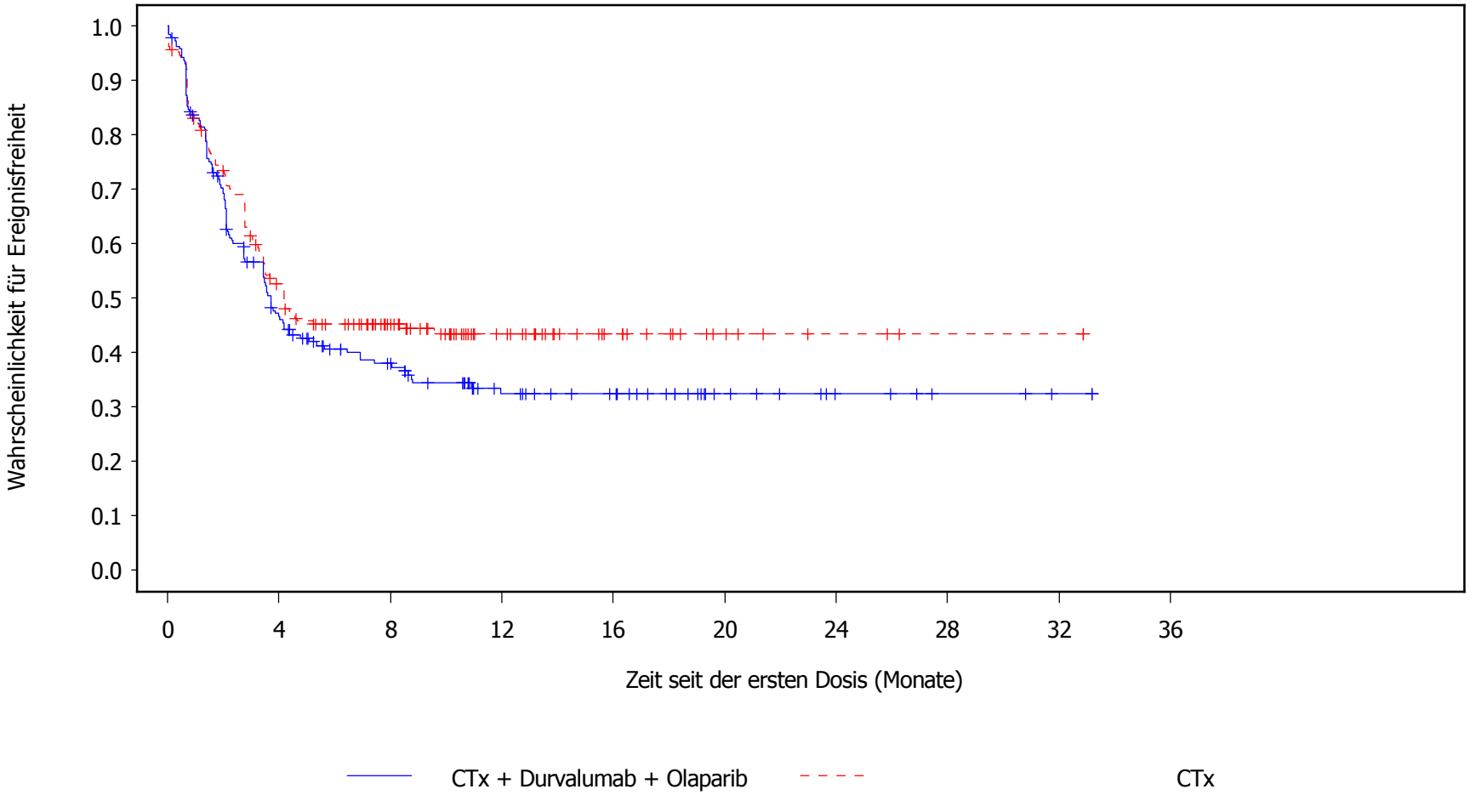


Anzahl an Patienten unter Risiko:

191	74	47	32	26	12	6	2	1	0	CTx + Durvalumab + Olaparib
190	82	52	28	15	7	3	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bay 17APR2024:11:32

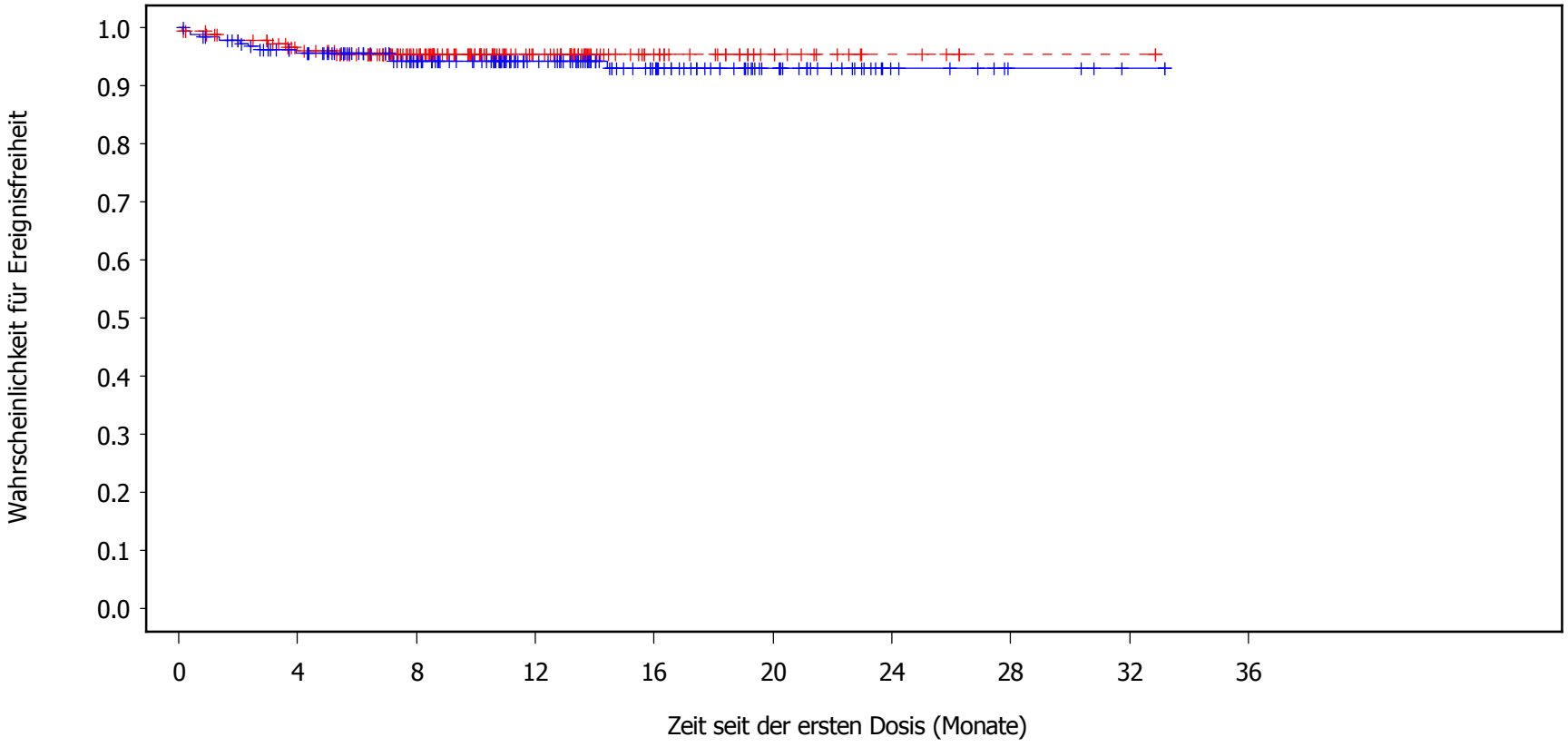
Figure 3.3.2.1D.26 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Anaemie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	83	55	33	26	12	6	3	1	0	CTx + Durvalumab + Olaparib
190	93	60	32	16	7	3	1	1	0	CTx

Figure 3.3.2.1D.27 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Leukopenie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	168	133	92	58	32	10	4	1	0	CTx + Durvalumab + Olaparib
190	168	124	68	33	15	5	1	1	0	CTx

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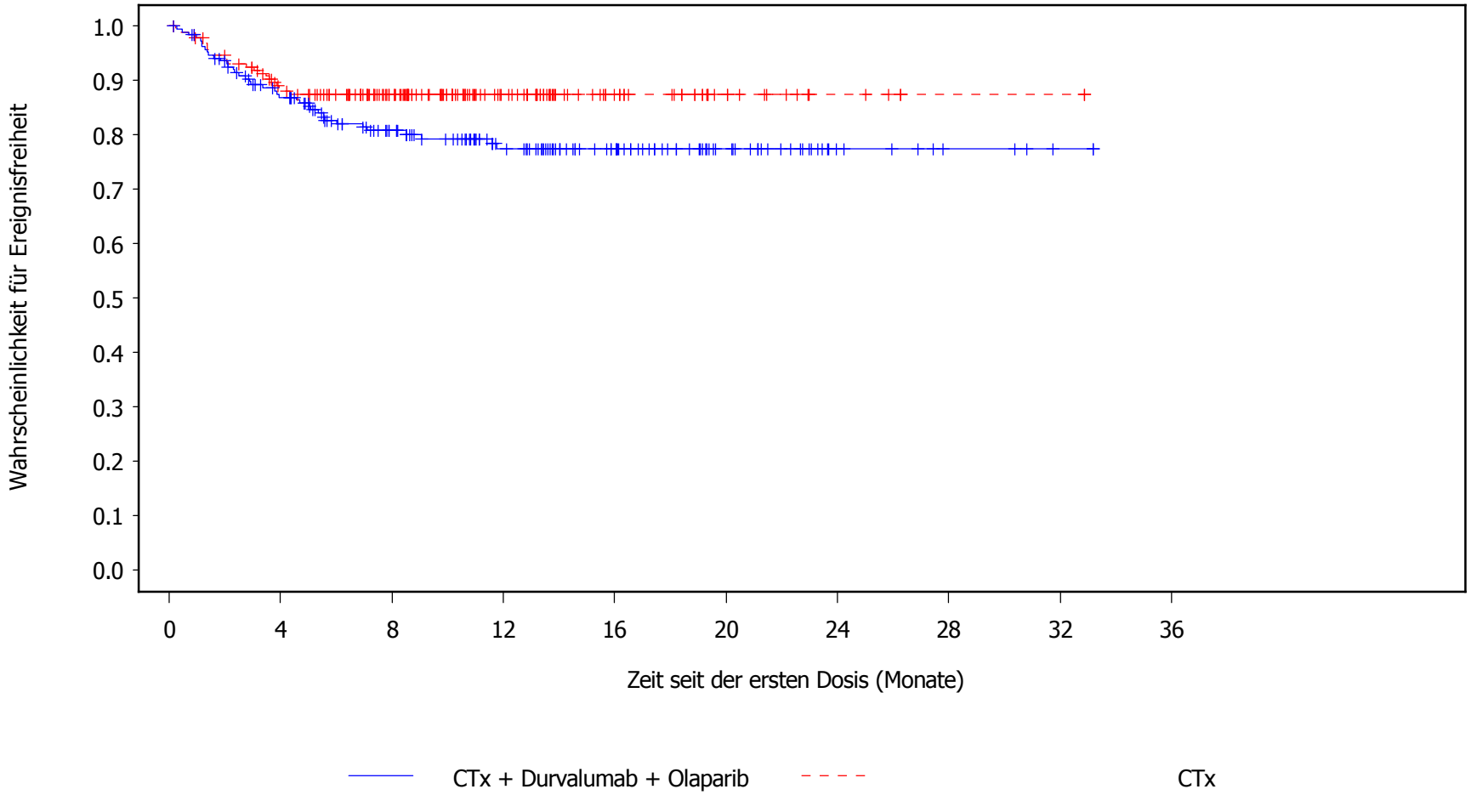
Figure 3.3.2.1D.28 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Neutropenie
Patients with pMMR tumour status, DCO 12APR2023

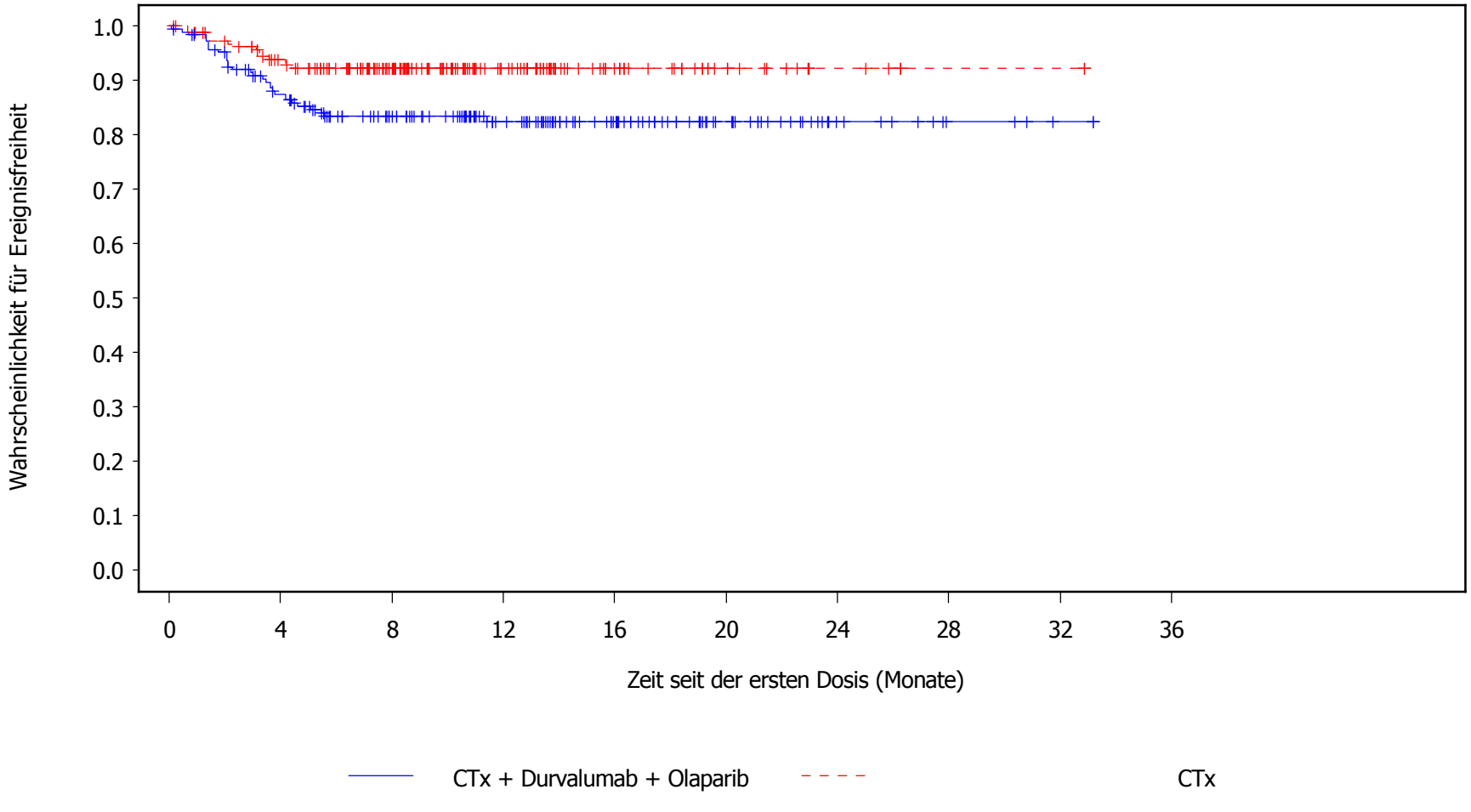


Anzahl an Patienten unter Risiko:

191	153	115	83	55	29	9	4	1	0	CTx + Durvalumab + Olaparib
190	155	114	63	32	14	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bbb 17APR2024:11:32

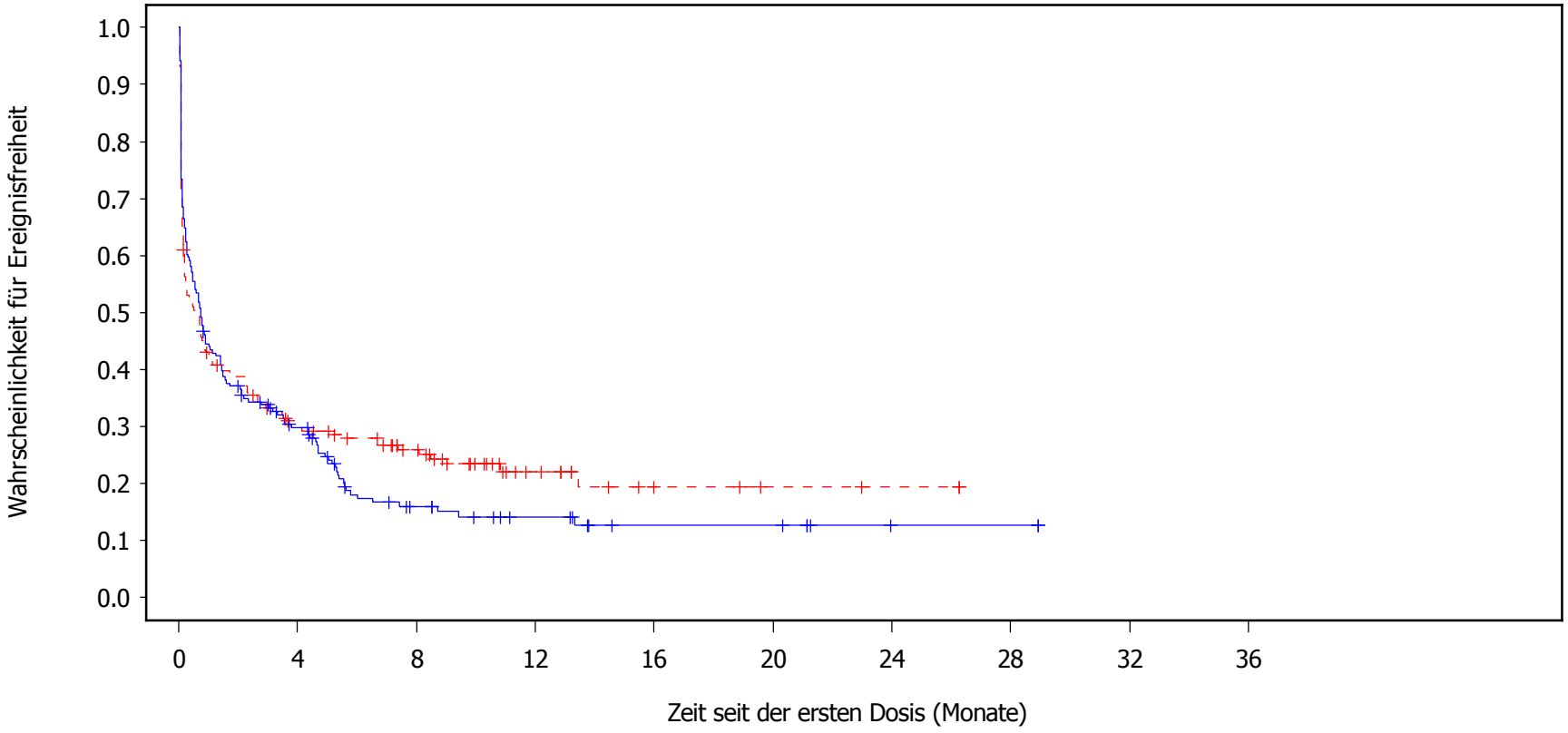
Figure 3.3.2.1D.29 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Thrombozytopenie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	155	120	85	55	30	11	4	1	0	CTx + Durvalumab + Olaparib
190	163	116	63	31	14	5	1	1	0	CTx

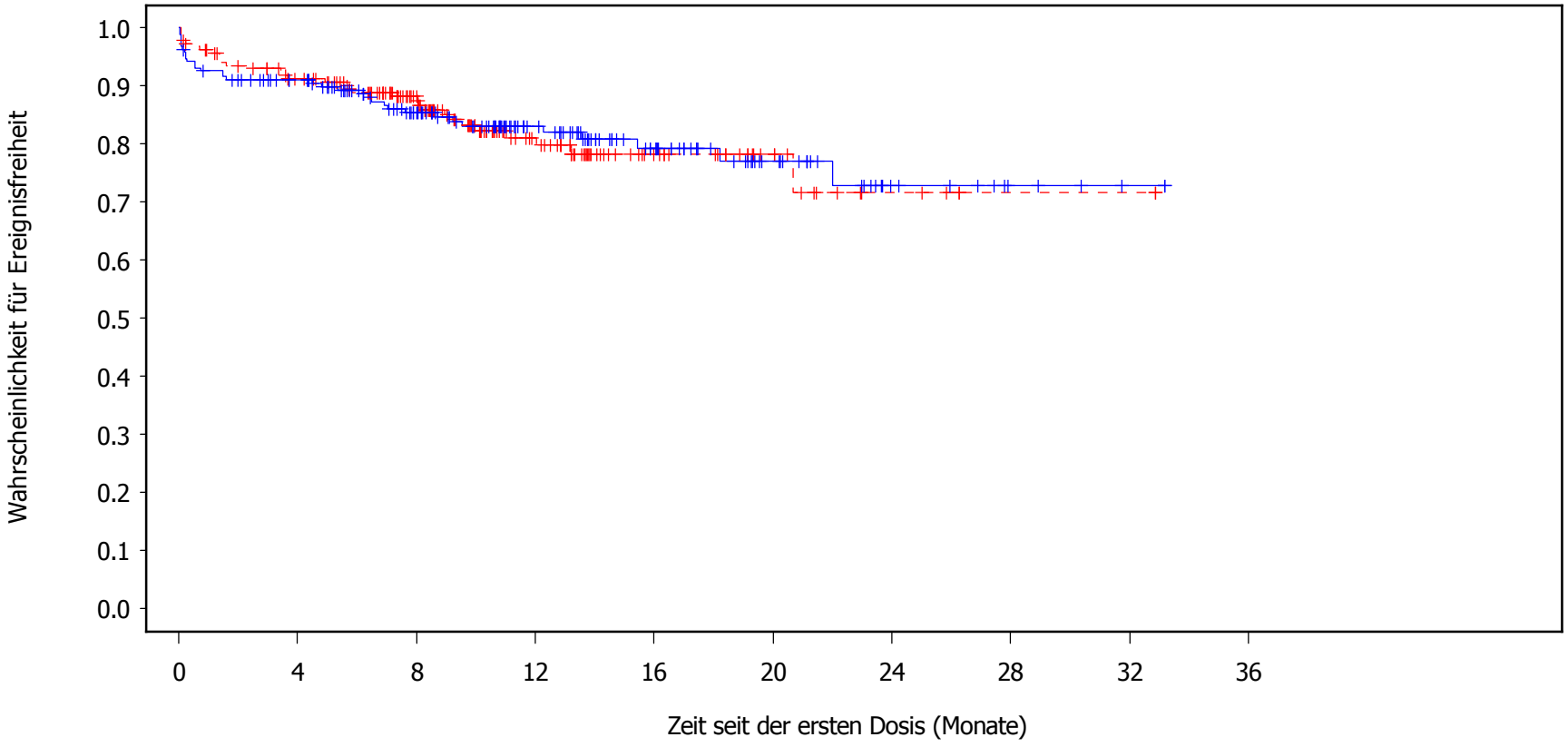
Figure 3.3.2.1D.30 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Gastrointestinaltrakts
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	50	20	12	6	6	1	1	0	0	CTx + Durvalumab + Olaparib
190	51	34	13	5	2	1	0	0	0	CTx

Figure 3.3.2.1D.31 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Abdominalschmerz
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	161	122	79	50	27	10	4	1	0	CTx + Durvalumab + Olaparib
190	160	117	62	30	15	5	1	1	0	CTx

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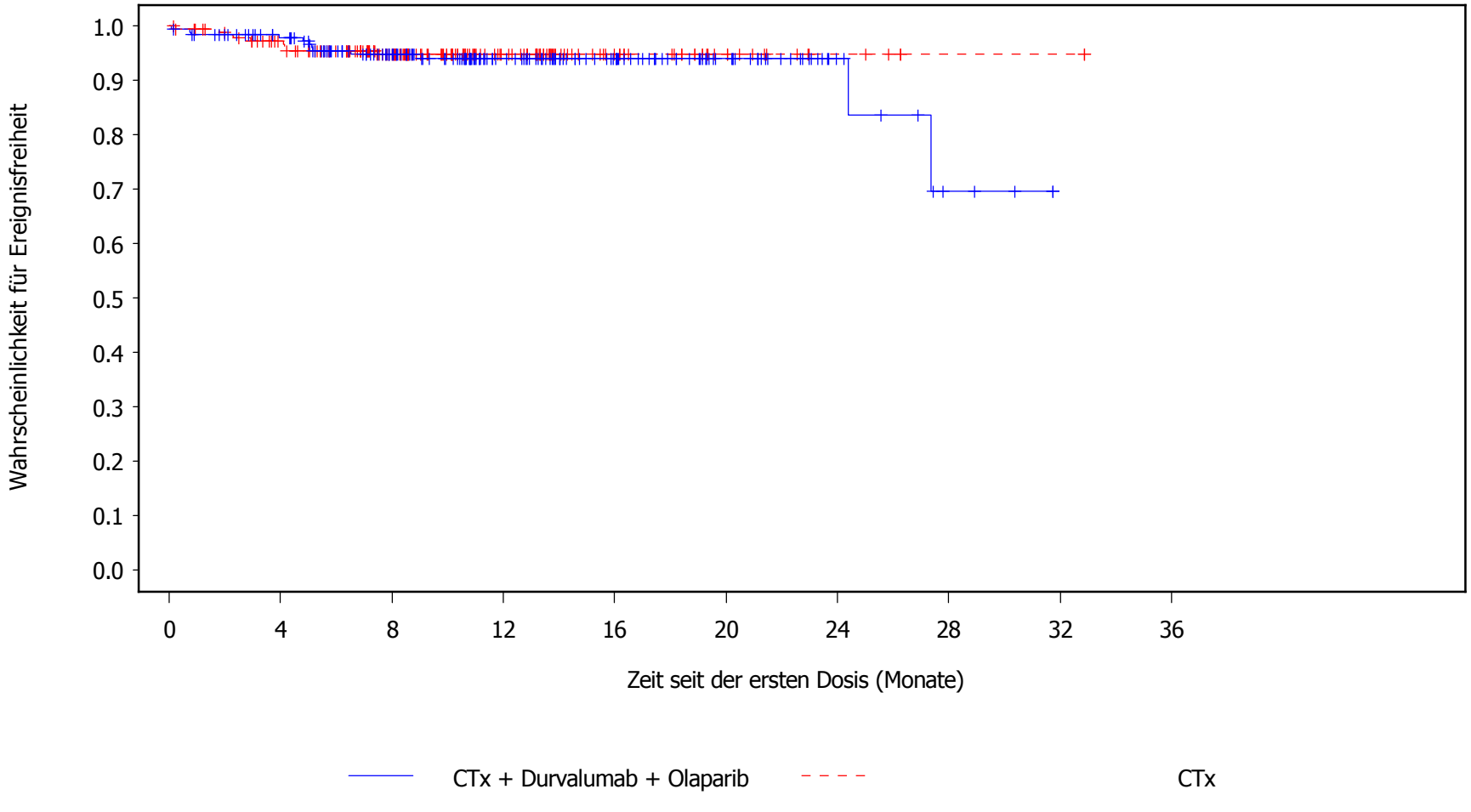
Figure 3.3.2.1D.32 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Bauch aufgetrieben
Patients with pMMR tumour status, DCO 12APR2023

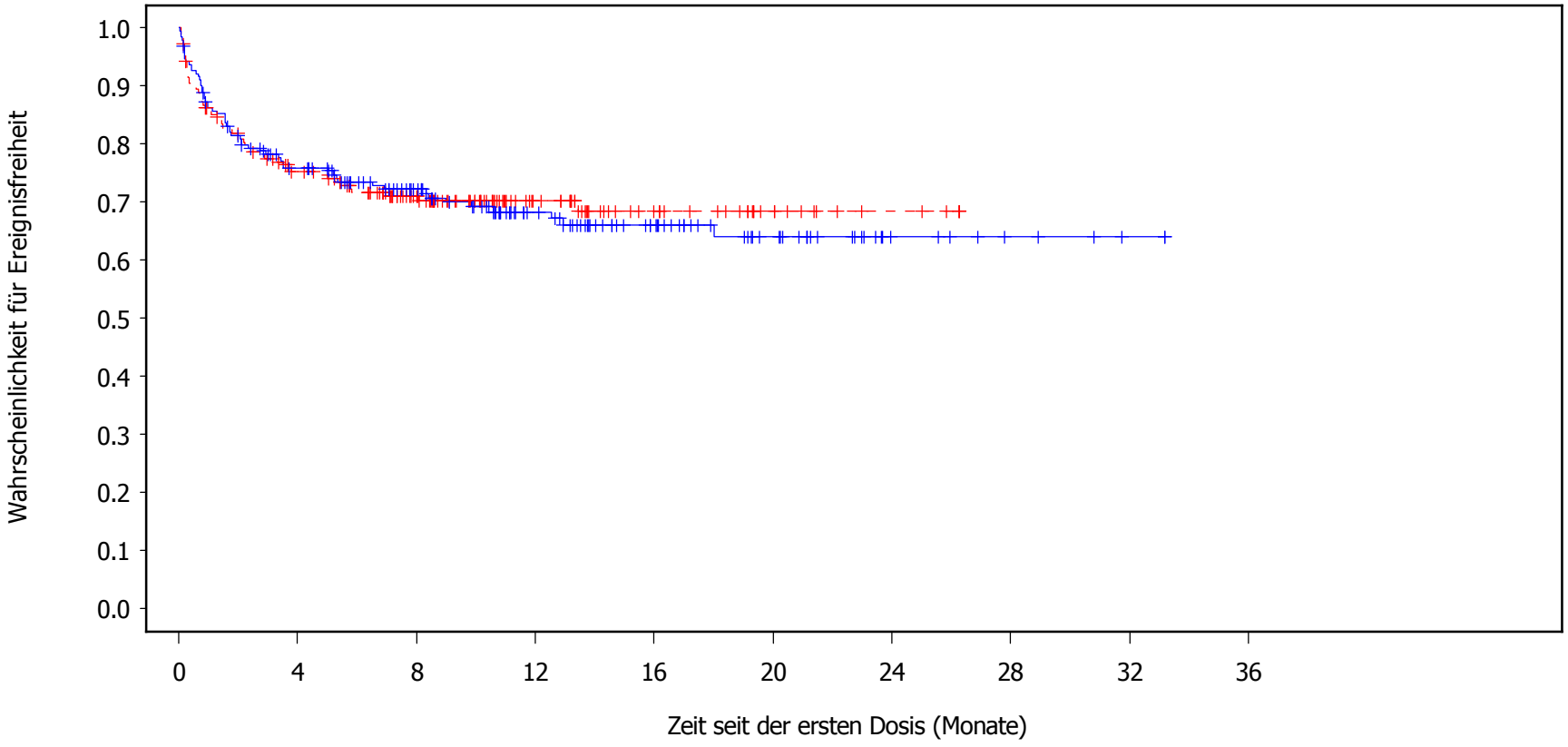


Anzahl an Patienten unter Risiko:

191	172	133	89	59	33	10	3	0	0	CTx + Durvalumab + Olaparib
190	169	120	65	31	14	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bbf 17APR2024:11:32

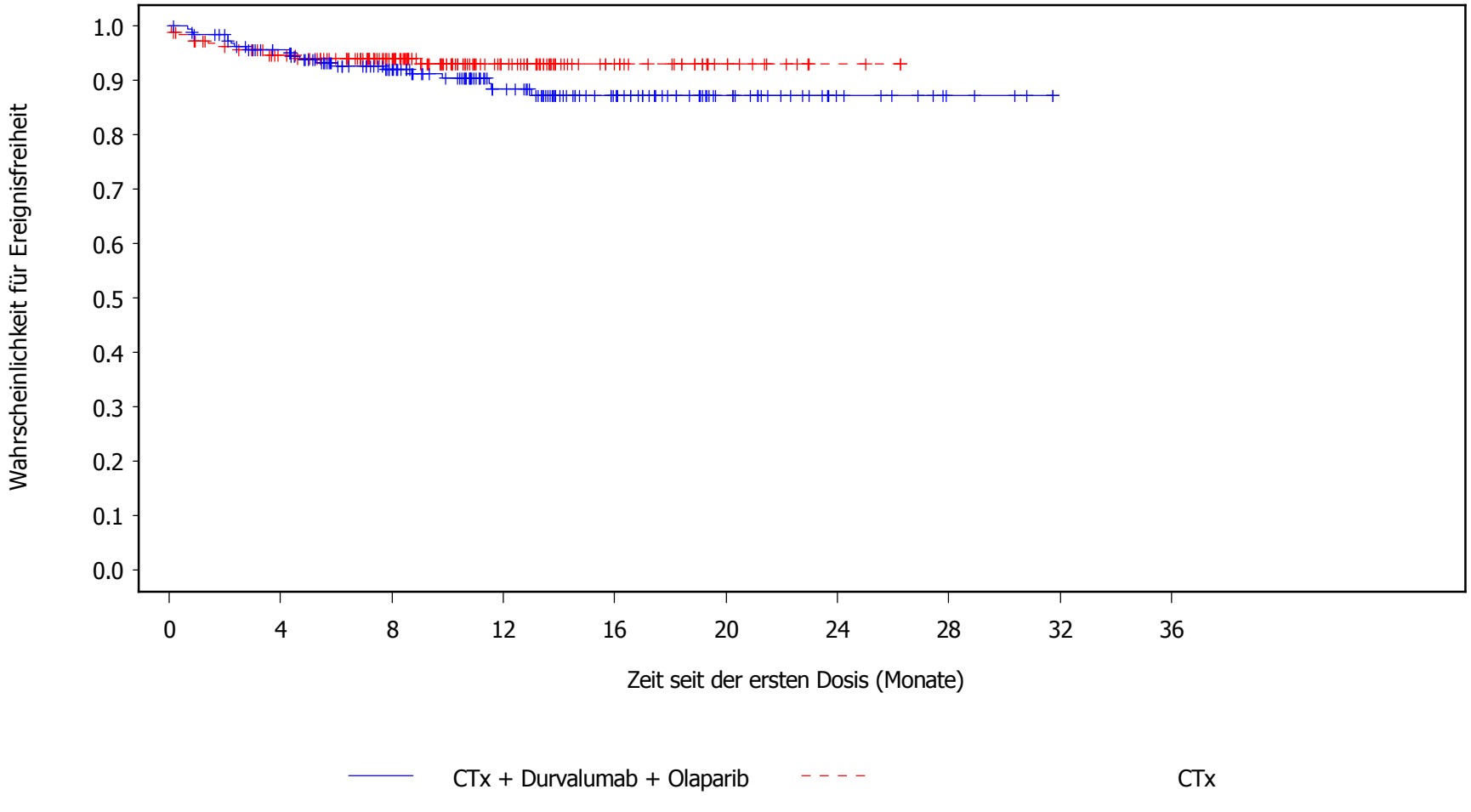
Figure 3.3.2.1D.33 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Diarrhoe
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	133	101	65	42	25	8	4	1	0	CTx + Durvalumab + Olaparib
190	131	92	48	26	12	4	0	0	0	CTx

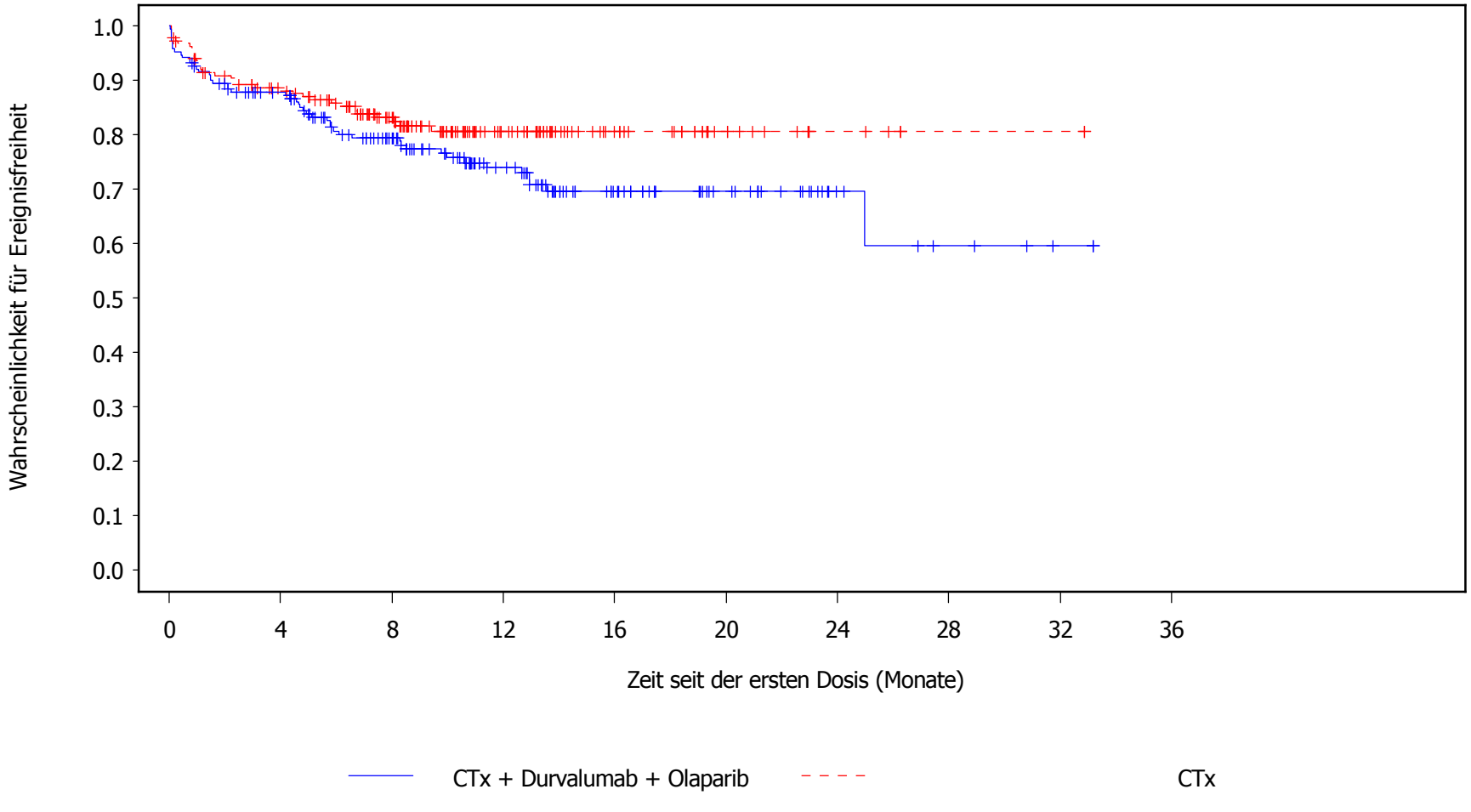
Figure 3.3.2.1D.34 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Dyspepsie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	168	128	86	55	29	11	4	0	0	CTx + Durvalumab + Olaparib
190	164	120	62	30	12	2	0	0	0	CTx

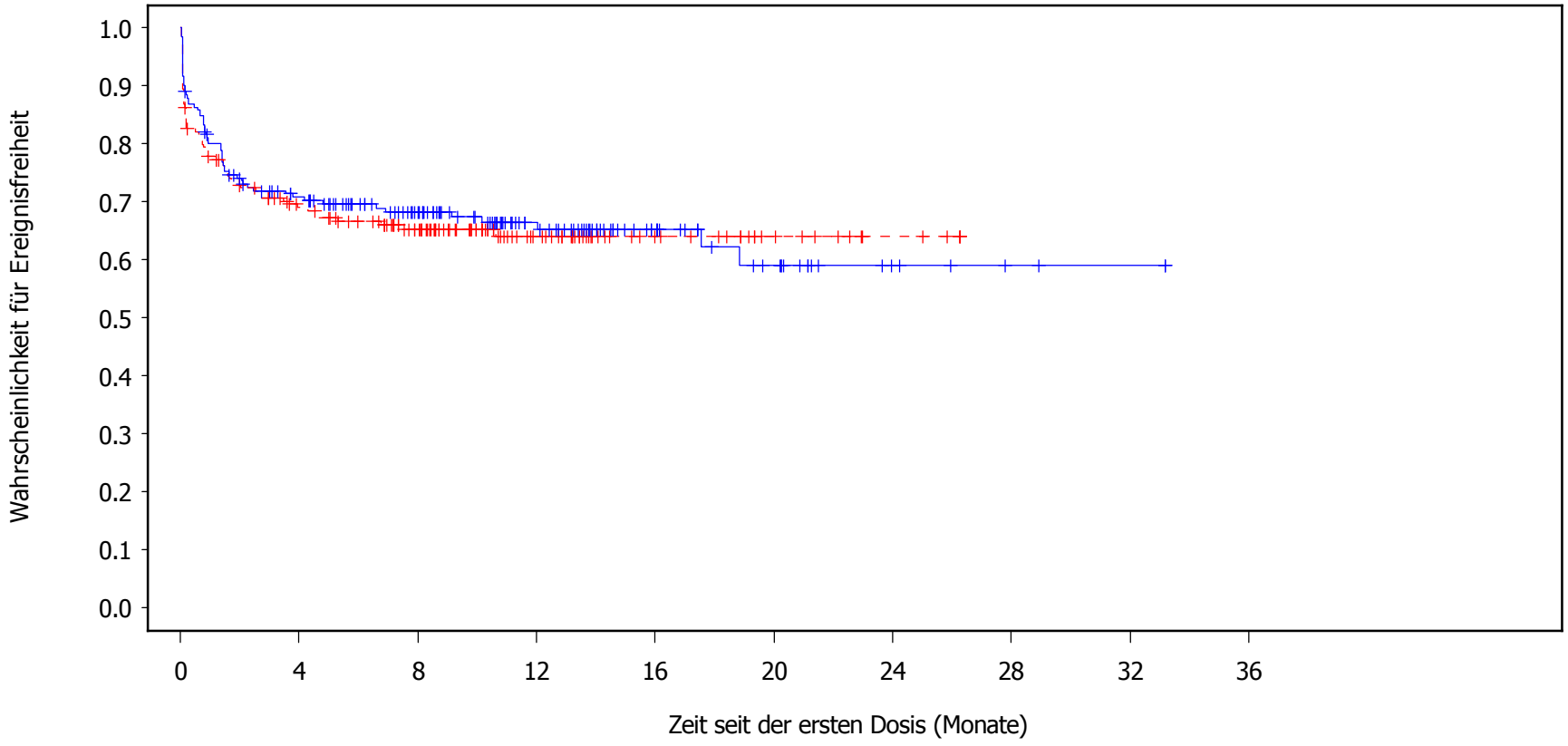
Figure 3.3.2.1D.35 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Erbrechen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	156	116	75	43	26	8	4	1	0	CTx + Durvalumab + Olaparib
190	155	112	59	30	13	5	1	1	0	CTx

Figure 3.3.2.1D.36 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Obstipation
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	123	92	57	29	16	5	2	1	0	CTx + Durvalumab + Olaparib
190	118	89	44	22	11	4	0	0	0	CTx

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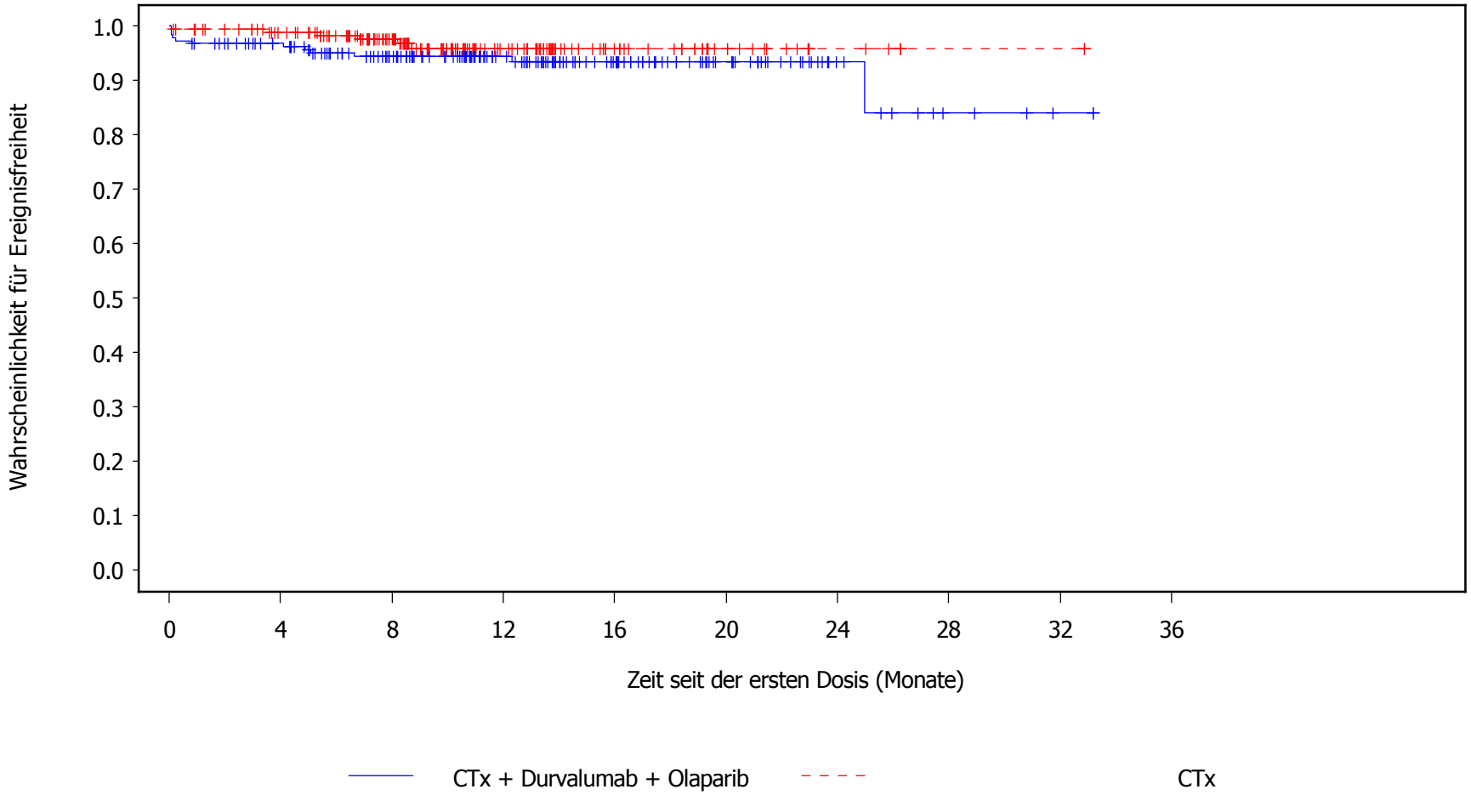
Figure 3.3.2.1D.37 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schmerzen Oberbauch
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	171	136	95	61	34	11	4	1	0	CTx + Durvalumab + Olaparib
190	172	124	66	32	15	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bbk 17APR2024:11:32

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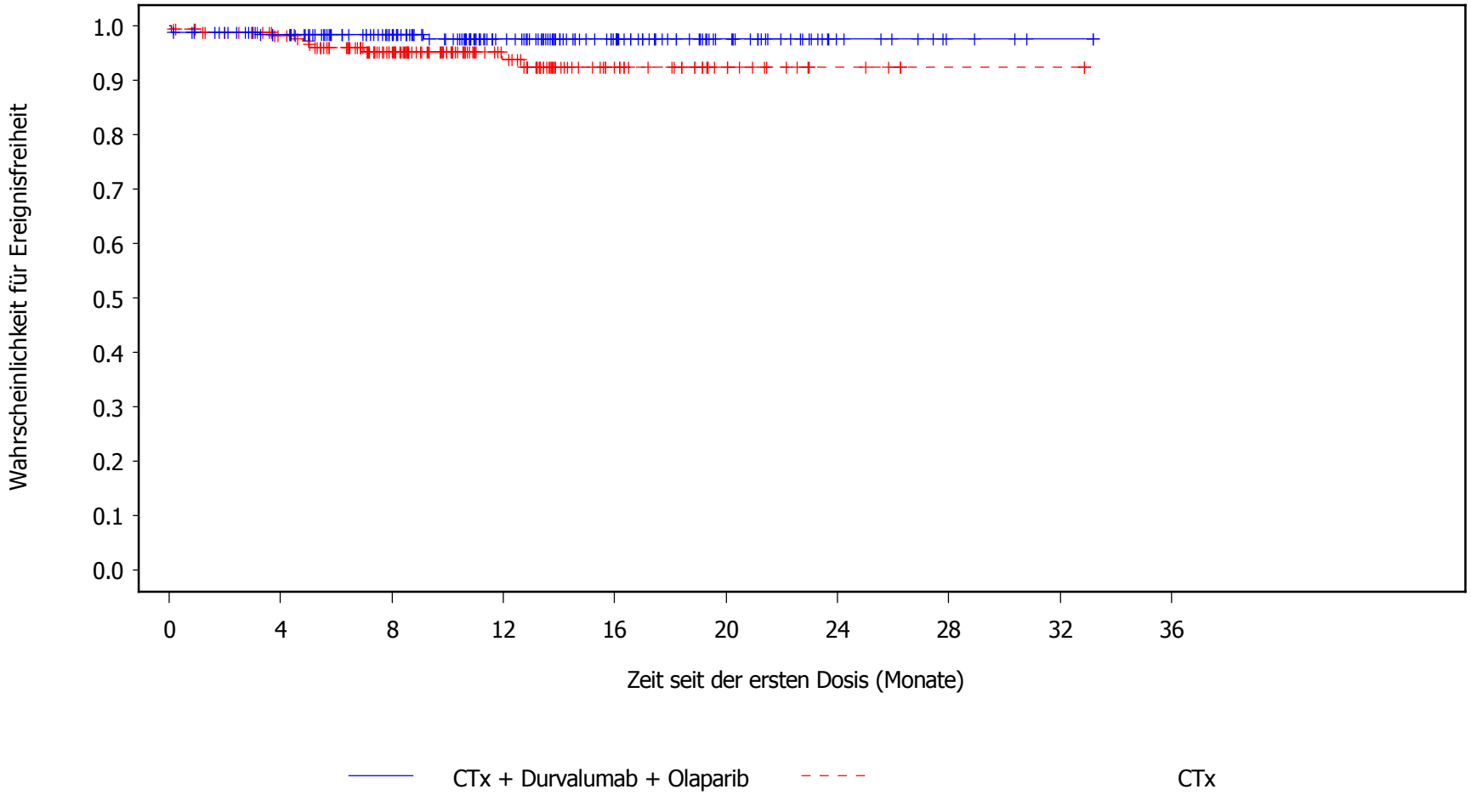
Figure 3.3.2.1D.38 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schmerzen Unterbauch
Patients with pMMR tumour status, DCO 12APR2023

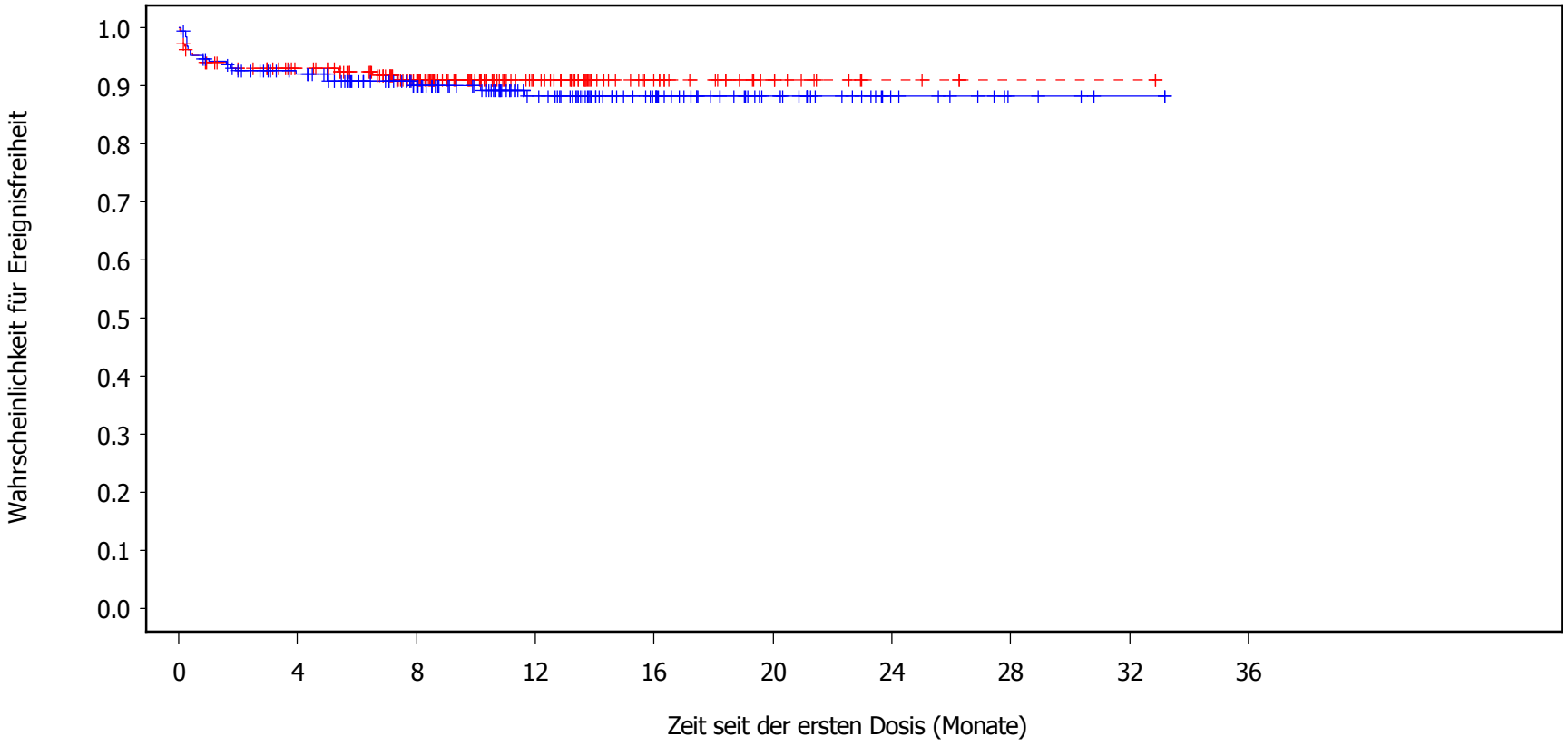


Anzahl an Patienten unter Risiko:

191	173	139	95	61	33	11	4	1	0	CTx + Durvalumab + Olaparib
190	171	123	69	34	15	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bbl 17APR2024:11:32

Figure 3.3.2.1D.39 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Stomatitis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	161	126	83	53	29	11	4	1	0	CTx + Durvalumab + Olaparib
190	161	117	60	29	13	4	1	1	0	CTx

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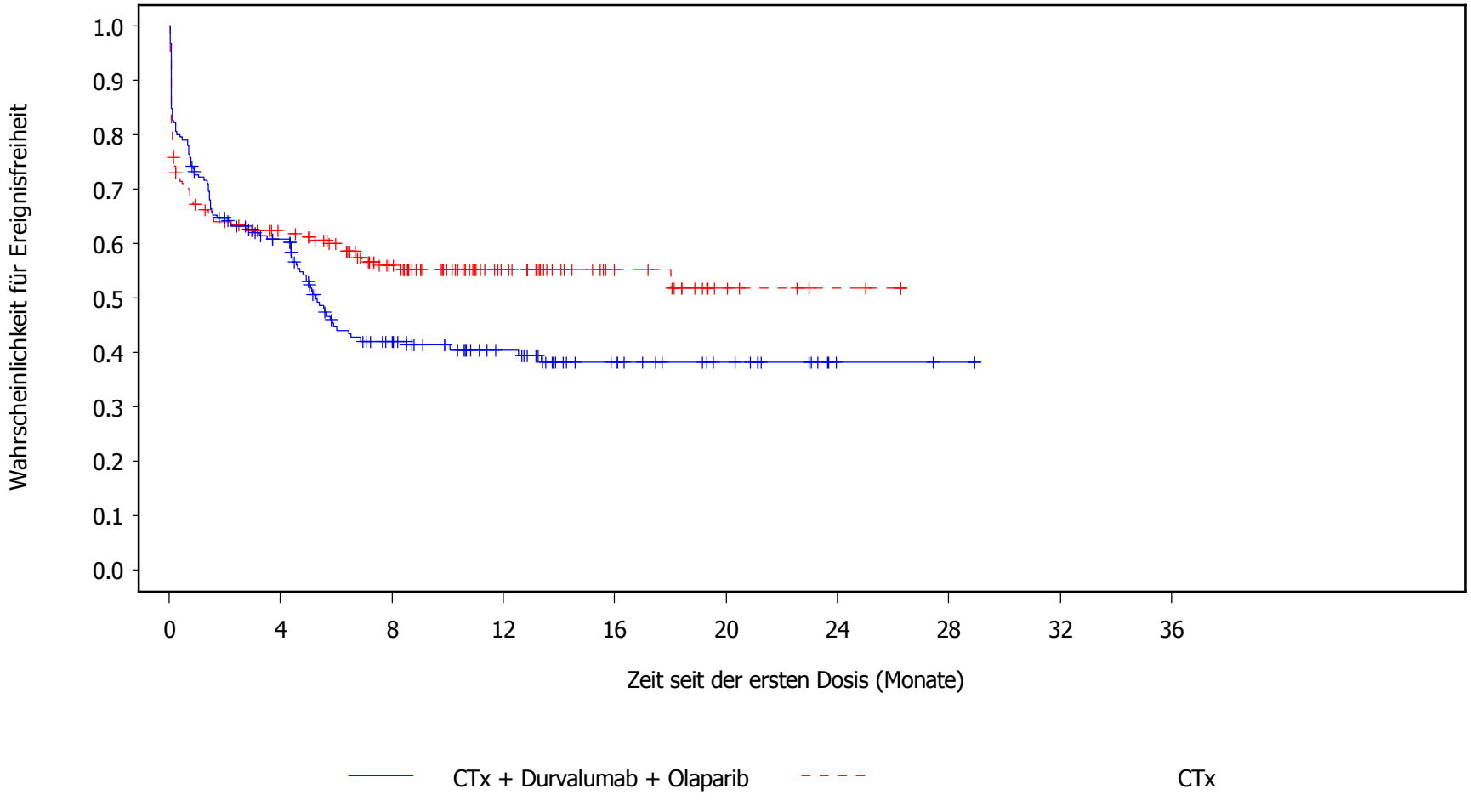
Figure 3.3.2.1D.40 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Uebelkeit
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	104	59	39	23	14	2	1	0	0	CTx + Durvalumab + Olaparib
190	107	73	39	19	7	3	0	0	0	CTx

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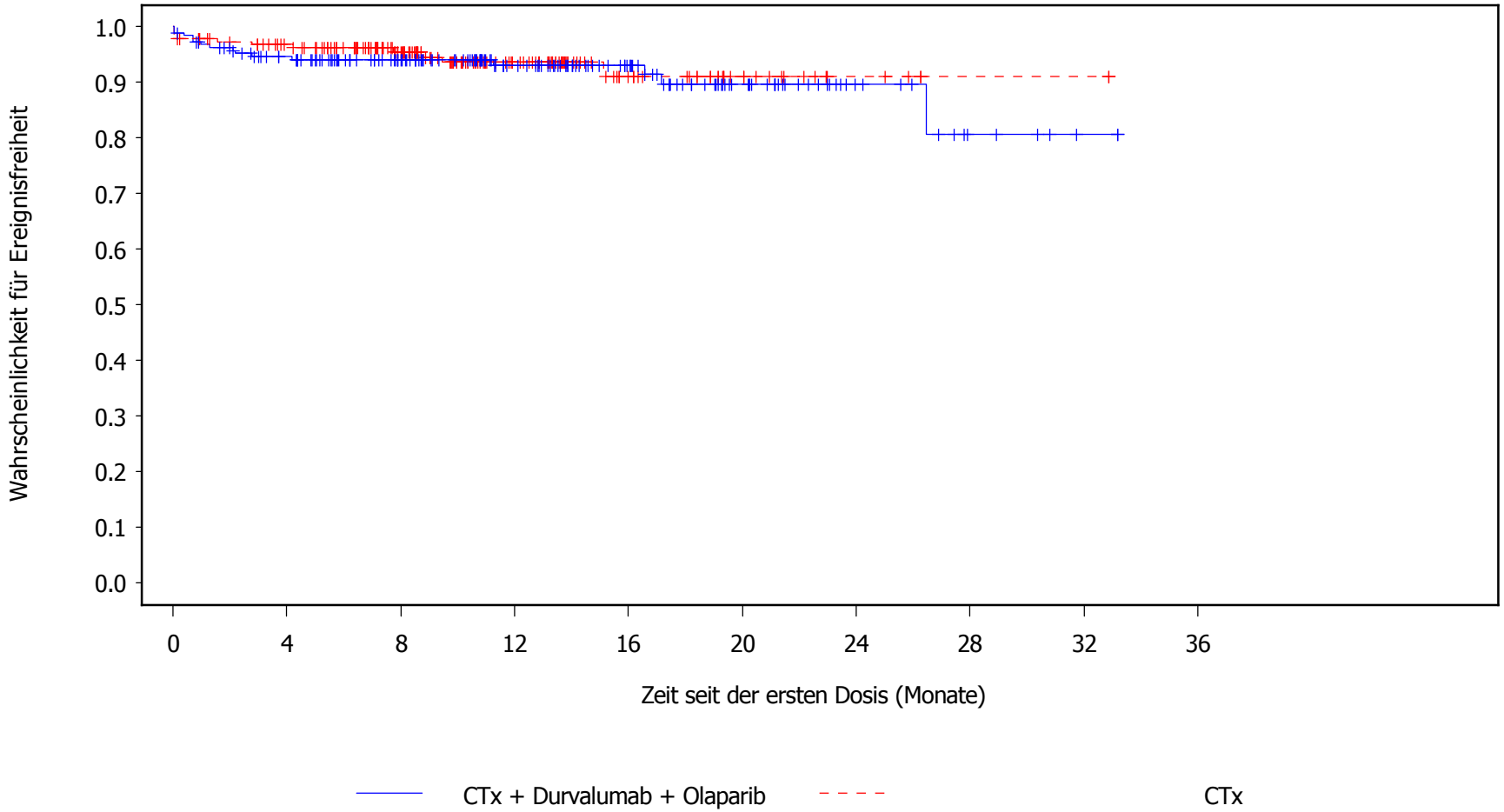
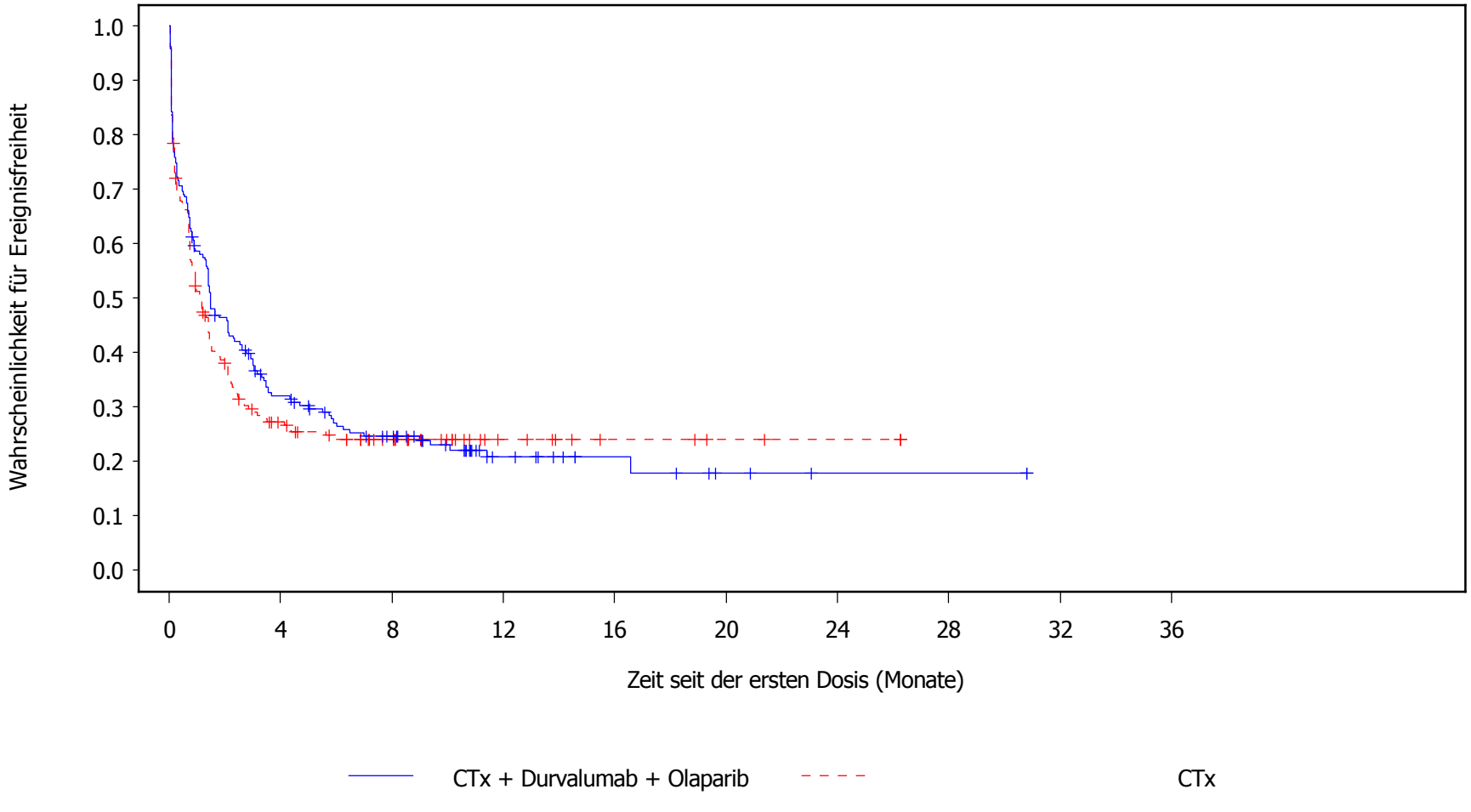
Figure 3.3.2.1D.41 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Immunsystems
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	166	131	90	61	34	13	5	1	0	CTx + Durvalumab + Olaparib
190	169	123	69	32	15	5	1	1	0	CTx

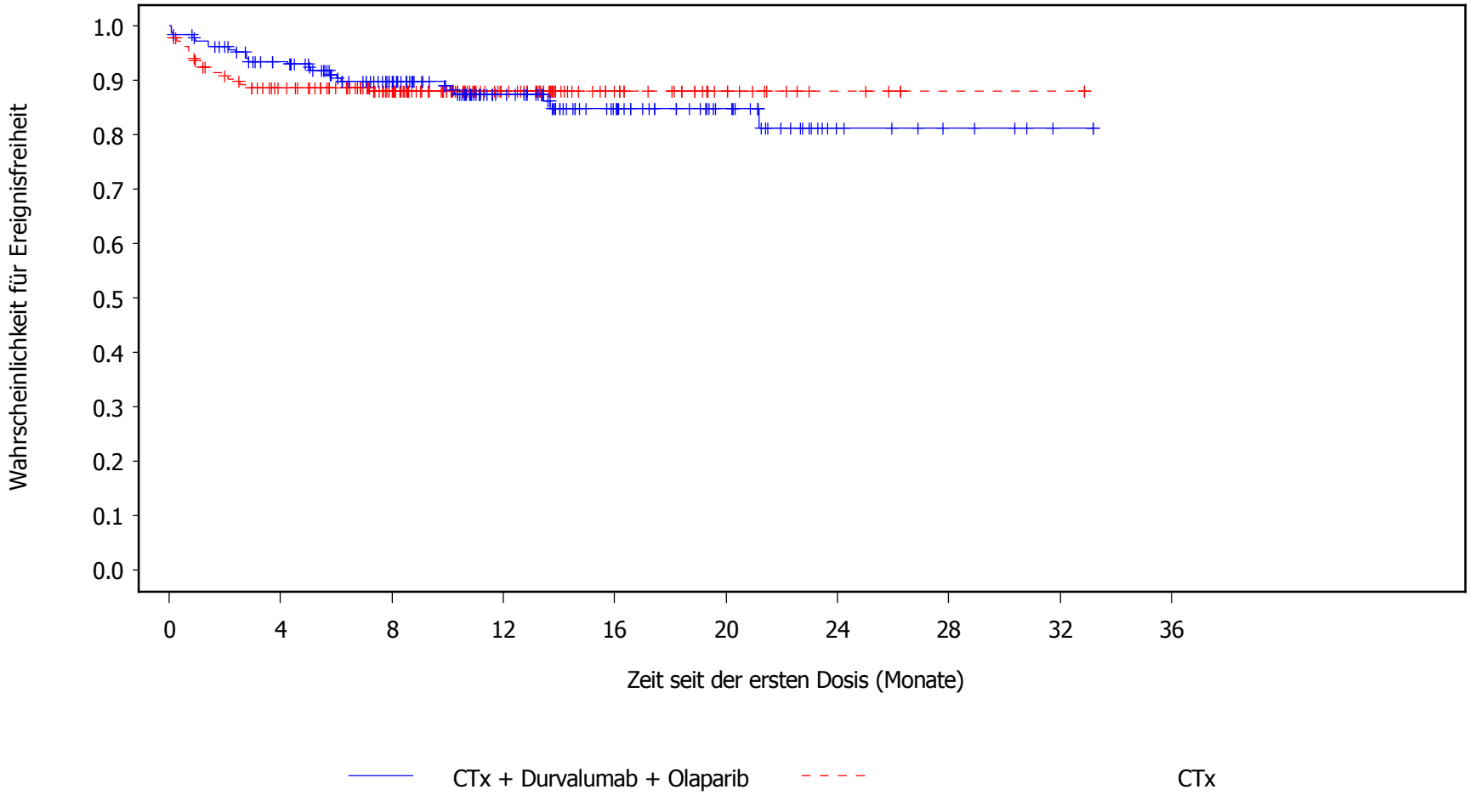
Figure 3.3.2.1D.42 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Nervensystems
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	56	36	14	7	3	1	1	0	0	CTx + Durvalumab + Olaparib
190	44	27	9	4	2	1	0	0	0	CTx

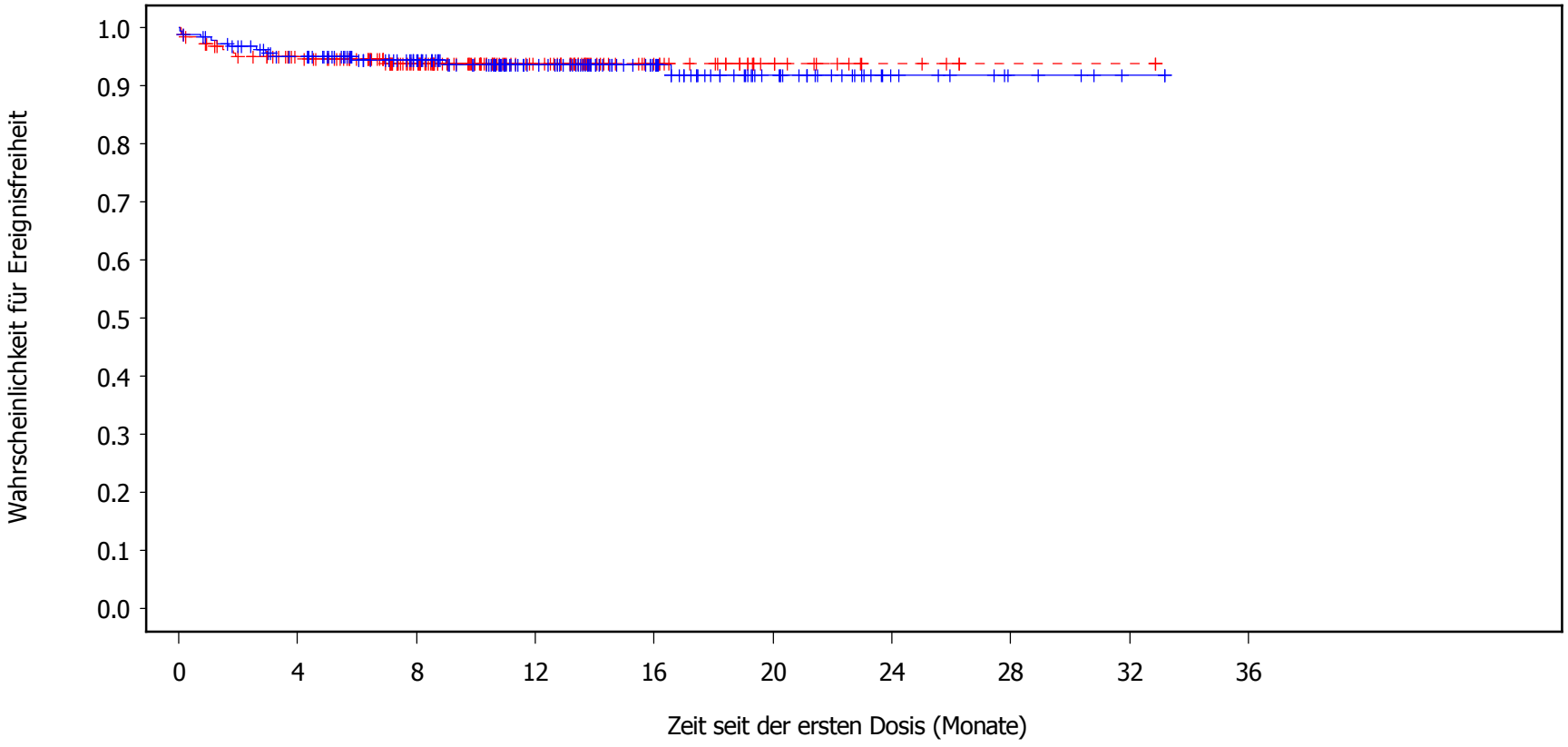
Figure 3.3.2.1D.43 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Dysgeusie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	164	126	82	52	32	9	5	1	0	CTx + Durvalumab + Olaparib
190	153	114	63	30	14	5	1	1	0	CTx

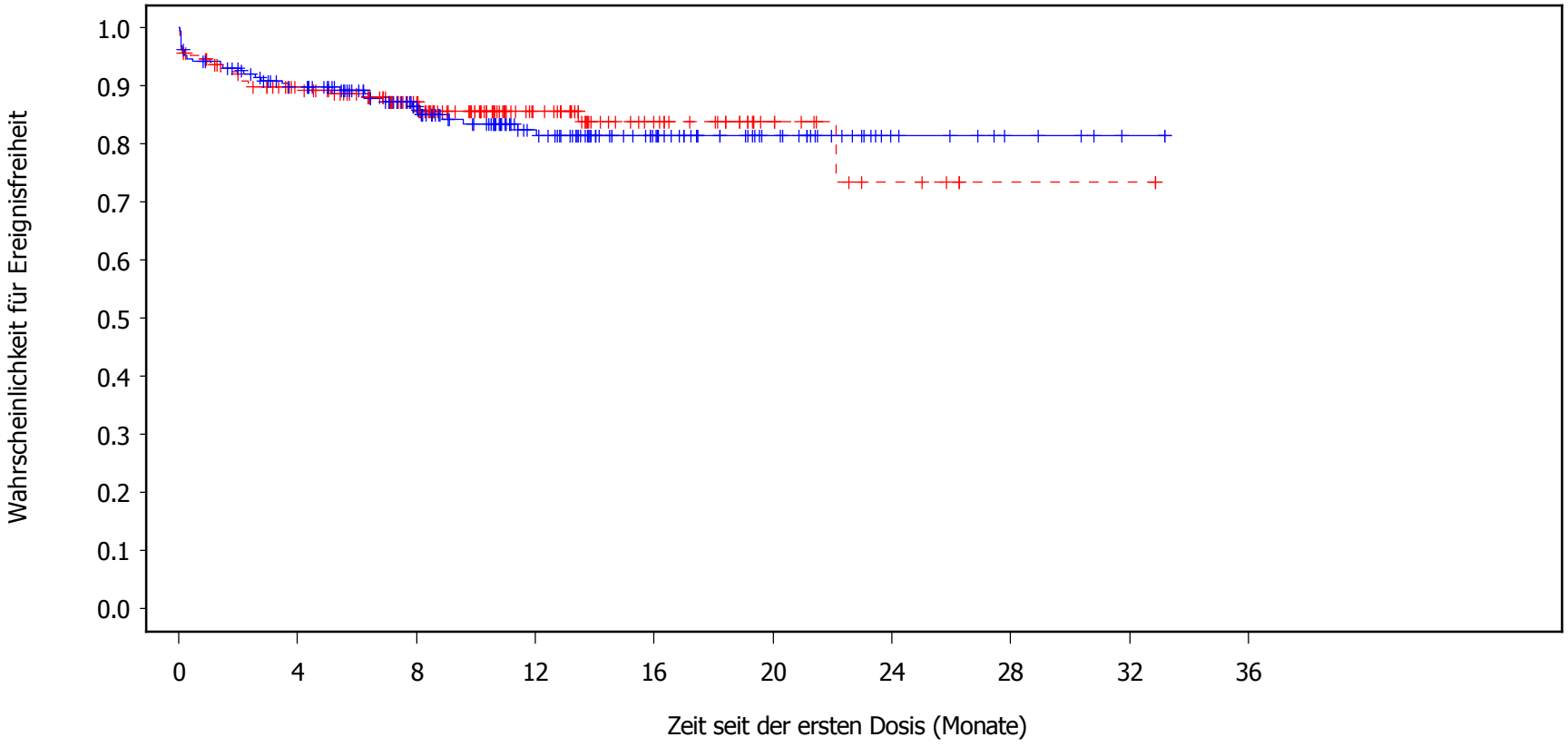
Figure 3.3.2.1D.44 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypoaesthesie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	167	132	90	58	31	11	5	1	0	CTx + Durvalumab + Olaparib
190	165	118	64	32	14	5	1	1	0	CTx

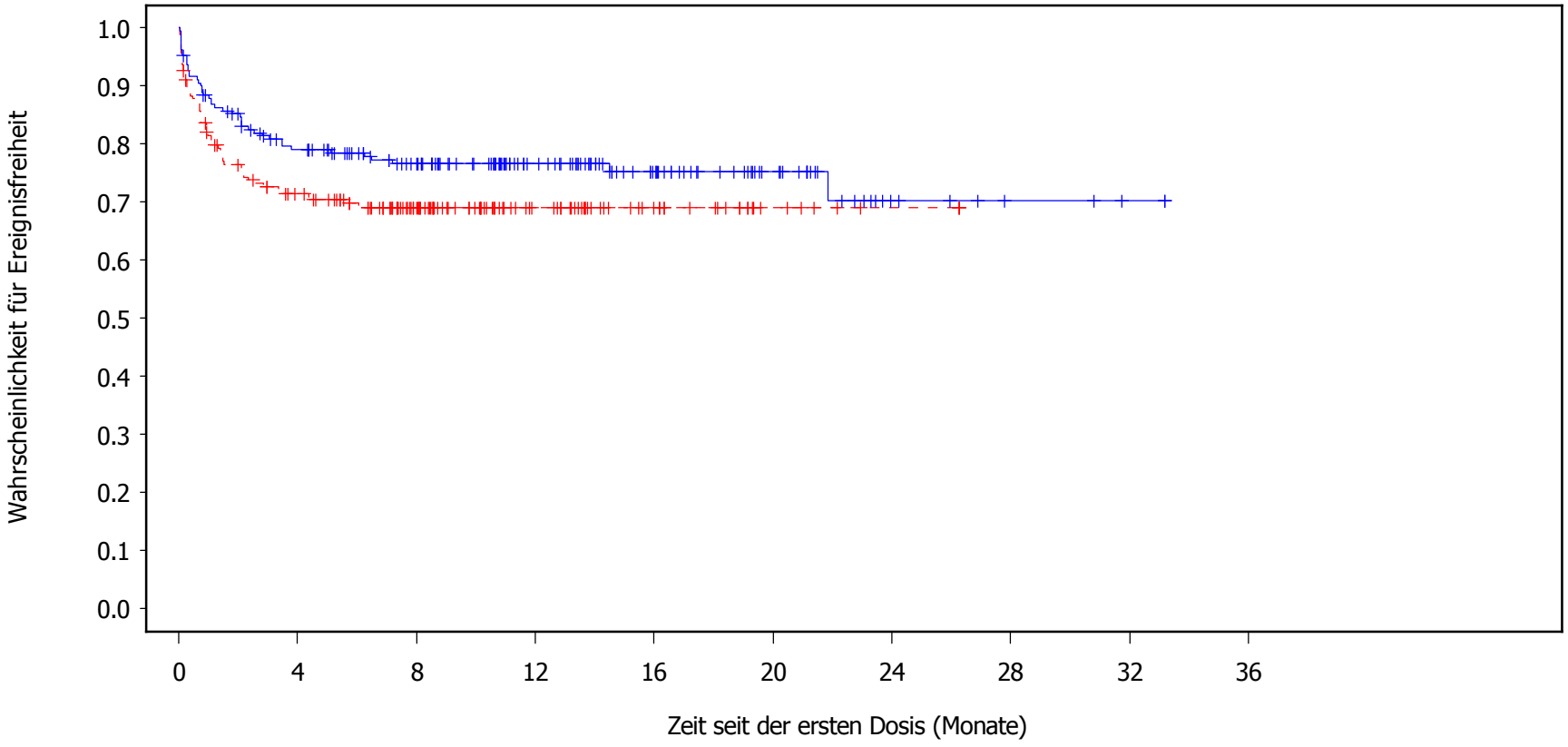
Figure 3.3.2.1D.45 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Kopfschmerzen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	158	120	79	48	28	10	5	1	0	CTx + Durvalumab + Olaparib
190	155	112	59	31	13	5	1	1	0	CTx

Figure 3.3.2.1D.46 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Periphere Neuropathie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	140	113	76	47	26	7	3	1	0	CTx + Durvalumab + Olaparib
190	124	84	43	23	7	2	0	0	0	CTx

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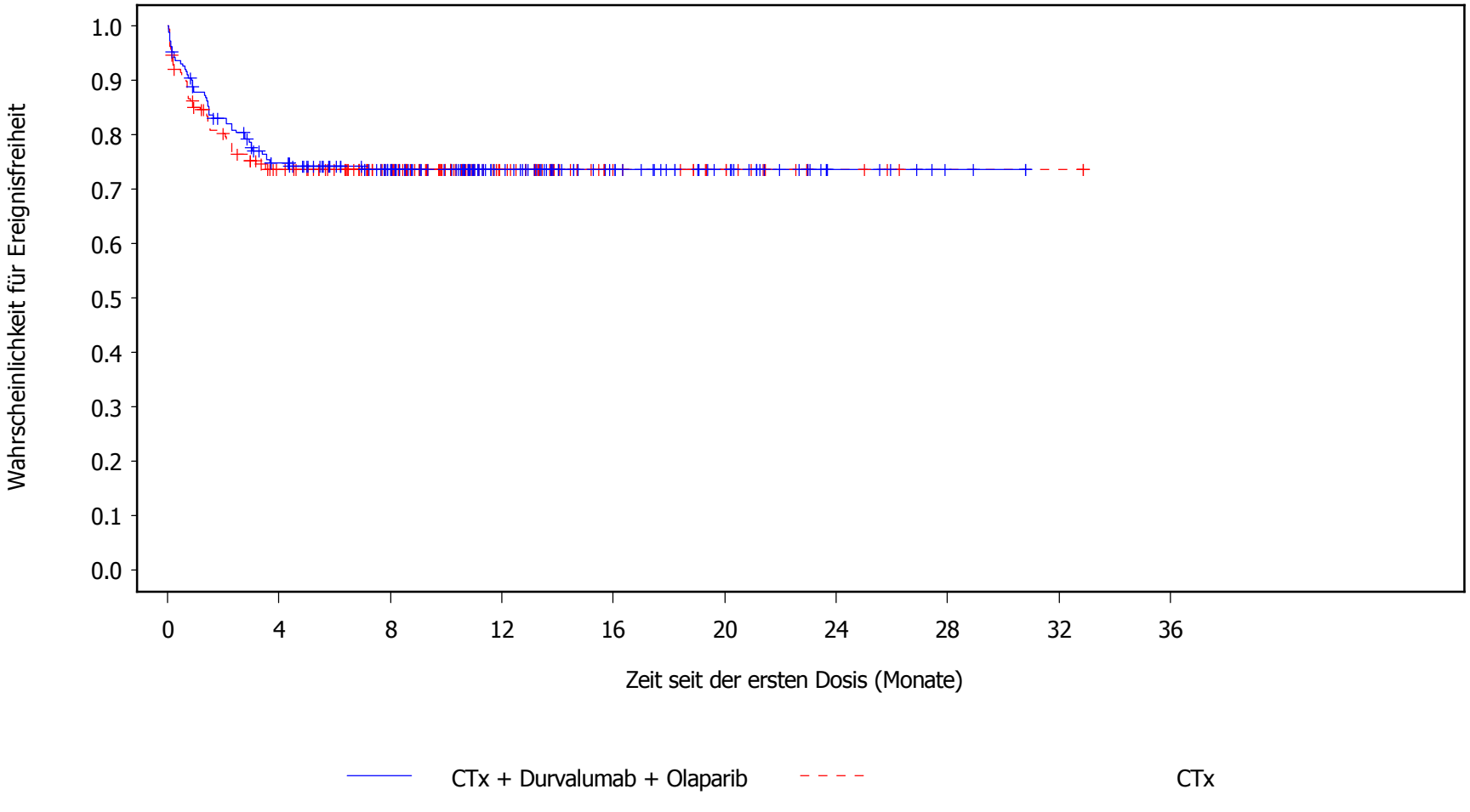
Figure 3.3.2.1D.47 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Periphere sensorische Neuropathie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	132	100	61	37	23	7	2	0	0	CTx + Durvalumab + Olaparib
190	125	93	45	20	13	4	1	1	0	CTx

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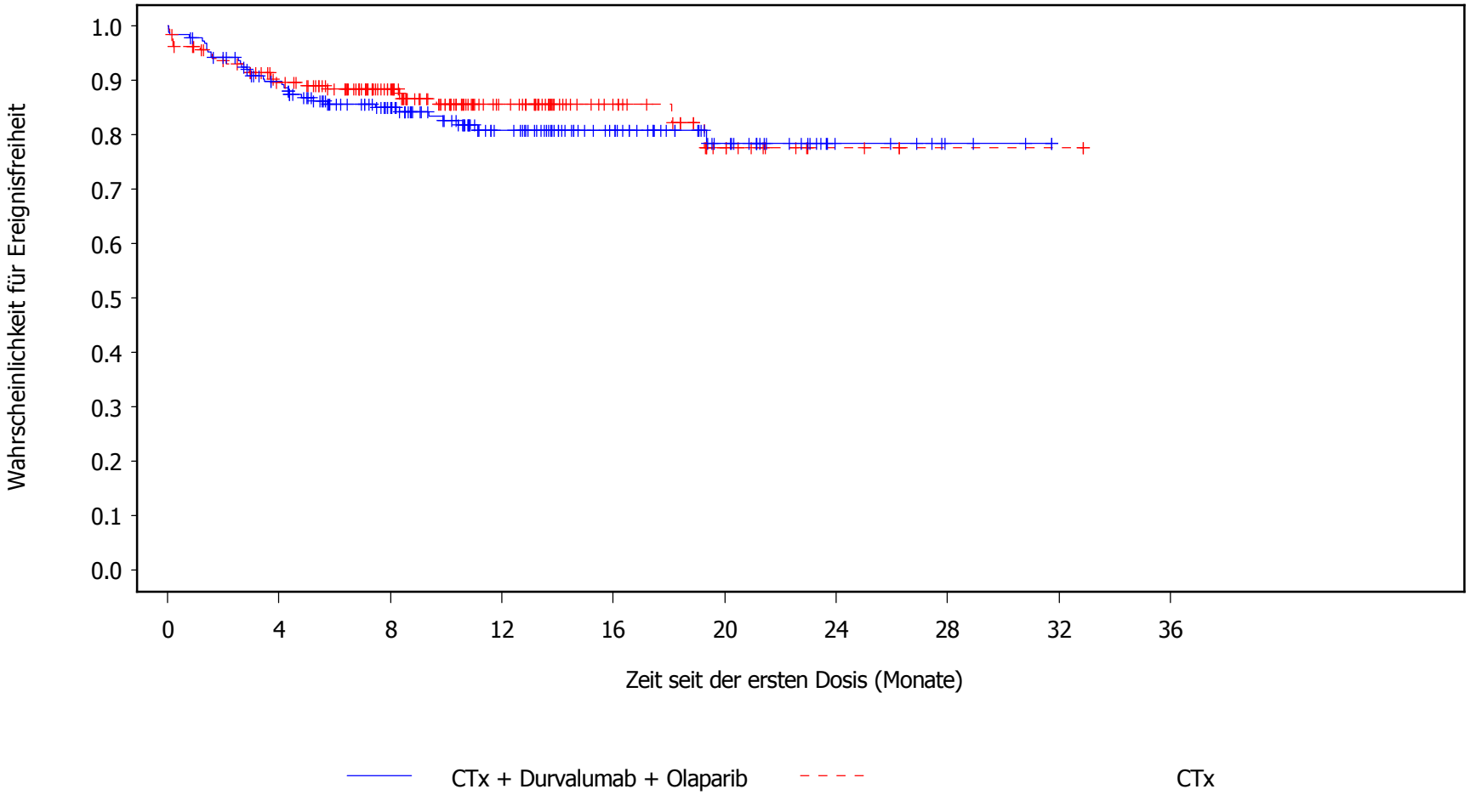
Figure 3.3.2.1D.48 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schwindelgefuehl
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	159	120	78	51	28	8	3	0	0	CTx + Durvalumab + Olaparib
190	155	111	59	30	13	4	1	1	0	CTx

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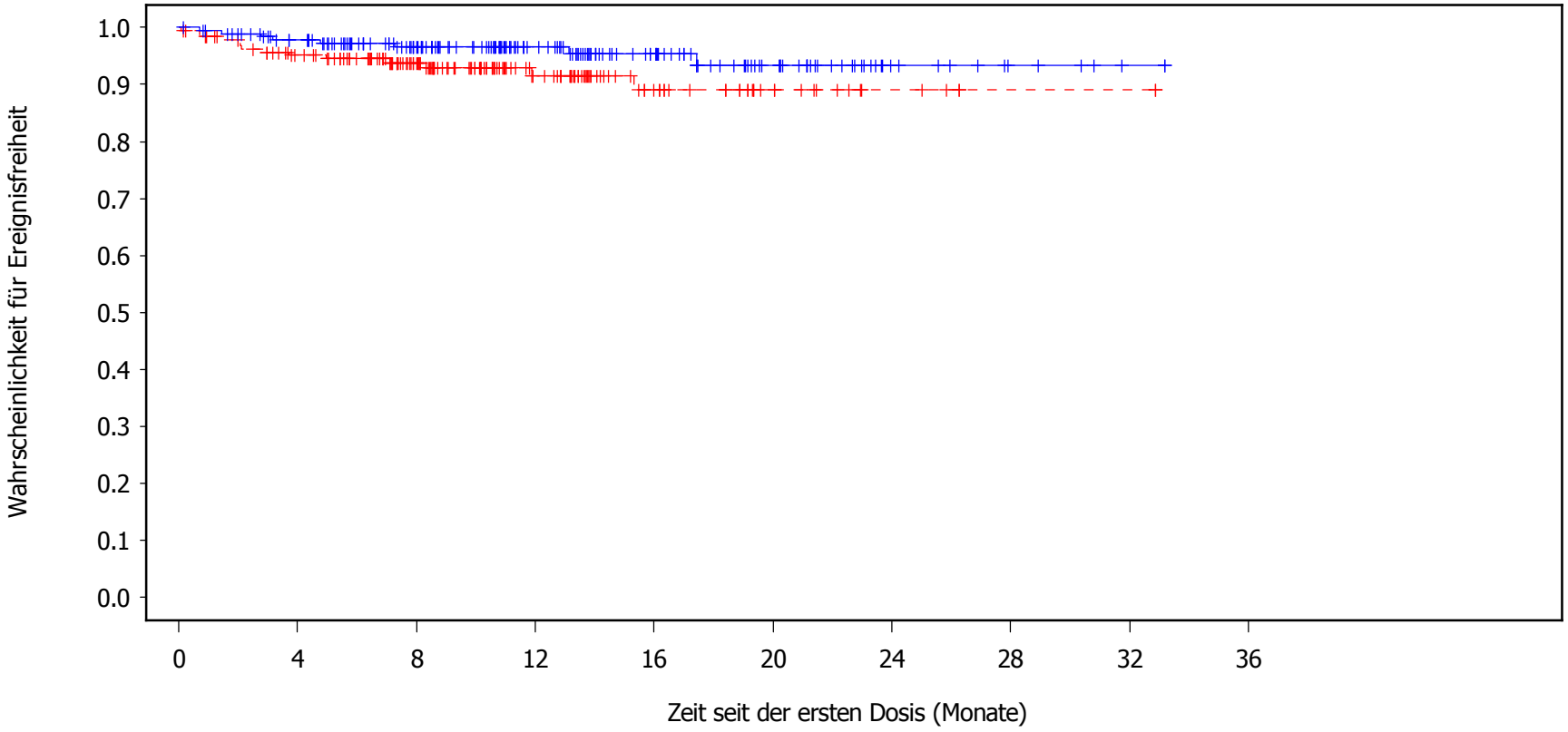
Figure 3.3.2.1D.49 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Ohrs und des Labyrinths
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	172	135	91	59	34	11	5	1	0	CTx + Durvalumab + Olaparib
190	165	119	64	31	14	5	1	1	0	CTx

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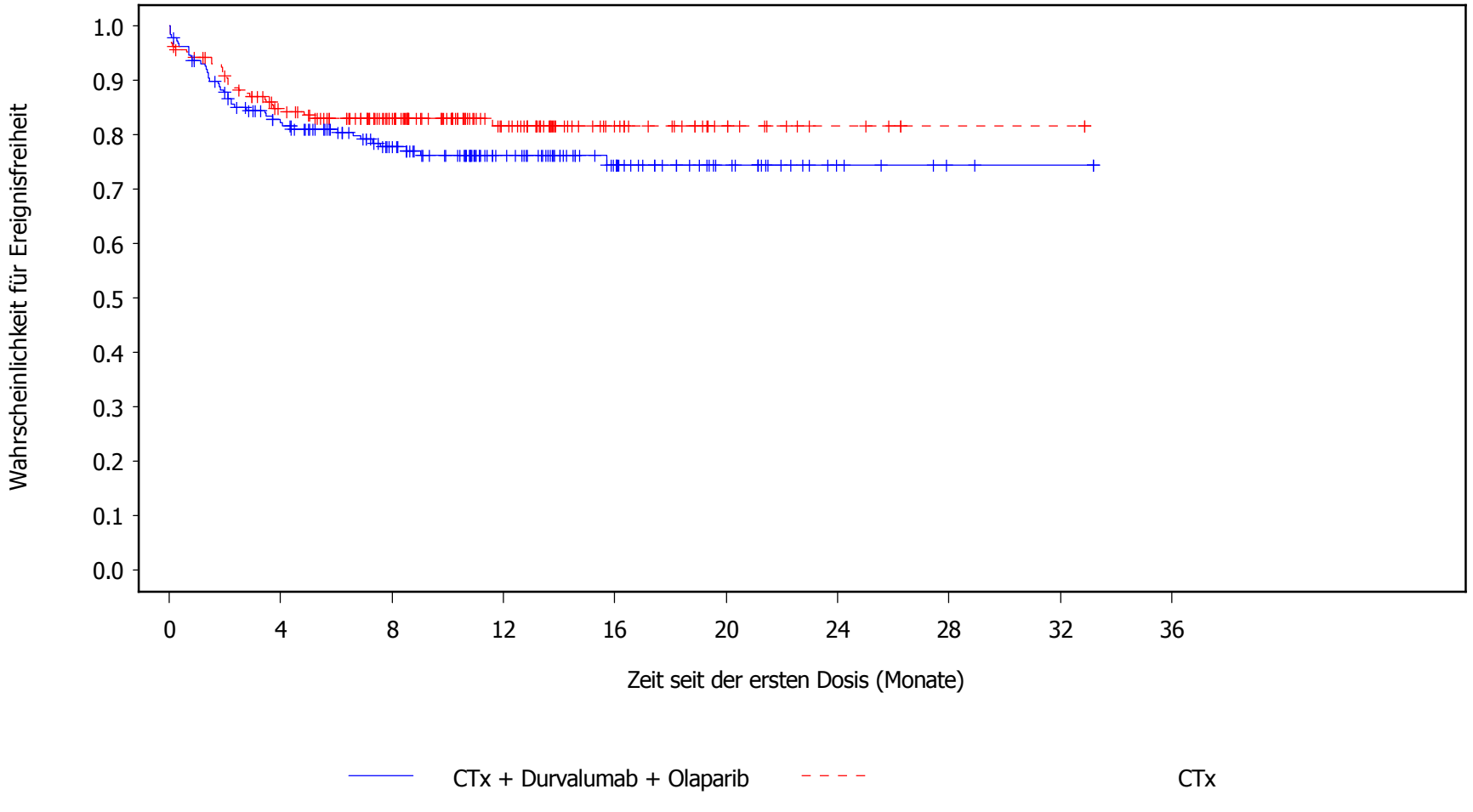
Figure 3.3.2.1D.50 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Gefaesserkrankungen
Patients with pMMR tumour status, DCO 12APR2023

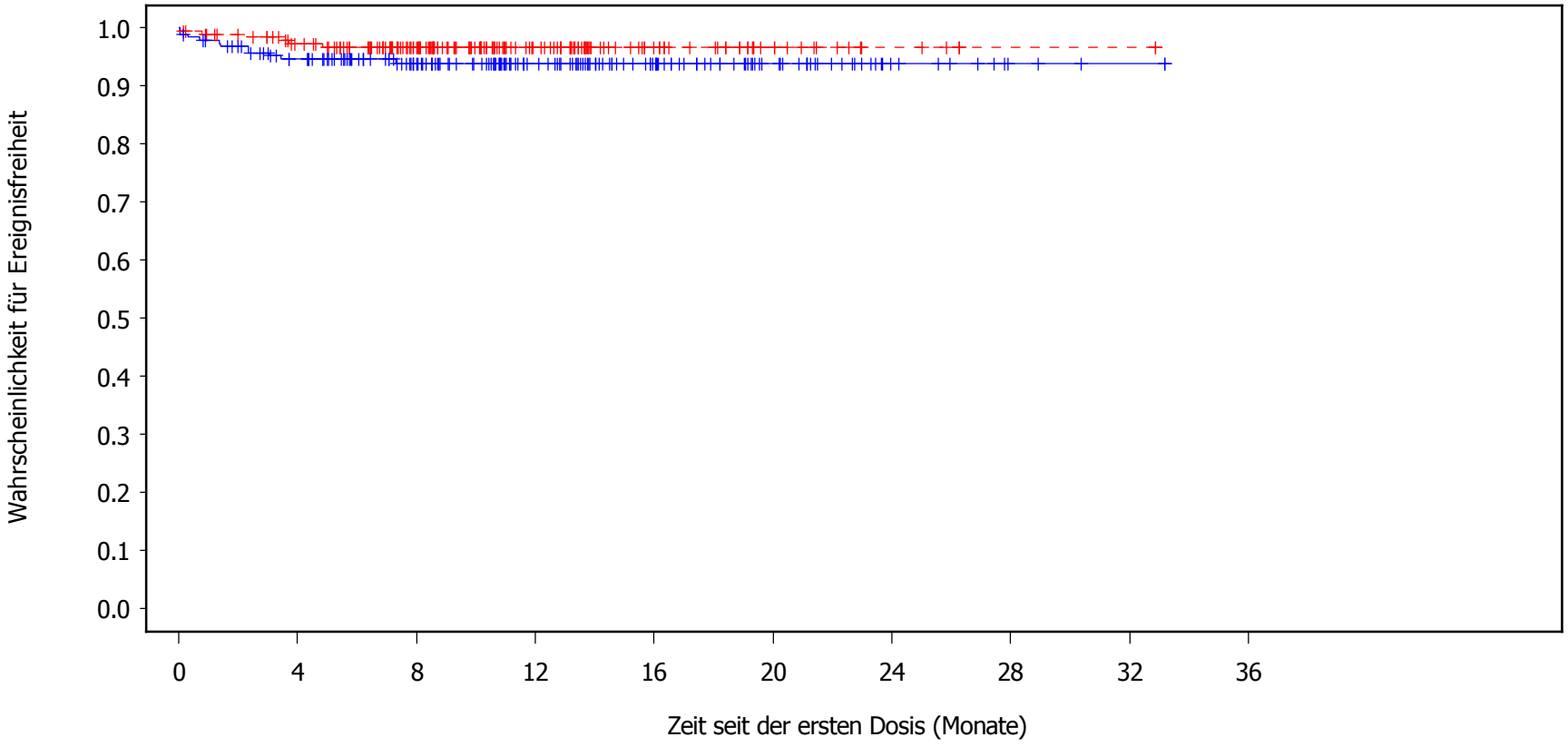


Anzahl an Patienten unter Risiko:

191	144	107	69	41	21	6	2	1	0	CTx + Durvalumab + Olaparib
190	146	108	59	28	13	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bbx 17APR2024:11:32

Figure 3.3.2.1D.51 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypertonie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	166	130	88	56	31	10	3	1	0	CTx + Durvalumab + Olaparib
190	169	124	69	34	15	5	1	1	0	CTx

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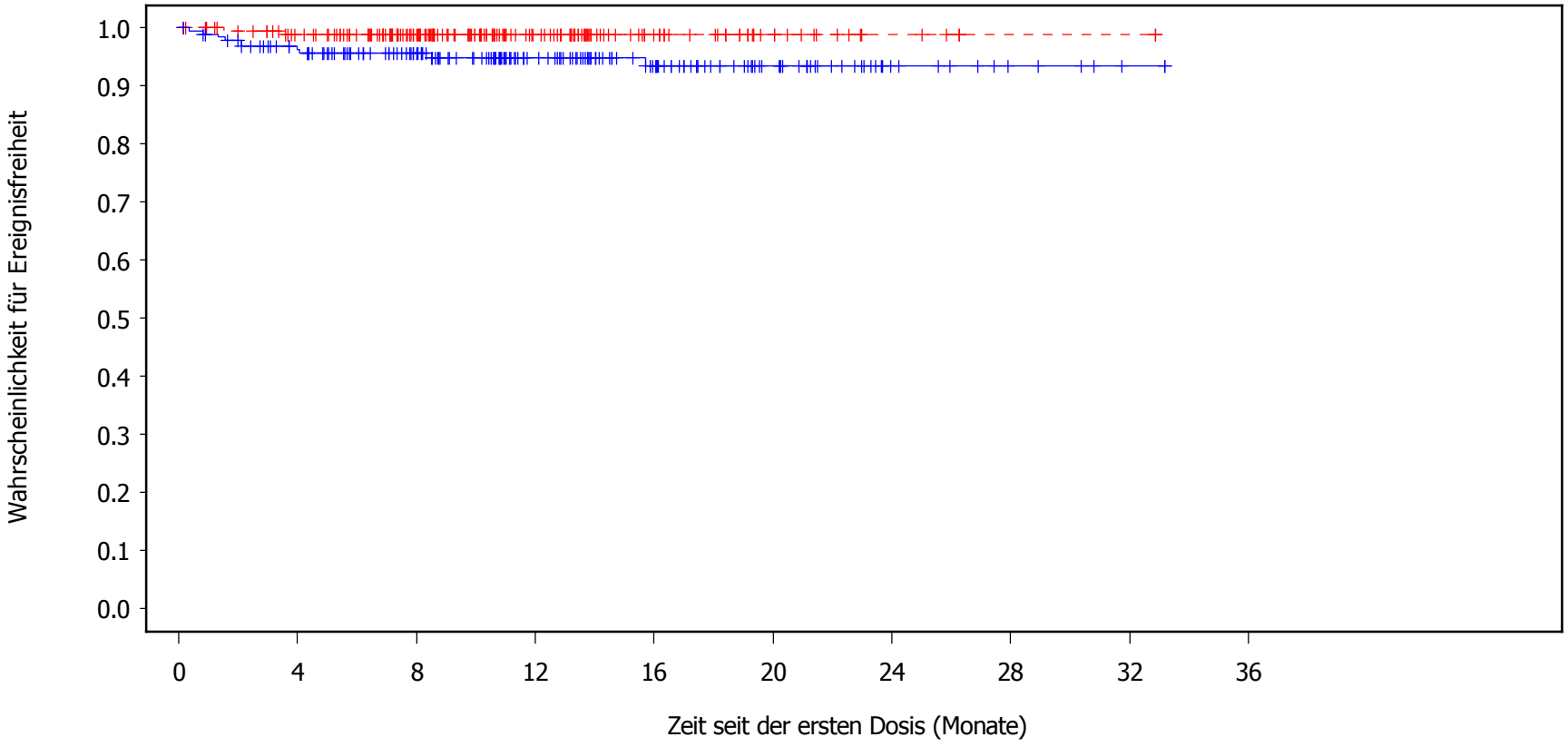
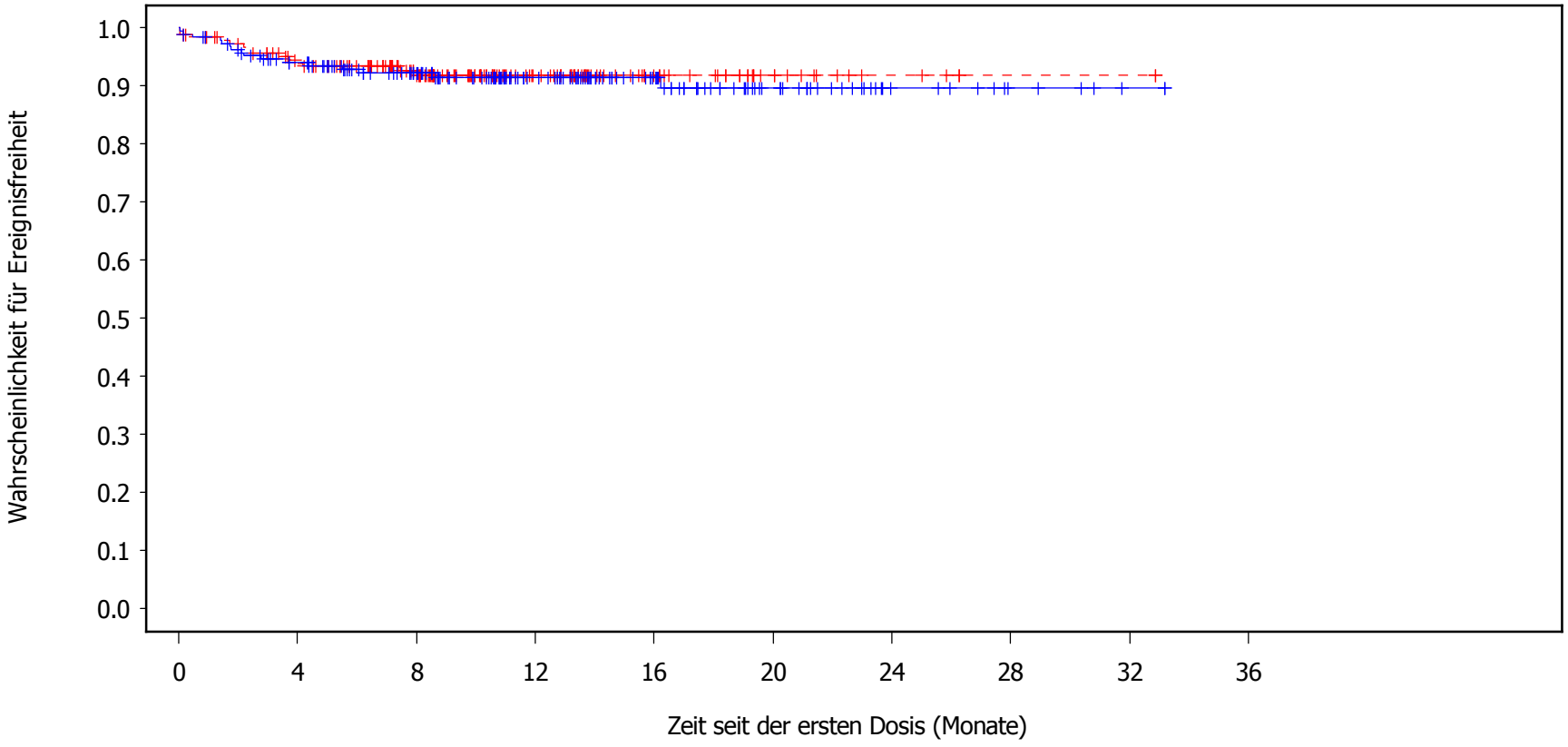
Figure 3.3.2.1D.52 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypotonie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	170	137	92	60	33	11	5	1	0	CTx + Durvalumab + Olaparib
190	172	126	70	34	15	5	1	1	0	CTx

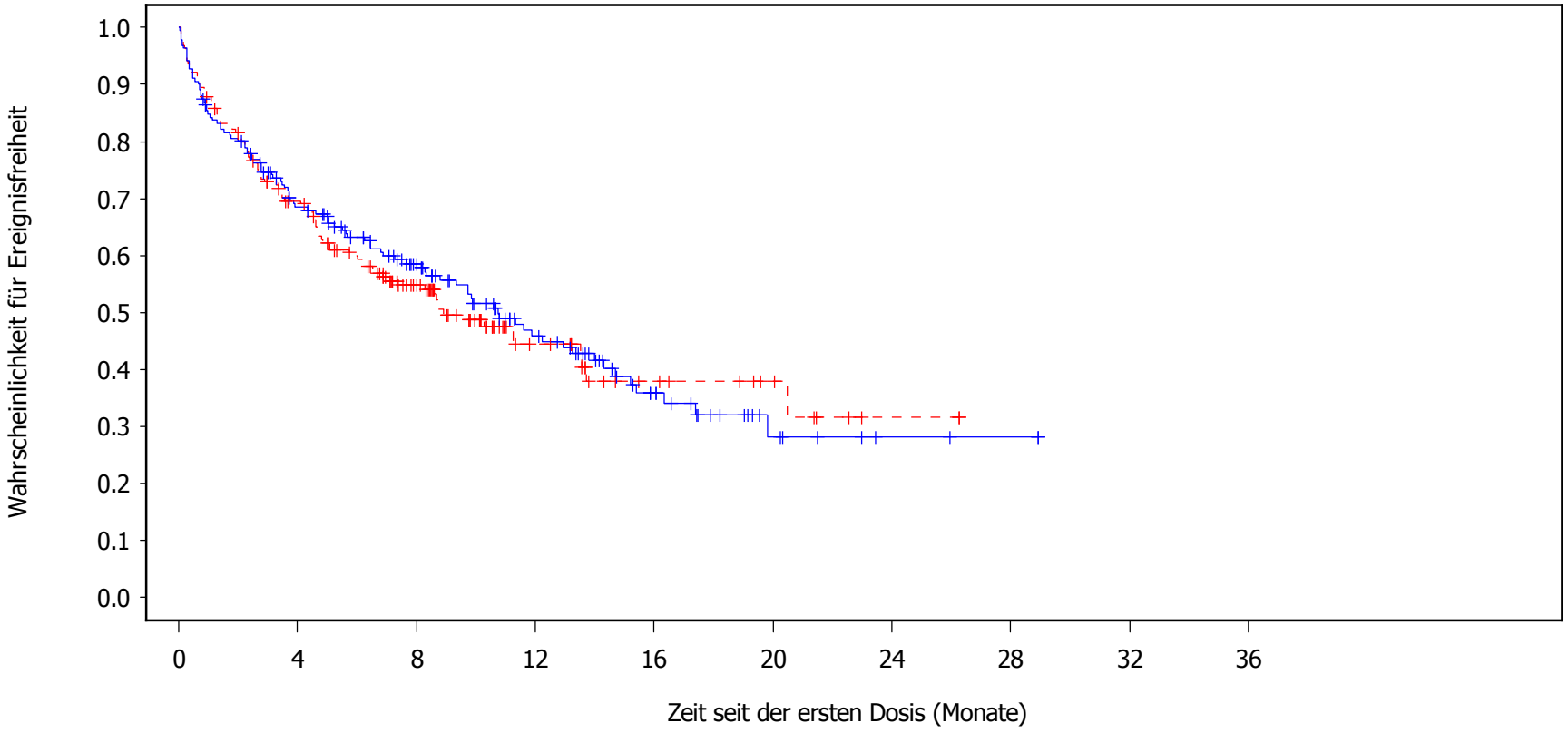
Figure 3.3.2.1D.53 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Herzerkrankungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	166	133	90	56	30	11	5	1	0	CTx + Durvalumab + Olaparib
190	164	119	64	32	14	5	1	1	0	CTx

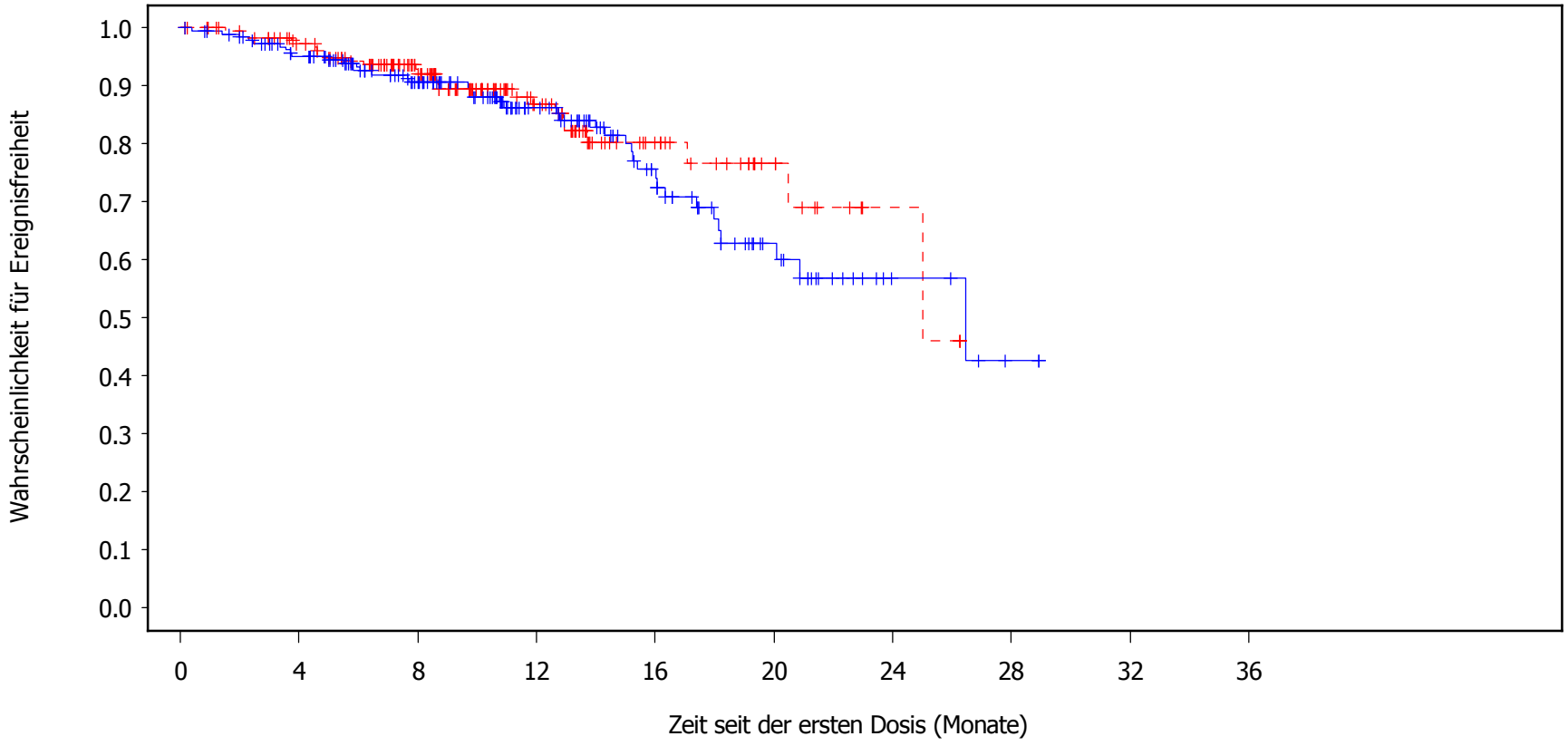
Figure 3.3.2.1D.54 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Infektionen und parasitaere Erkrankungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	121	83	46	22	7	2	1	0	0	CTx + Durvalumab + Olaparib
190	124	72	26	12	7	1	0	0	0	CTx

Figure 3.3.2.1D.55 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: COVID-19
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	168	129	81	48	22	5	1	0	0	CTx + Durvalumab + Olaparib
190	169	120	62	28	12	3	0	0	0	CTx

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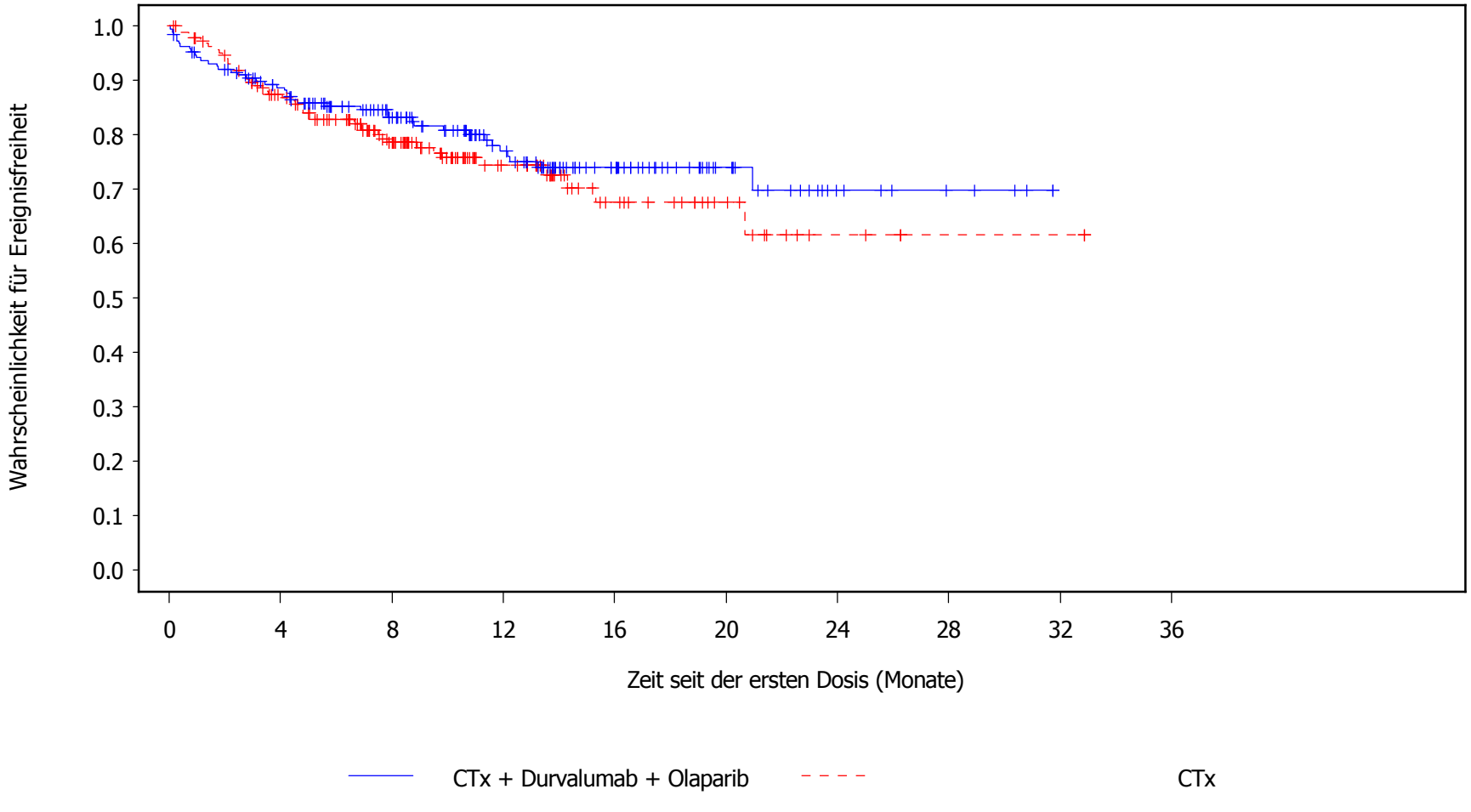
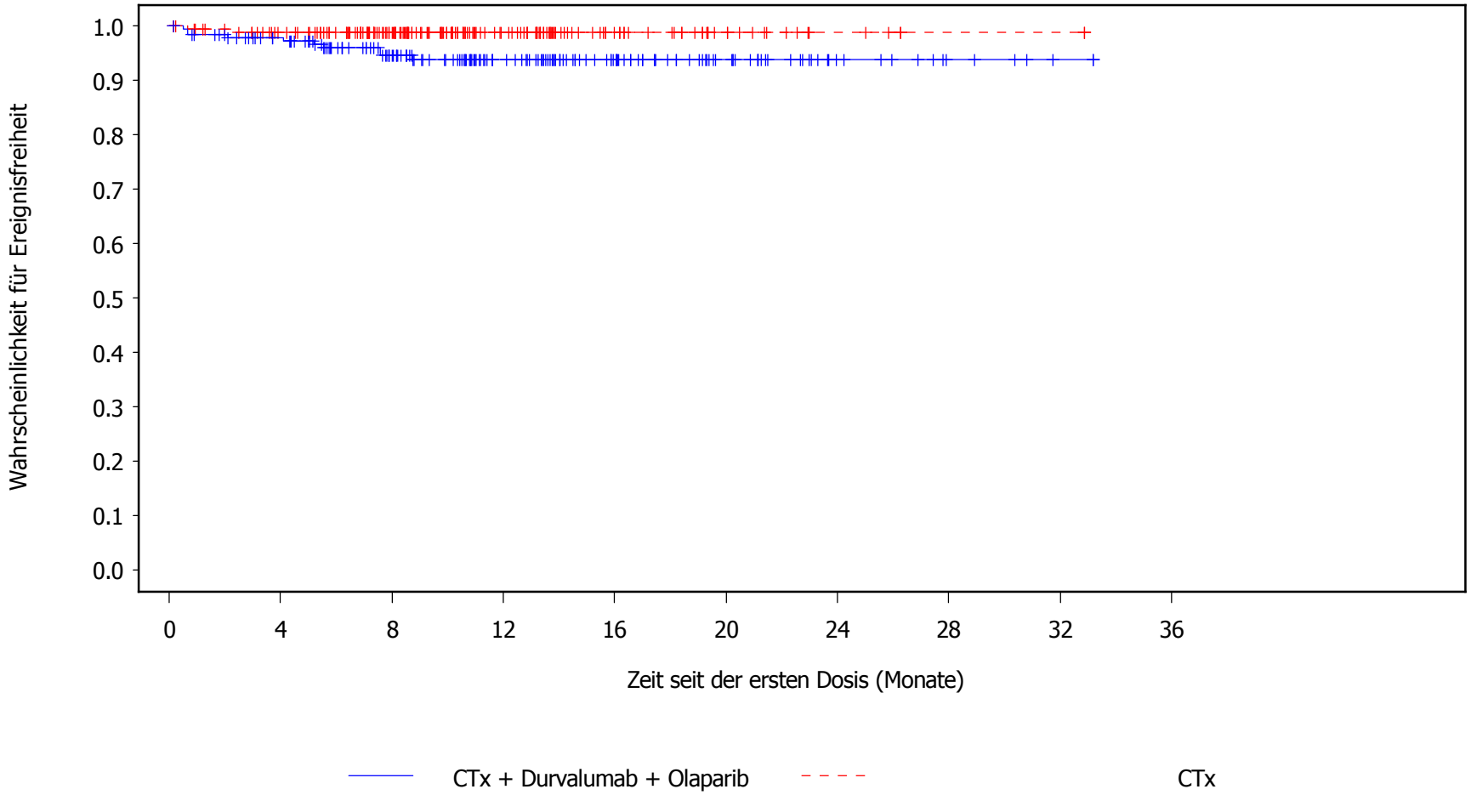
Figure 3.3.2.1D.56 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Harnwegsinfektion
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	157	118	78	46	22	8	4	0	0	CTx + Durvalumab + Olaparib
190	152	103	51	24	13	4	1	1	0	CTx

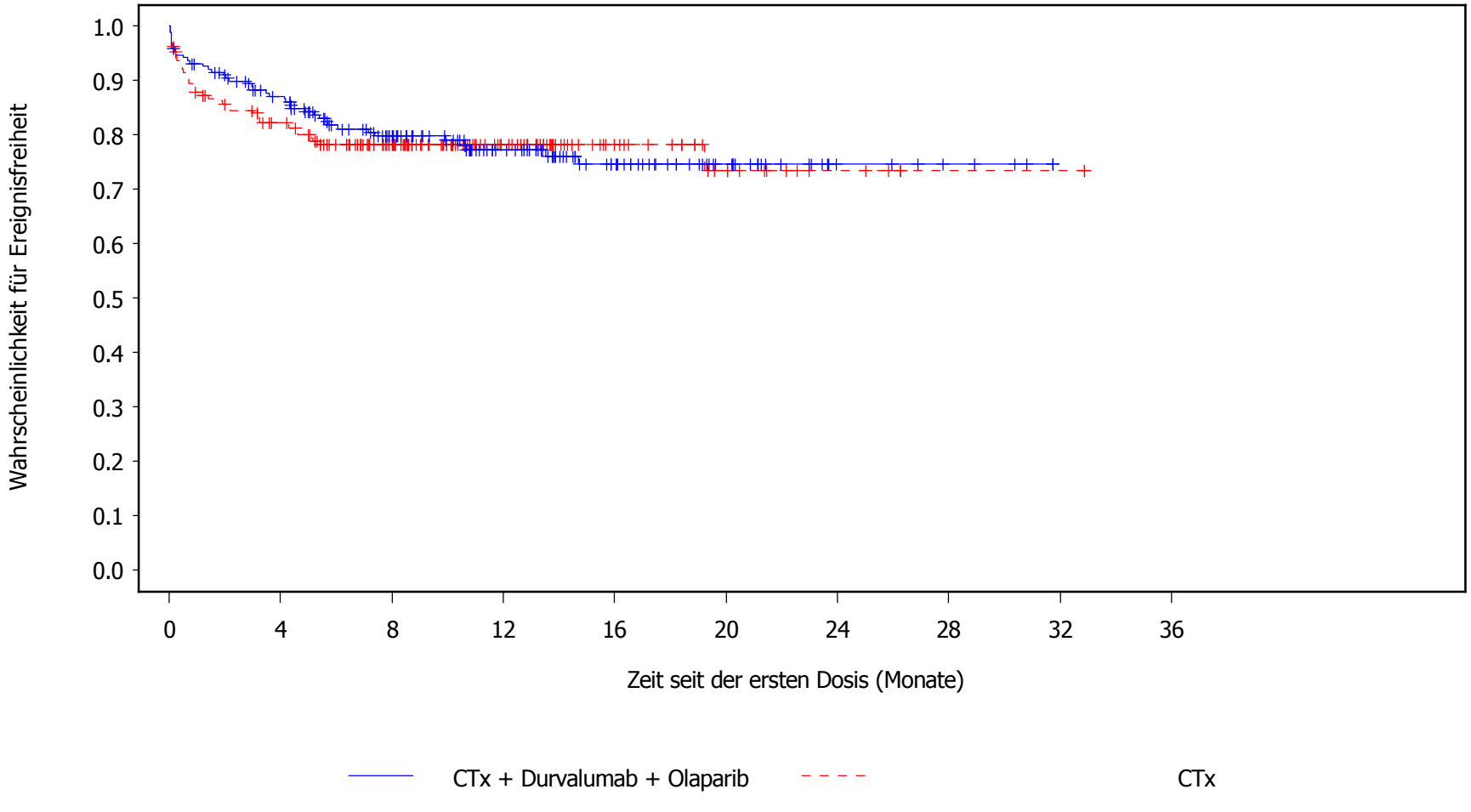
Figure 3.3.2.1D.57 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Leber- und Gallenerkrankungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	172	133	91	58	33	12	5	1	0	CTx + Durvalumab + Olaparib
190	172	126	69	33	15	5	1	1	0	CTx

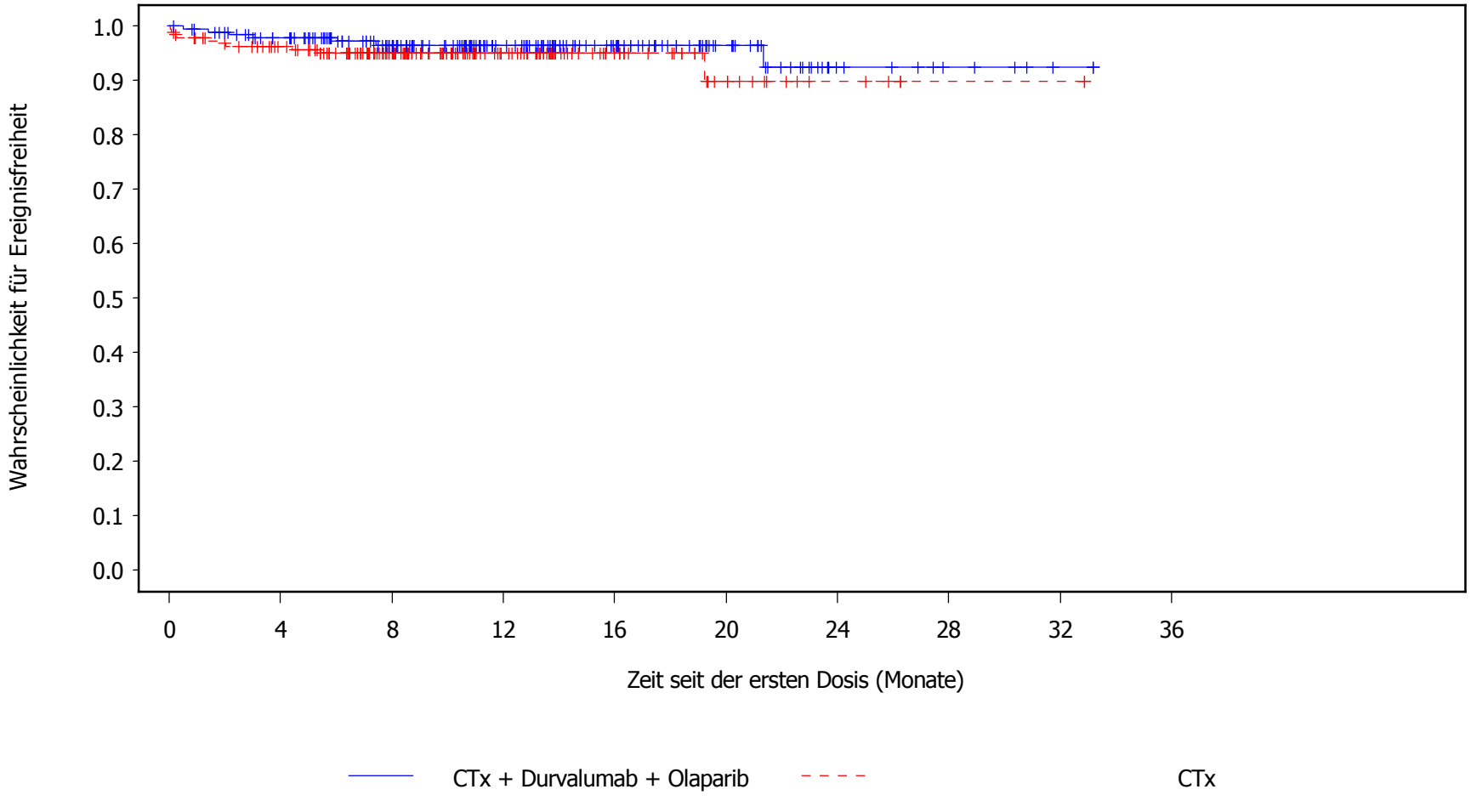
Figure 3.3.2.1D.58 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Psychiatrische Erkrankungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	153	112	74	46	25	7	4	0	0	CTx + Durvalumab + Olaparib
190	146	105	58	27	13	5	1	1	0	CTx

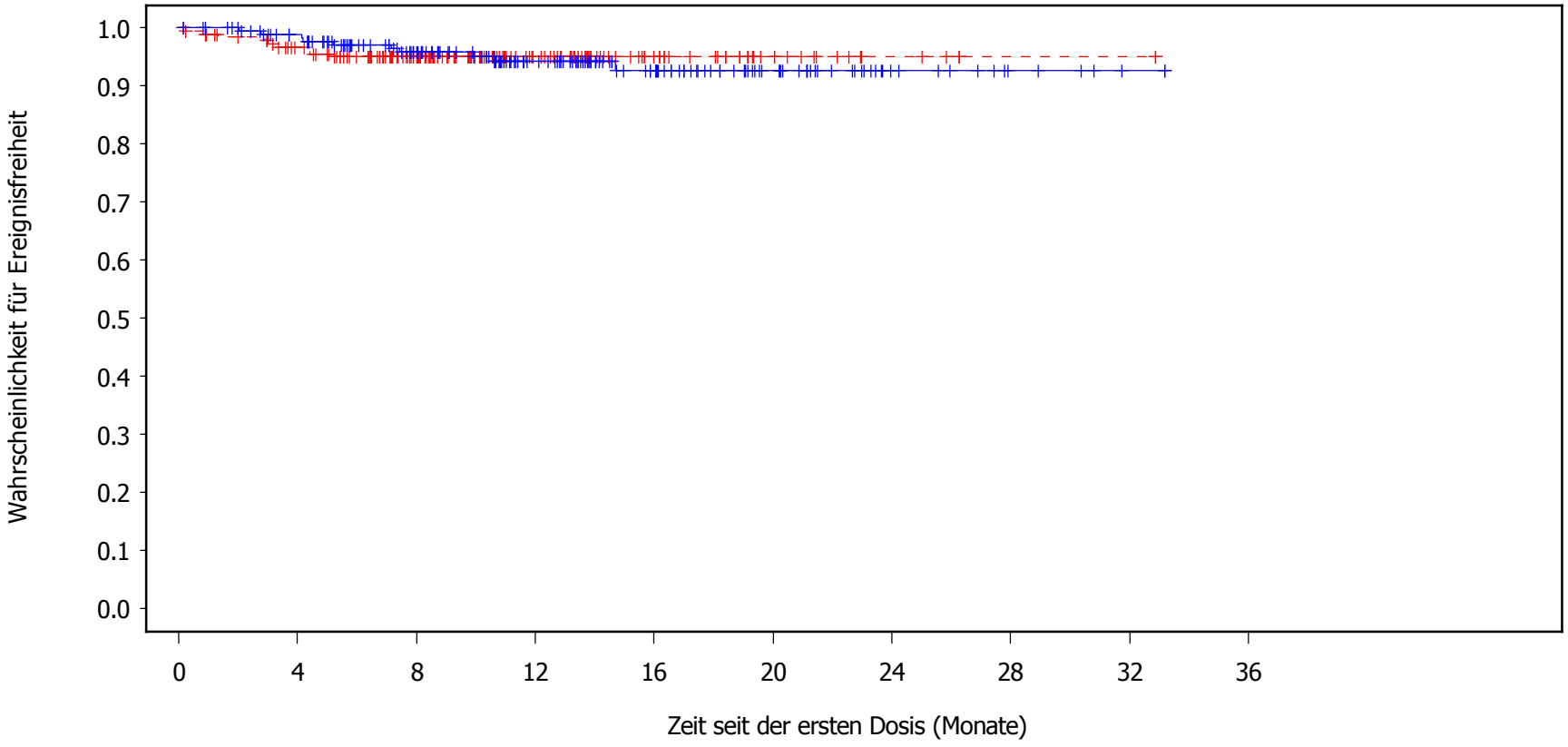
Figure 3.3.2.1D.59 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Angst
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	172	135	92	60	34	10	5	1	0	CTx + Durvalumab + Olaparib
190	168	122	68	32	14	5	1	1	0	CTx

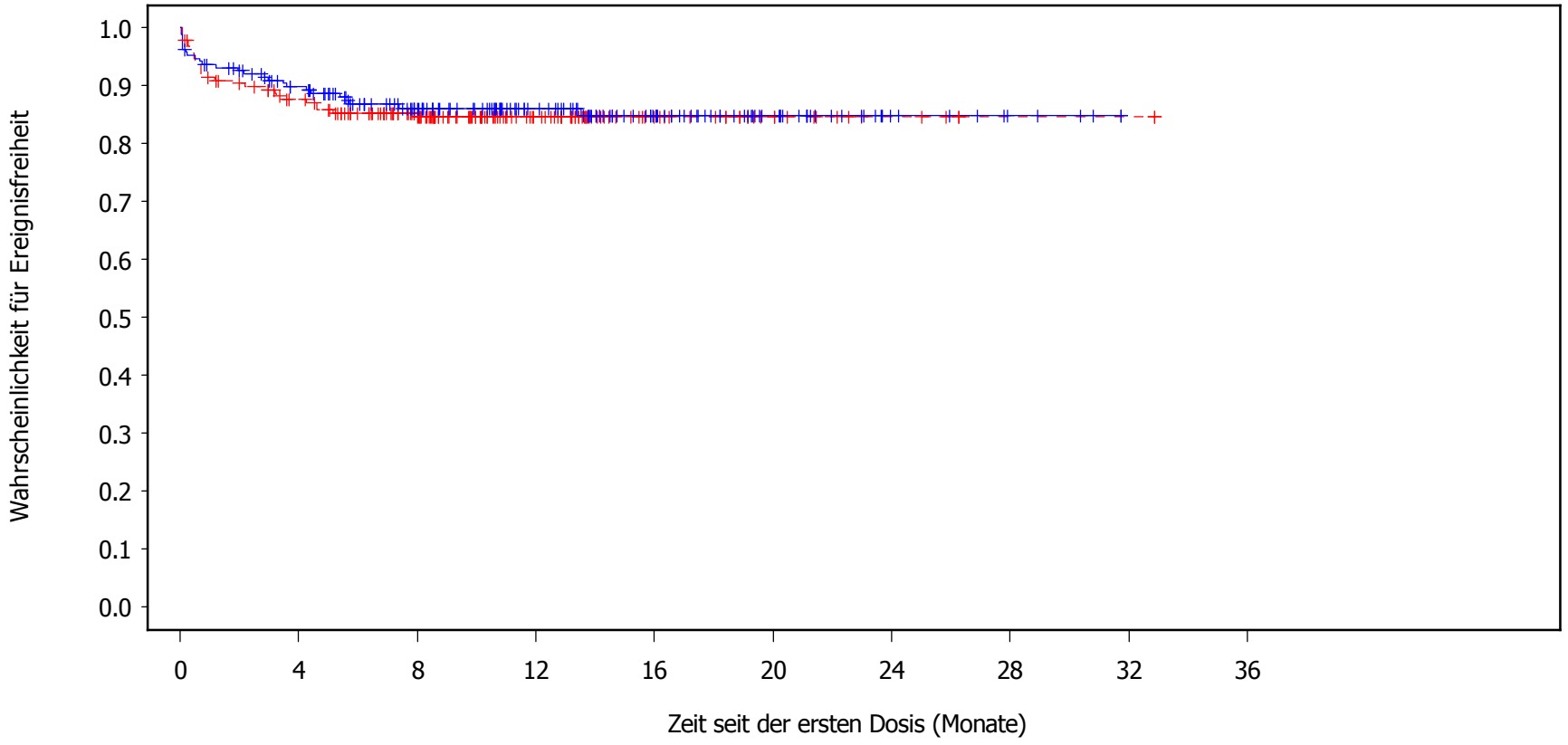
Figure 3.3.2.1D.60 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Depression
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	174	136	93	60	34	12	5	1	0	CTx + Durvalumab + Olaparib
190	169	123	67	33	15	5	1	1	0	CTx

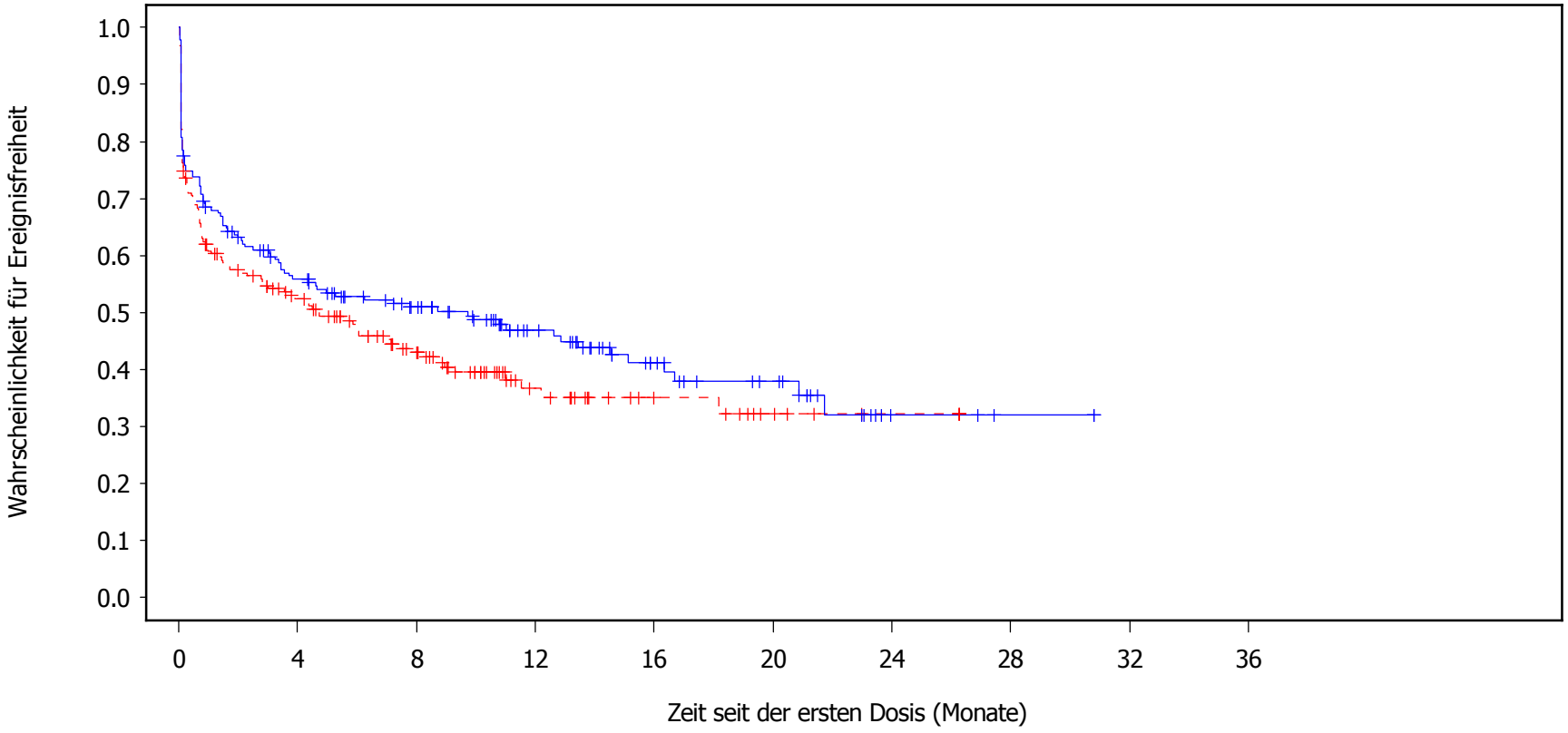
Figure 3.3.2.1D.61 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schlaflosigkeit
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	157	119	82	52	28	9	4	0	0	CTx + Durvalumab + Olaparib
190	154	112	59	27	13	5	1	1	0	CTx

Figure 3.3.2.1D.62 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	98	75	48	27	18	3	1	0	0	CTx + Durvalumab + Olaparib
190	87	55	24	13	6	2	0	0	0	CTx

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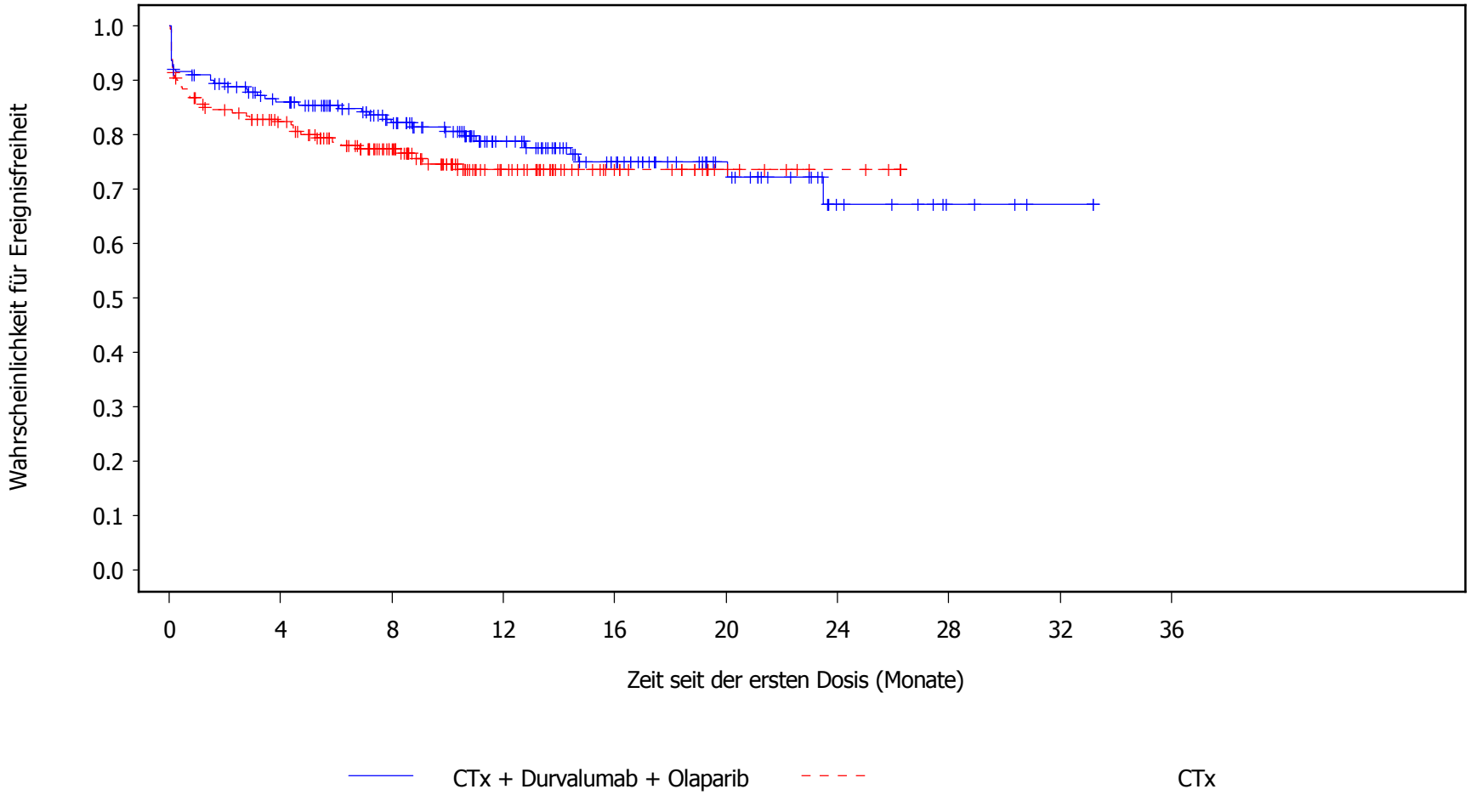
Figure 3.3.2.1D.63 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Arthralgie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	151	117	76	48	28	10	4	1	0	CTx + Durvalumab + Olaparib
190	141	99	49	24	10	4	0	0	0	CTx

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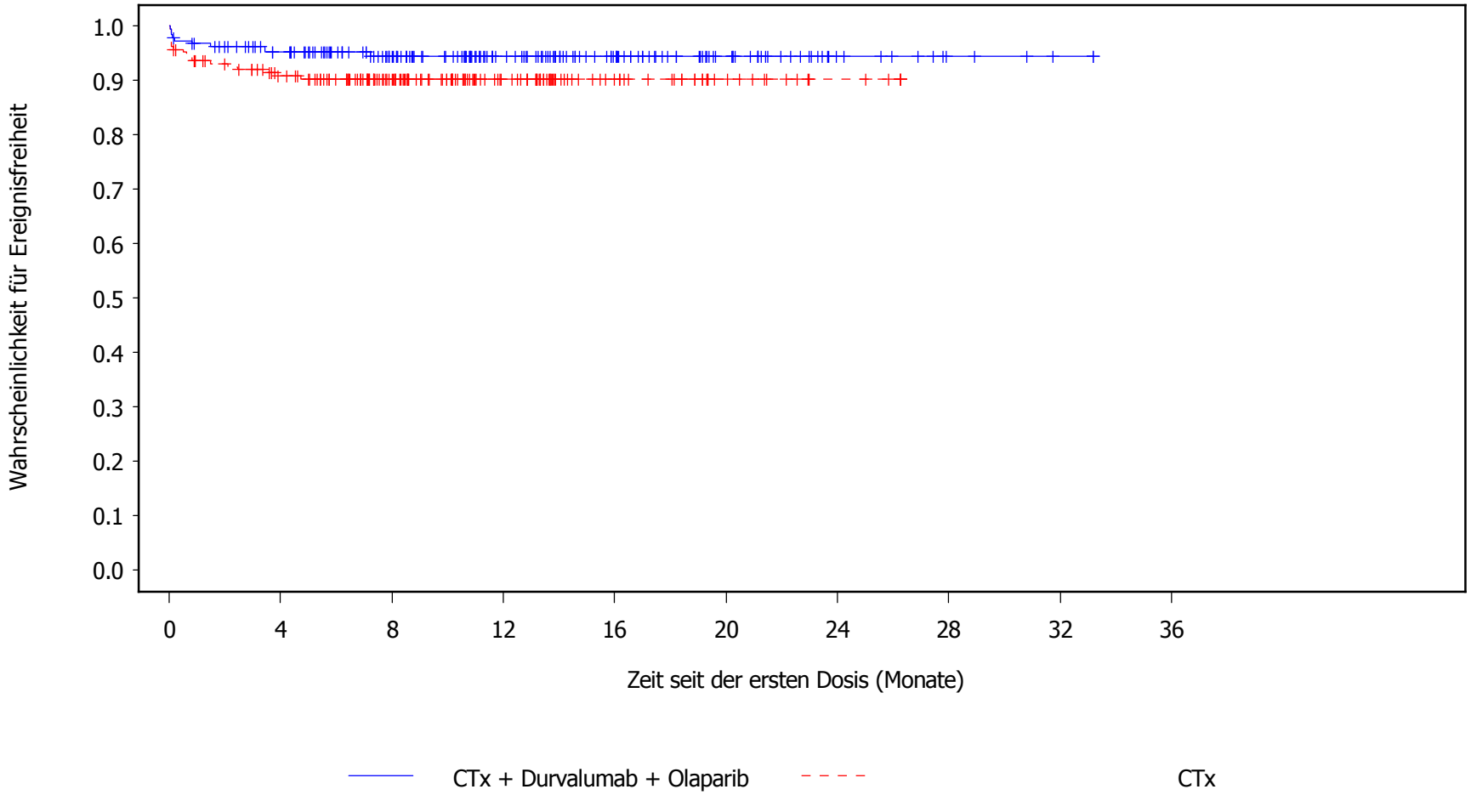
Figure 3.3.2.1D.64 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Knochenschmerzen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	167	131	90	59	33	11	4	1	0	CTx + Durvalumab + Olaparib
190	157	112	63	31	13	4	0	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bcl 17APR2024:11:32

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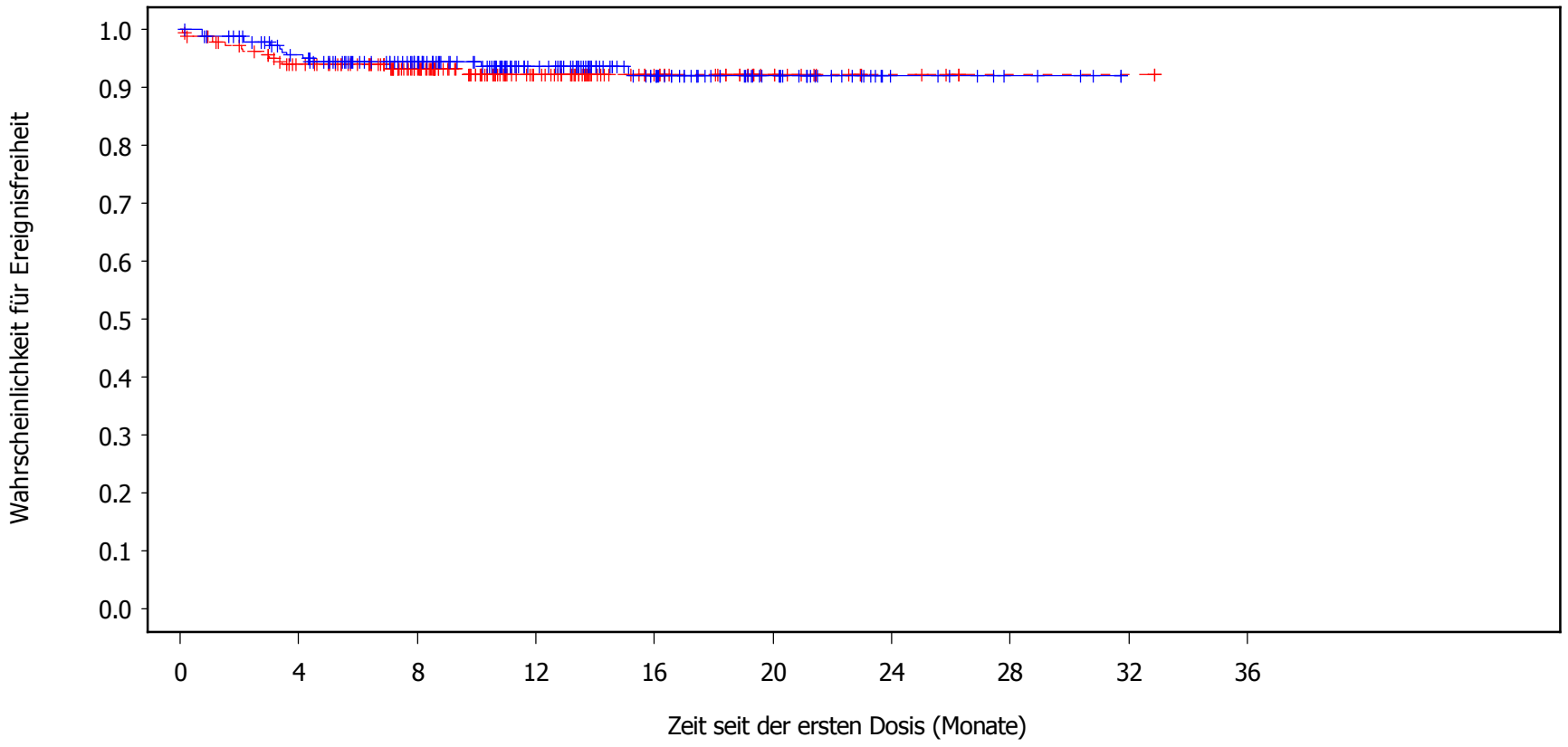
Figure 3.3.2.1D.65 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Muskulaere Schwaeche
Patients with pMMR tumour status, DCO 12APR2023

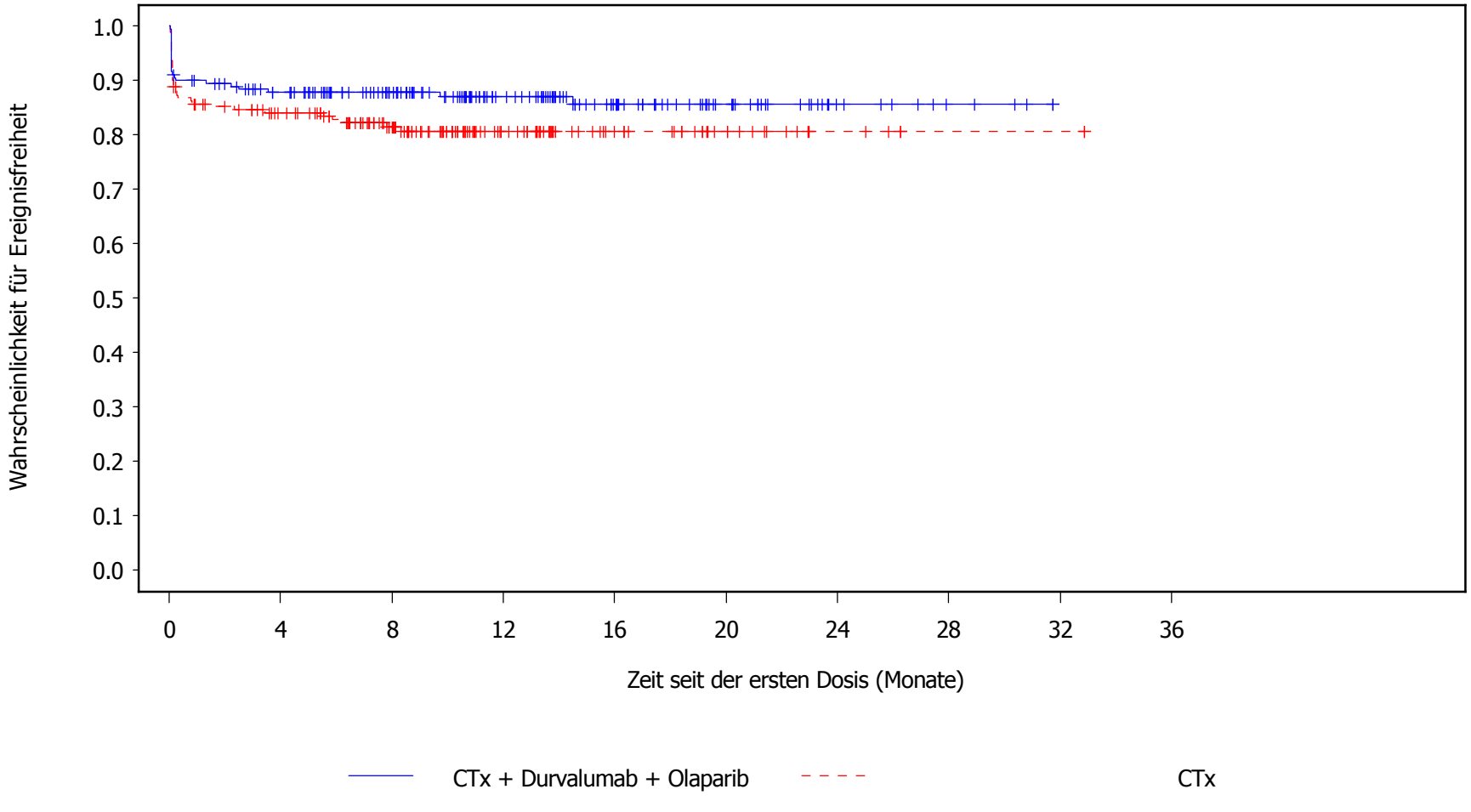


Anzahl an Patienten unter Risiko:

191	169	135	91	57	31	9	4	0	0	CTx + Durvalumab + Olaparib
190	163	122	65	32	14	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bcm 17APR2024:11:32

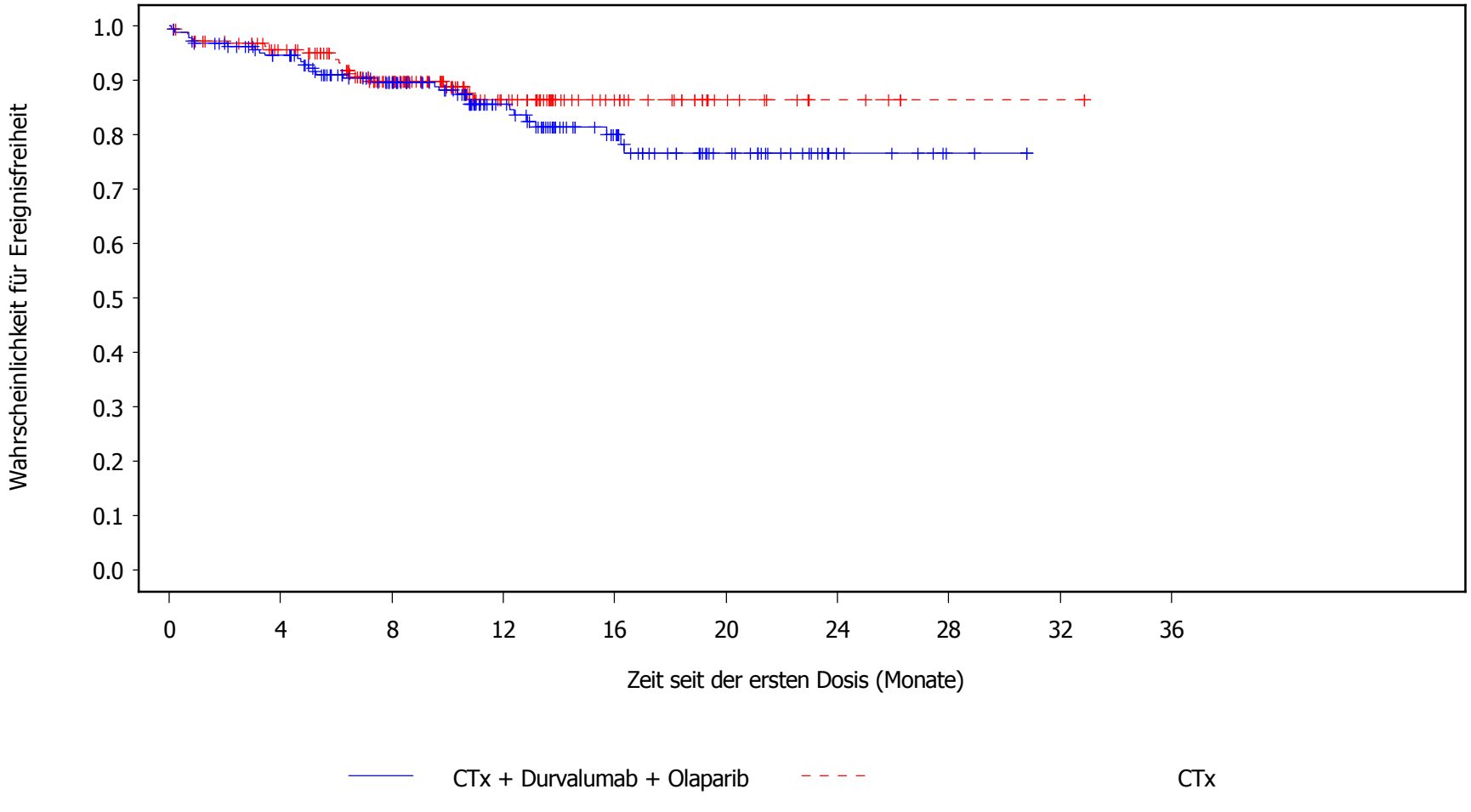
Figure 3.3.2.1D.66 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Myalgie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	154	122	83	52	29	10	4	0	0	CTx + Durvalumab + Olaparib
190	144	105	55	29	15	5	1	1	0	CTx

Figure 3.3.2.1D.67 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Rueckenschmerzen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	167	128	84	51	28	8	2	0	0	CTx + Durvalumab + Olaparib
190	166	117	59	30	12	5	1	1	0	CTx

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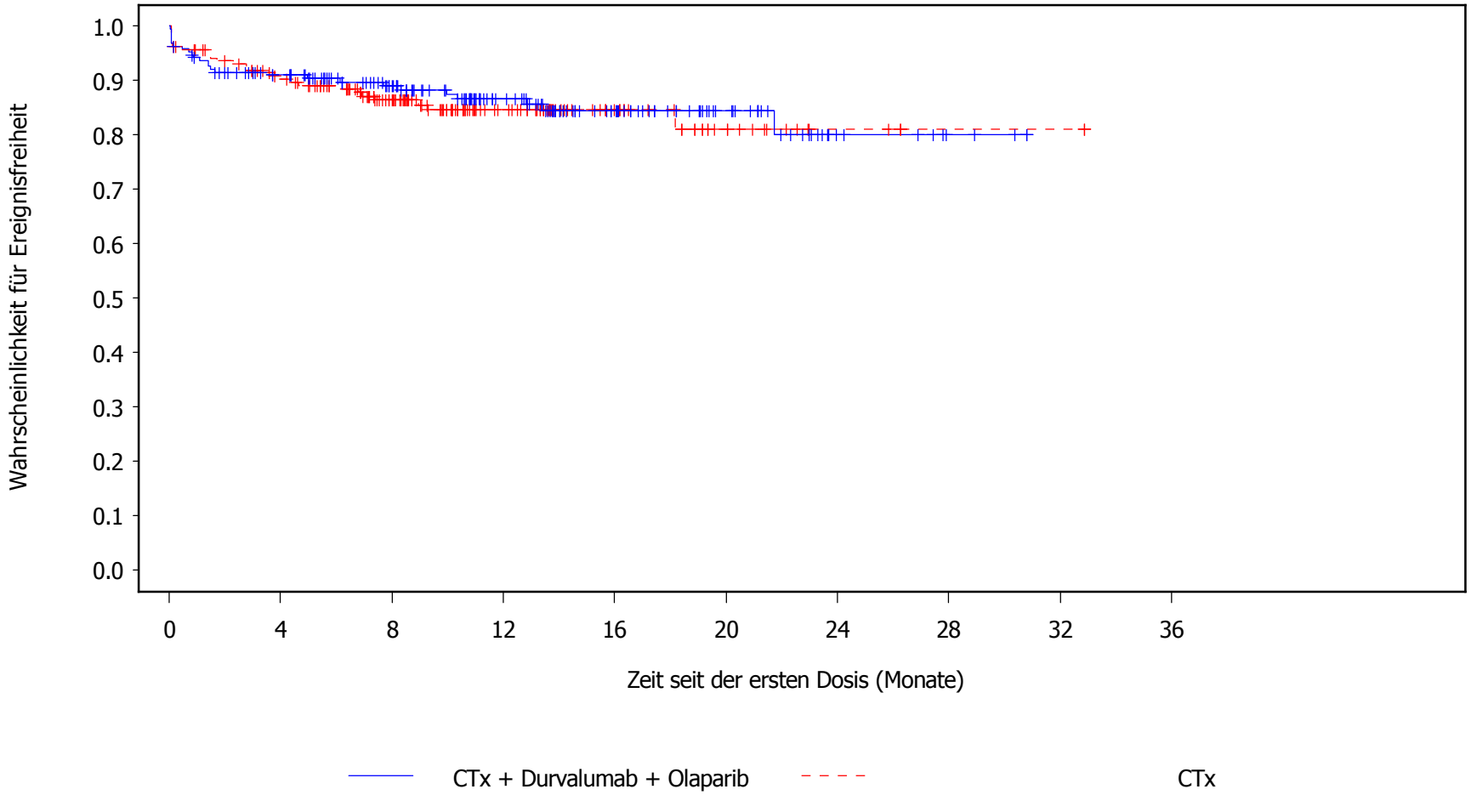
Figure 3.3.2.1D.68 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schmerz in einer Extremitaet
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	159	126	85	52	29	8	3	0	0	CTx + Durvalumab + Olaparib
190	158	112	61	32	14	4	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bcp 17APR2024:11:32

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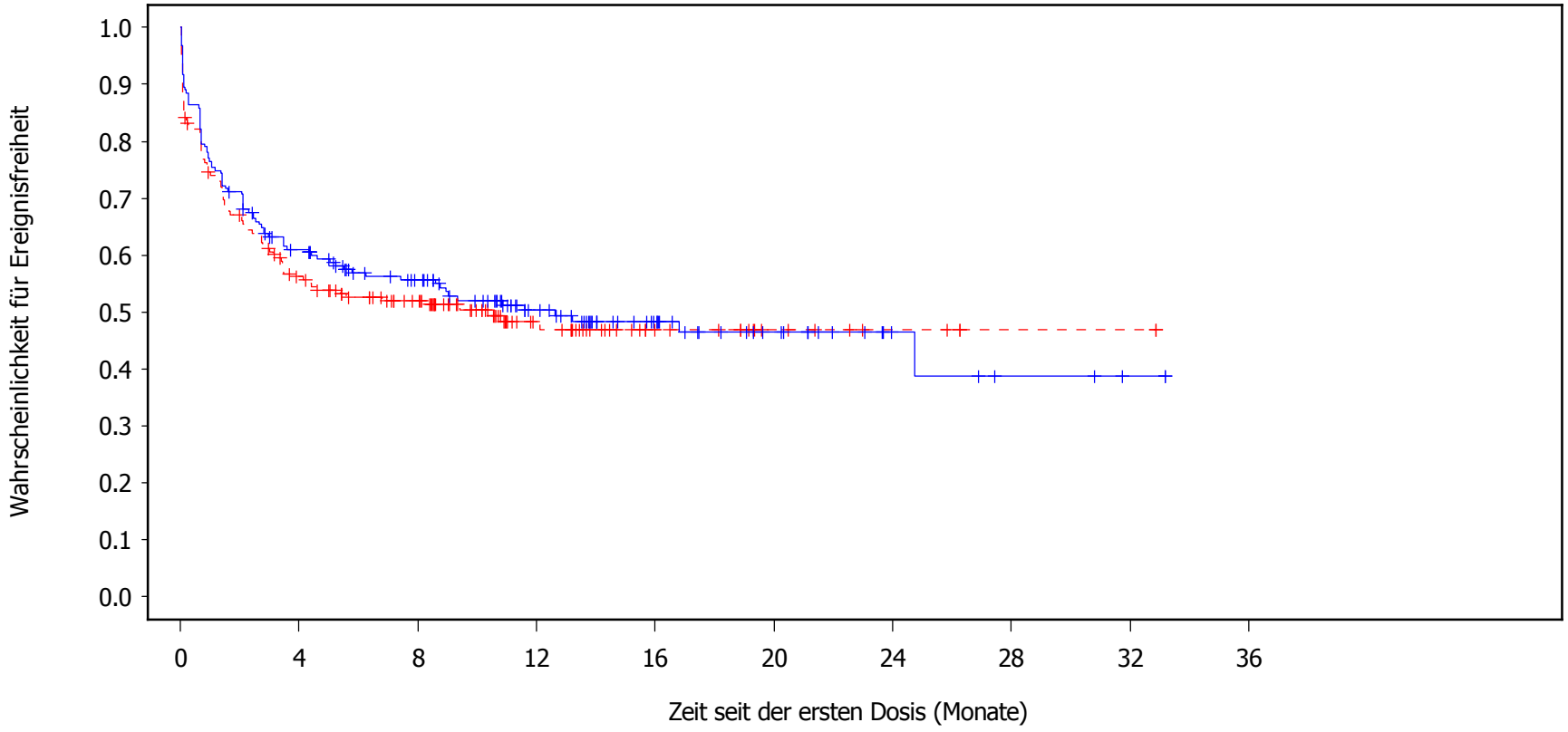
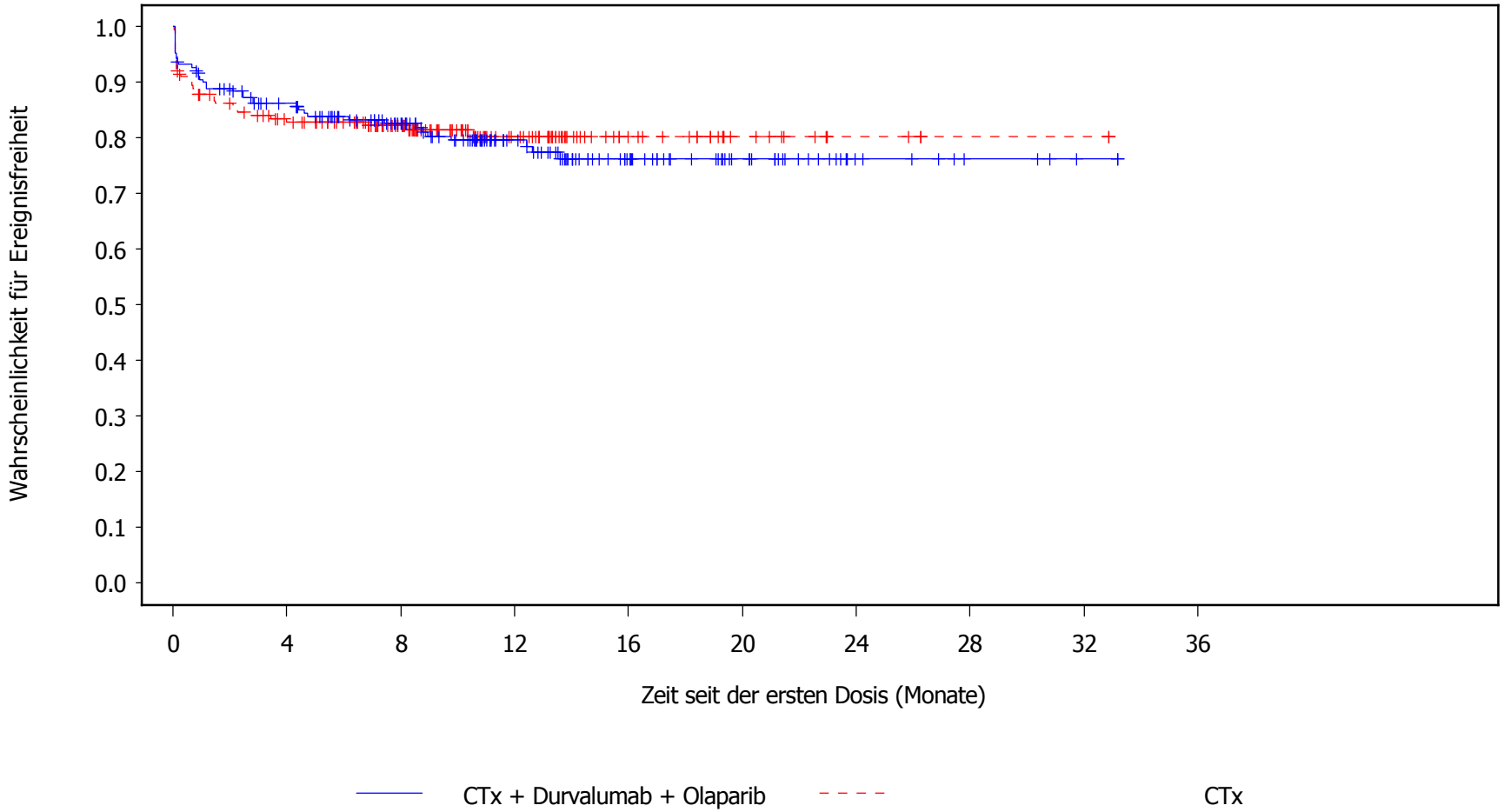
Figure 3.3.2.1D.69 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Stoffwechsel- und Ernaehrungsstoerungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	110	84	53	30	17	6	3	1	0	CTx + Durvalumab + Olaparib
190	99	74	35	17	8	4	1	1	0	CTx

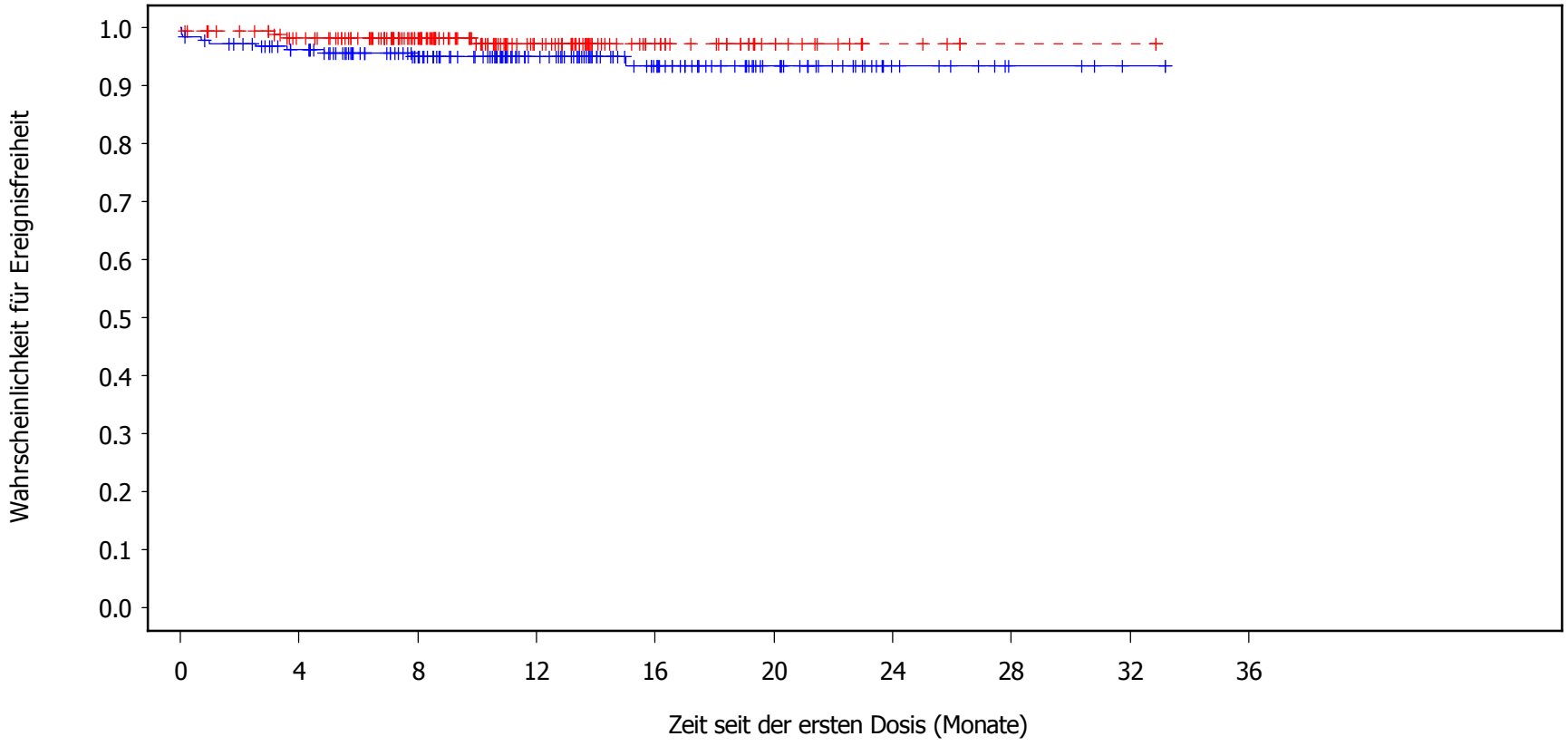
Figure 3.3.2.1D.70 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Appetit vermindert
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	151	120	78	46	27	9	4	1	0	CTx + Durvalumab + Olaparib
190	146	106	57	25	11	4	1	1	0	CTx

Figure 3.3.2.1D.71 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypalbuminaemie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	171	136	94	60	33	11	4	1	0	CTx + Durvalumab + Olaparib
190	172	126	70	34	15	5	1	1	0	CTx

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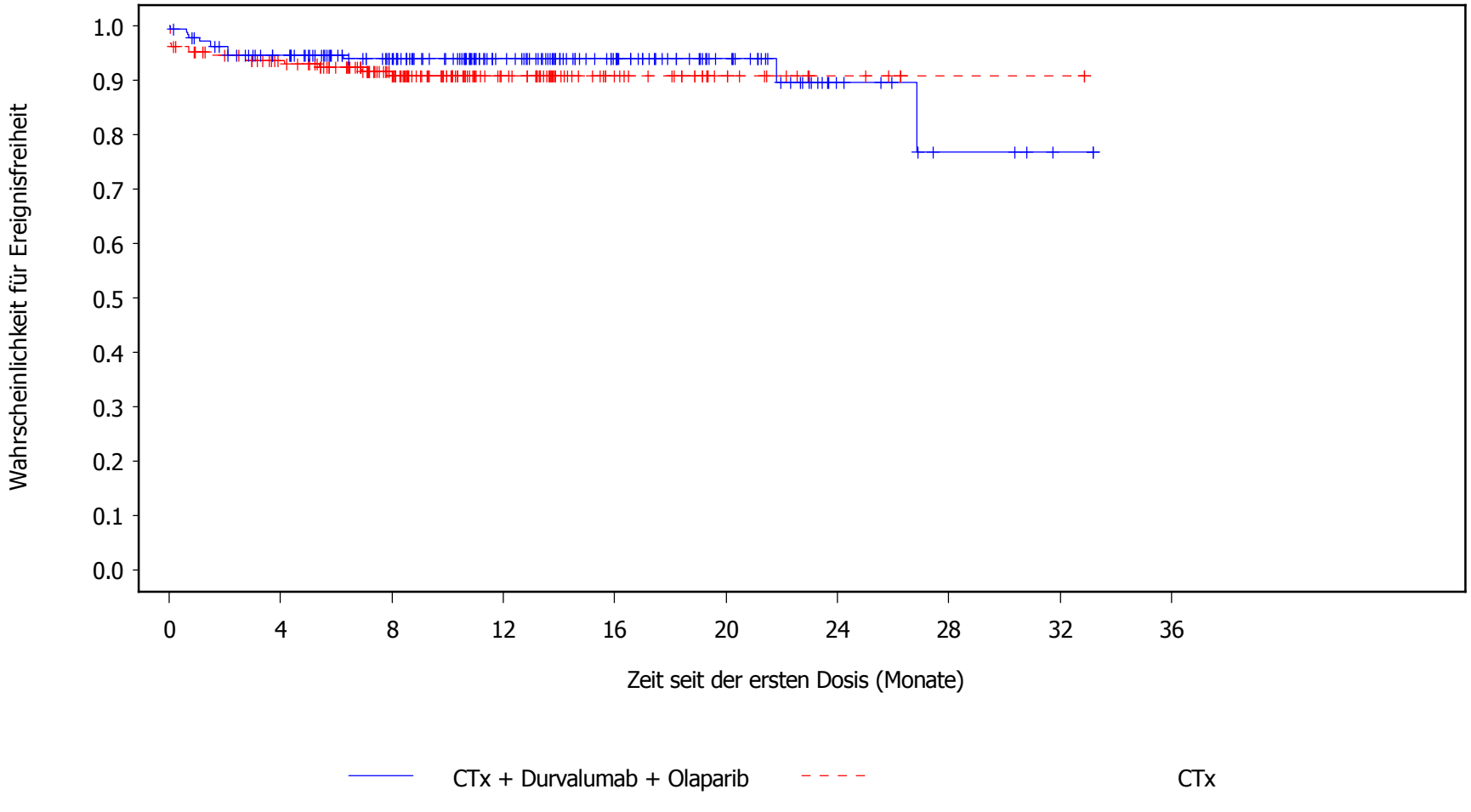
Figure 3.3.2.1D.72 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hyperglykaemie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	167	135	93	60	34	10	4	1	0	CTx + Durvalumab + Olaparib
190	162	116	62	31	14	5	1	1	0	CTx

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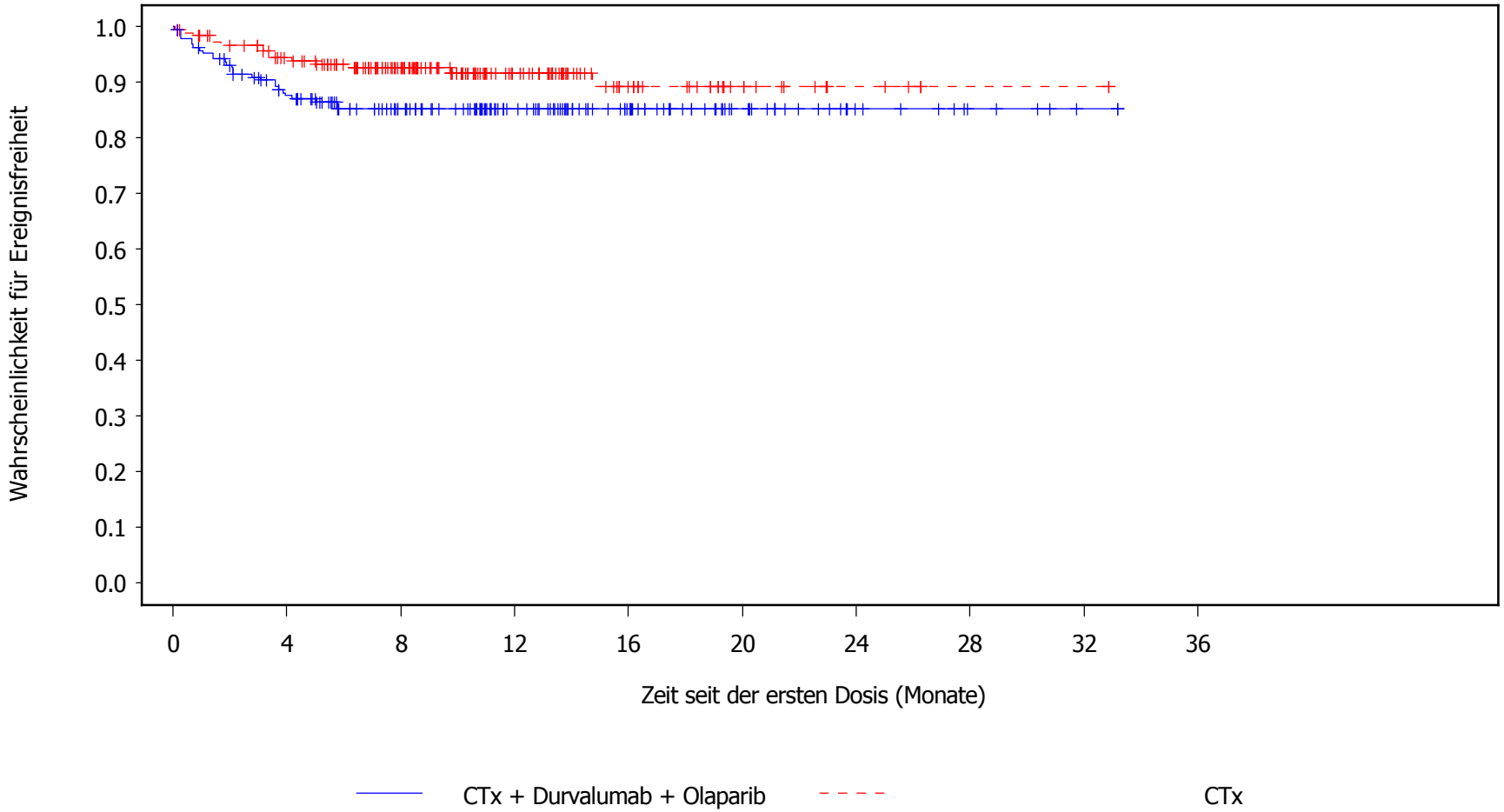
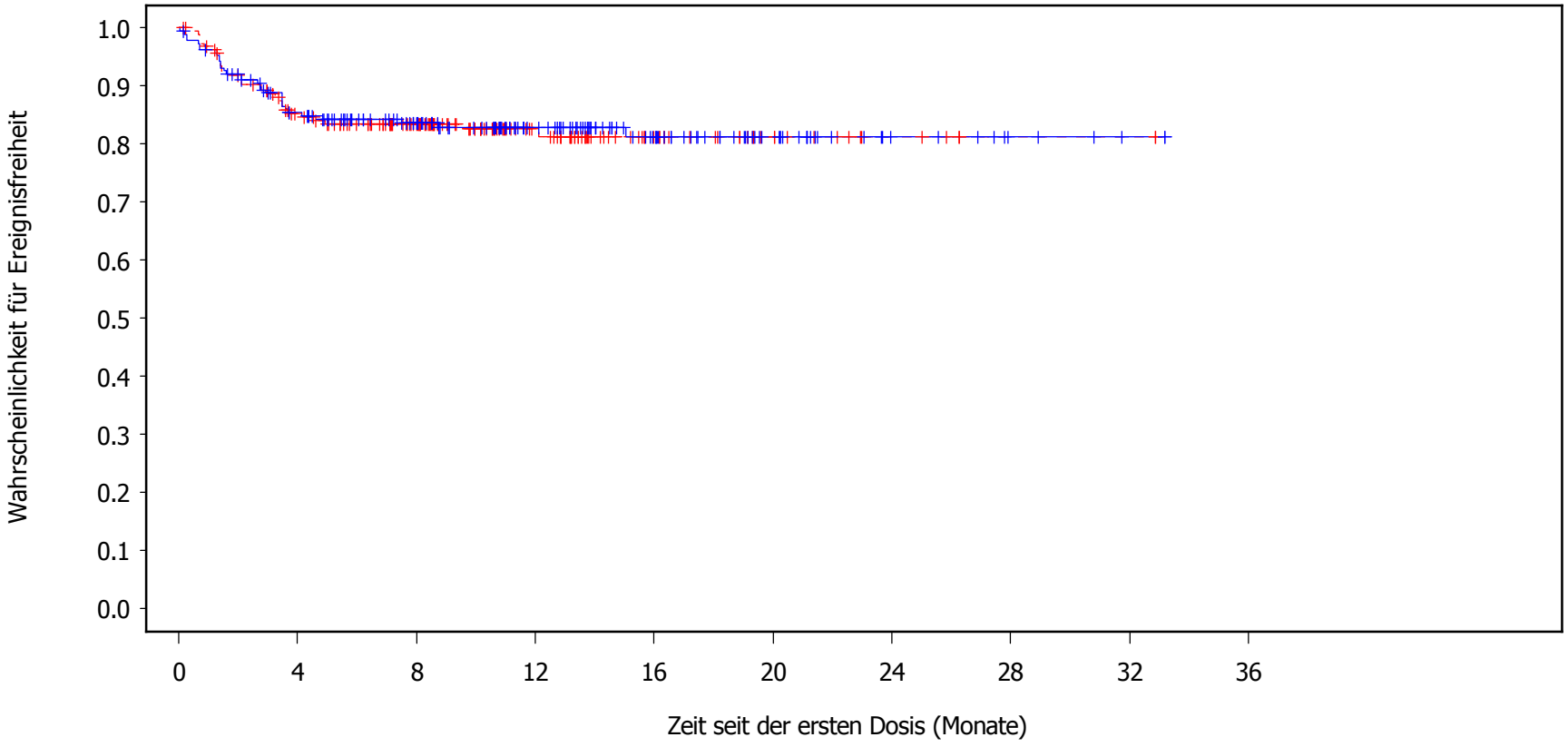
Figure 3.3.2.1D.73 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypokaliaemie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	155	120	82	52	28	11	5	1	0	CTx + Durvalumab + Olaparib
190	164	119	64	30	13	5	1	1	0	CTx

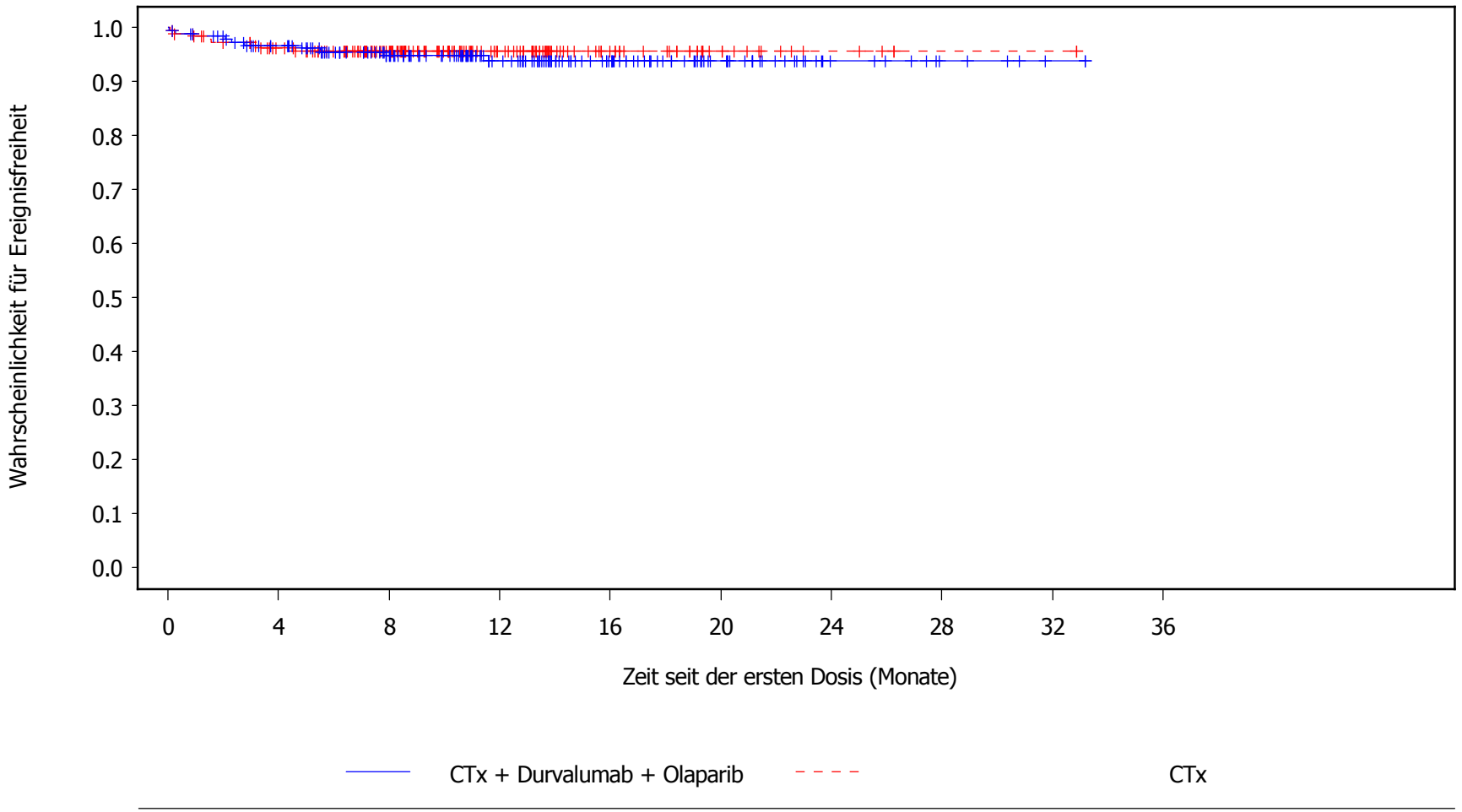
Figure 3.3.2.1D.74 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypomagnesiaemie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	151	118	81	49	26	9	4	1	0	CTx + Durvalumab + Olaparib
190	148	112	61	30	13	5	1	1	0	CTx

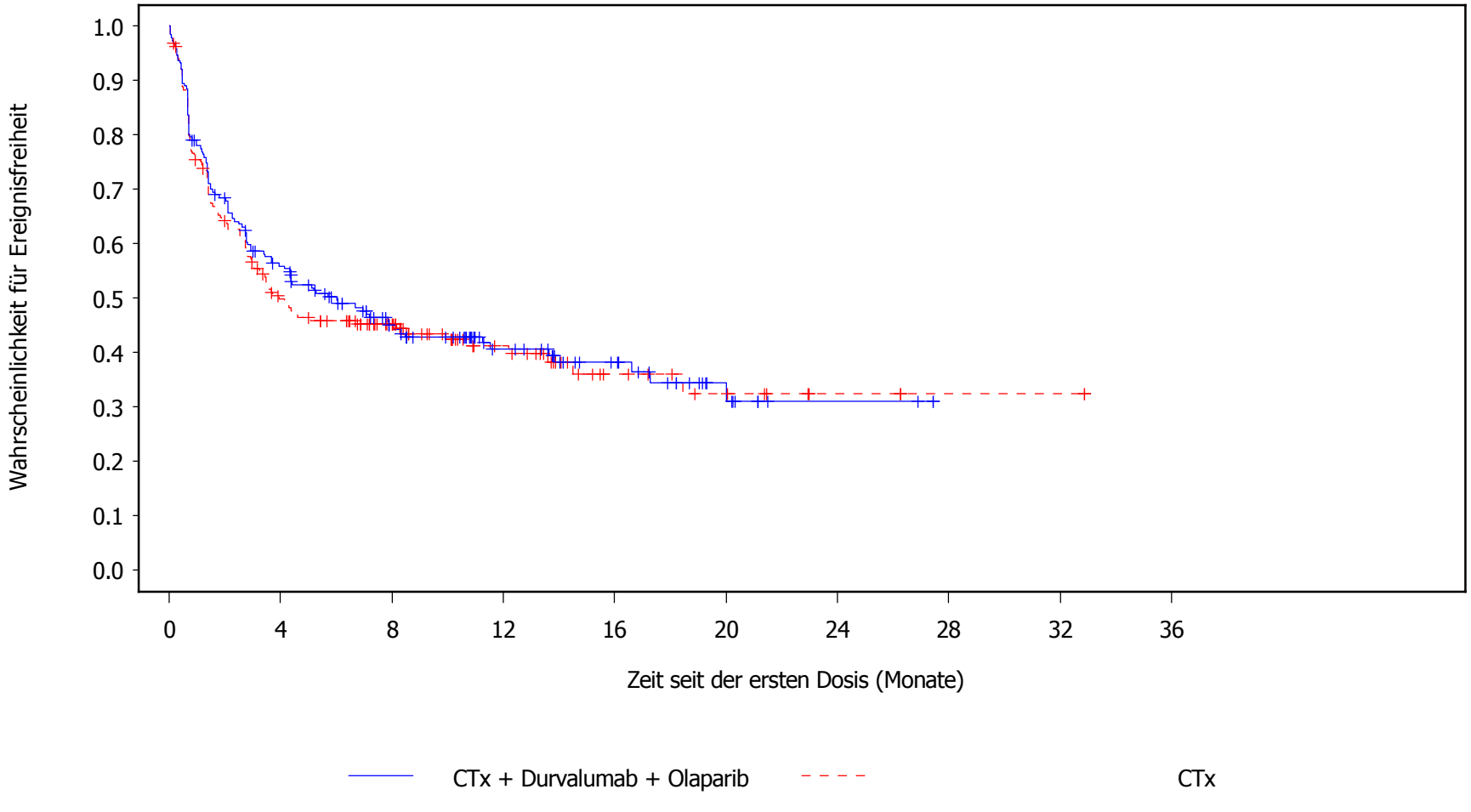
Figure 3.3.2.1D.75 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hyponatriaemie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	170	135	93	59	32	11	5	1	0	CTx + Durvalumab + Olaparib
190	168	124	68	33	14	5	1	1	0	CTx

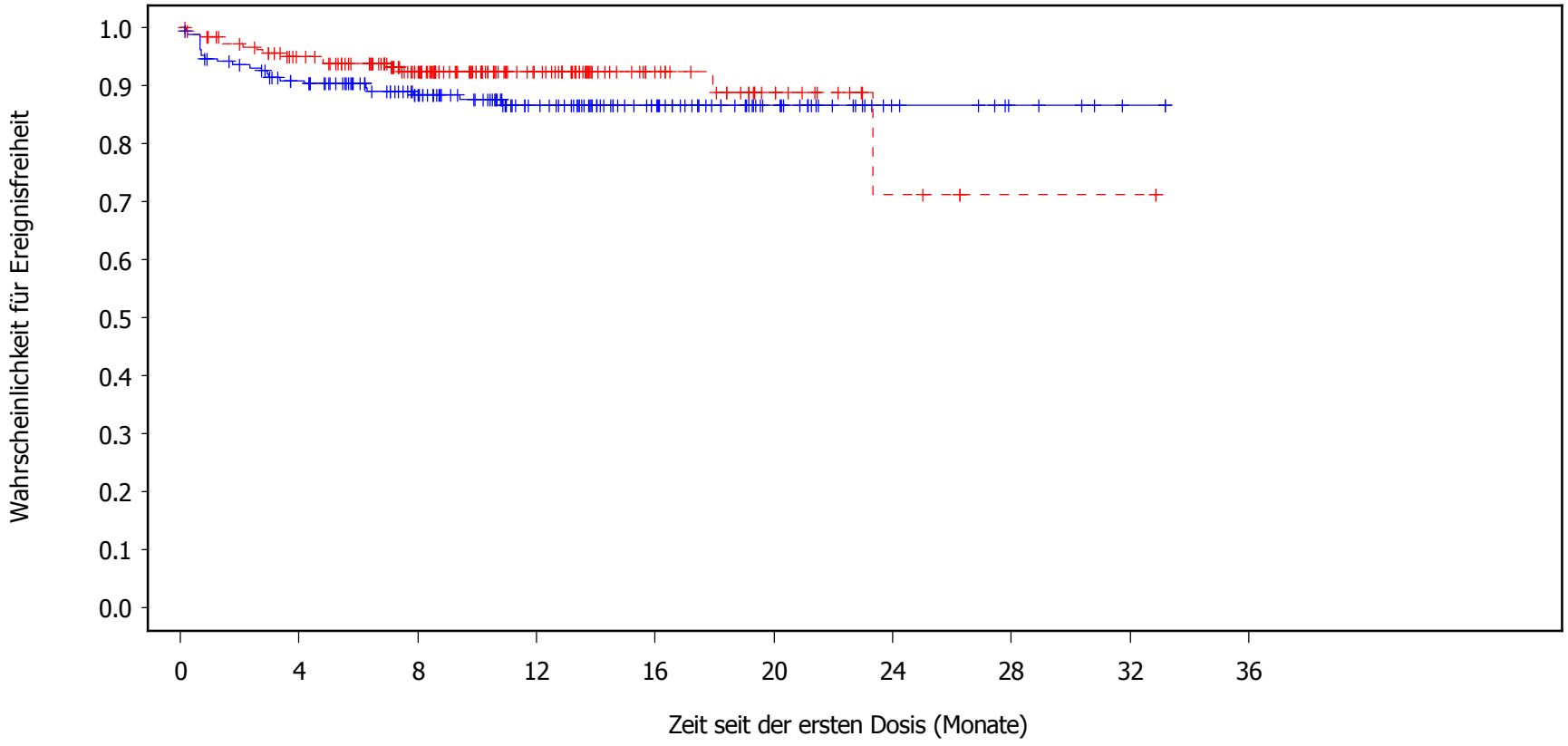
Figure 3.3.2.1D.76 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Untersuchungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	100	62	38	24	10	2	0	0	0	CTx + Durvalumab + Olaparib
190	87	58	30	13	8	3	1	1	0	CTx

Figure 3.3.2.1D.77 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Alaninaminotransferase erhoeht
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	162	125	86	56	30	10	5	1	0	CTx + Durvalumab + Olaparib
190	165	119	66	32	15	4	1	1	0	CTx

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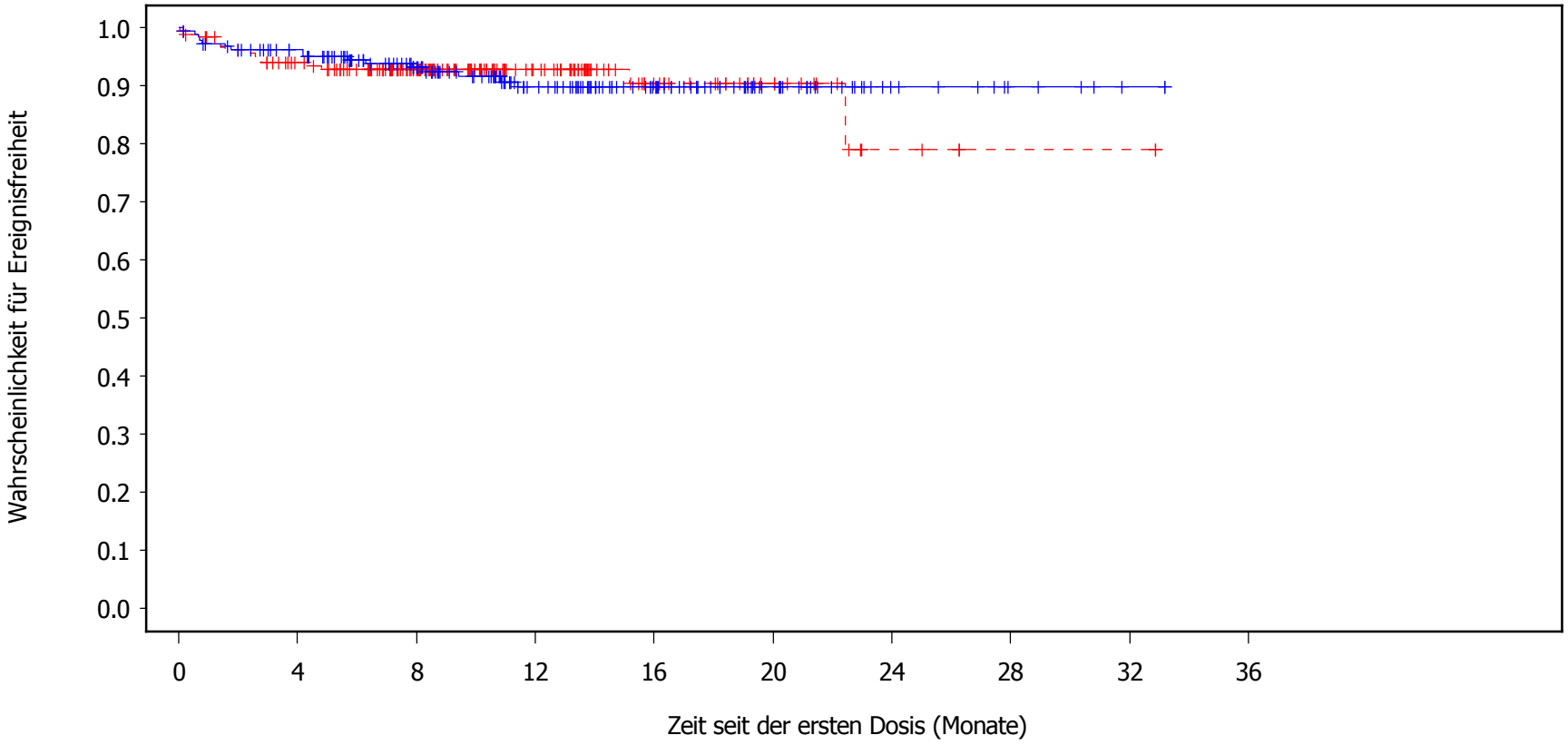
Figure 3.3.2.1D.78 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Aspartataminotransferase erhoeht
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	170	131	89	58	32	11	5	1	0	CTx + Durvalumab + Olaparib
190	165	119	65	31	15	4	1	1	0	CTx

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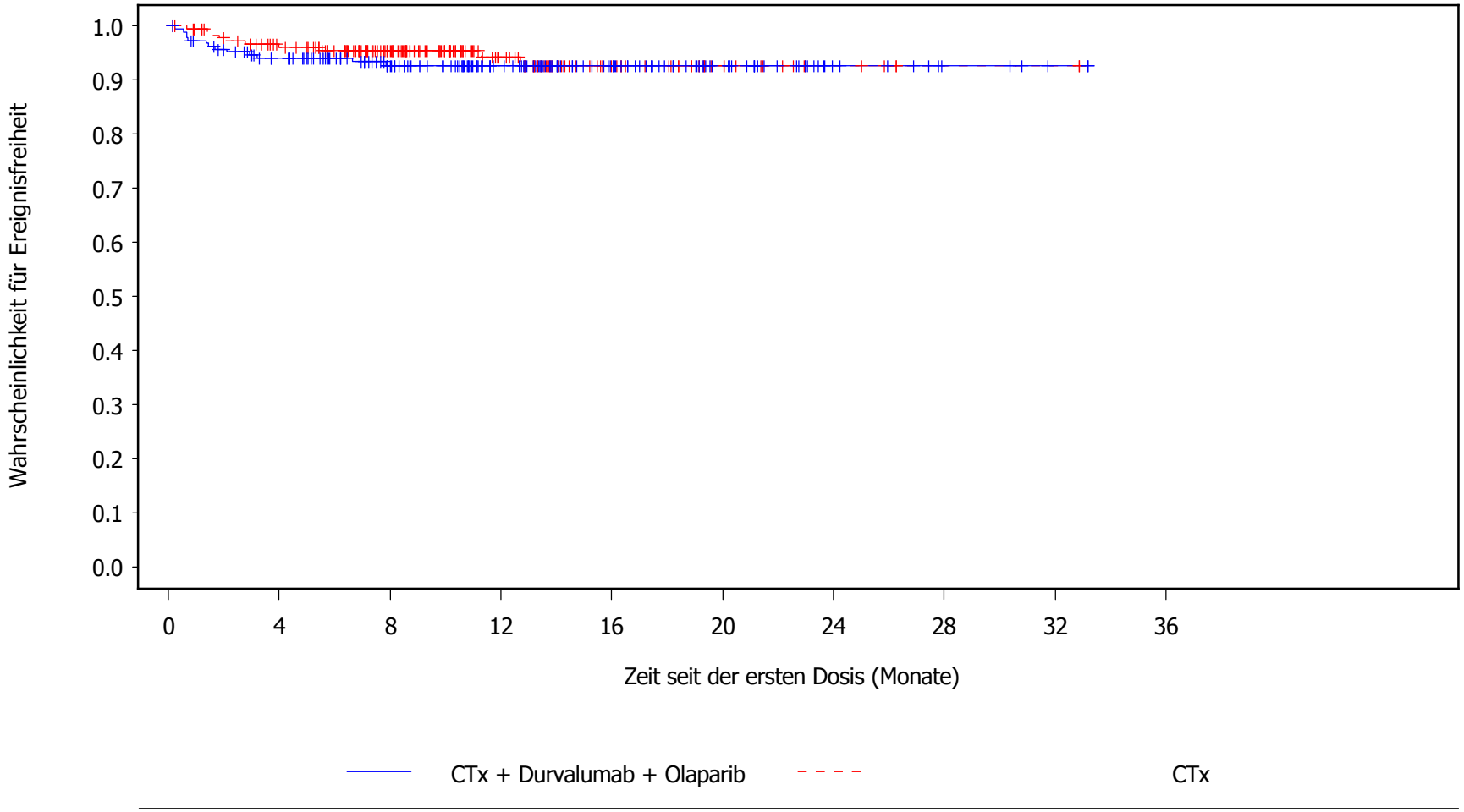
Figure 3.3.2.1D.79 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Gamma-Glutamyltransferase erhoeht
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	166	130	91	59	32	10	4	1	0	CTx + Durvalumab + Olaparib
190	167	124	66	32	14	5	1	1	0	CTx

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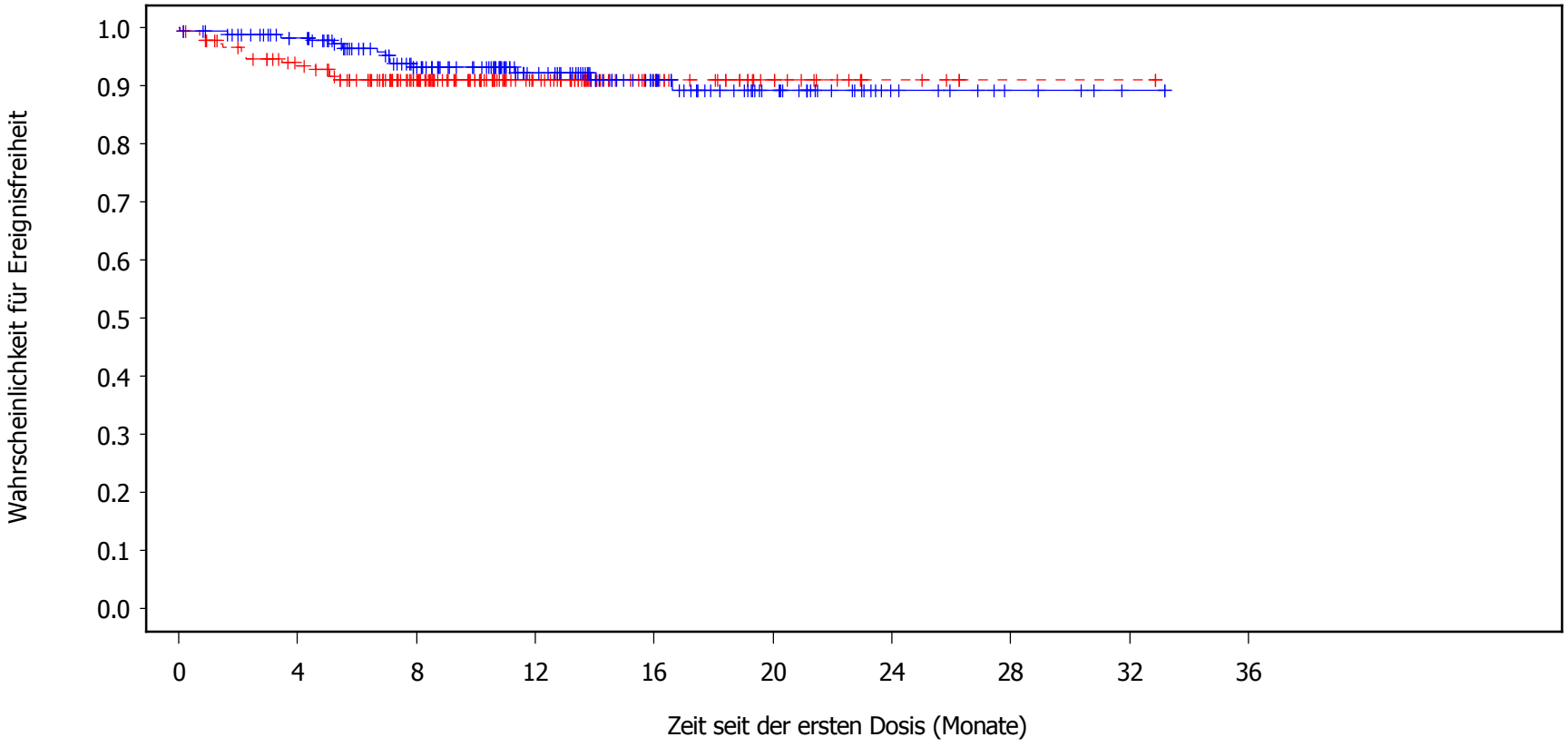
Figure 3.3.2.1D.80 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Gewicht erniedrigt
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	173	133	91	58	32	11	5	1	0	CTx + Durvalumab + Olaparib
190	164	120	66	32	15	5	1	1	0	CTx

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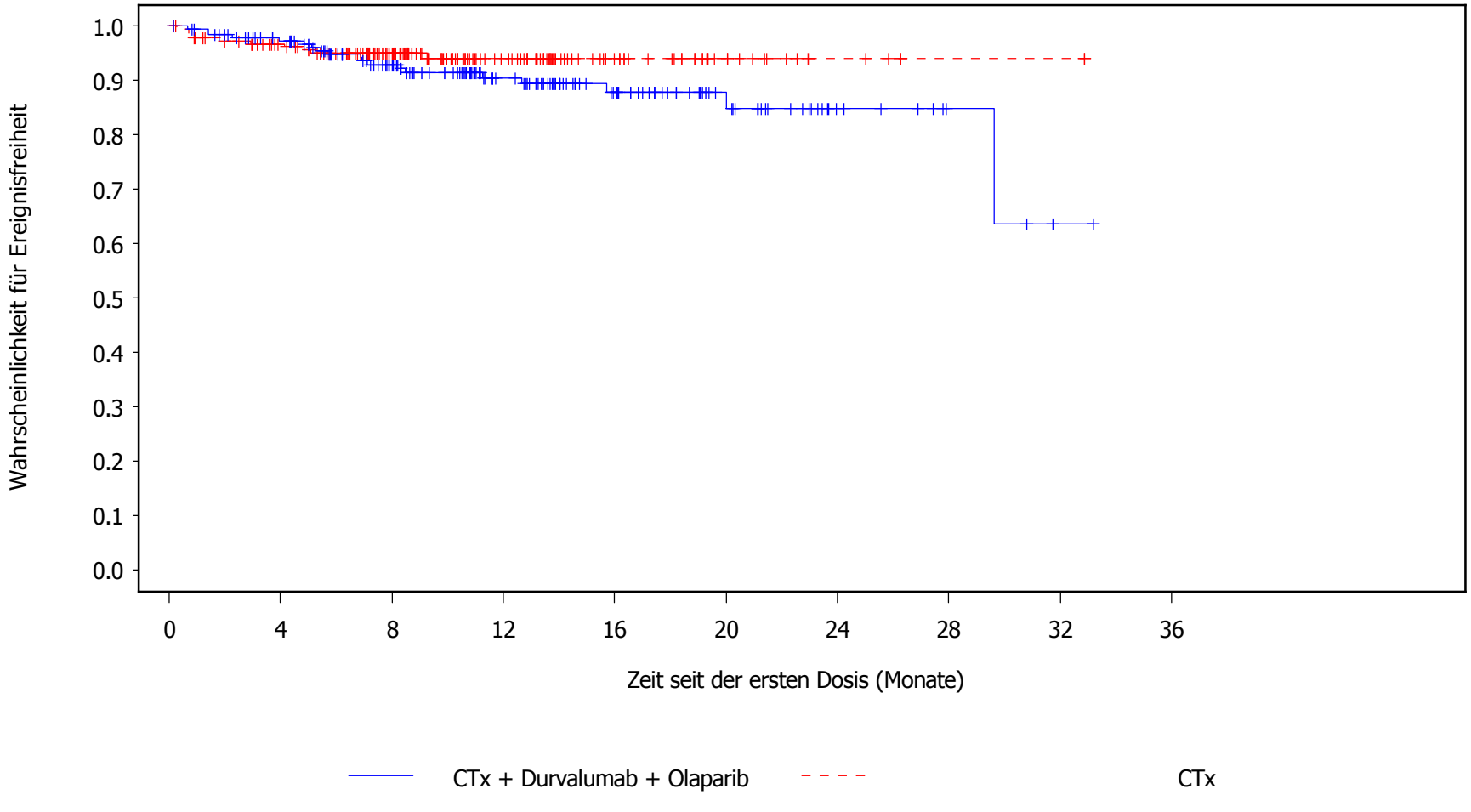
Figure 3.3.2.1D.81 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Kreatinin im Blut erhoeht
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	171	131	86	55	30	10	4	1	0	CTx + Durvalumab + Olaparib
190	168	124	68	34	15	5	1	1	0	CTx

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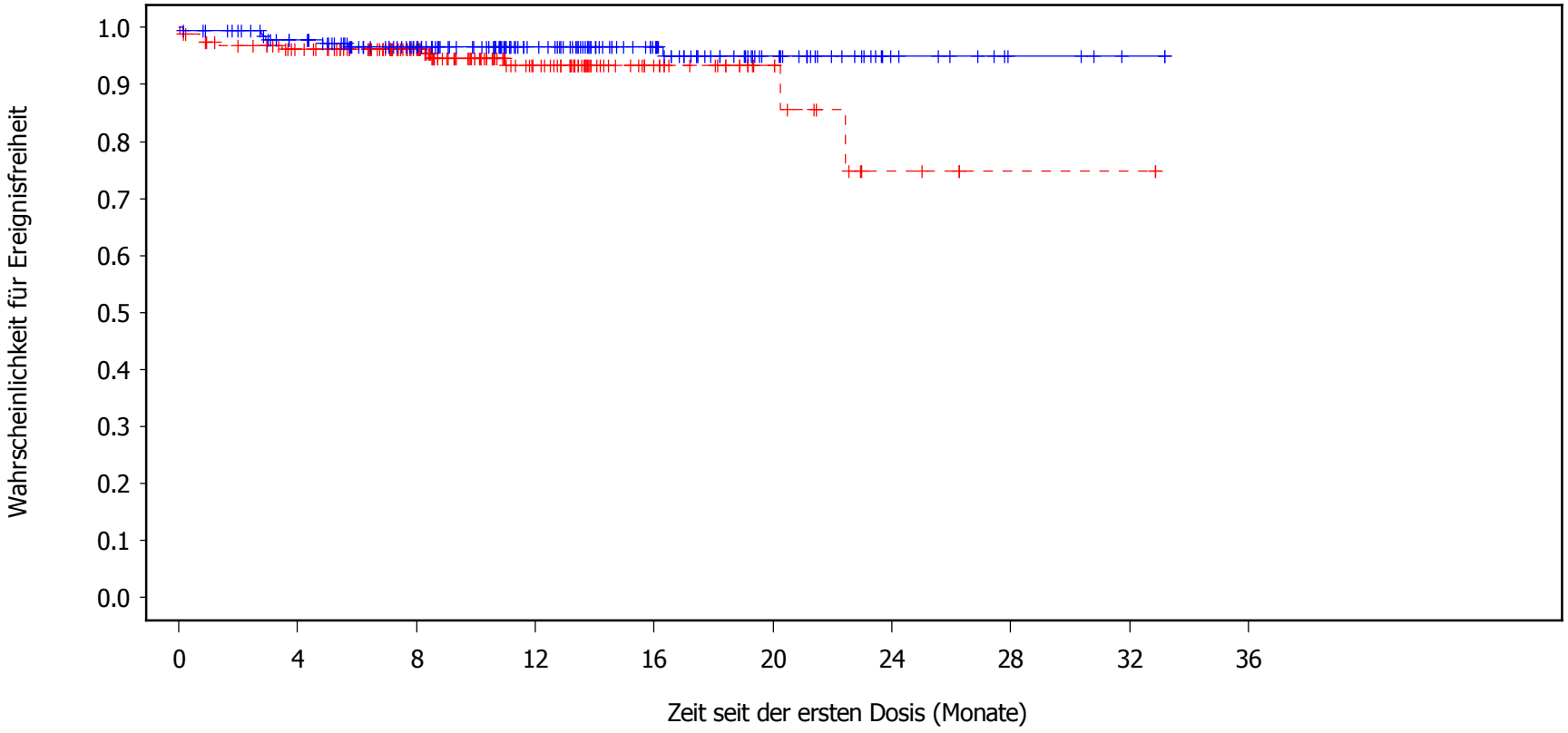
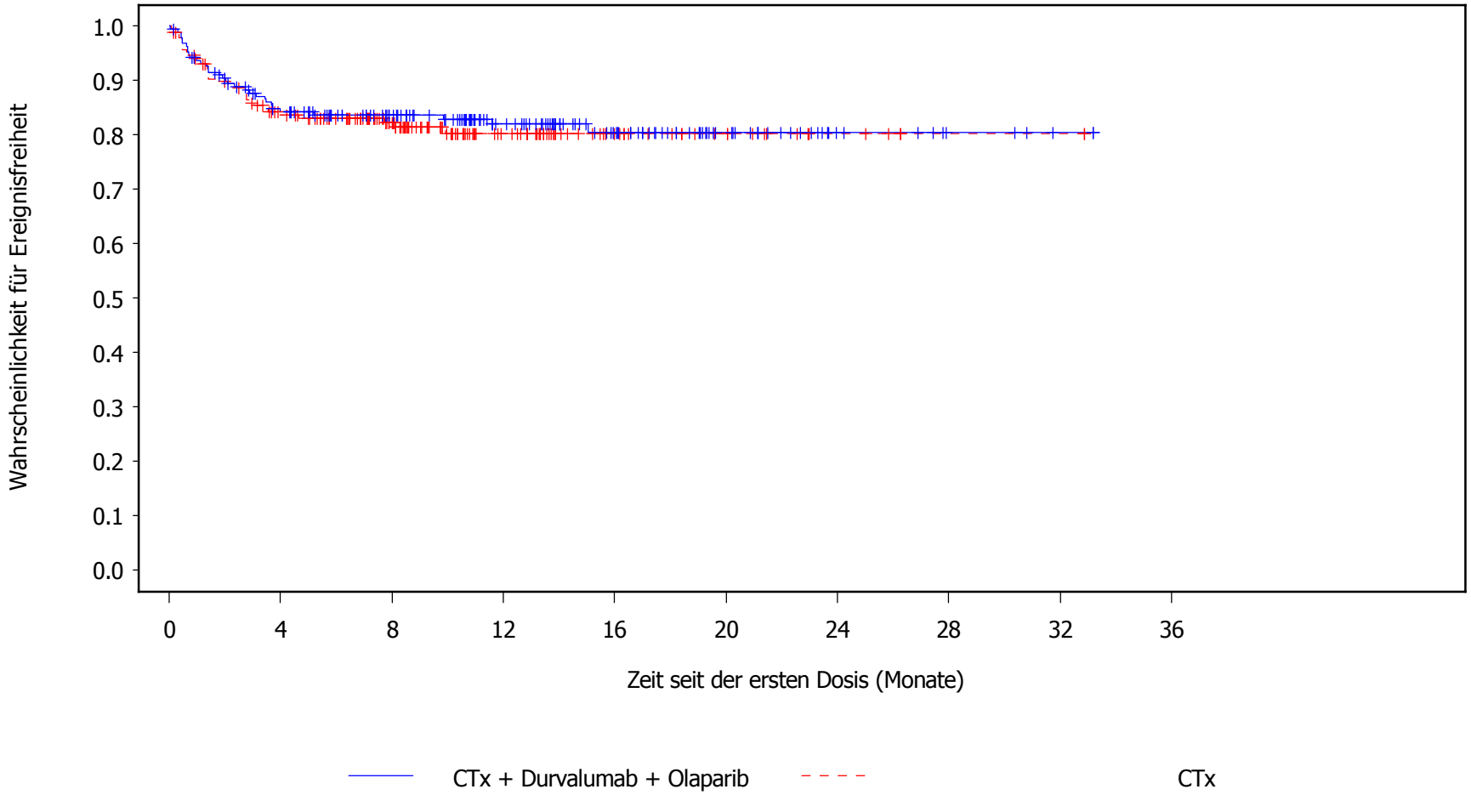
Figure 3.3.2.1D.82 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Laktatdehydrogenase im Blut erhoeht
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	172	137	96	62	33	11	4	1	0	CTx + Durvalumab + Olaparib
190	168	123	66	31	14	4	1	1	0	CTx

Figure 3.3.2.1D.83 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Leukozytenzahl erniedrigt
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	149	118	80	51	27	9	4	1	0	CTx + Durvalumab + Olaparib
190	145	99	51	24	13	5	1	1	0	CTx

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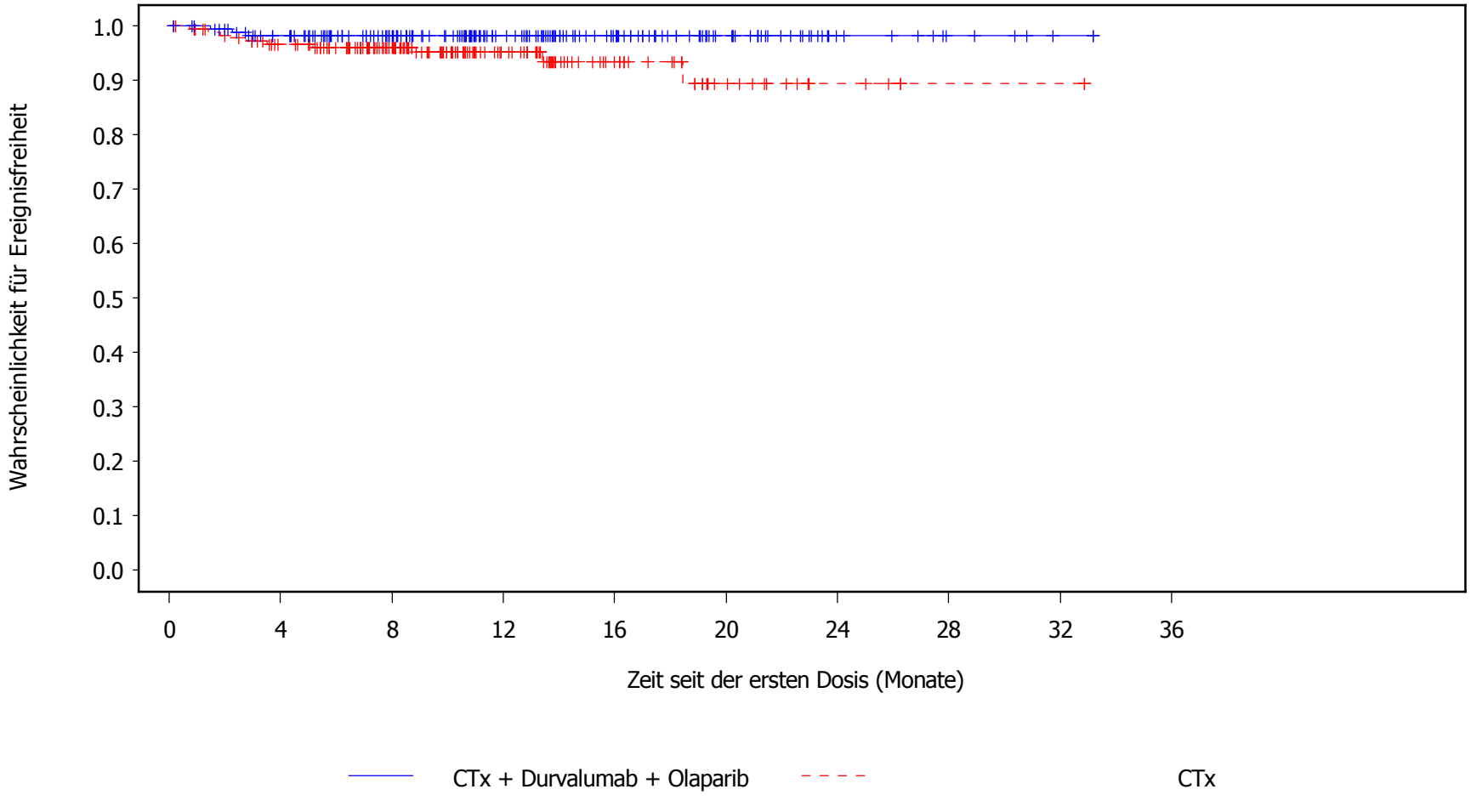
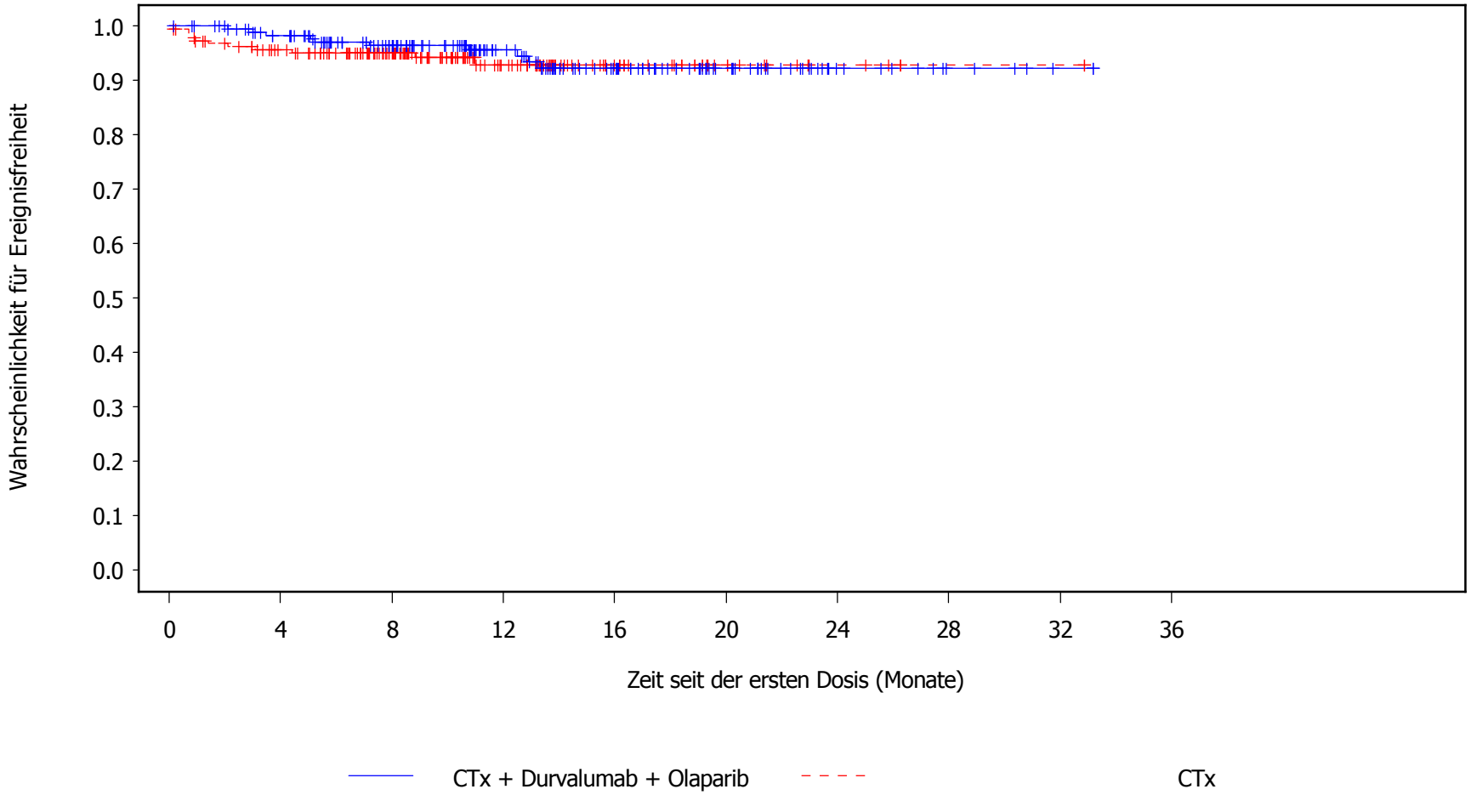
Figure 3.3.2.1D.84 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Lipase erhoeht
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	173	138	96	62	34	11	5	1	0	CTx + Durvalumab + Olaparib
190	168	124	68	34	14	5	1	1	0	CTx

Figure 3.3.2.1D.85 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Lymphozytenzahl erniedrigt
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	173	137	92	61	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	166	122	65	31	13	5	1	1	0	CTx

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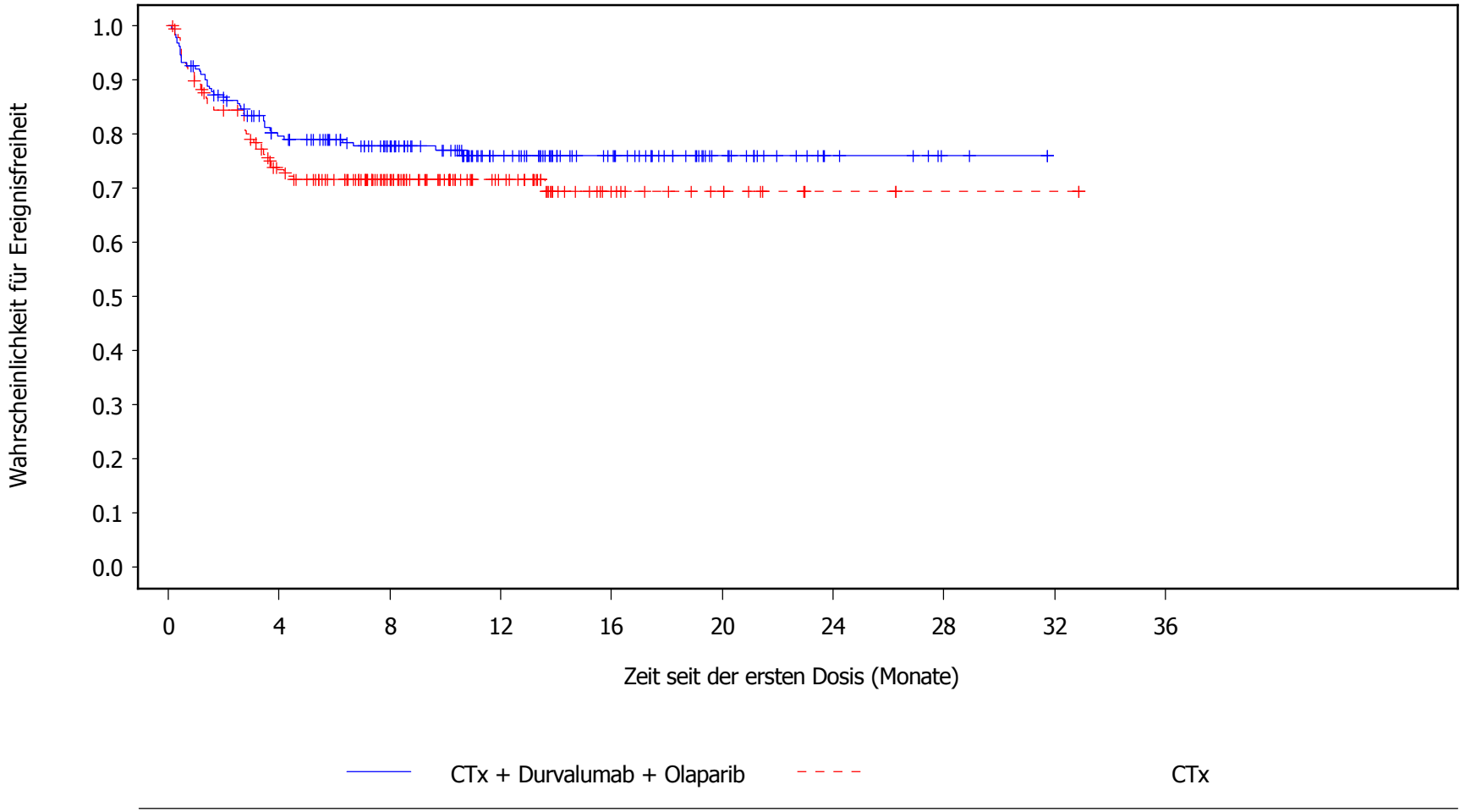
Figure 3.3.2.1D.86 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Neutrophilenzahl erniedrigt
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	140	109	70	46	23	7	2	0	0	CTx + Durvalumab + Olaparib
190	127	83	45	18	10	3	1	1	0	CTx

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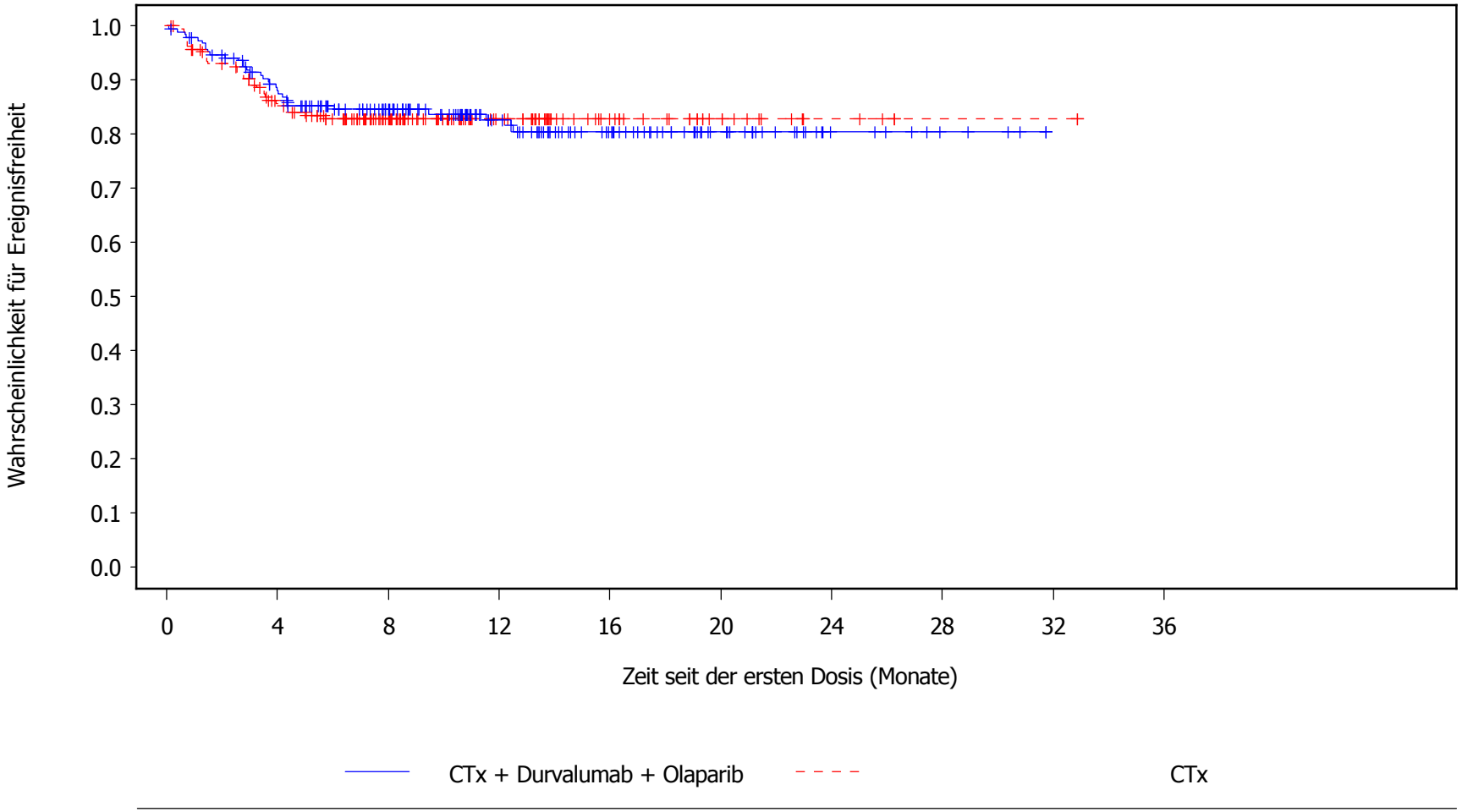
Figure 3.3.2.1D.87 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Thrombozytenzahl vermindert
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	157	118	76	50	28	9	4	0	0	CTx + Durvalumab + Olaparib
190	148	102	54	29	14	5	1	1	0	CTx

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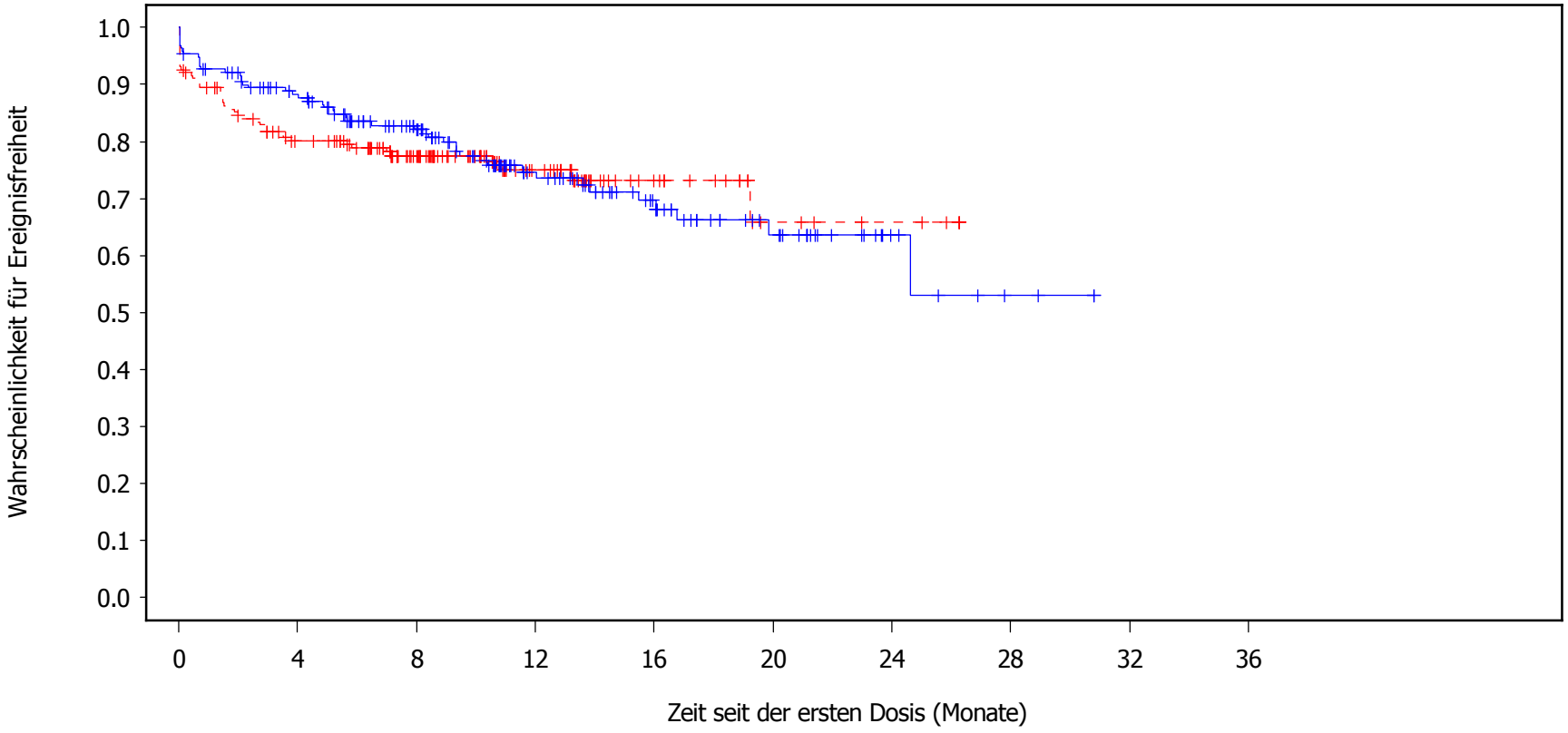
Figure 3.3.2.1D.88 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	154	115	69	44	25	7	2	0	0	CTx + Durvalumab + Olaparib
190	139	99	50	21	7	4	0	0	0	CTx

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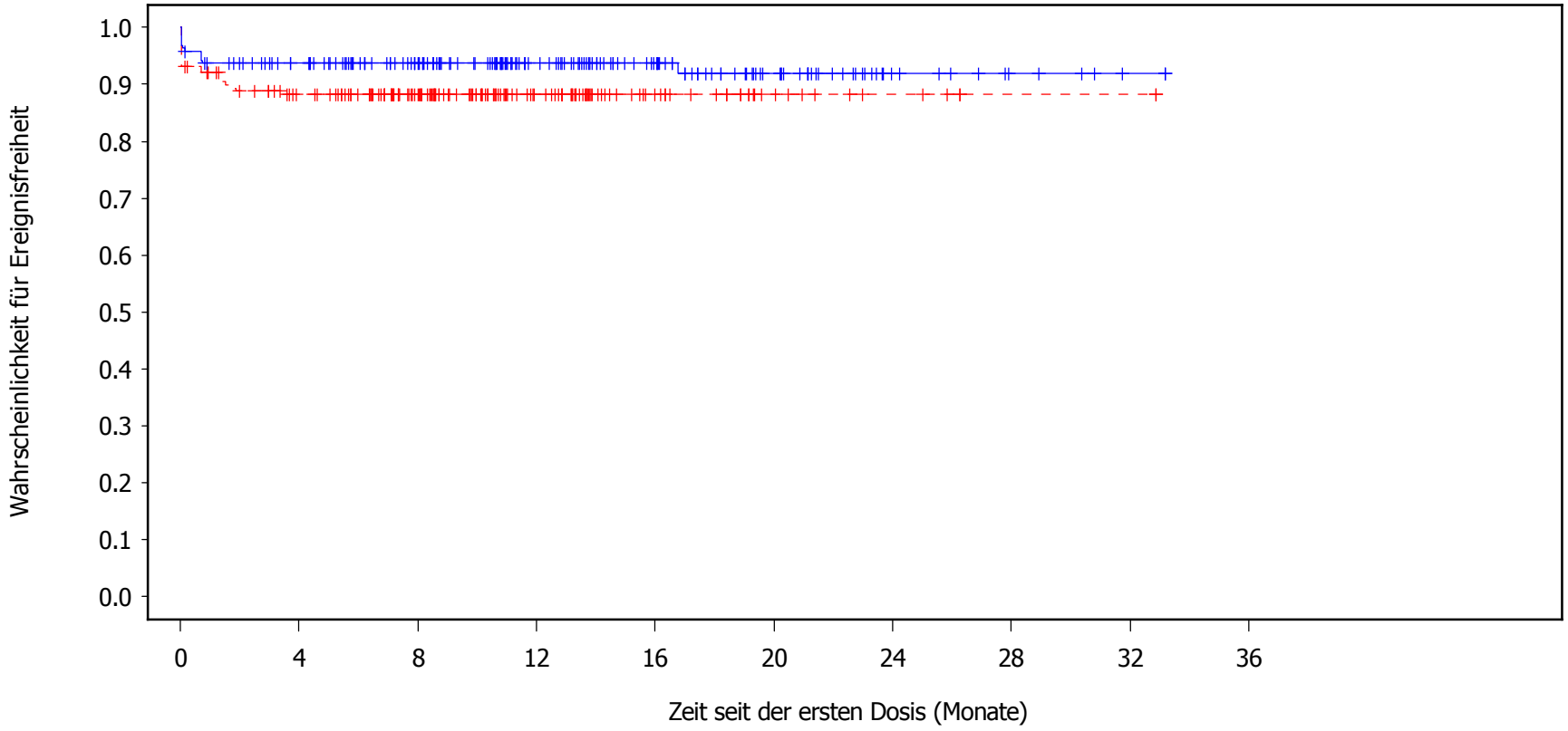
Figure 3.3.2.1D.89 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Reaktion im Zusammenhang mit einer Infusion
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	164	133	90	60	34	11	5	1	0	CTx + Durvalumab + Olaparib
190	152	112	60	27	11	5	1	1	0	CTx

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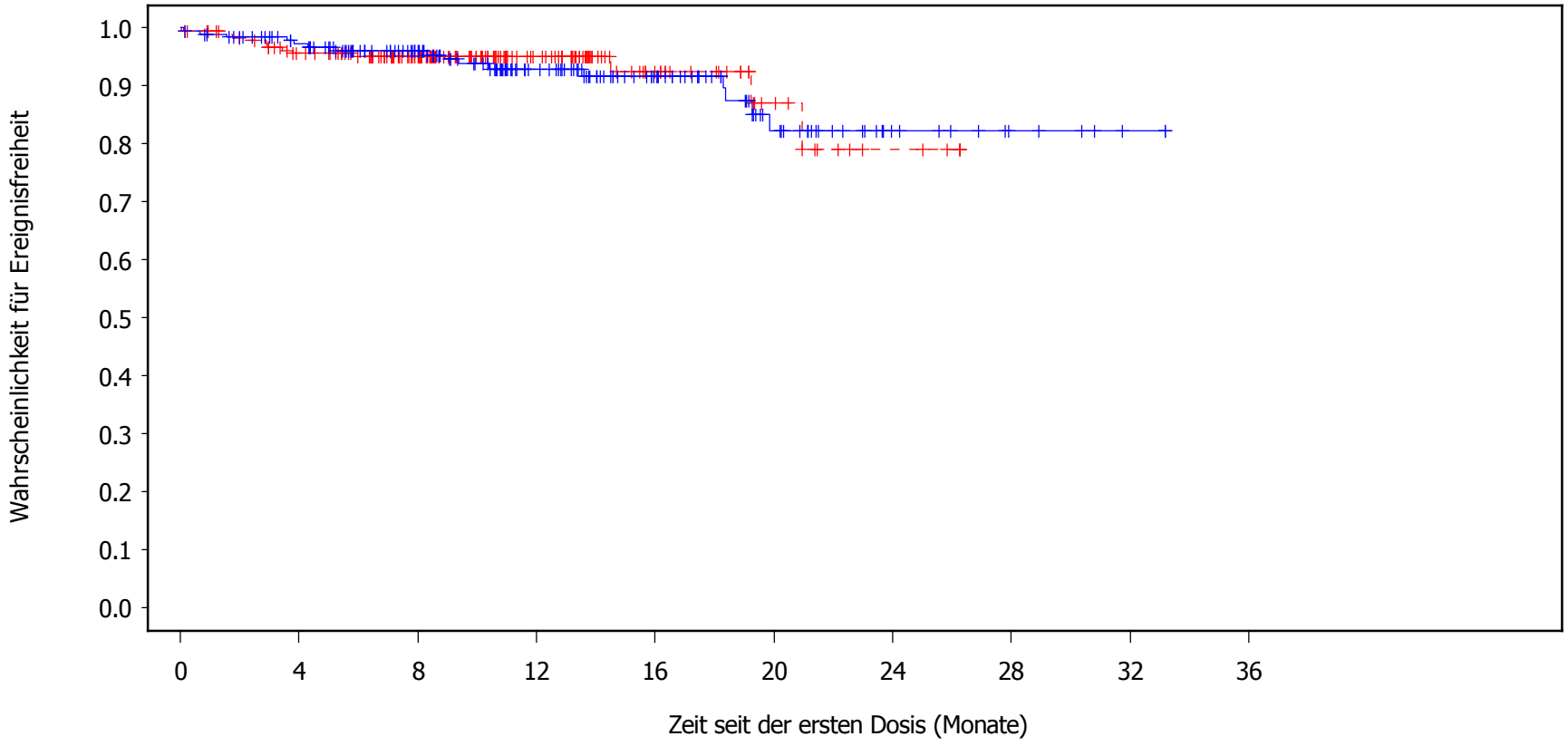
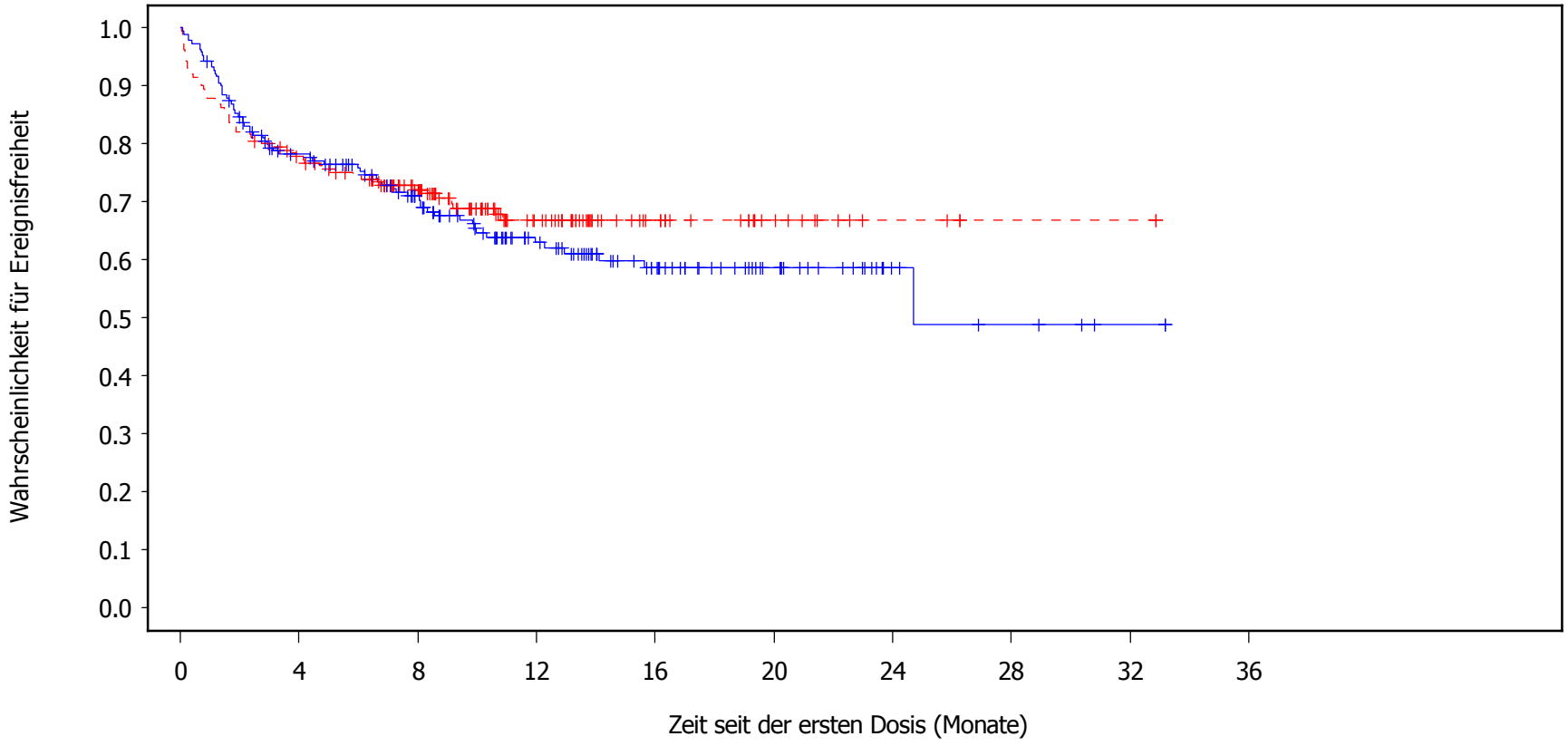
Figure 3.3.2.1D.90 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Sturz
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	171	135	90	58	30	11	5	1	0	CTx + Durvalumab + Olaparib
190	167	124	68	31	13	4	0	0	0	CTx

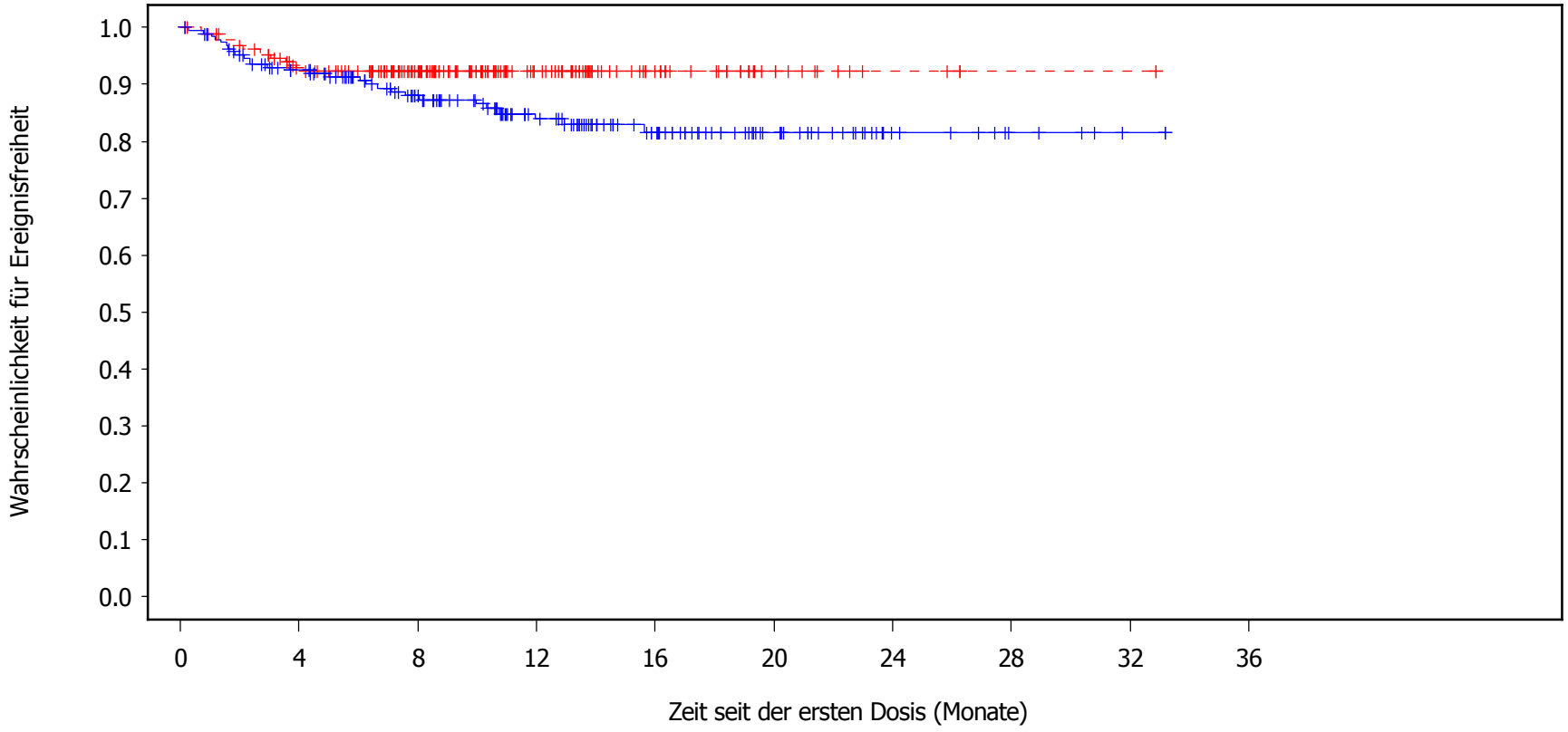
Figure 3.3.2.1D.91 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUE
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	139	107	69	42	23	7	4	1	0	CTx + Durvalumab + Olaparib
190	143	104	54	25	12	4	1	1	0	CTx

Figure 3.3.2.1D.92 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	162	125	86	56	31	11	5	1	0	CTx + Durvalumab + Olaparib
190	161	120	65	32	13	4	1	1	0	CTx

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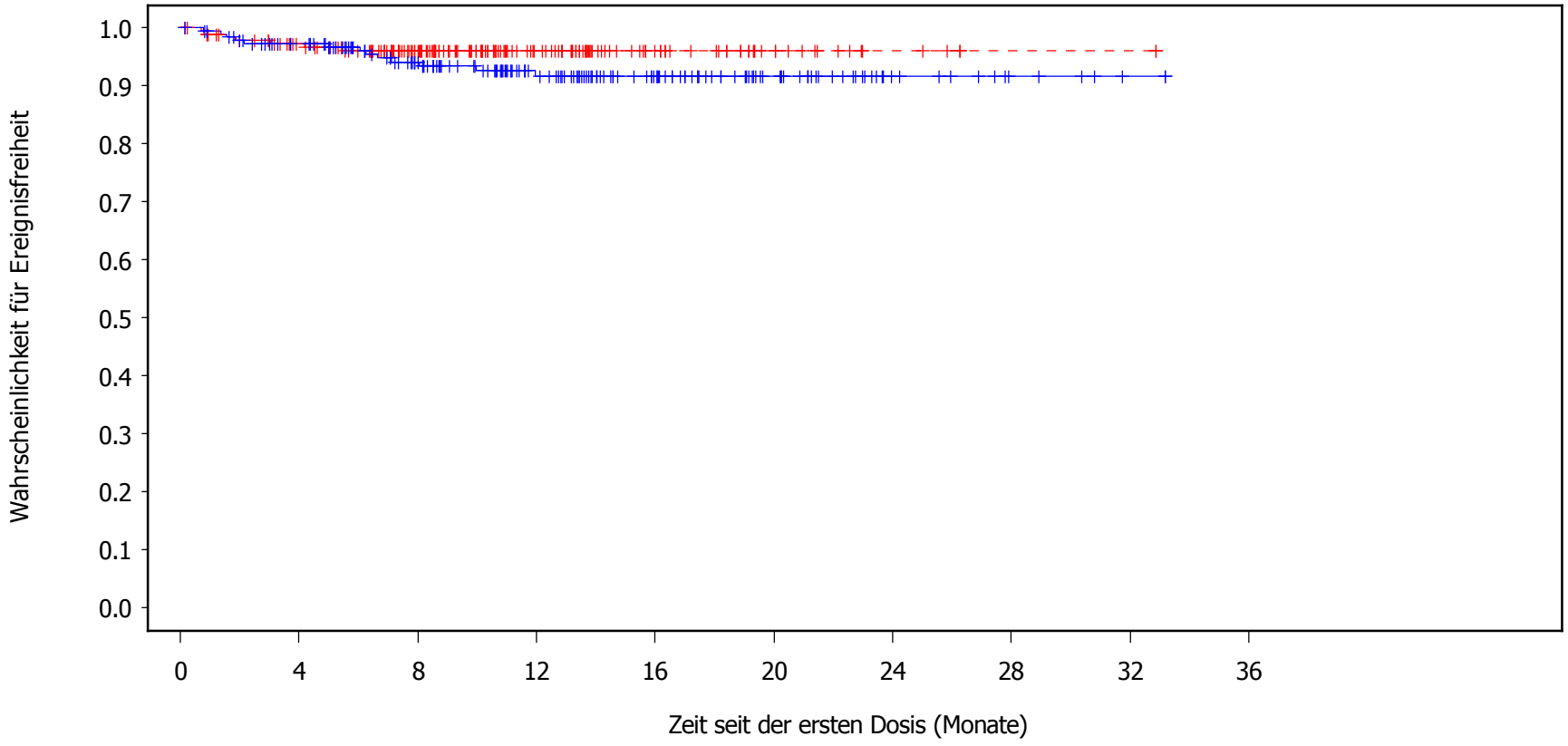
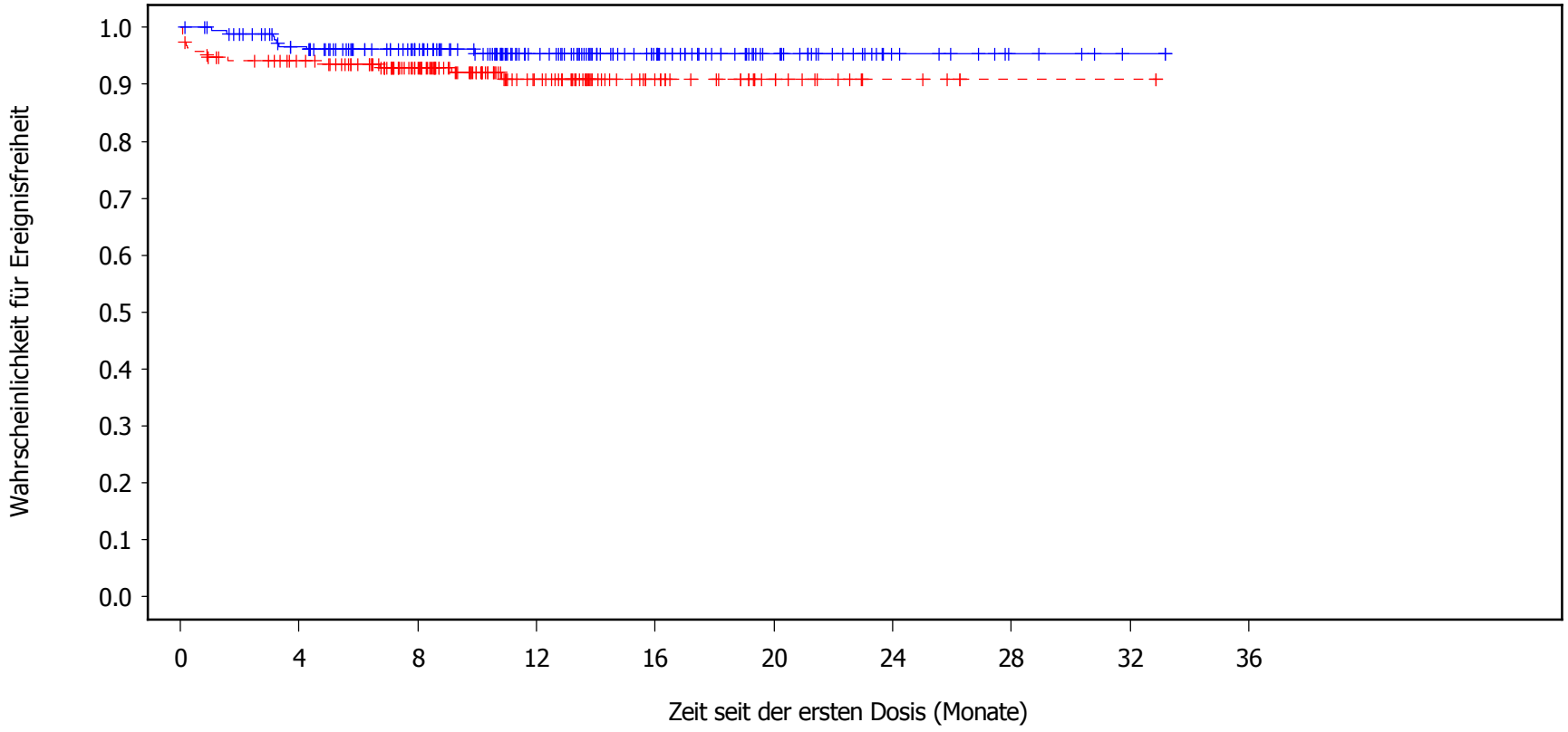
Figure 3.3.2.1D.93 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUE PT: Anaemie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	171	134	93	61	34	12	5	1	0	CTx + Durvalumab + Olaparib
190	169	125	69	34	15	5	1	1	0	CTx

Figure 3.3.2.1D.94 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Gastrointestinaltrakts
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	170	138	94	61	33	12	5	1	0	CTx + Durvalumab + Olaparib
190	167	124	67	32	15	5	1	1	0	CTx

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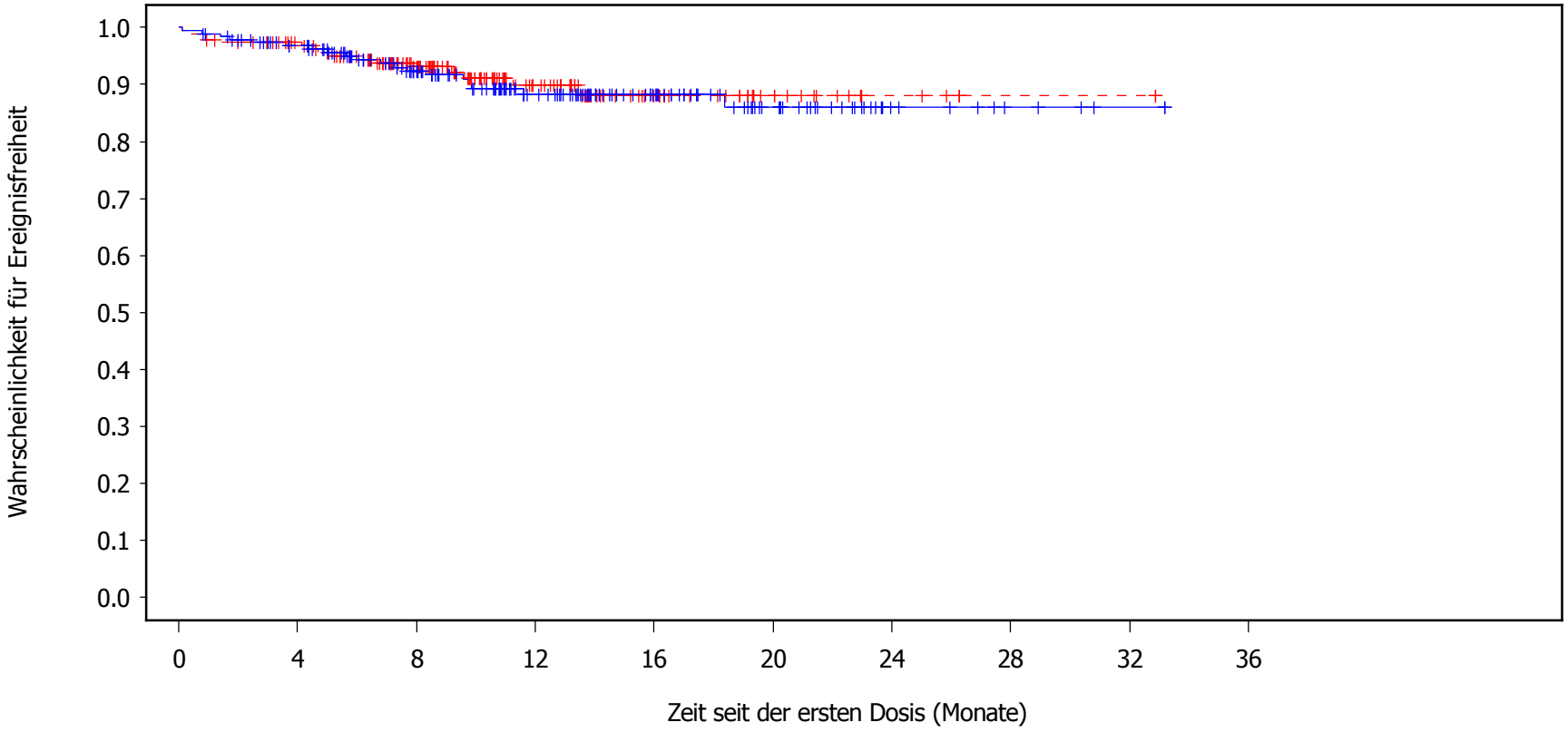
Figure 3.3.2.1D.95 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUE SOC: Infektionen und parasitaere Erkrankungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	171	130	87	54	29	9	4	1	0	CTx + Durvalumab + Olaparib
190	173	122	64	32	15	5	1	1	0	CTx

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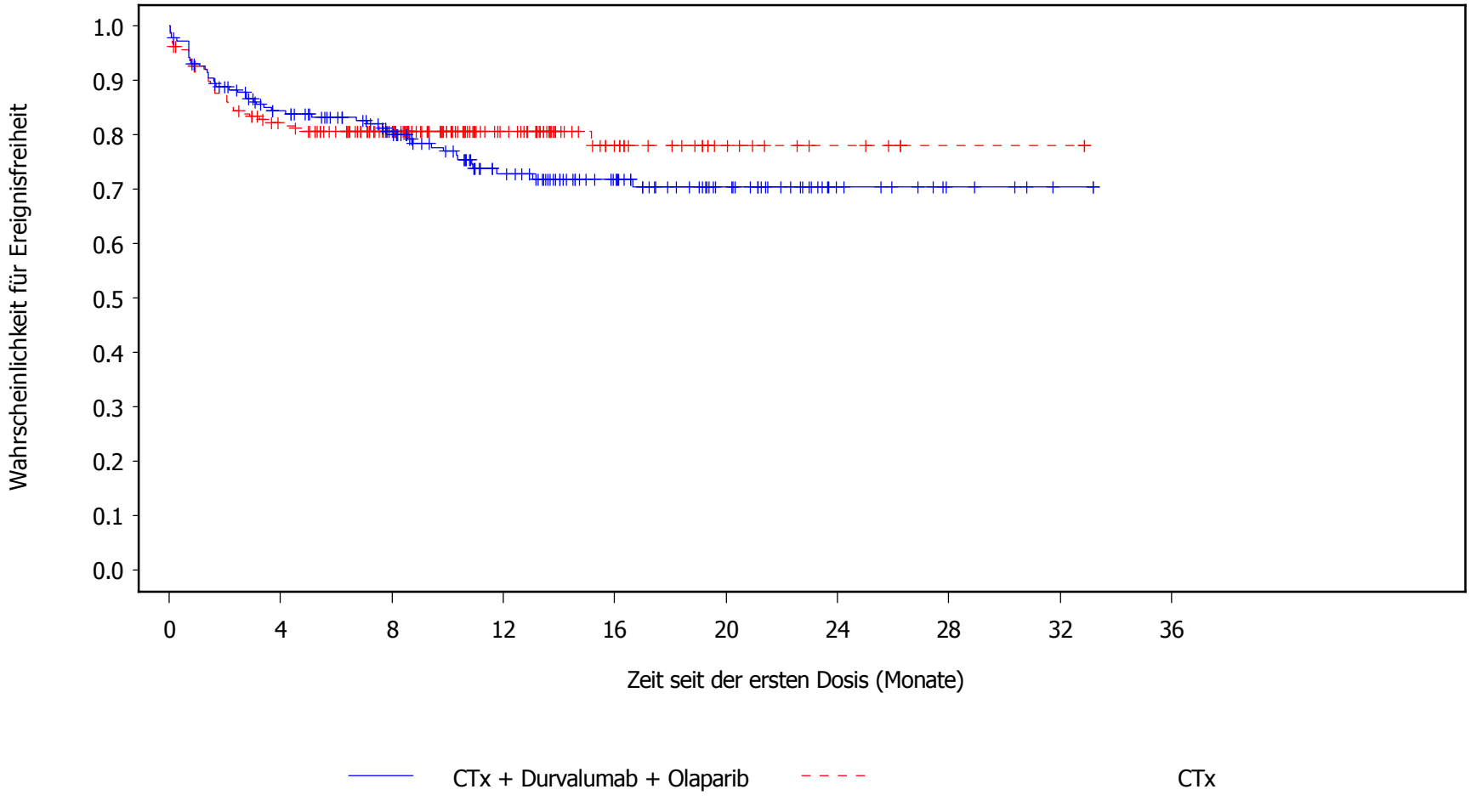
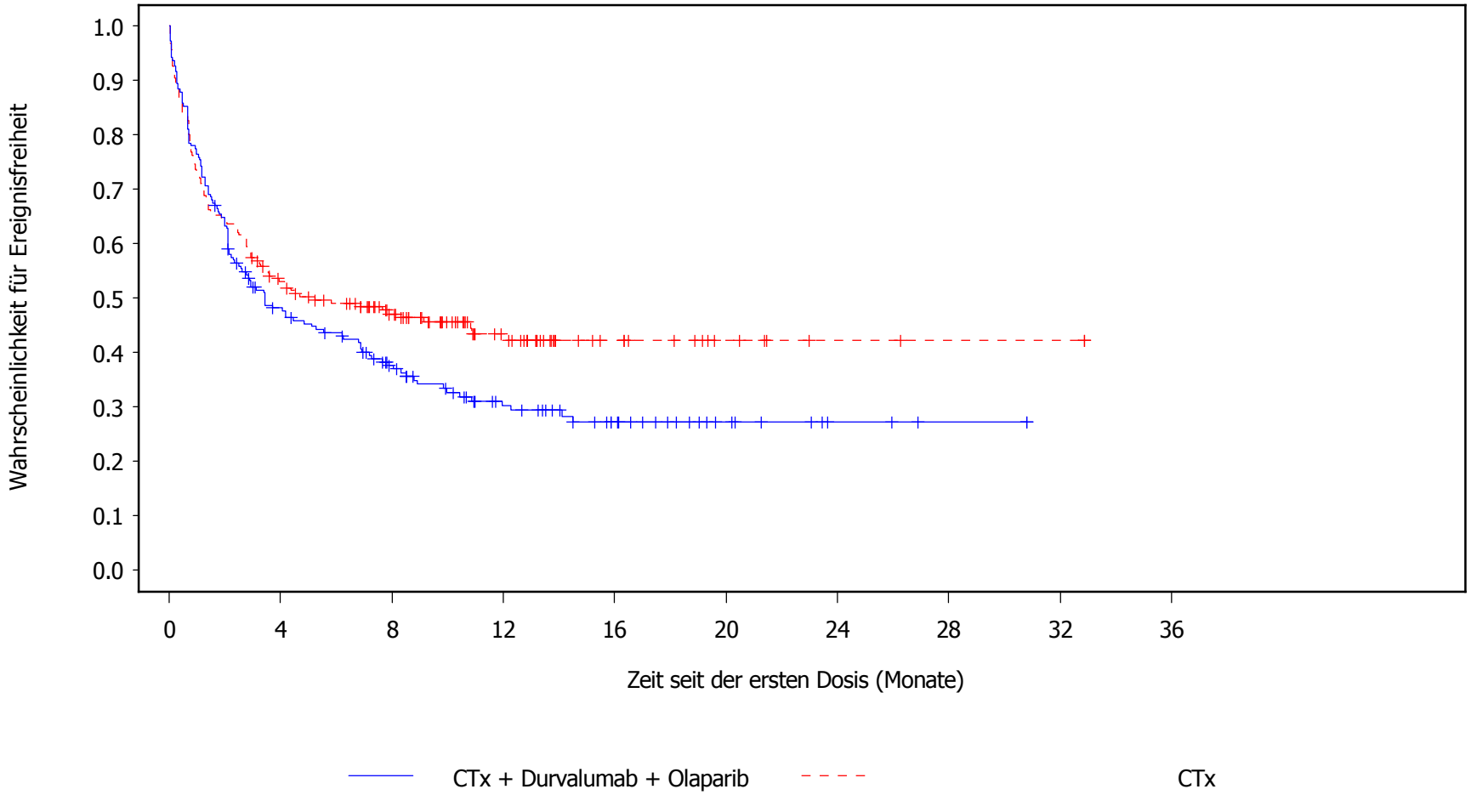
Figure 3.3.2.1D.96 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of Therapieabbruch aufgrund von UE
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	147	119	82	56	33	12	5	1	0	CTx + Durvalumab + Olaparib
190	146	111	58	26	11	5	1	1	0	CTx

Figure 3.3.2.1D.97 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UE mit CTCAE Grad >=3
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	85	57	34	20	9	3	1	0	0	CTx + Durvalumab + Olaparib
190	96	67	35	14	6	2	1	1	0	CTx

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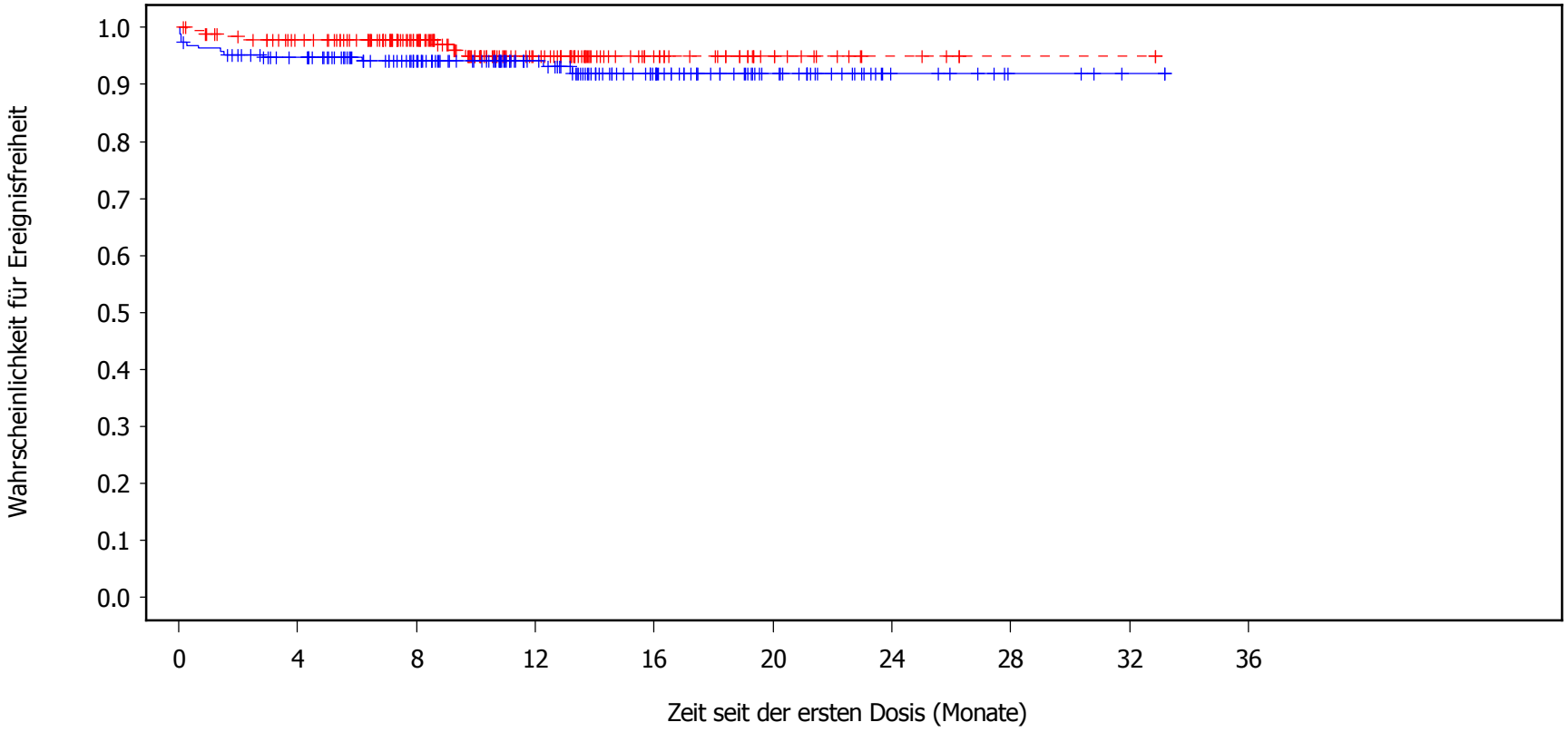
Figure 3.3.2.1D.98 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	169	134	93	59	32	10	4	1	0	CTx + Durvalumab + Olaparib
190	170	126	69	34	15	5	1	1	0	CTx

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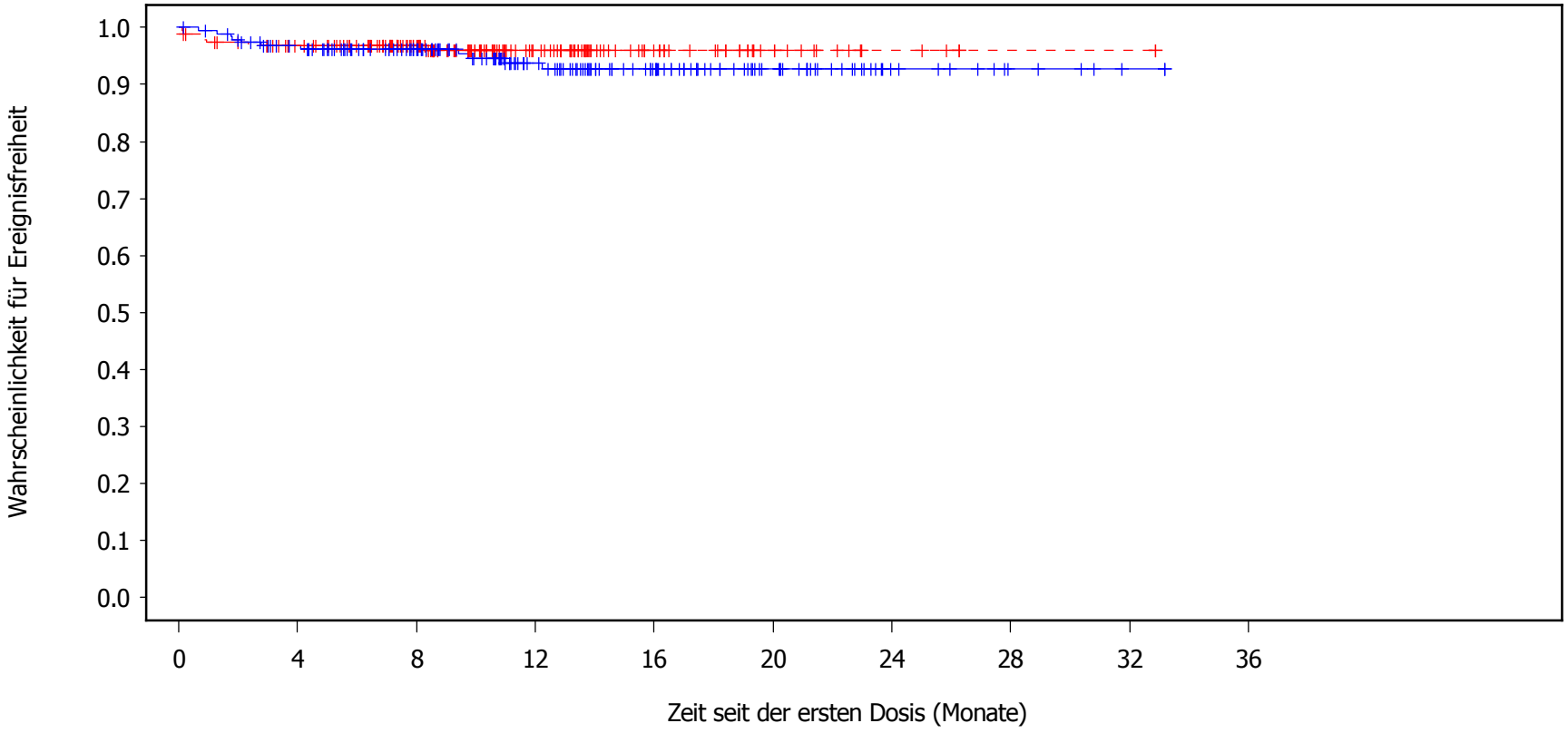
Figure 3.3.2.1D.99 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	172	137	93	62	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	172	127	70	34	15	5	1	1	0	CTx

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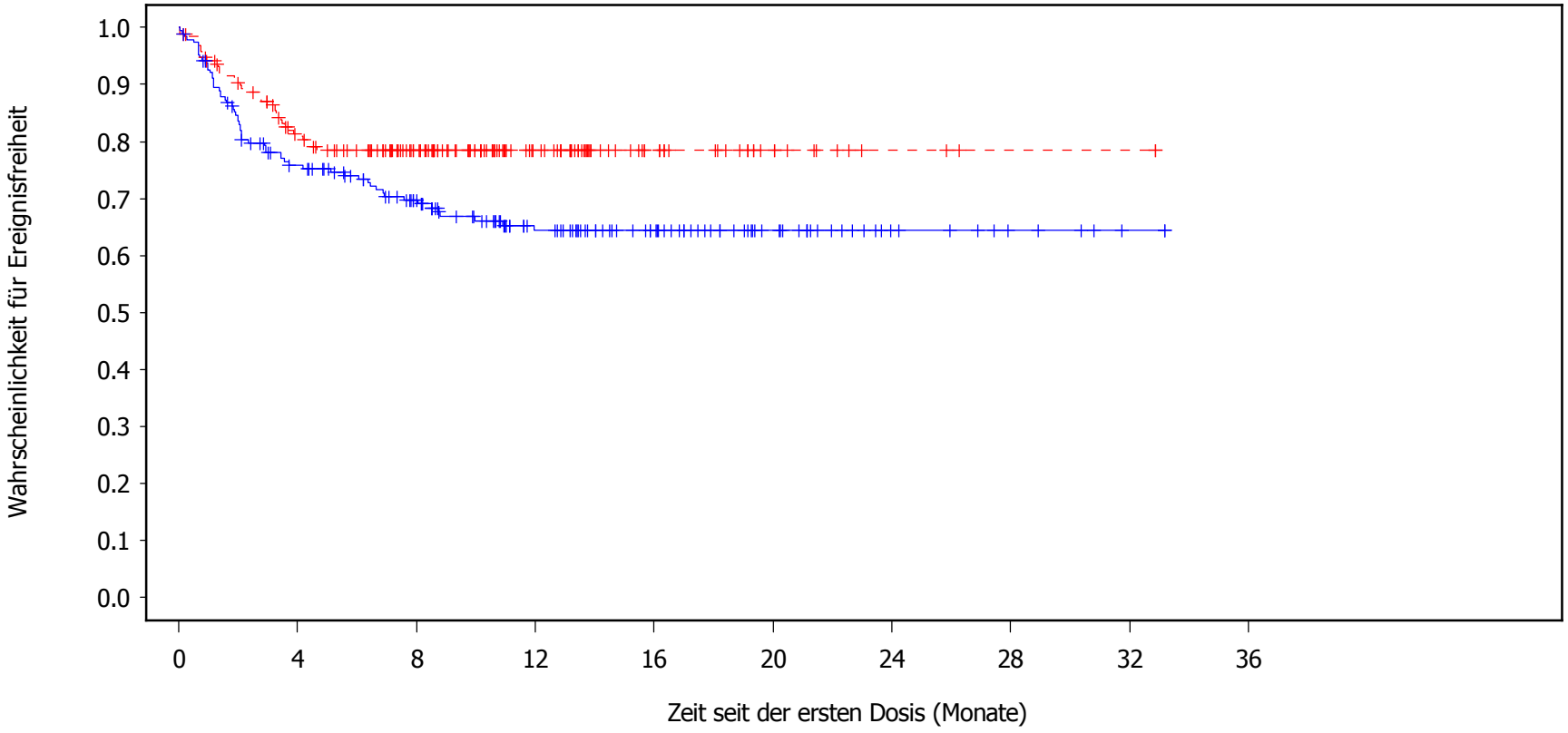
Figure 3.3.2.1D.100 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	134	104	69	47	26	10	5	1	0	CTx + Durvalumab + Olaparib
190	140	103	55	25	11	3	1	1	0	CTx

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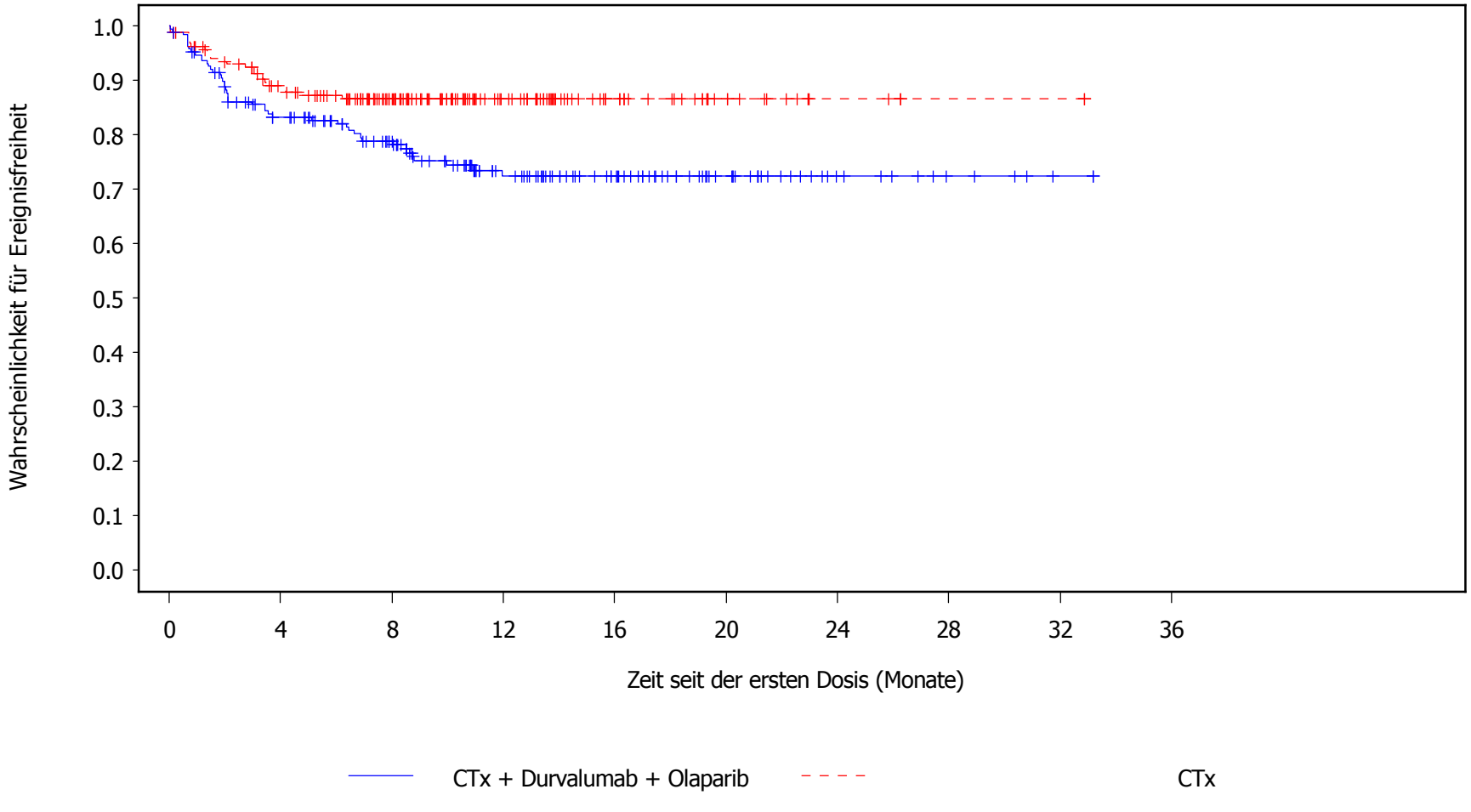
Figure 3.3.2.1D.101 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Anaemie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	146	115	74	51	29	11	5	1	0	CTx + Durvalumab + Olaparib
190	155	114	61	29	13	4	1	1	0	CTx

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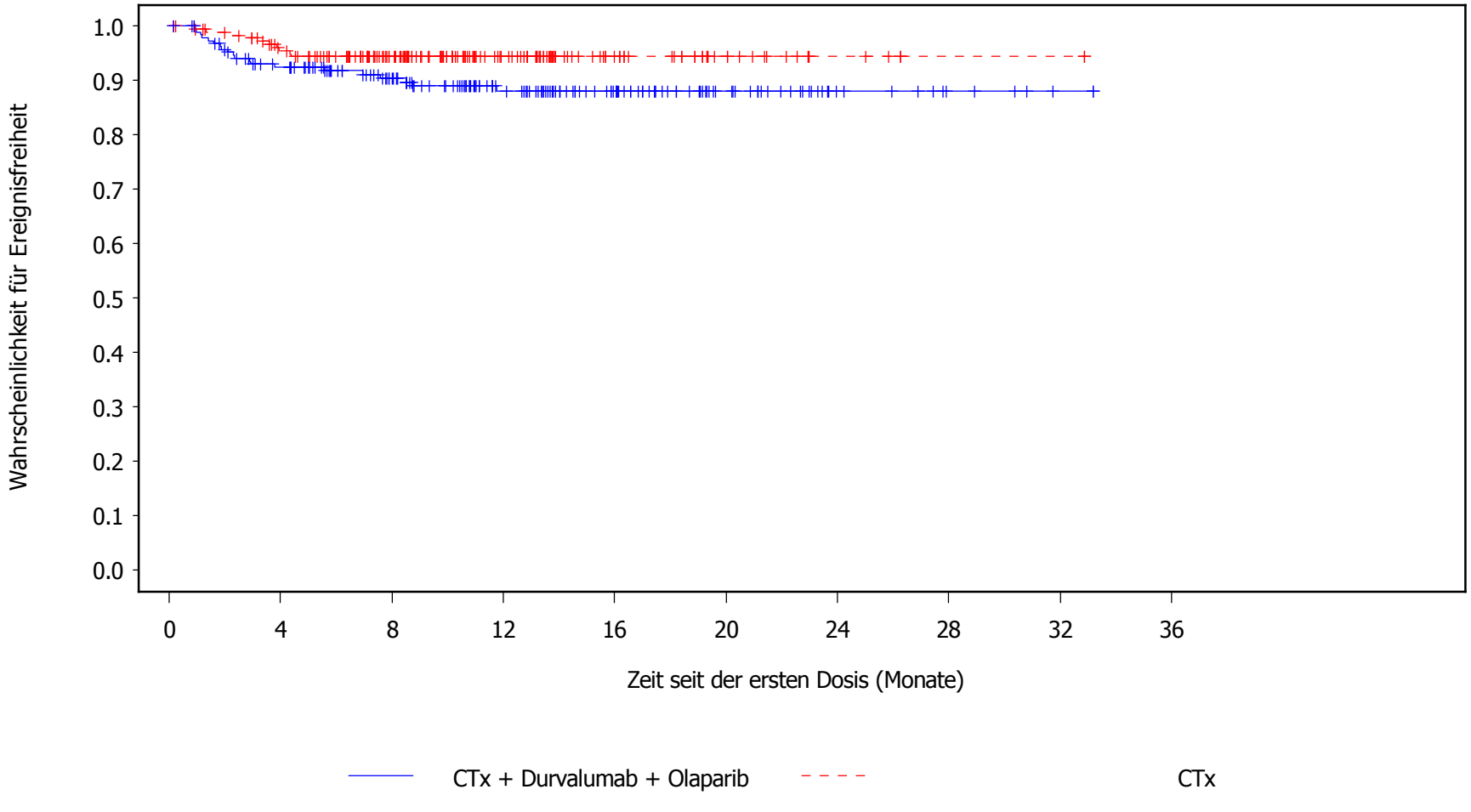
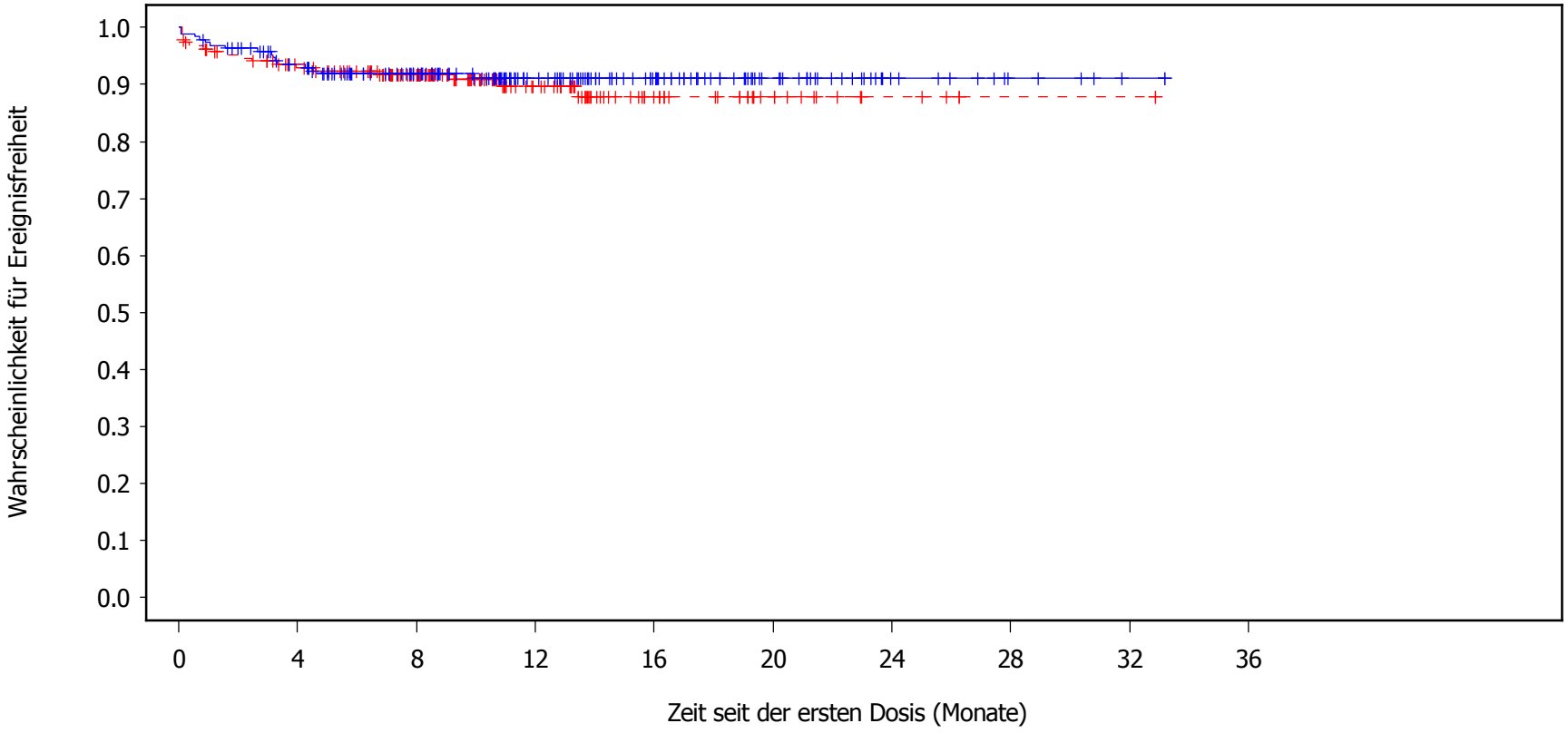
Figure 3.3.2.1D.102 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Neutropenie
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	163	129	90	59	31	11	5	1	0	CTx + Durvalumab + Olaparib
190	166	121	68	33	15	5	1	1	0	CTx

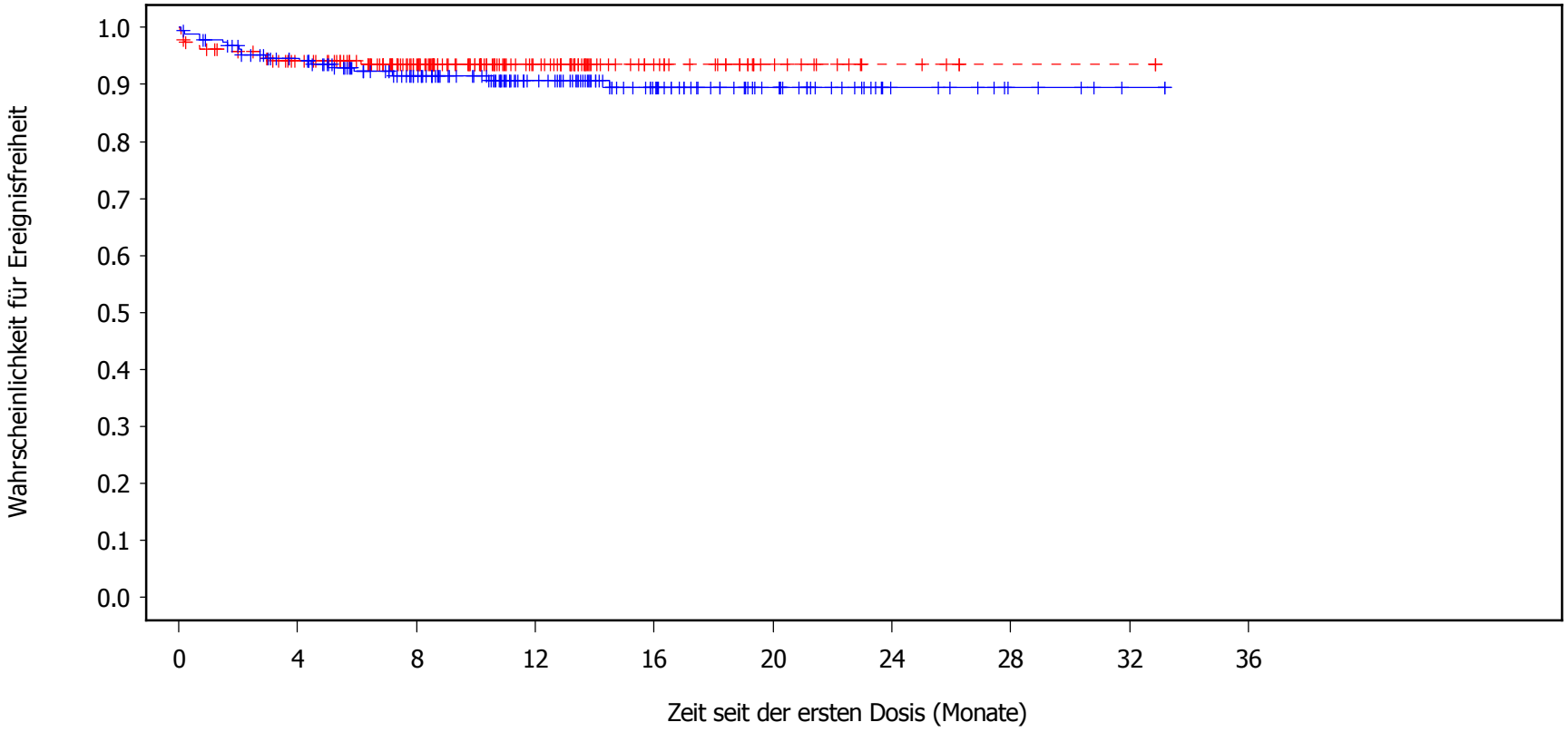
Figure 3.3.2.1D.103 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Gastrointestinaltrakts
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	166	133	90	60	32	12	5	1	0	CTx + Durvalumab + Olaparib
190	163	120	64	30	14	5	1	1	0	CTx

Figure 3.3.2.1D.104 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Nervensystems
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	166	130	88	54	31	11	5	1	0	CTx + Durvalumab + Olaparib
190	164	120	66	32	14	5	1	1	0	CTx

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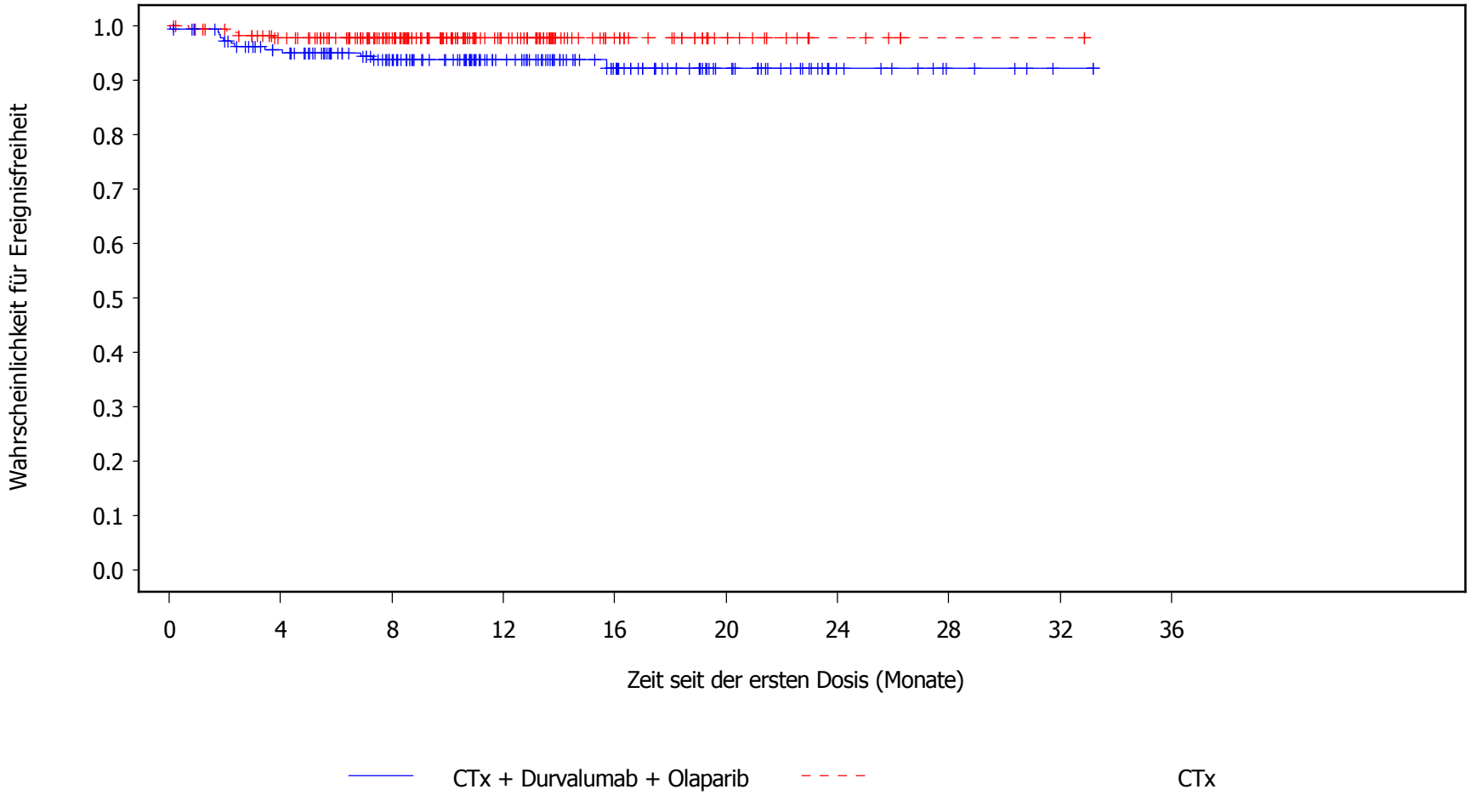
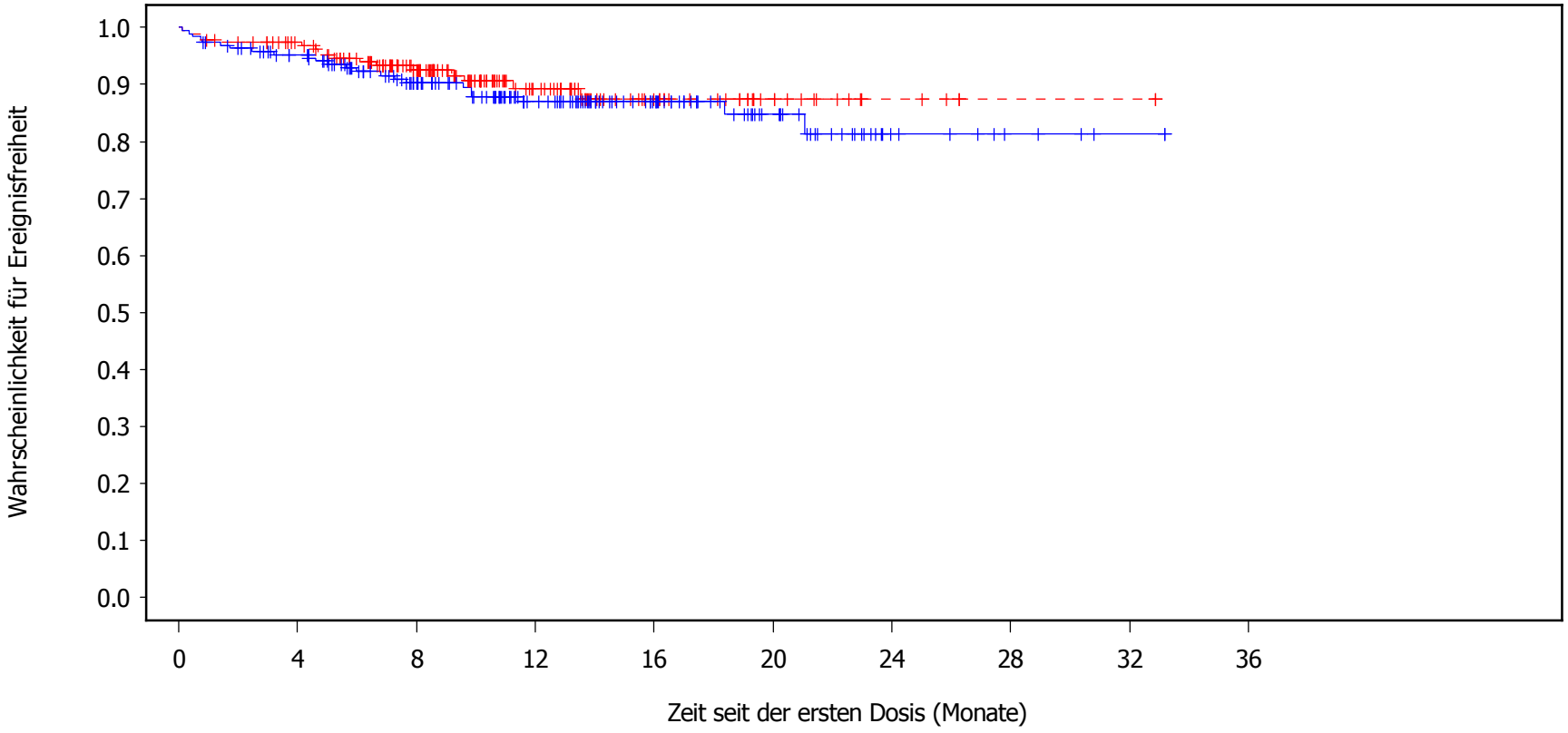
Figure 3.3.2.1D.105 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Gefaesserkrankungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	169	132	92	60	33	12	5	1	0	CTx + Durvalumab + Olaparib
190	170	127	70	34	15	5	1	1	0	CTx

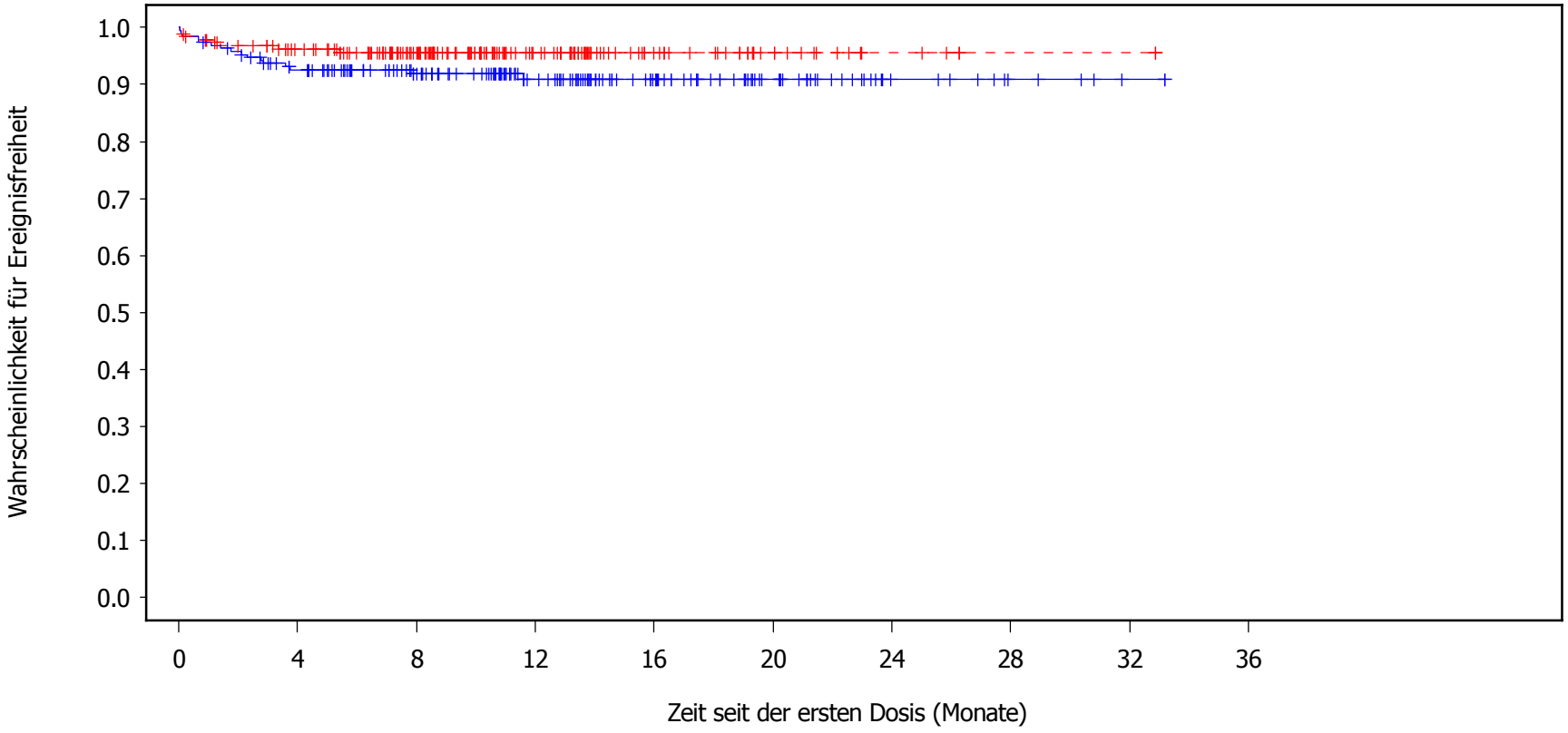
Figure 3.3.2.1D.106 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Infektionen und parasitaere Erkrankungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	169	129	88	55	30	9	4	1	0	CTx + Durvalumab + Olaparib
190	173	122	64	32	15	5	1	1	0	CTx

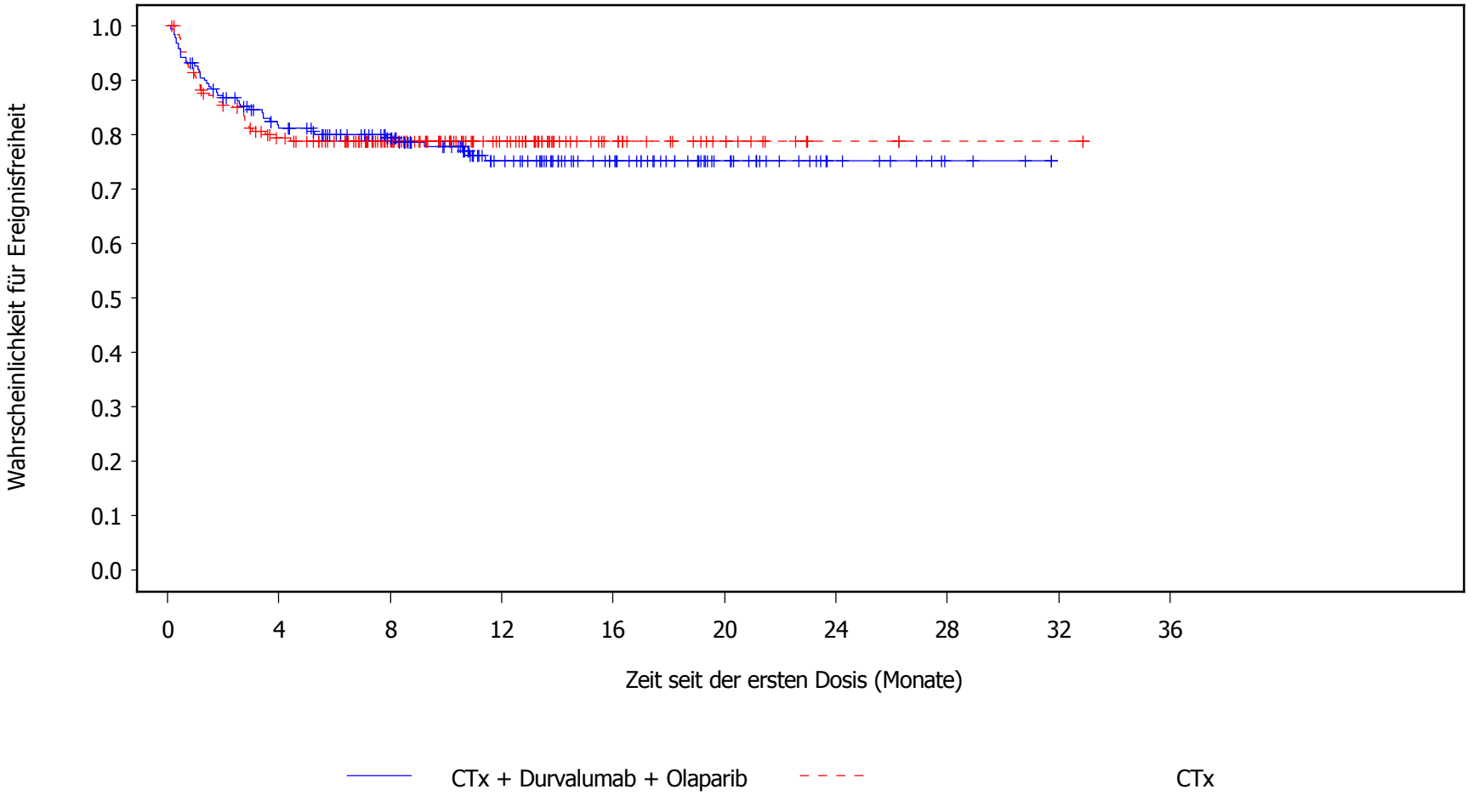
Figure 3.3.2.1D.107 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Stoffwechsel- und Ernaehrungsstoerungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	166	132	91	58	33	11	5	1	0	CTx + Durvalumab + Olaparib
190	167	124	67	32	15	5	1	1	0	CTx

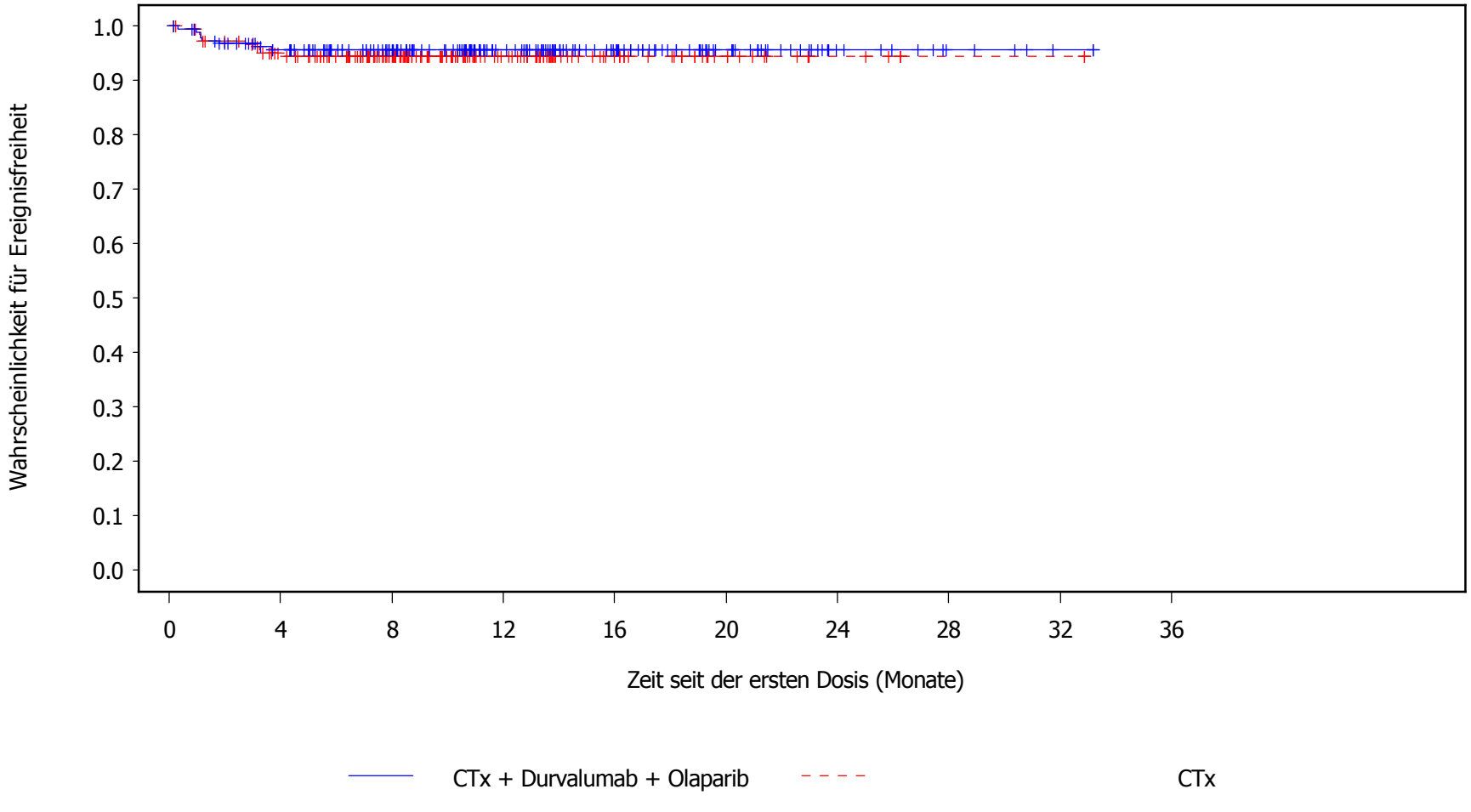
Figure 3.3.2.1D.108 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Untersuchungen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	144	115	76	50	27	10	3	0	0	CTx + Durvalumab + Olaparib
190	139	96	53	24	12	3	1	1	0	CTx

Figure 3.3.2.1D.109 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Leukozytenzahl erniedrigt
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	168	136	94	60	34	12	5	1	0	CTx + Durvalumab + Olaparib
190	165	119	64	31	14	5	1	1	0	CTx

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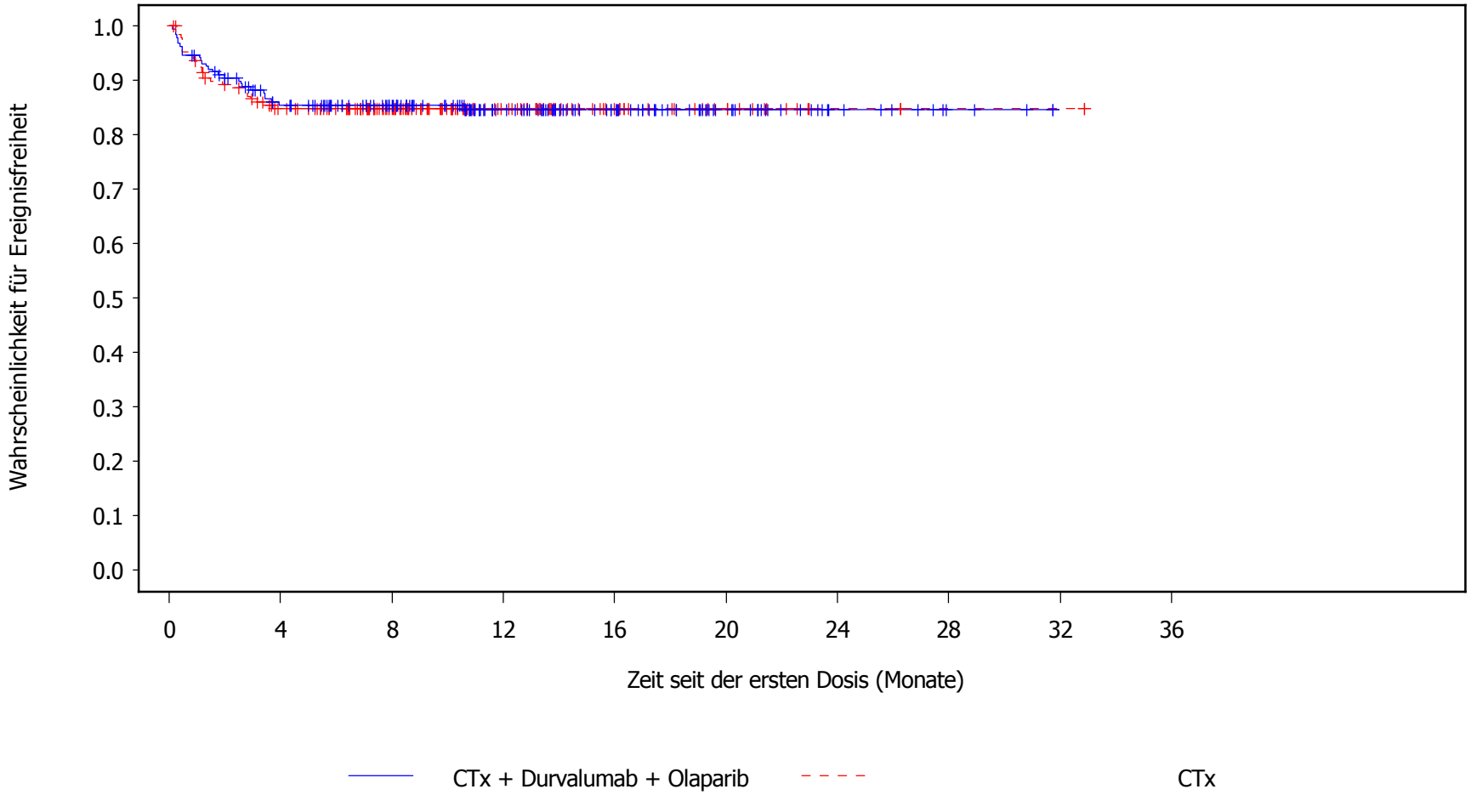
Figure 3.3.2.1D.110 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Neutrophilenzahl erniedrigt
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	150	121	81	53	28	10	3	0	0	CTx + Durvalumab + Olaparib
190	148	103	55	26	13	3	1	1	0	CTx

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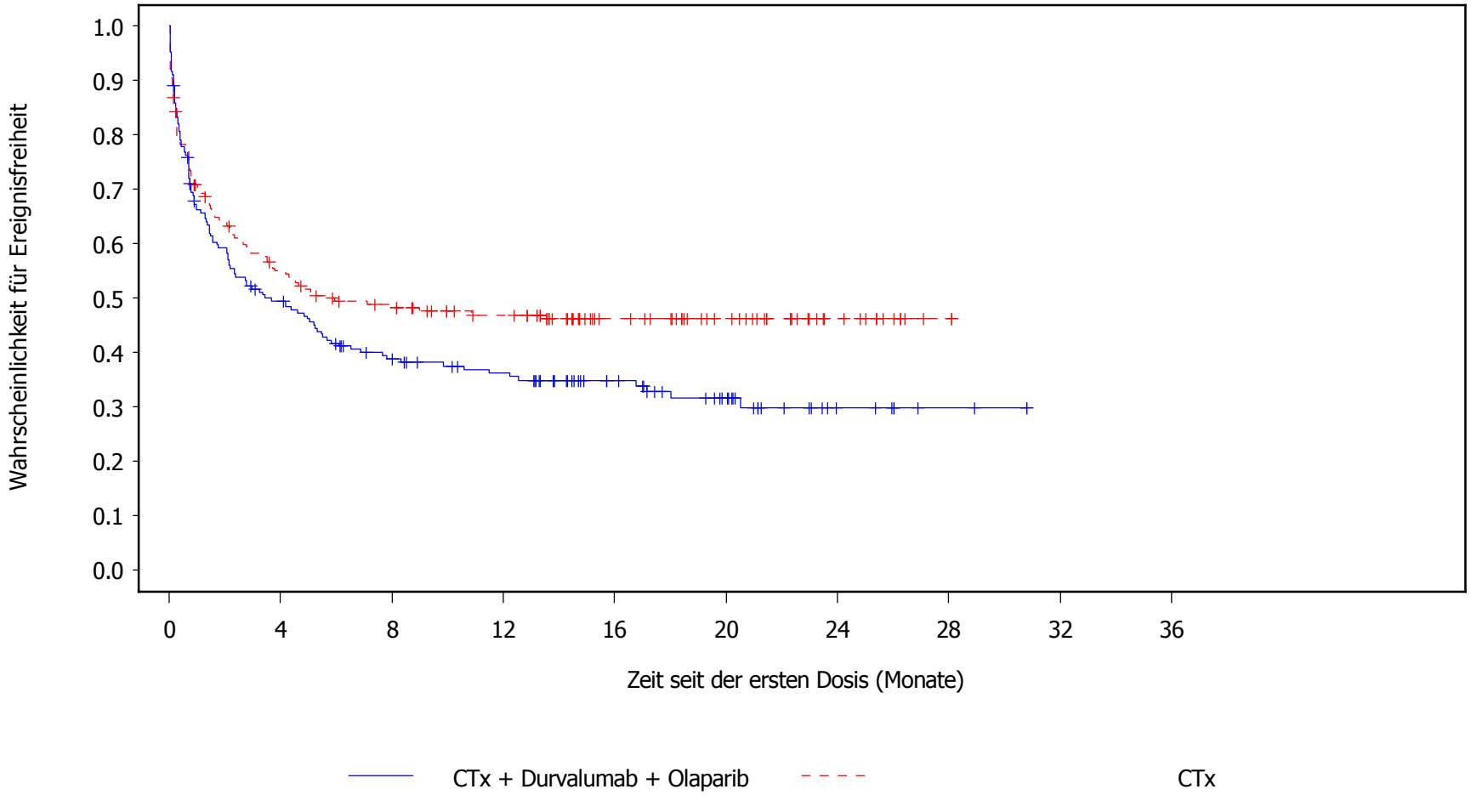
Figure 3.3.2.1D.111 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	90	65	55	36	23	7	2	0	0	CTx + Durvalumab + Olaparib
190	99	83	70	42	29	12	1	0	0	CTx

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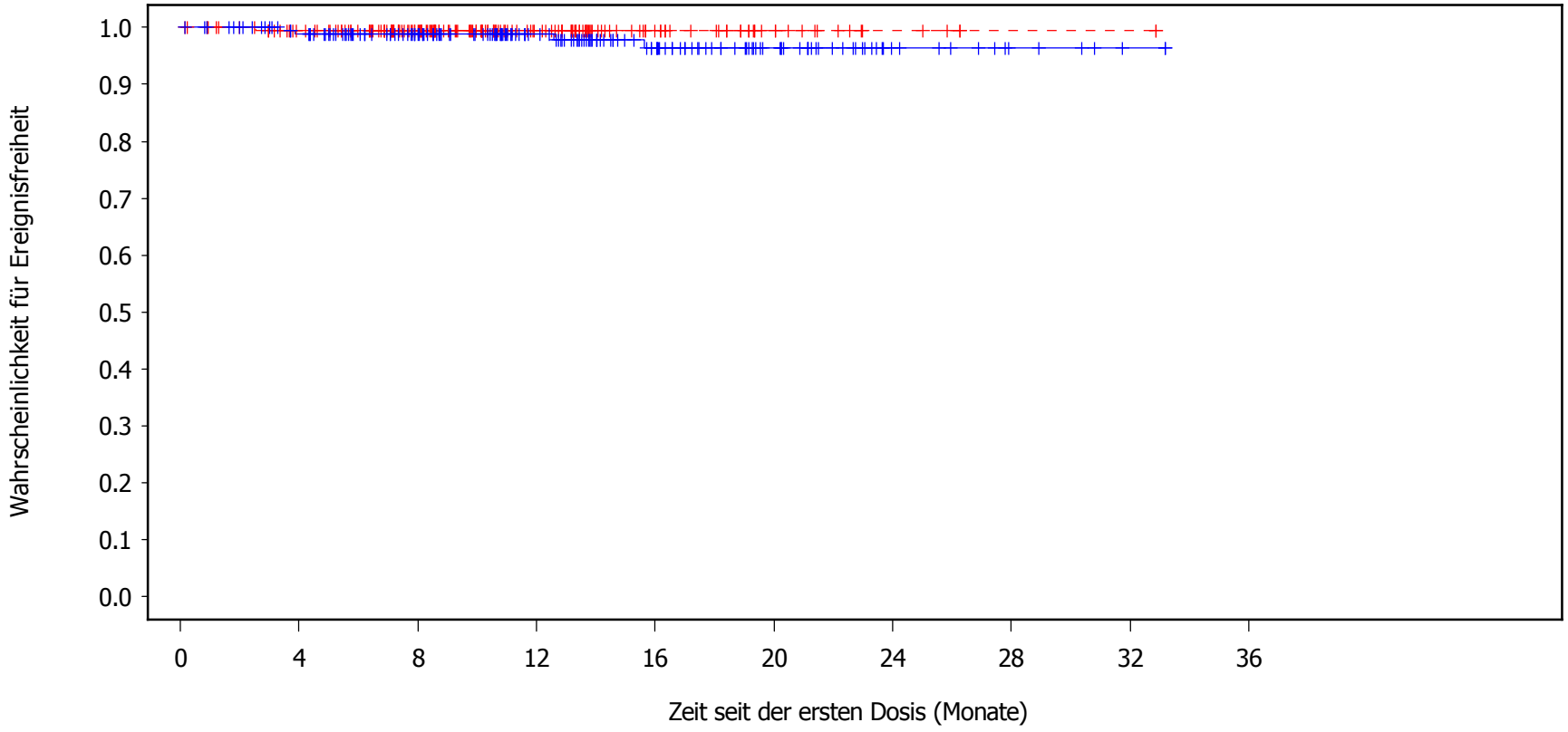
Figure 3.3.2.1D.112 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Andere seltene/sonstige Ereignisse
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	174	139	97	62	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	173	127	70	34	15	5	1	1	0	CTx

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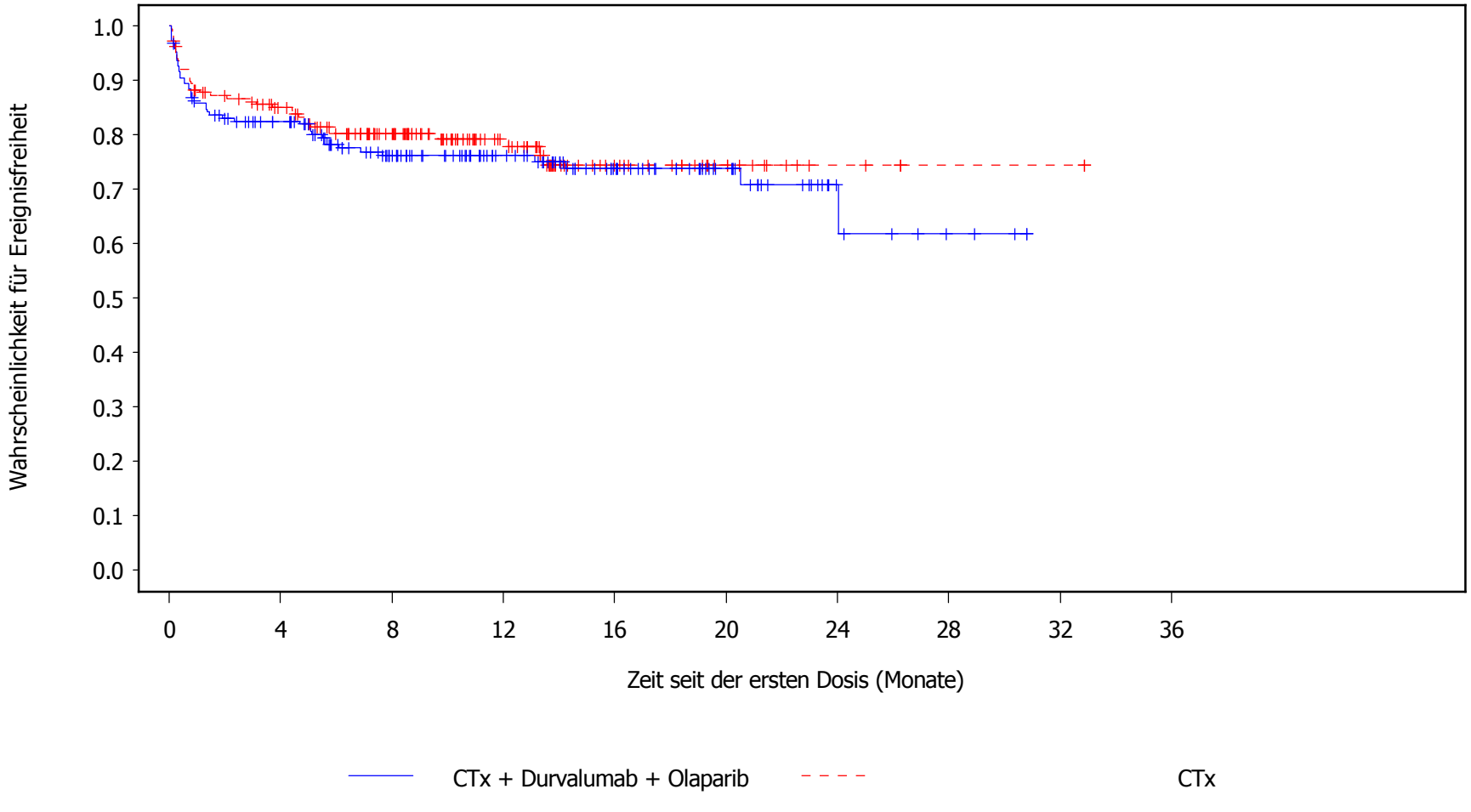
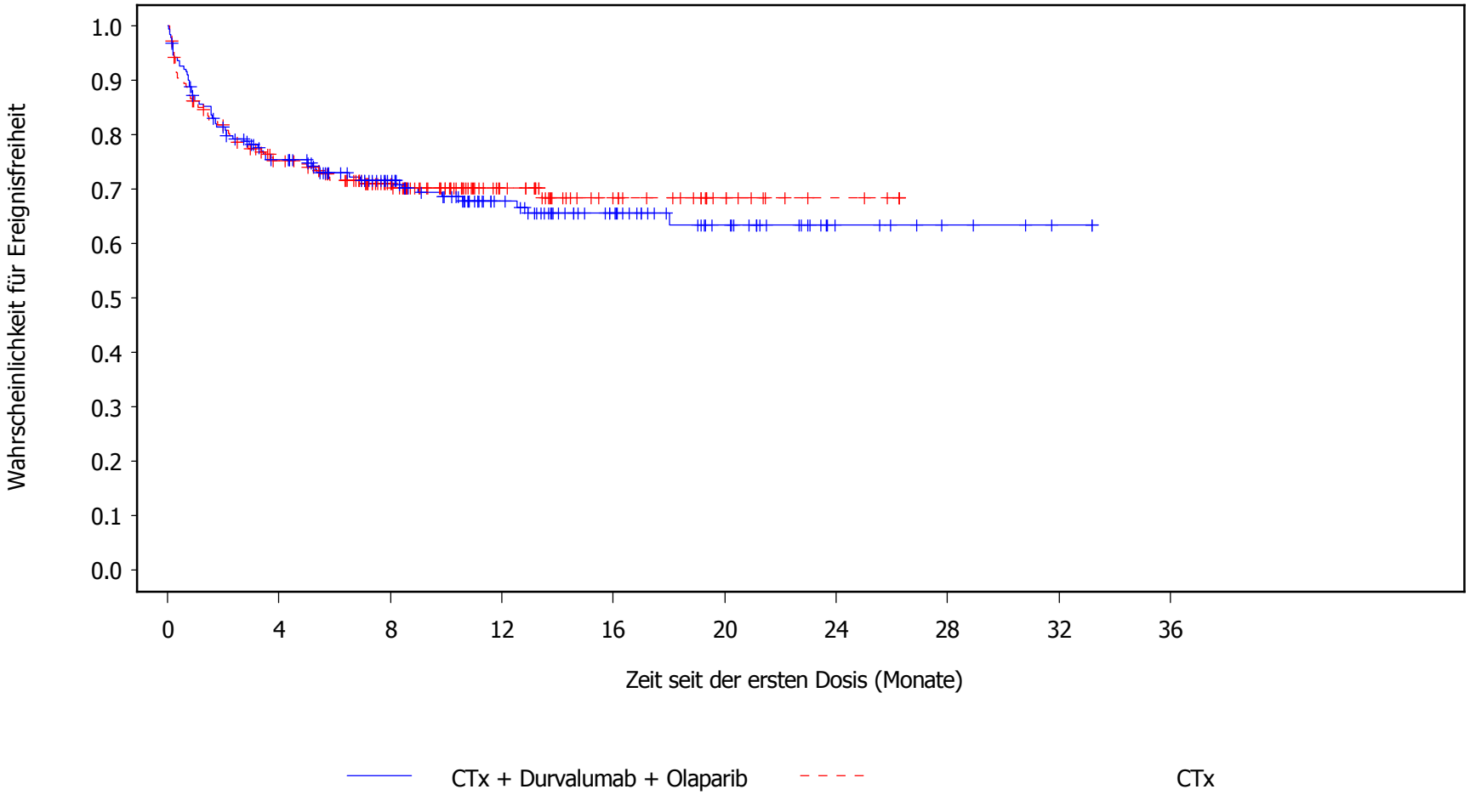
Figure 3.3.2.1D.113 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Dermatitis/Hautausschlag
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	143	104	75	48	28	8	3	0	0	CTx + Durvalumab + Olaparib
190	147	105	59	26	13	4	1	1	0	CTx

Figure 3.3.2.1D.114 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Diarrhö/Kolitis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	132	101	65	42	25	8	4	1	0	CTx + Durvalumab + Olaparib
190	131	92	48	26	12	4	0	0	0	CTx

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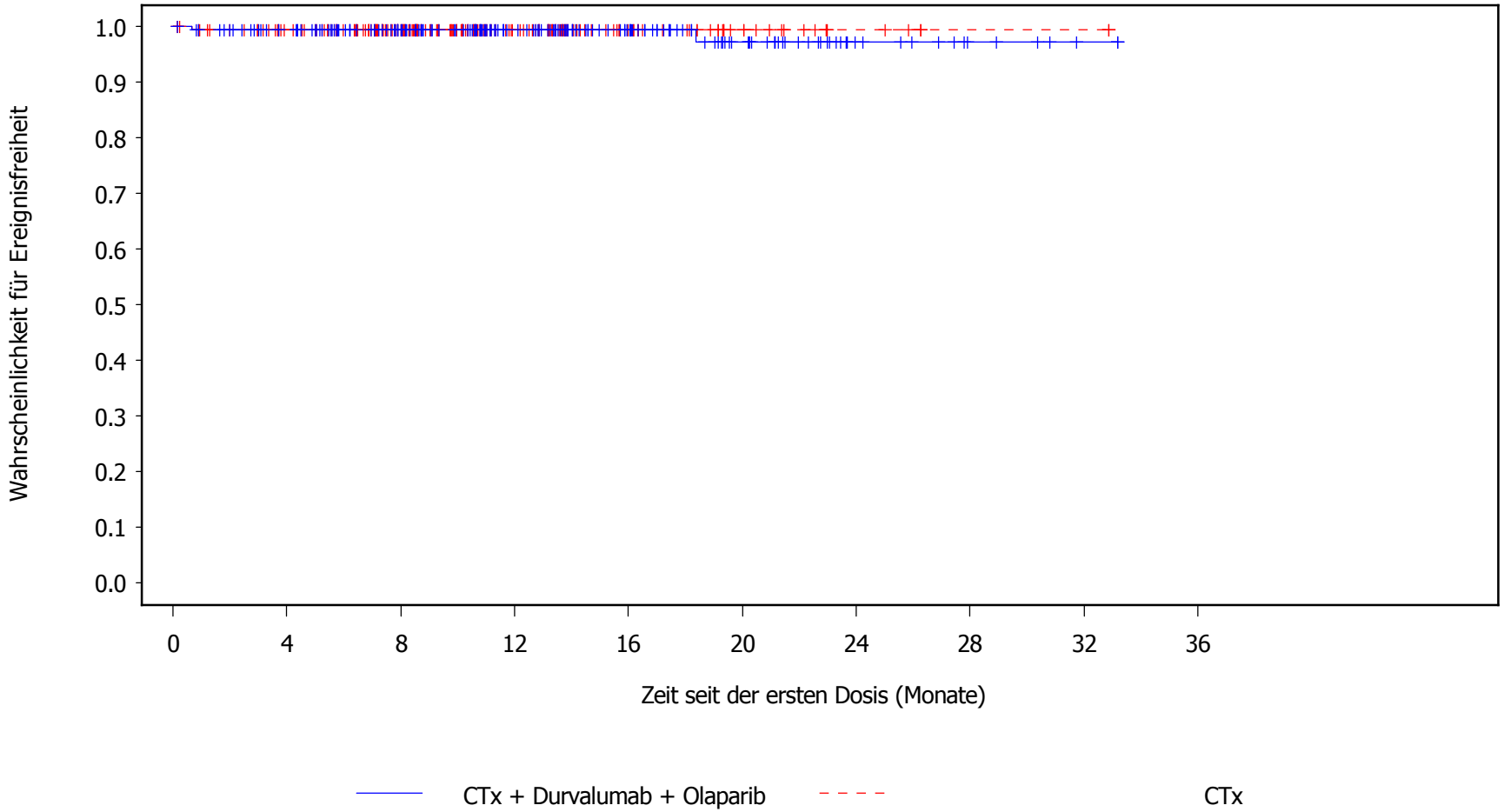
Figure 3.3.2.1D.115 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Hepatische Ereignisse
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	175	141	97	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	173	127	69	33	15	5	1	1	0	CTx

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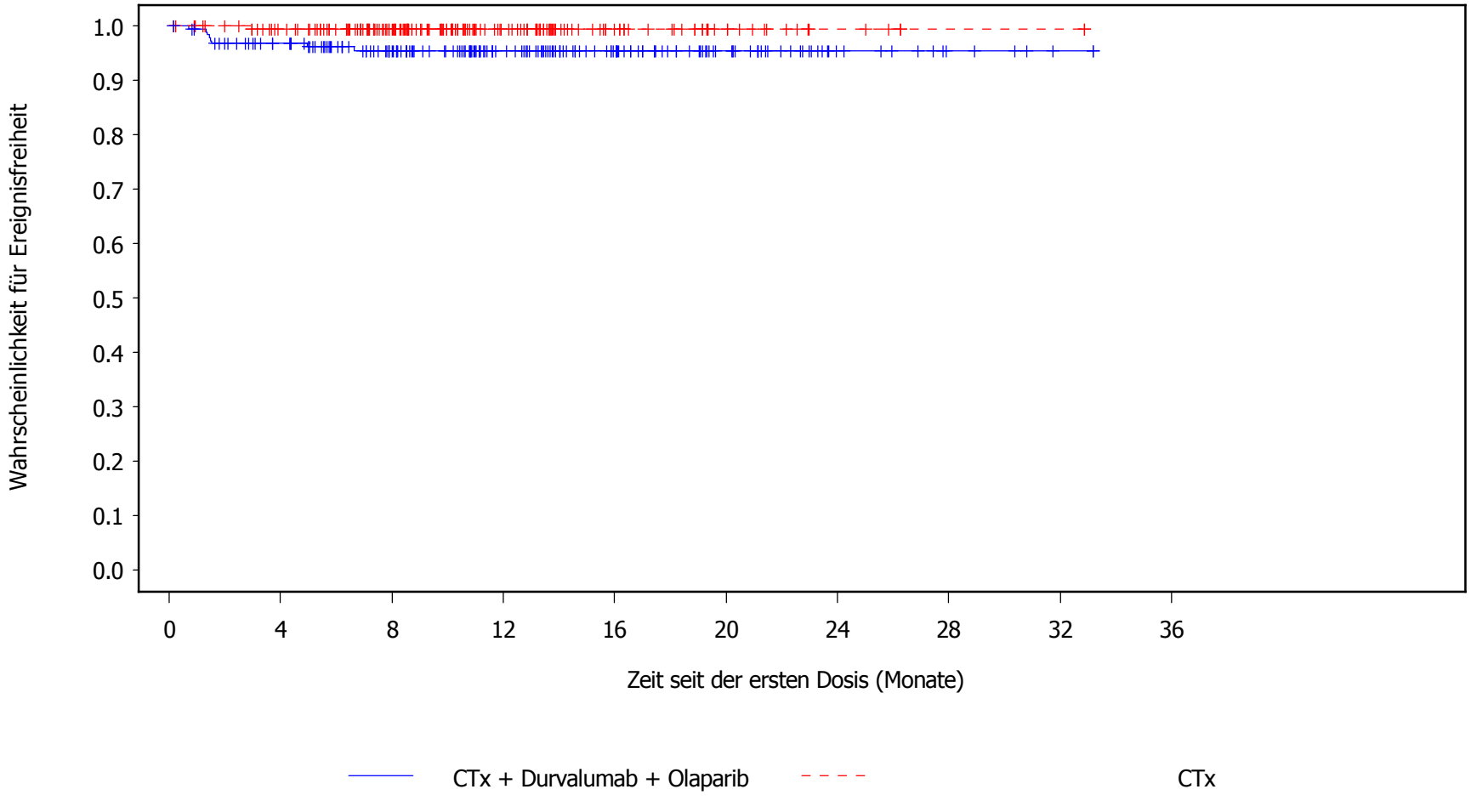
Figure 3.3.2.1D.116 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Hyperthyreose Ereignisse
Patients with pMMR tumour status, DCO 12APR2023



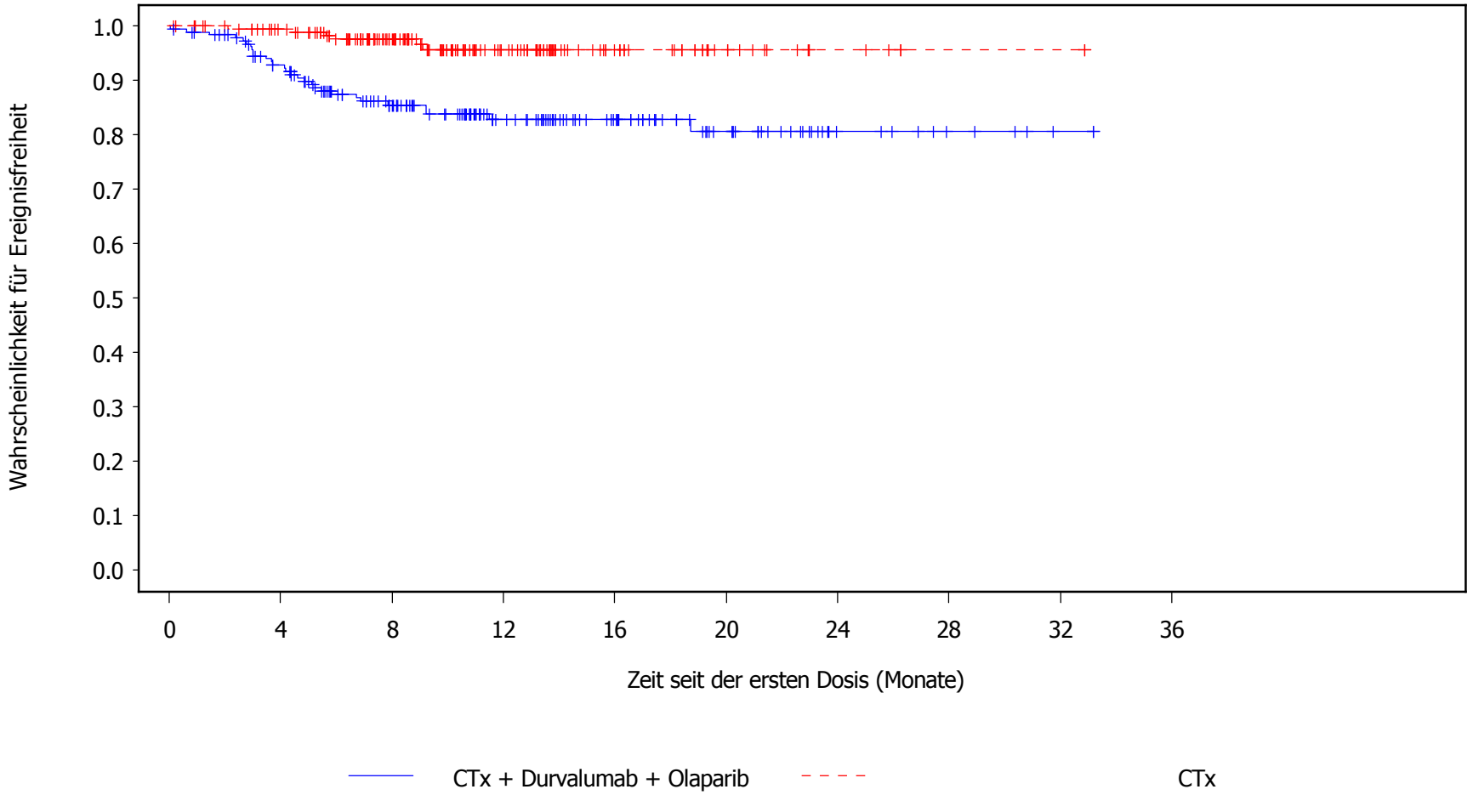
Anzahl an Patienten unter Risiko:

191	170	136	95	62	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	173	127	69	33	15	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bel 17APR2024:11:32

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.2.1D.117 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Hypothyreose Ereignisse
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	163	121	79	53	30	10	5	1	0	CTx + Durvalumab + Olaparib
190	173	124	67	32	14	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bem 17APR2024:11:32

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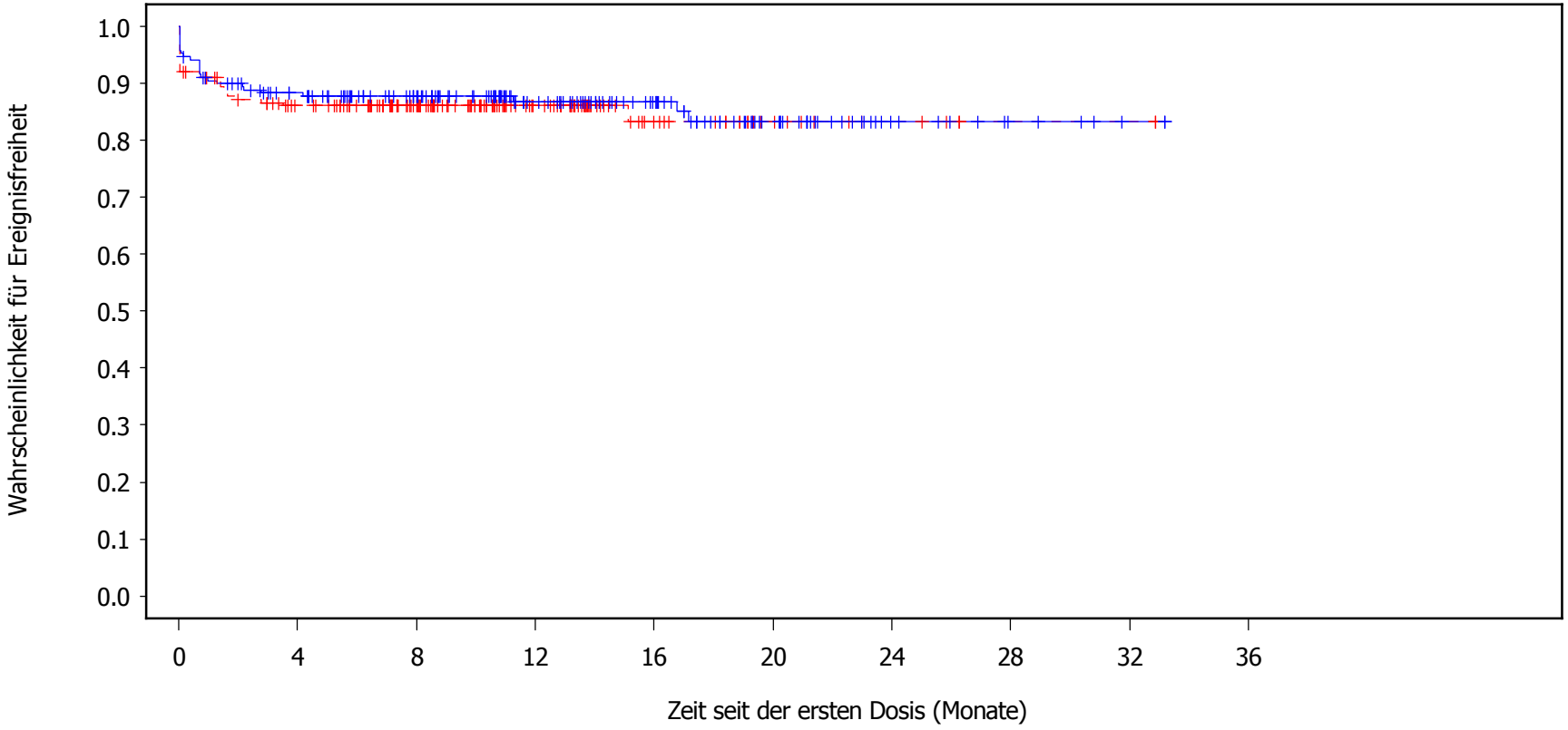
Figure 3.3.2.1D.118 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	154	124	83	57	32	11	5	1	0	CTx + Durvalumab + Olaparib
190	149	110	59	25	11	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1ben 17APR2024:11:32

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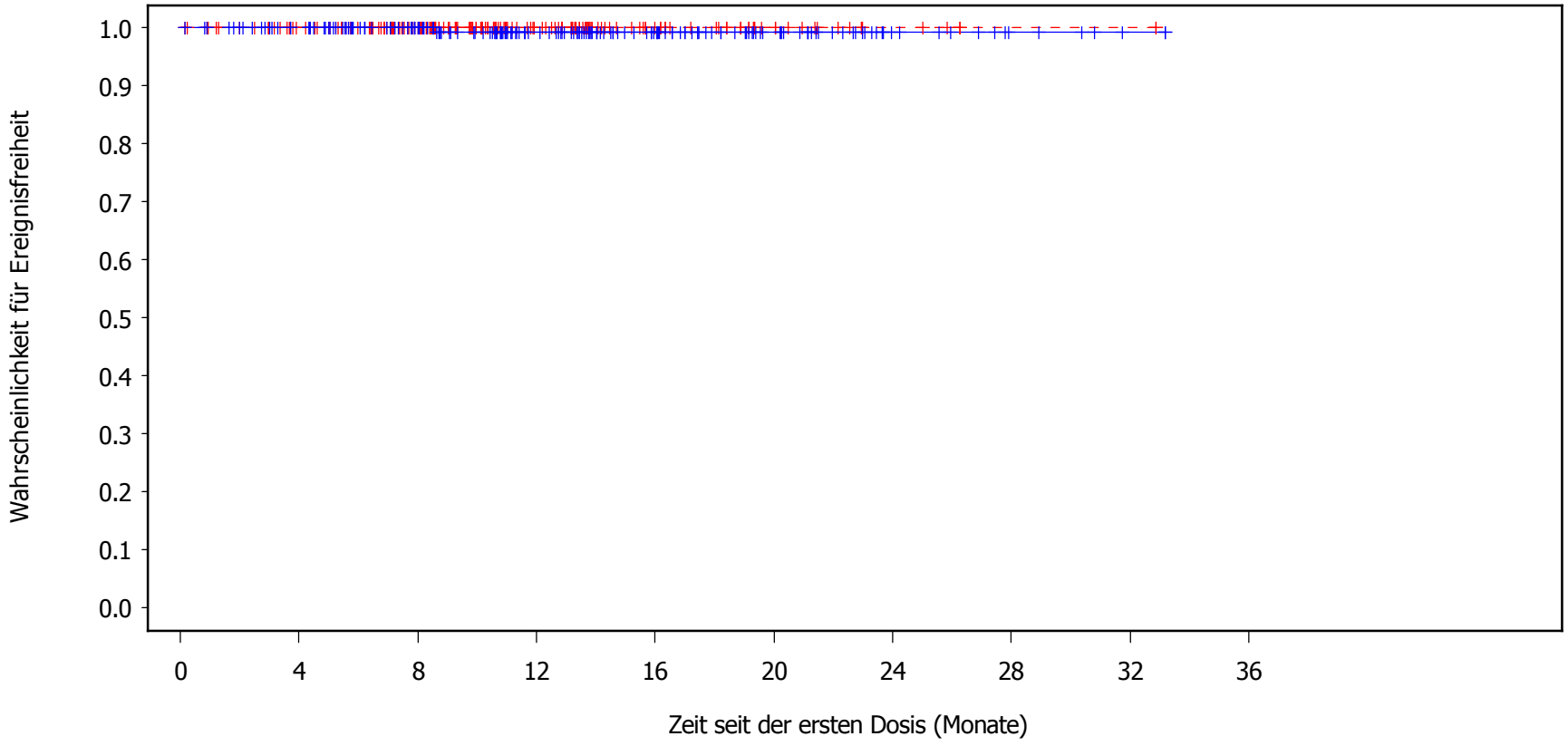
Figure 3.3.2.1D.119 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Myositis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	176	141	97	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	70	34	15	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1beo 17APR2024:11:32

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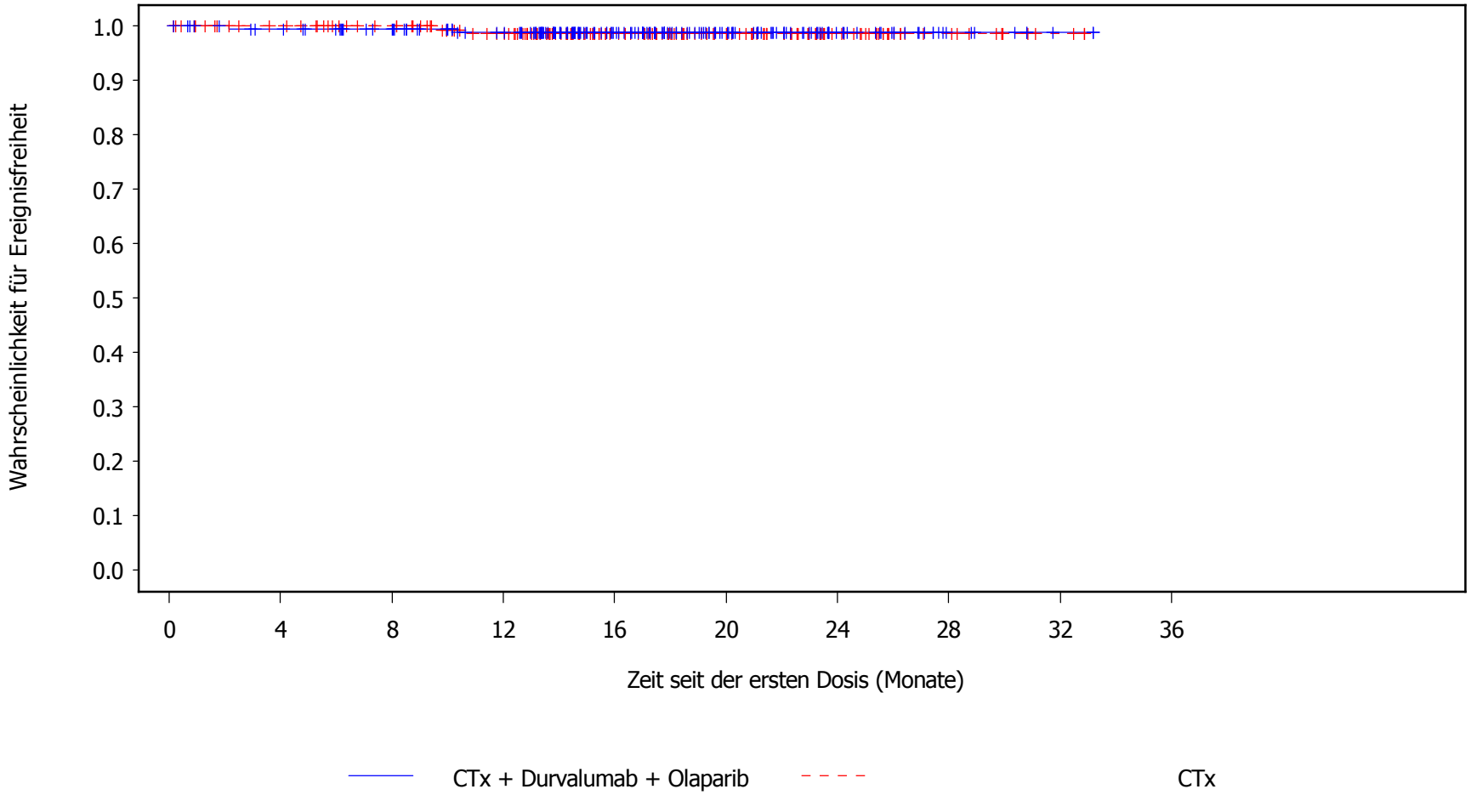
Figure 3.3.2.1D.120 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Neue primäre Malignität
Patients with pMMR tumour status, DCO 12APR2023

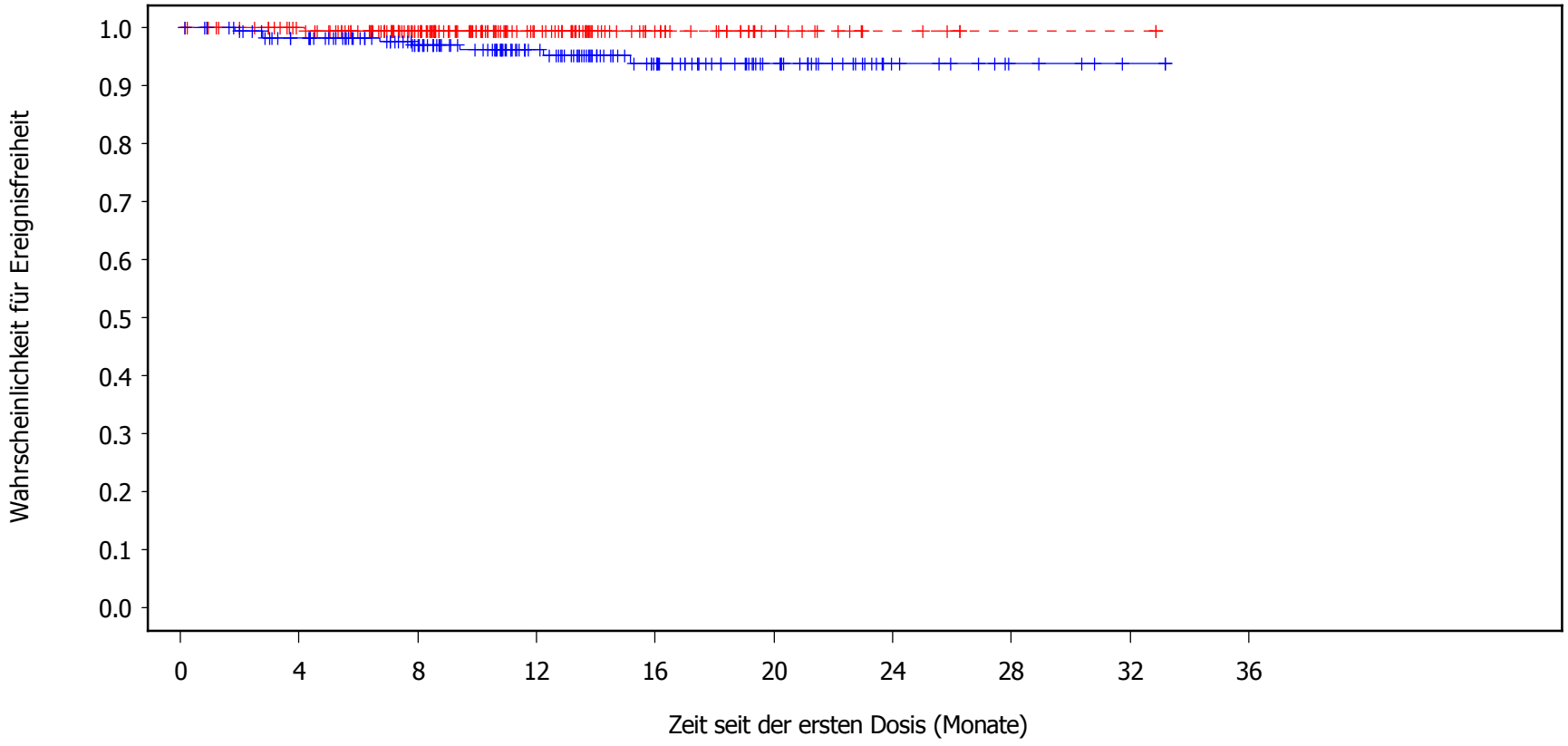


Anzahl an Patienten unter Risiko:

191	183	173	157	105	60	26	7	1	0	CTx + Durvalumab + Olaparib
190	178	167	148	96	64	30	10	2	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bep 17APR2024:11:32

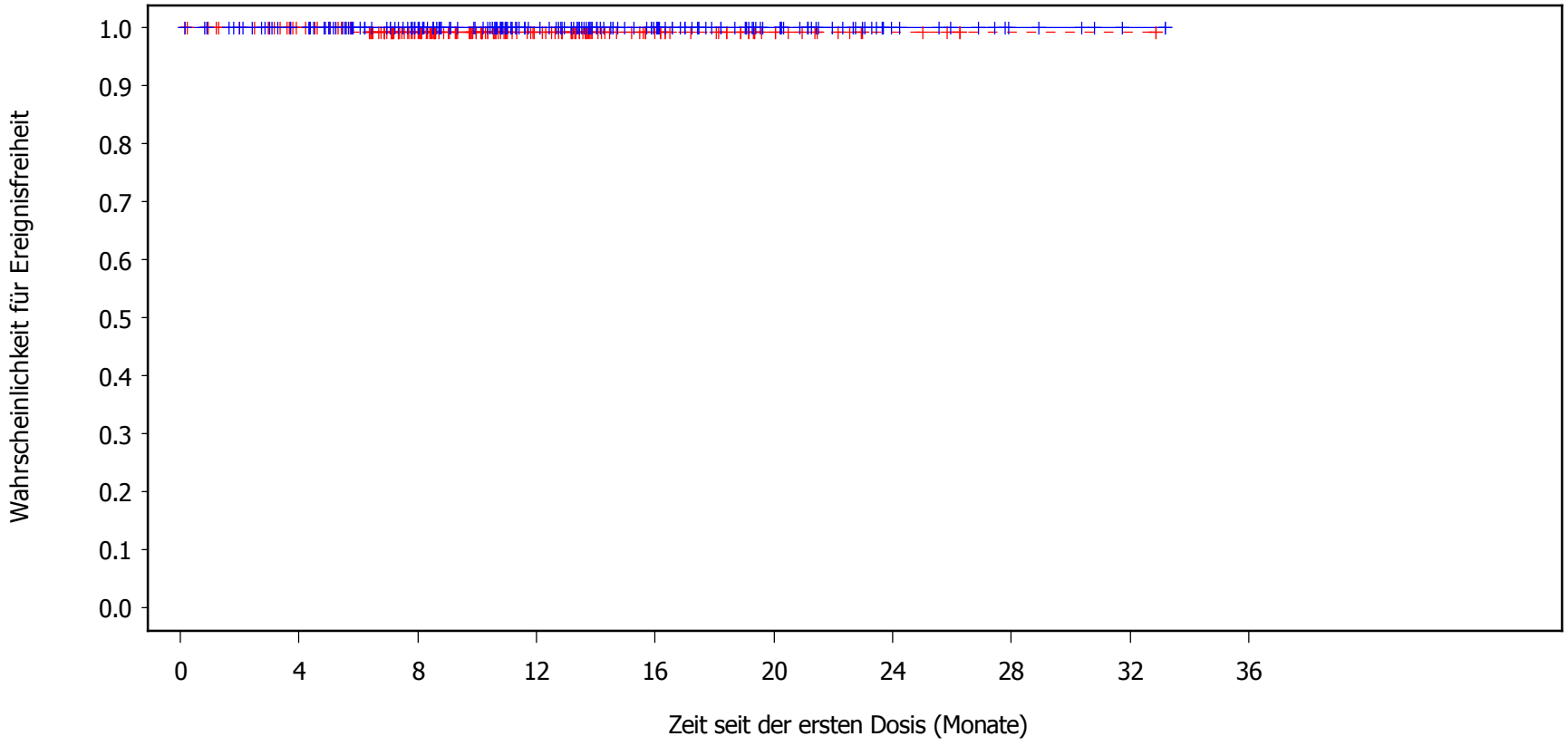
Figure 3.3.2.1D.121 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Pneumonitis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	173	140	98	62	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	127	70	34	15	5	1	1	0	CTx

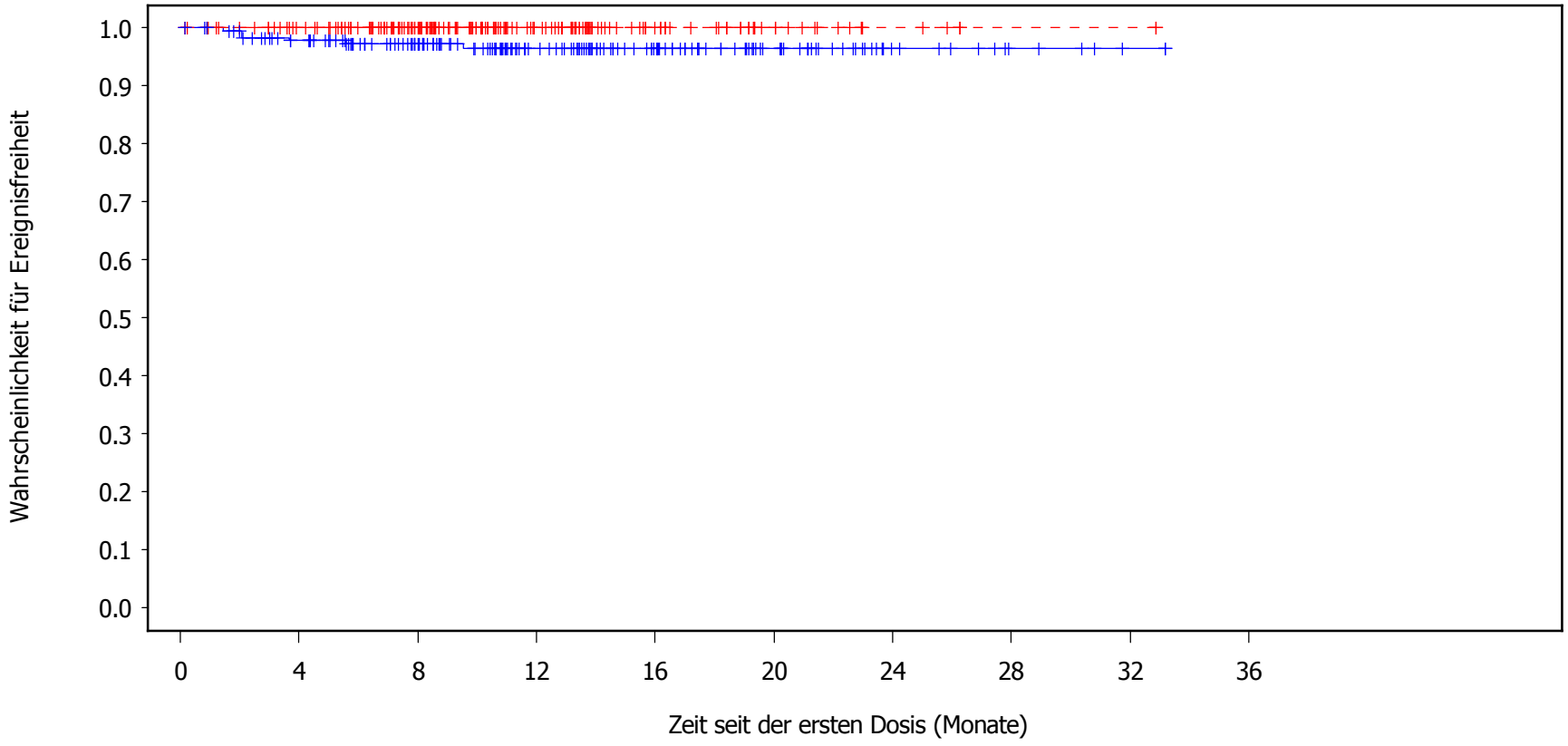
Figure 3.3.2.1D.122 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Renale Ereignisse
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	176	141	97	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	70	34	15	5	1	1	0	CTx

Figure 3.3.2.1D.123 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Thyreoiditis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	172	138	94	62	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	70	34	15	5	1	1	0	CTx

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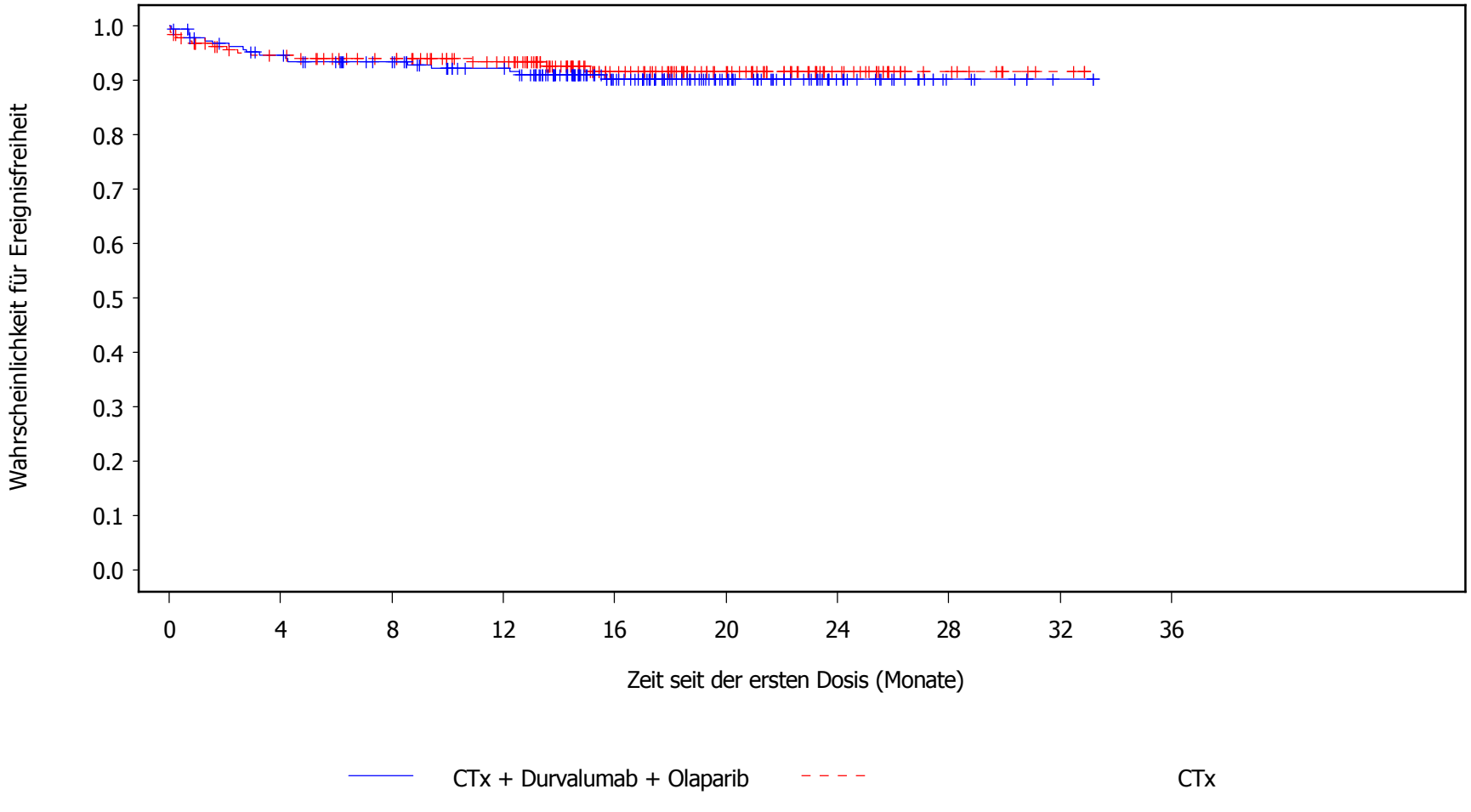
Figure 3.3.2.1D.124 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	174	162	147	98	55	25	7	1	0	CTx + Durvalumab + Olaparib
190	169	158	141	88	59	29	10	2	0	CTx

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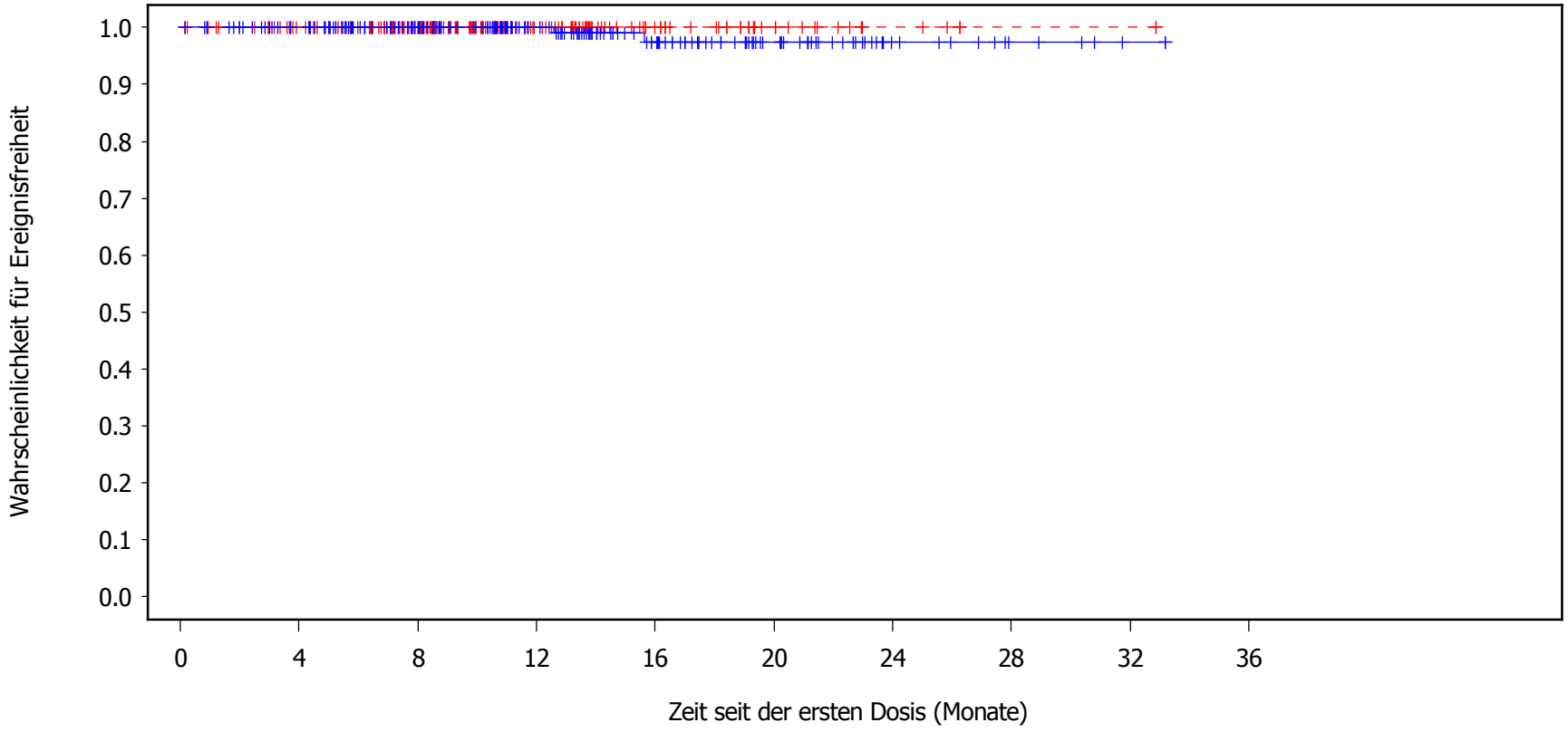
Figure 3.3.2.1D.125 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	176	141	98	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	70	34	15	5	1	1	0	CTx

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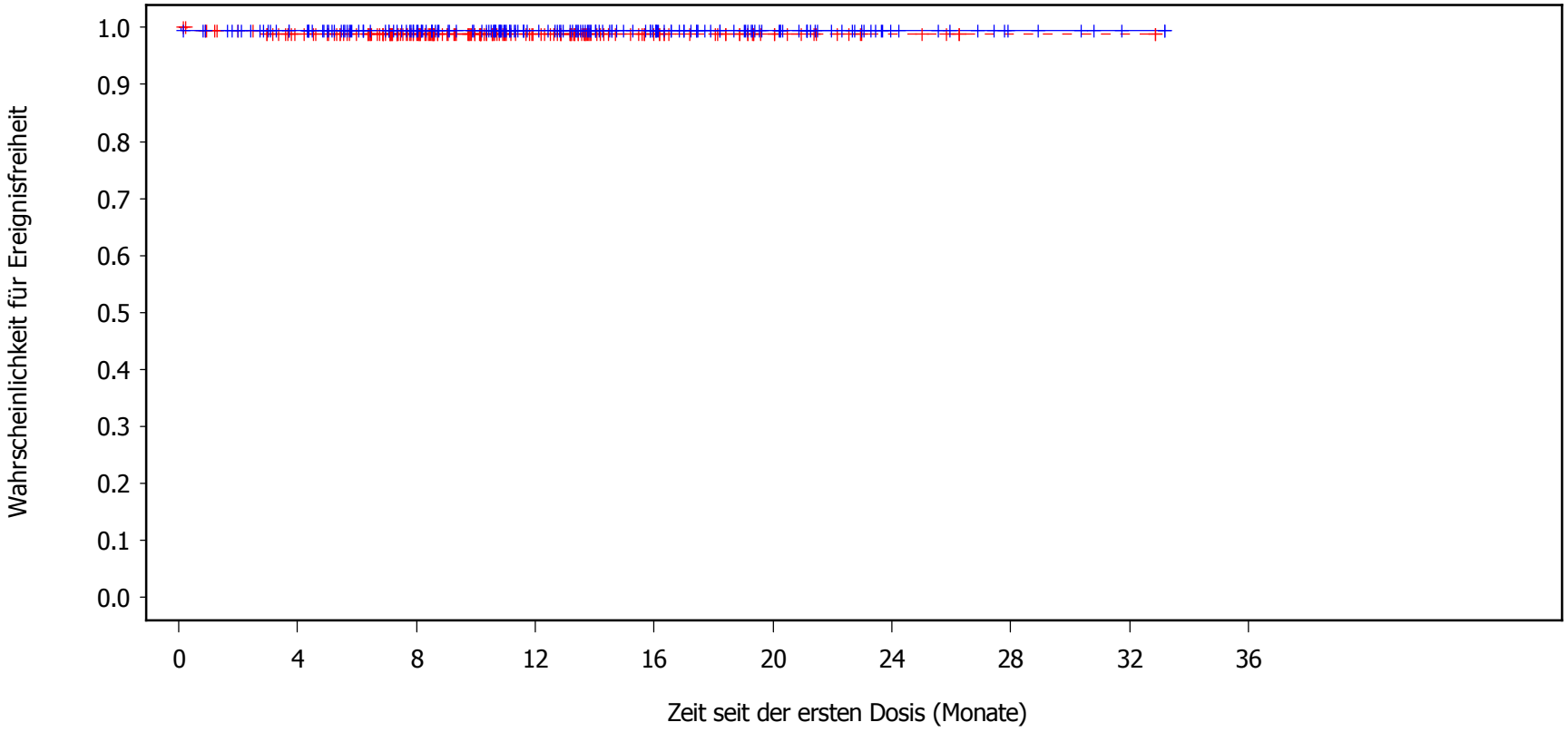
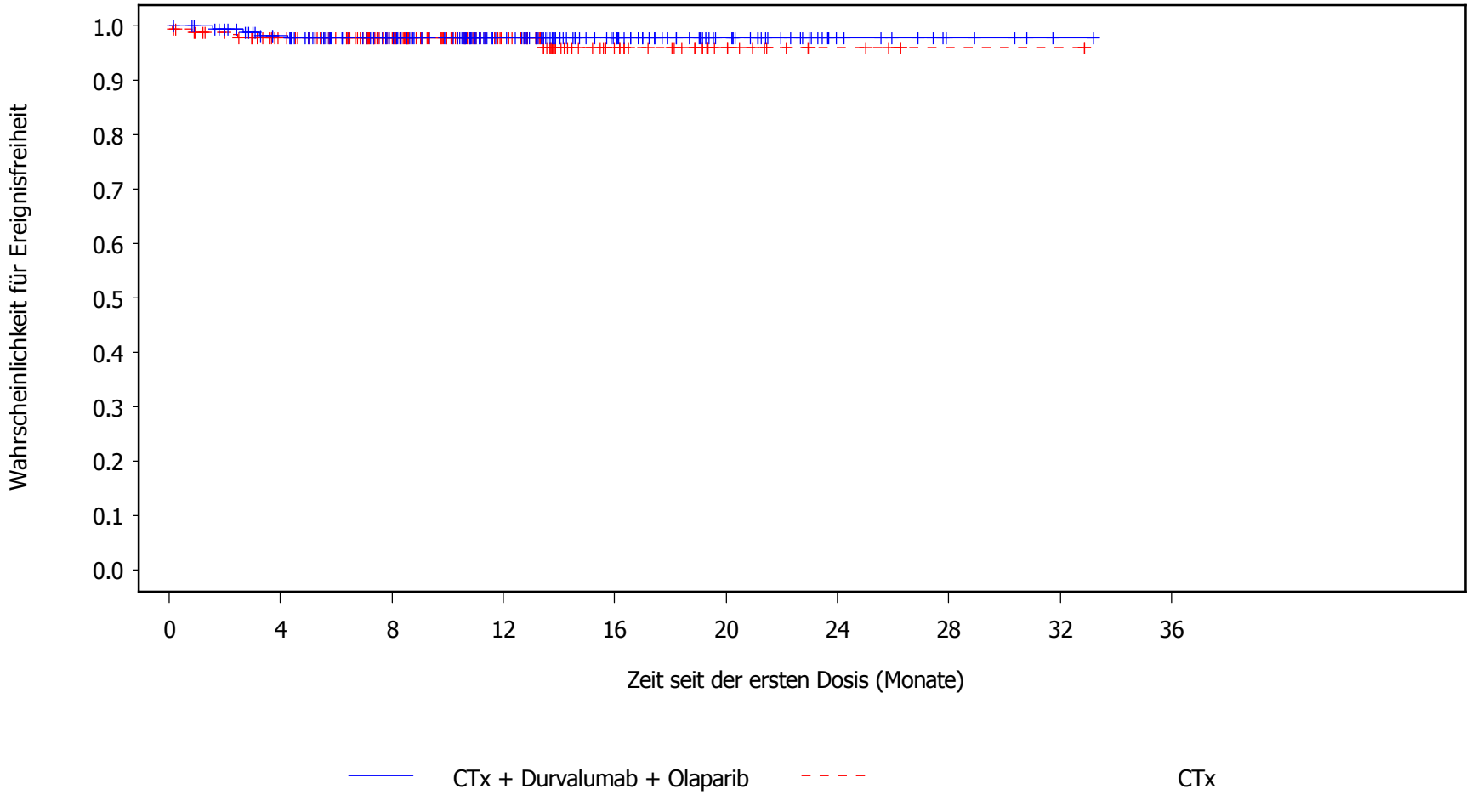
Figure 3.3.2.1D.126 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Dermatitis/Hautausschlag
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	175	140	97	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	172	127	70	34	15	5	1	1	0	CTx

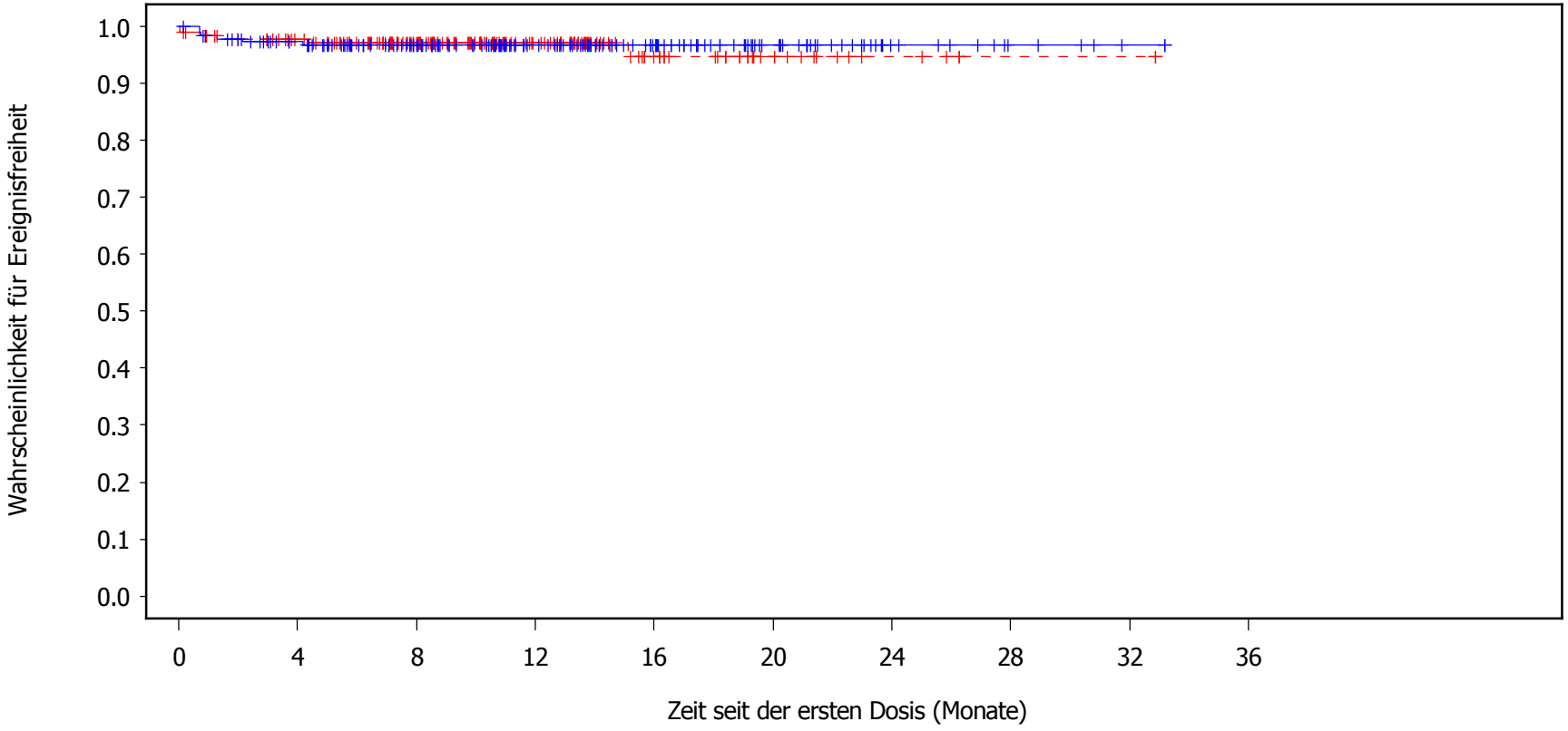
Figure 3.3.2.1D.127 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Diarrhö/Kolitis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	173	138	95	62	34	12	5	1	0	CTx + Durvalumab + Olaparib
190	170	124	67	32	14	5	1	1	0	CTx

Figure 3.3.2.1D.128 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Infusions- und Überempfindlichkeitsreaktionen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	171	136	94	62	34	12	5	1	0	CTx + Durvalumab + Olaparib
190	171	125	69	32	14	5	1	1	0	CTx

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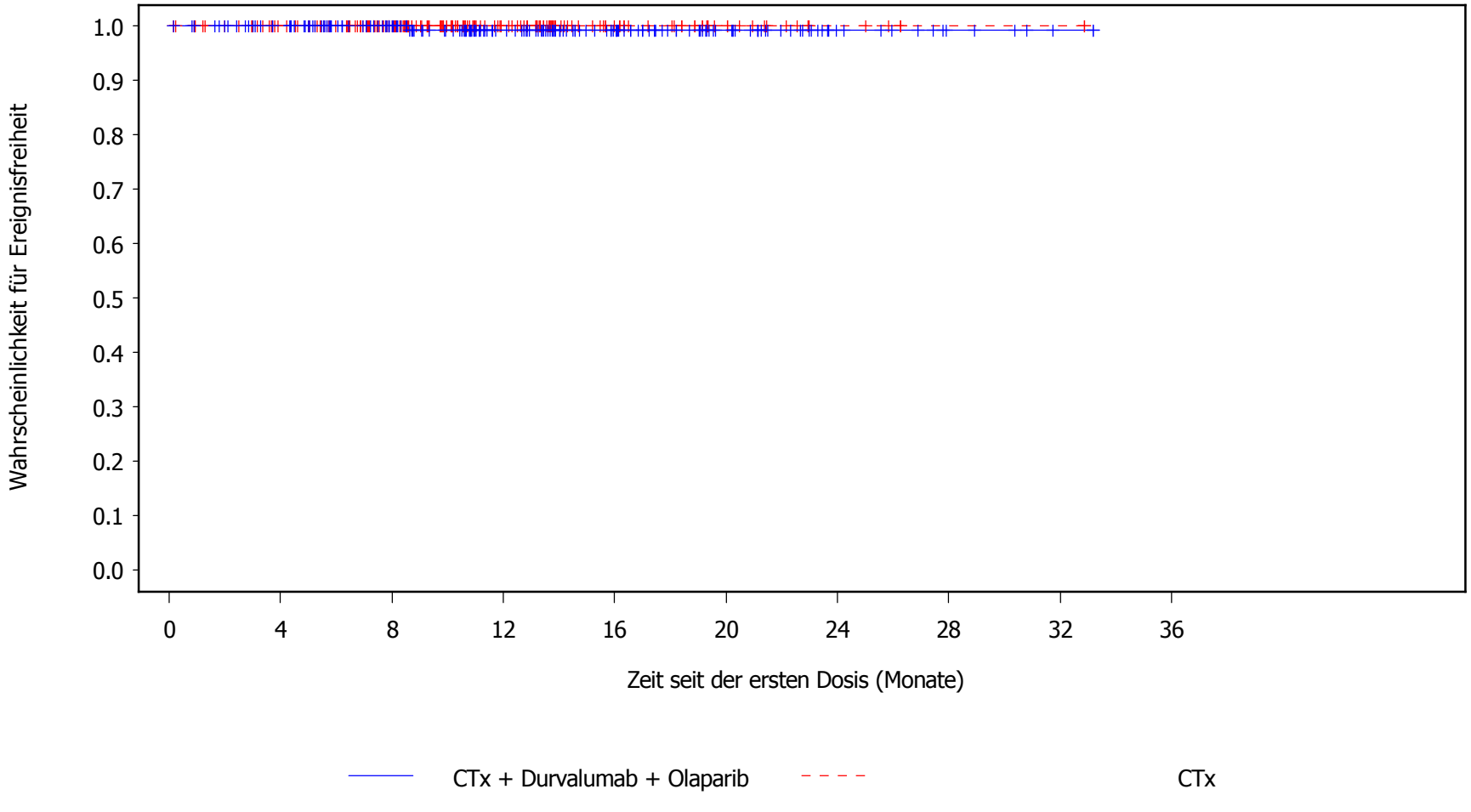
Figure 3.3.2.1D.129 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Myositis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	176	141	97	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	70	34	15	5	1	1	0	CTx

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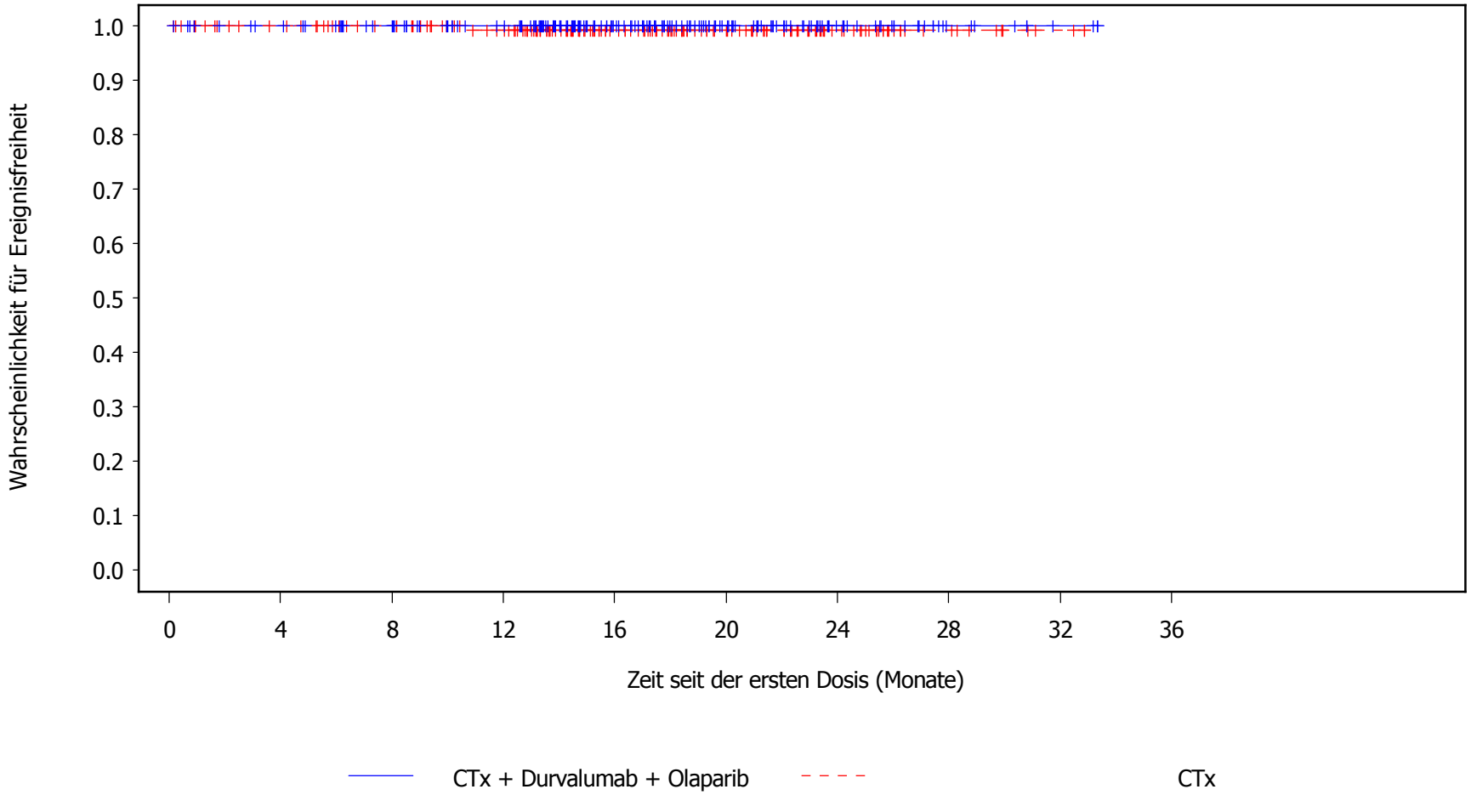
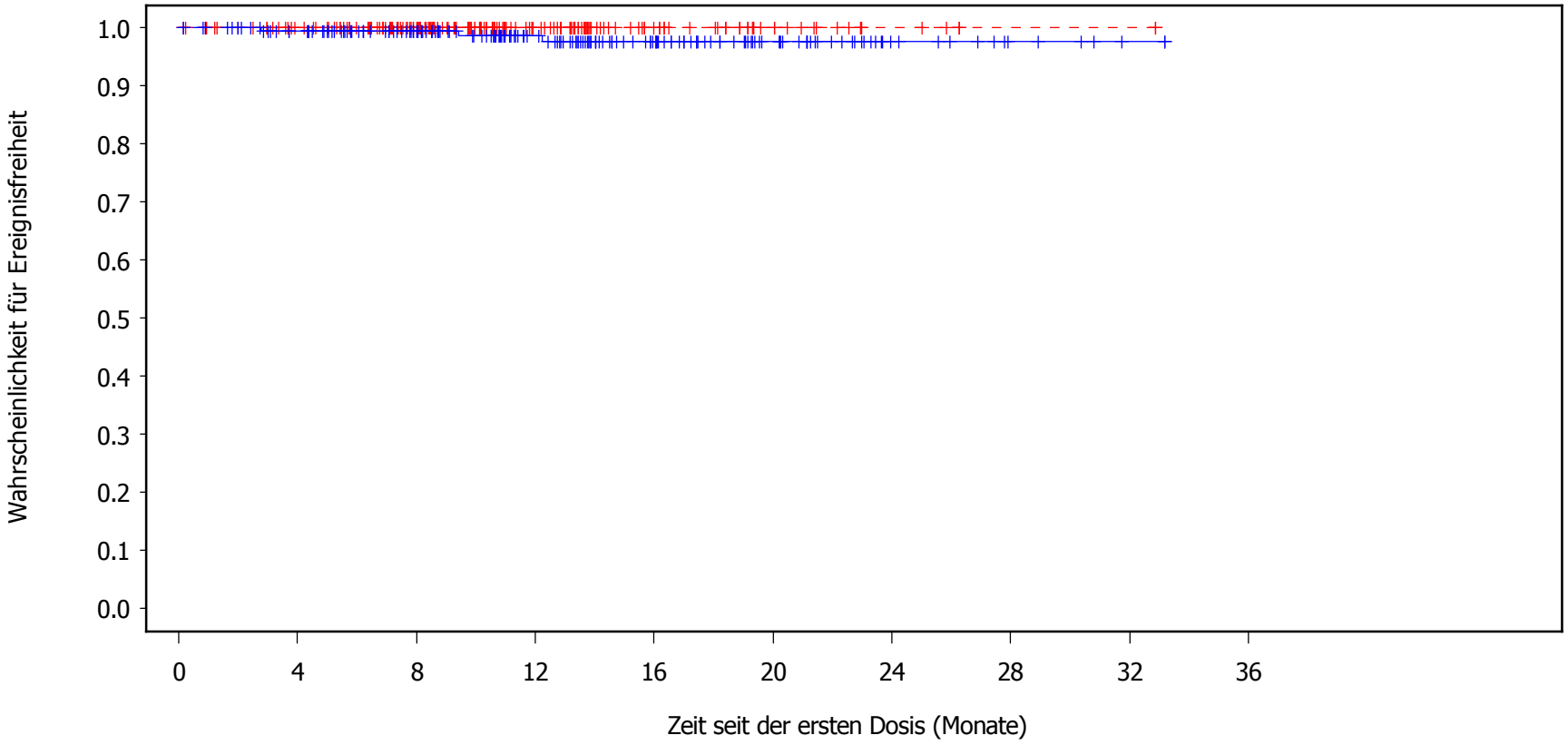
Figure 3.3.2.1D.130 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Neue primäre Malignität
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	184	174	159	107	61	27	8	2	0	CTx + Durvalumab + Olaparib
190	178	167	149	97	64	30	10	2	0	CTx

Figure 3.3.2.1D.131 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Pneumonitis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	175	141	98	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	70	34	15	5	1	1	0	CTx

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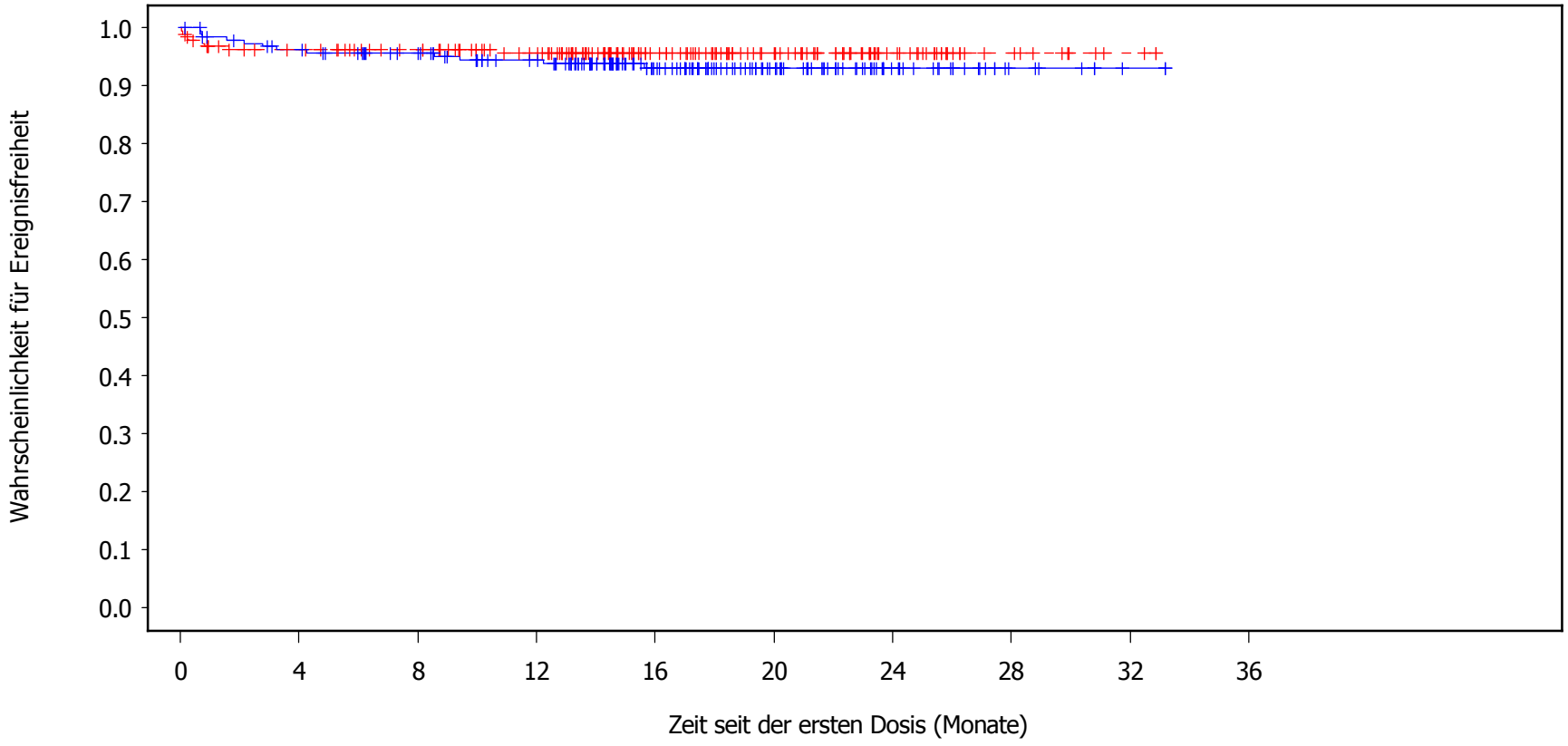
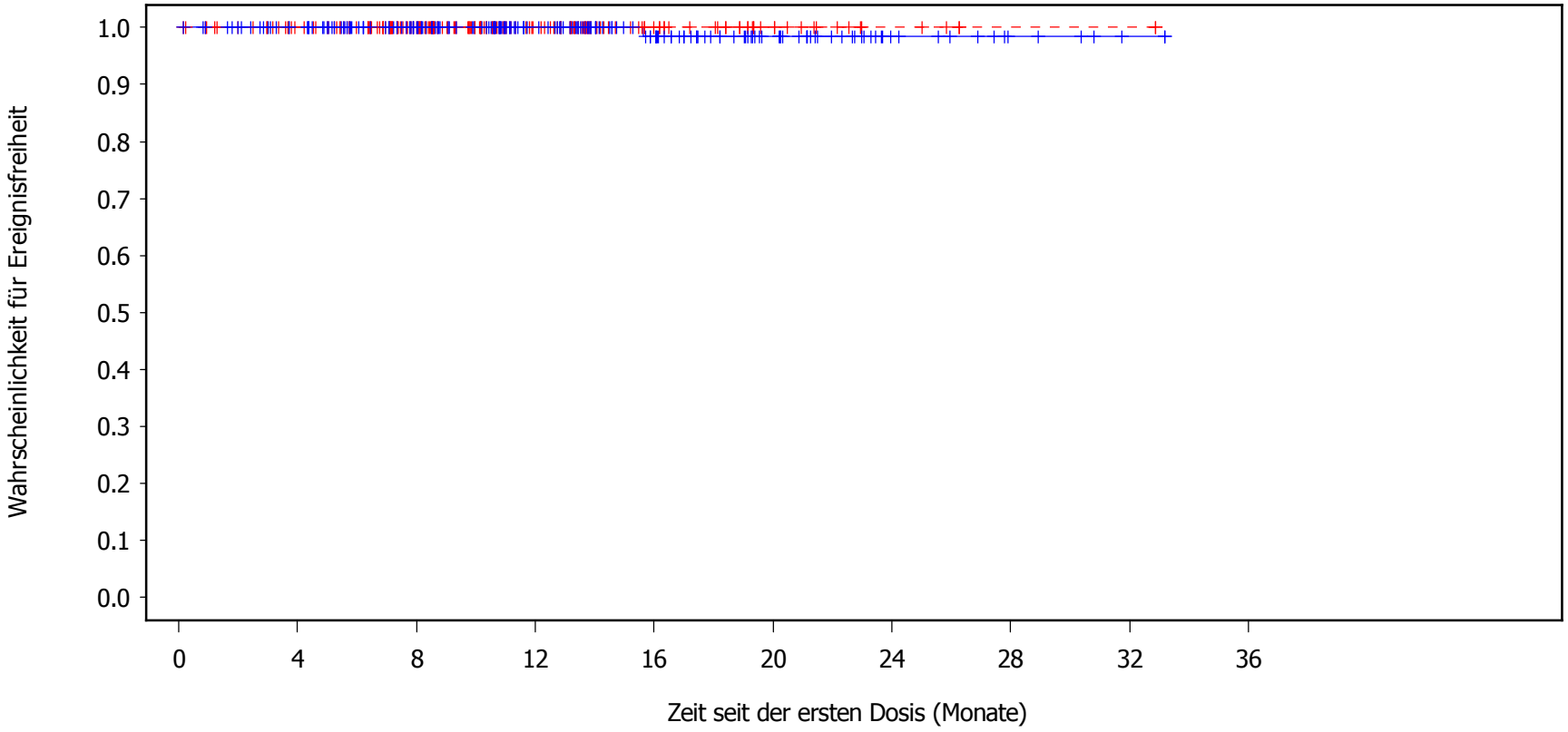
Figure 3.3.2.1D.132 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	177	166	150	100	58	25	7	1	0	CTx + Durvalumab + Olaparib
190	172	161	143	91	62	30	10	2	0	CTx

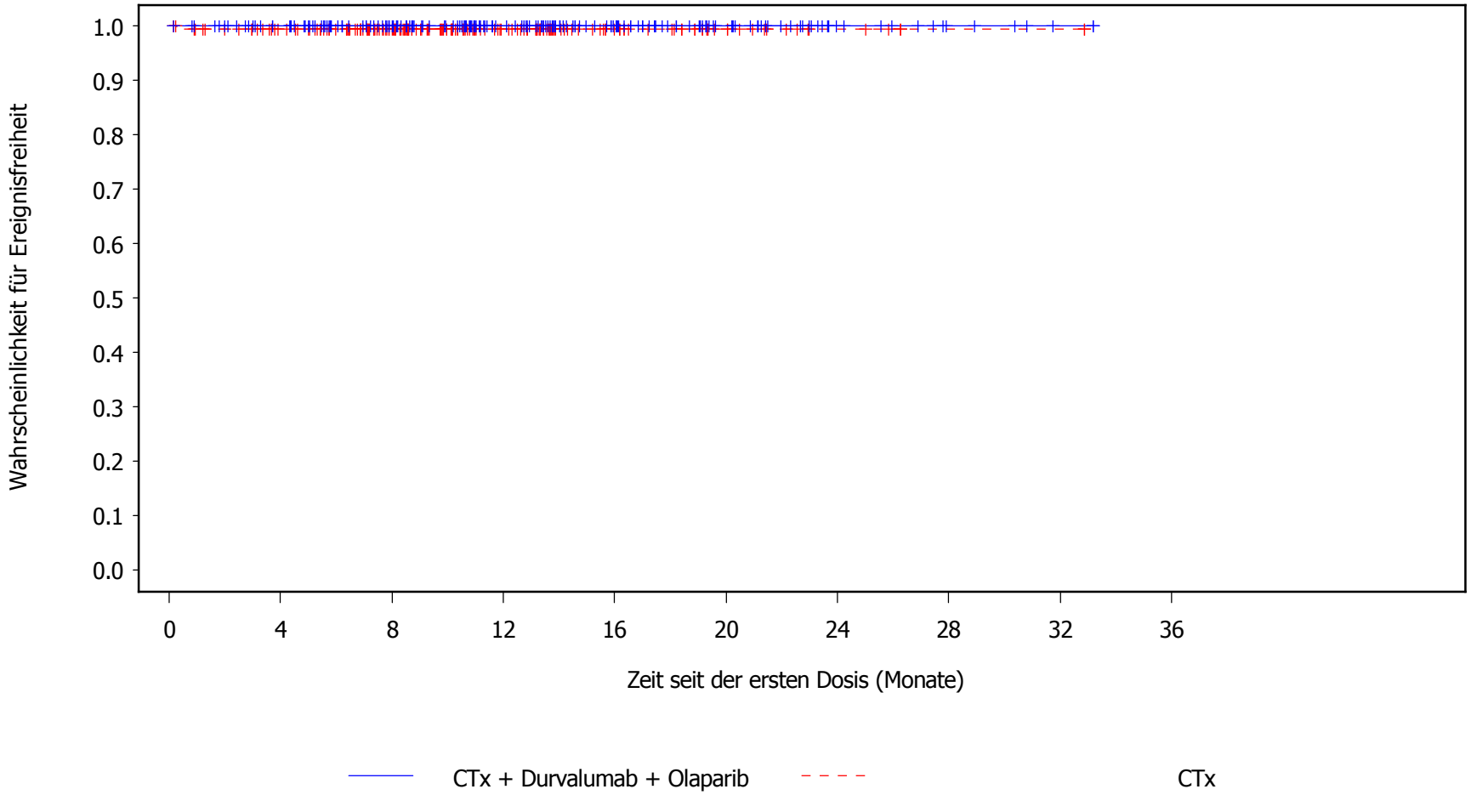
Figure 3.3.2.1D.133 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Andere seltene/sonstige Ereignisse
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	176	141	97	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	70	34	15	5	1	1	0	CTx

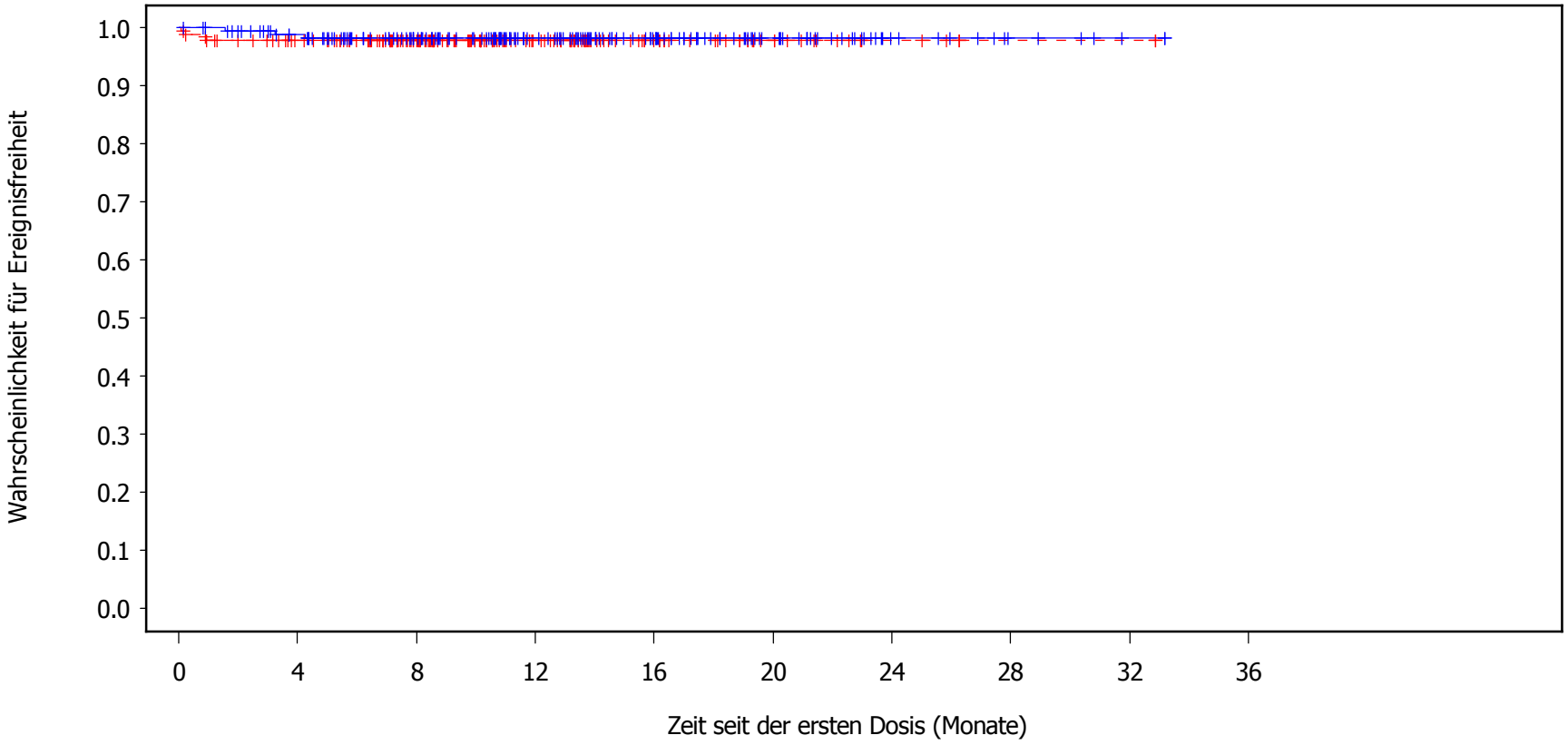
Figure 3.3.2.1D.134 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Dermatitis/Hautausschlag
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	176	141	97	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	173	127	70	34	15	5	1	1	0	CTx

Figure 3.3.2.1D.135 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Diarrhö/Kolitis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	174	139	96	62	34	12	5	1	0	CTx + Durvalumab + Olaparib
190	171	126	69	33	15	5	1	1	0	CTx

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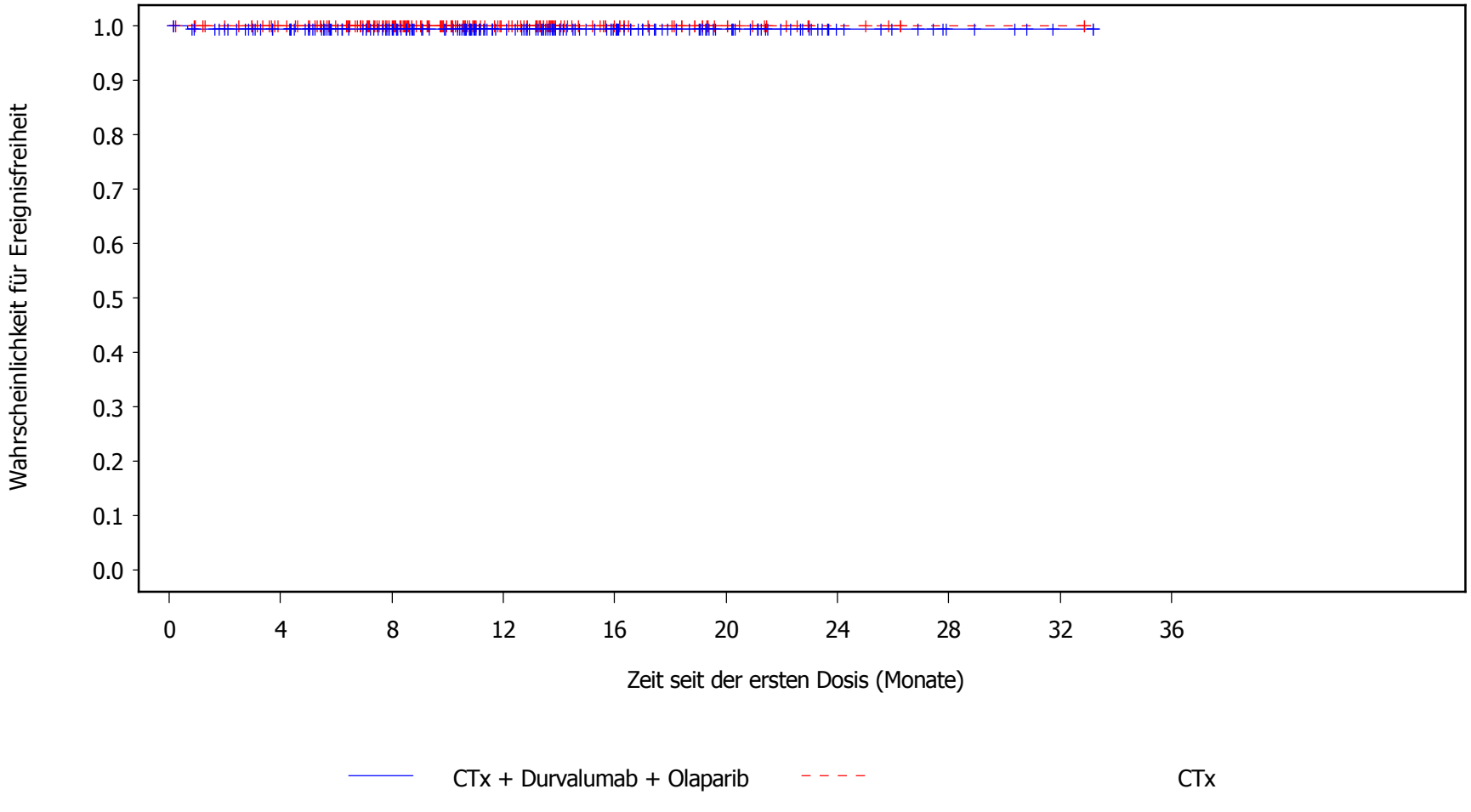
Figure 3.3.2.1D.136 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Hepatische Ereignisse
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	175	141	97	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	70	34	15	5	1	1	0	CTx

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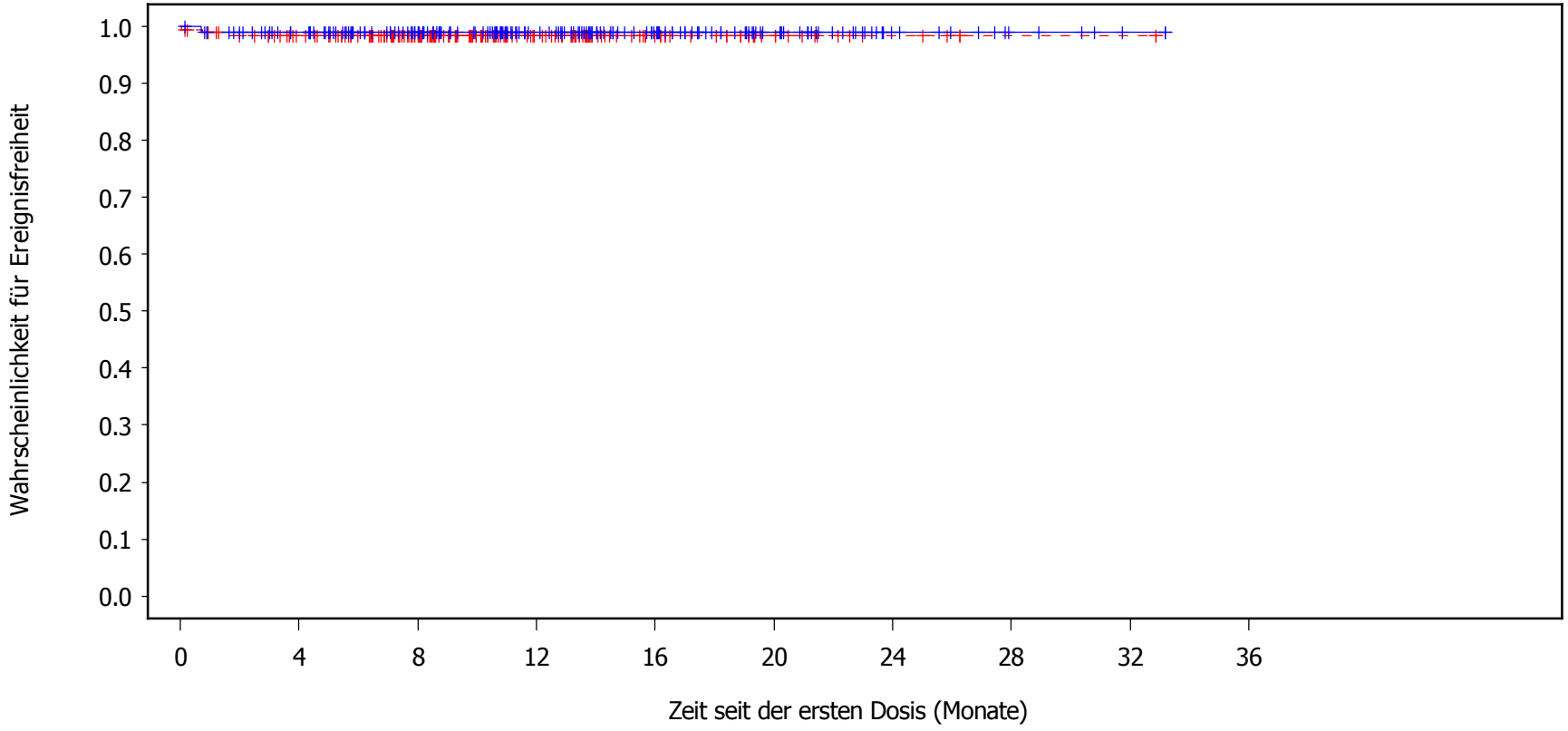
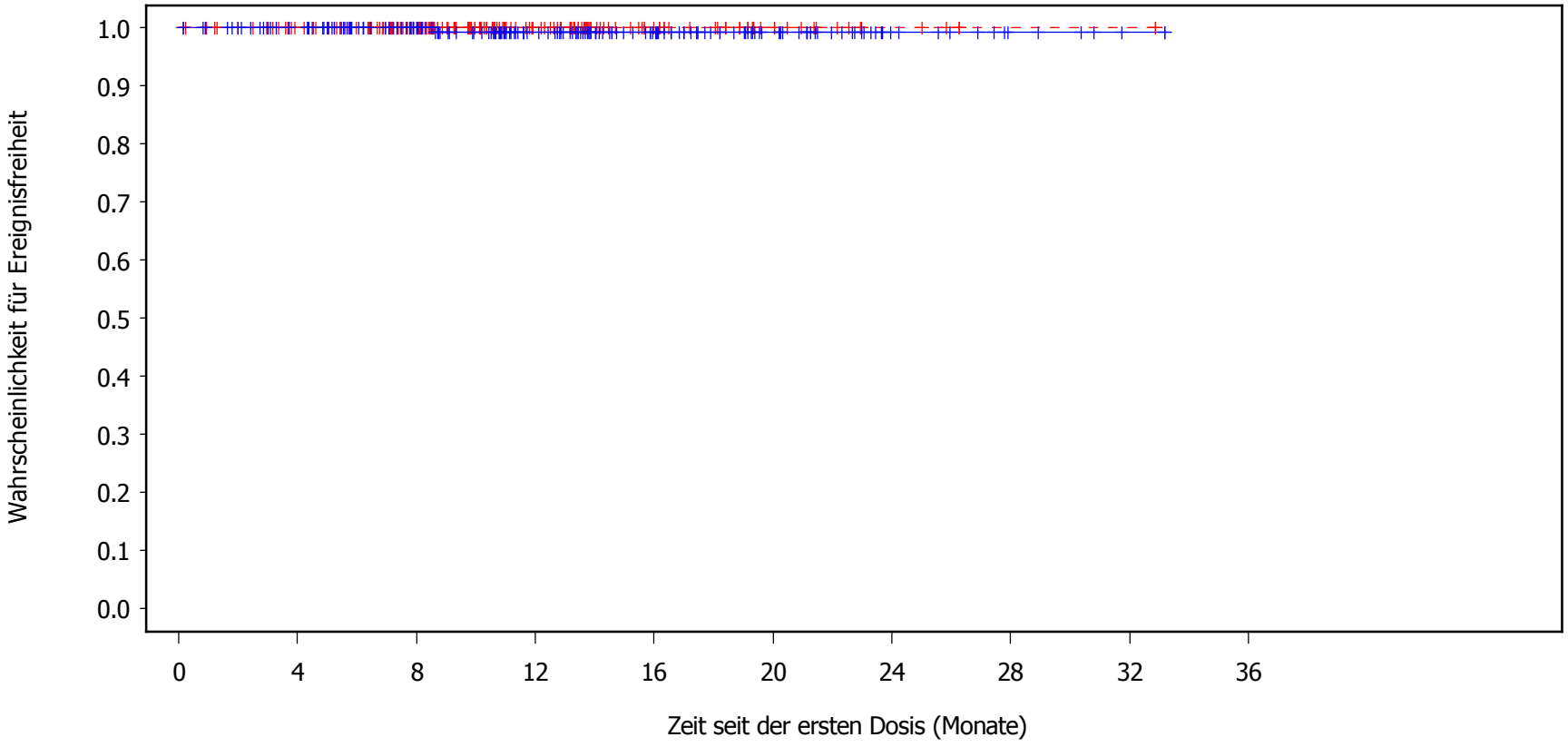
Figure 3.3.2.1D.137 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Infusions- und Überempfindlichkeitsreaktionen
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	174	139	96	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	171	125	68	32	14	5	1	1	0	CTx

Figure 3.3.2.1D.138 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Myositis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	176	141	97	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	70	34	15	5	1	1	0	CTx

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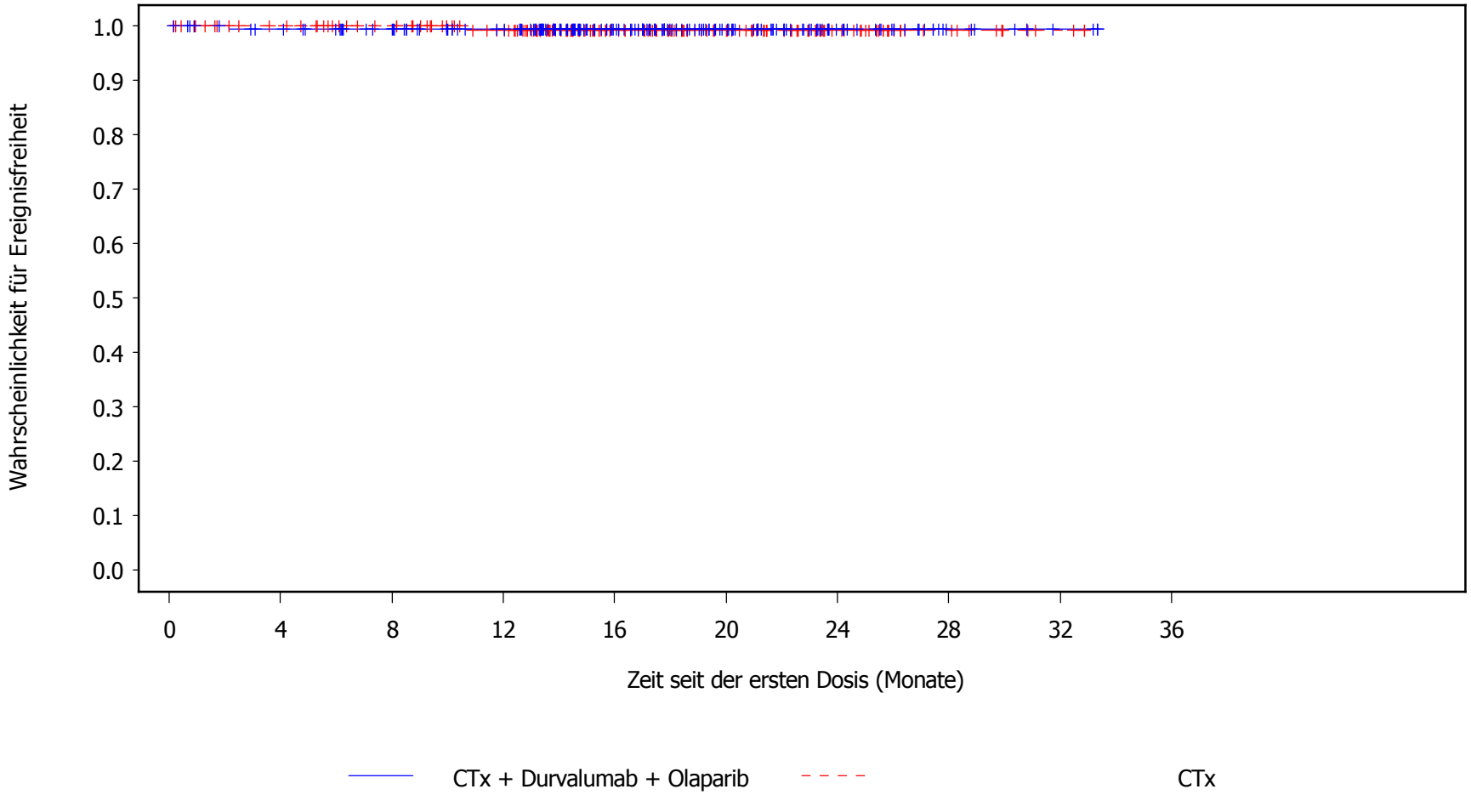
Figure 3.3.2.1D.139 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Neue primäre Malignität
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	183	173	158	106	61	27	8	2	0	CTx + Durvalumab + Olaparib
190	178	167	149	97	64	30	10	2	0	CTx

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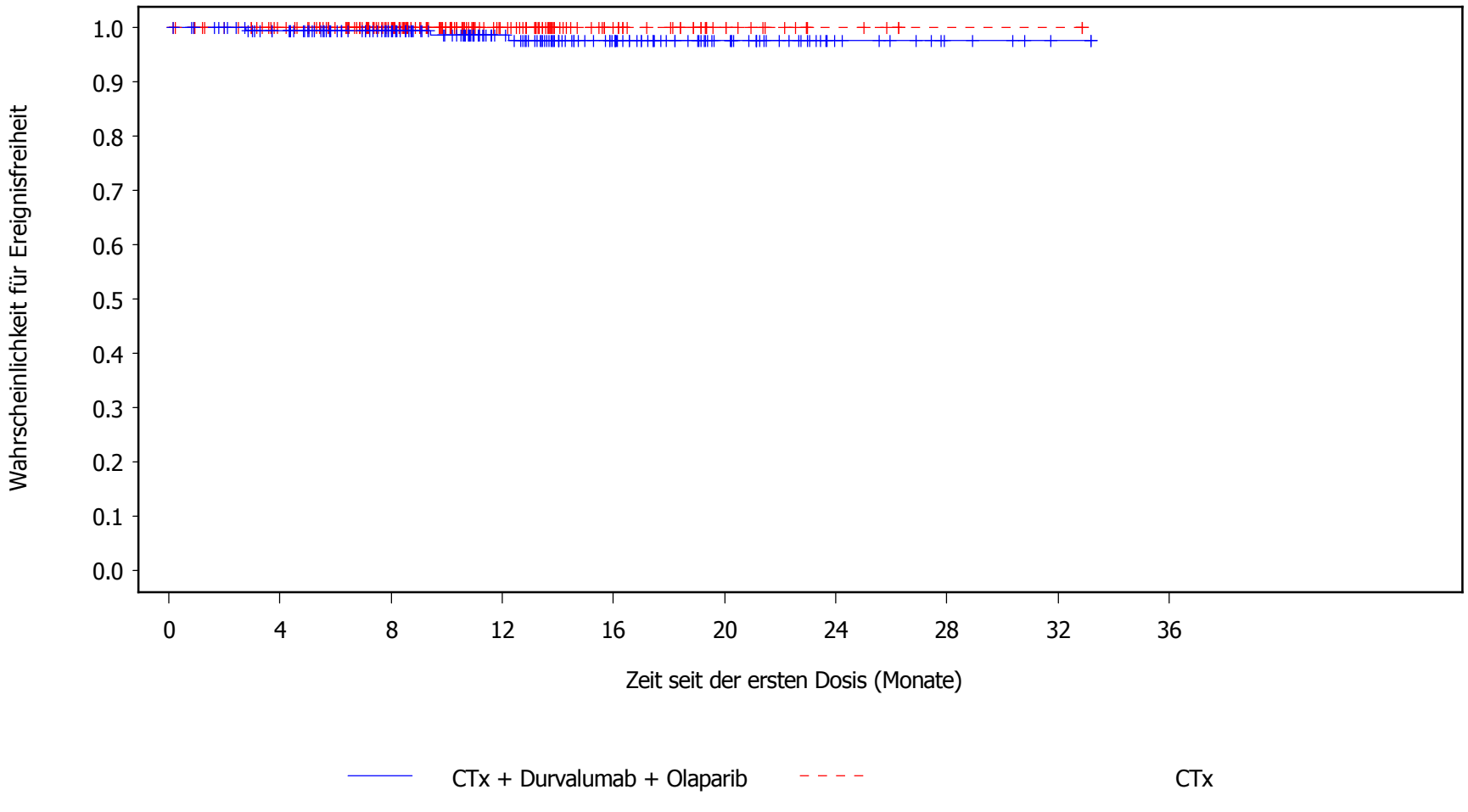
Figure 3.3.2.1D.140 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Pneumonitis
Patients with pMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

191	175	141	98	63	35	12	5	1	0	CTx + Durvalumab + Olaparib
190	174	128	70	34	15	5	1	1	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1bfj 17APR2024:11:32

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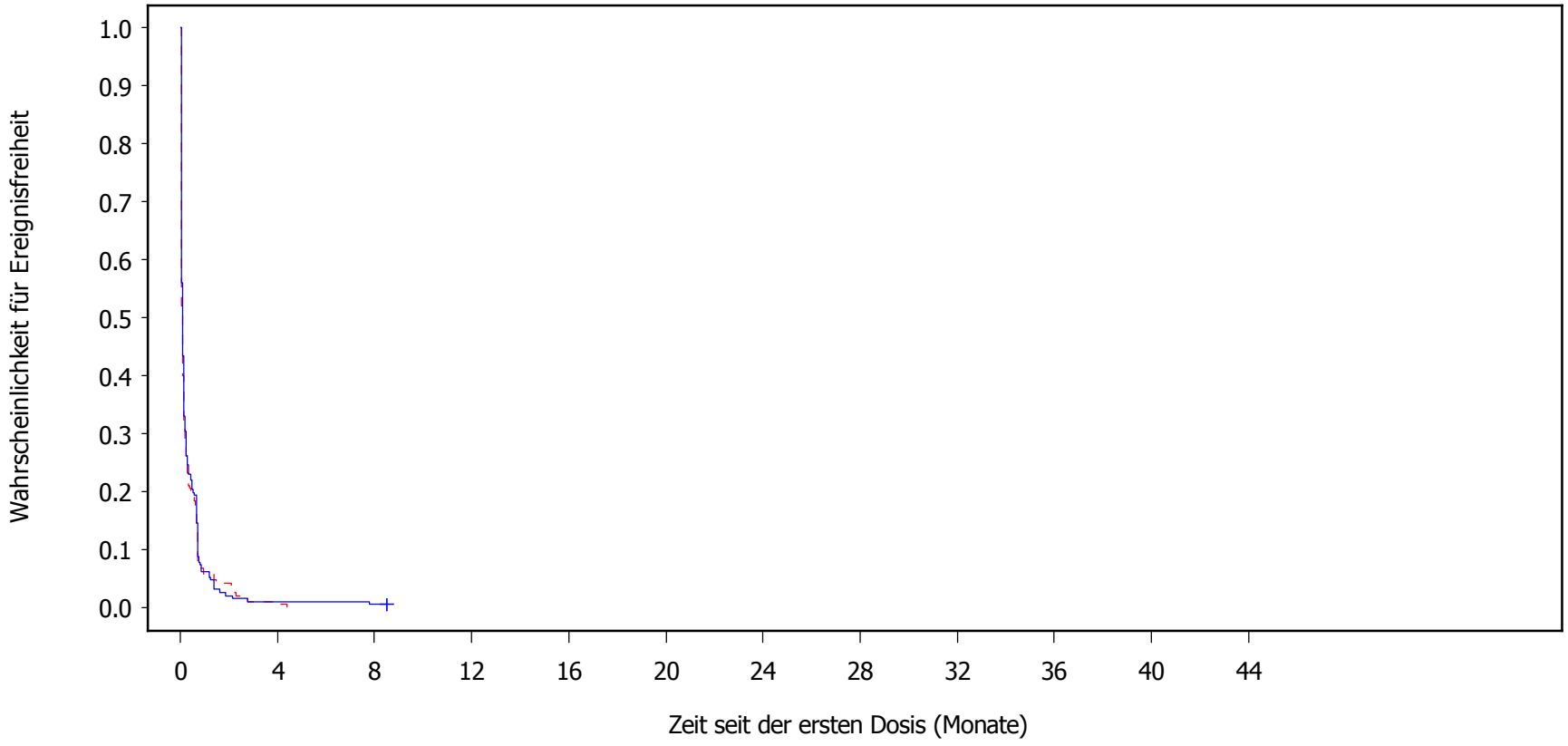
Figure 3.3.2.2D.1 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UE
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	2	1	0	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
190	2	0	0	0	0	0	0	0	0	0	0	CTx

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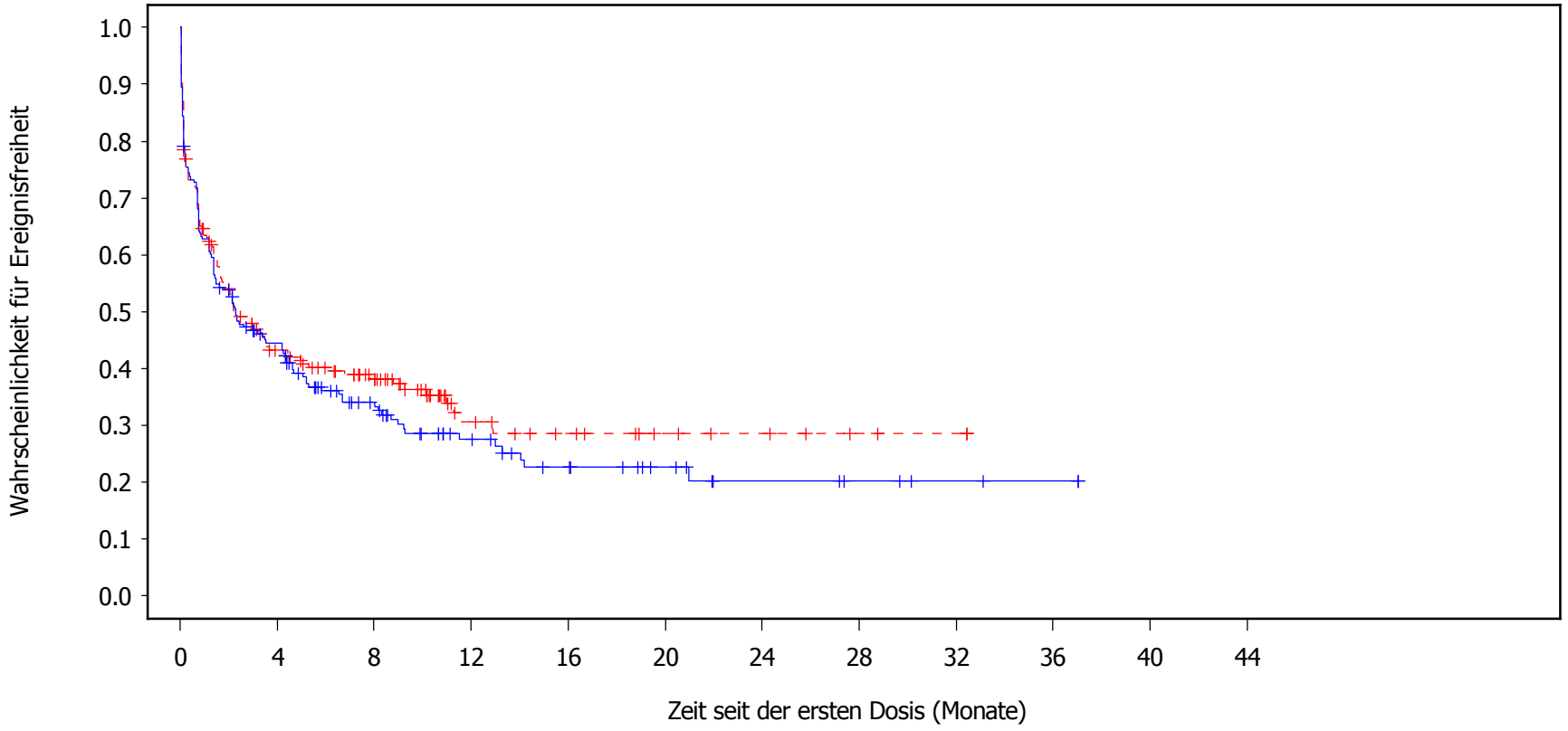
Figure 3.3.2.2D.2 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	78	46	26	17	11	6	4	2	1	0	0	CTx + Durvalumab + Olaparib
190	72	50	18	12	7	5	2	1	0	0	0	CTx

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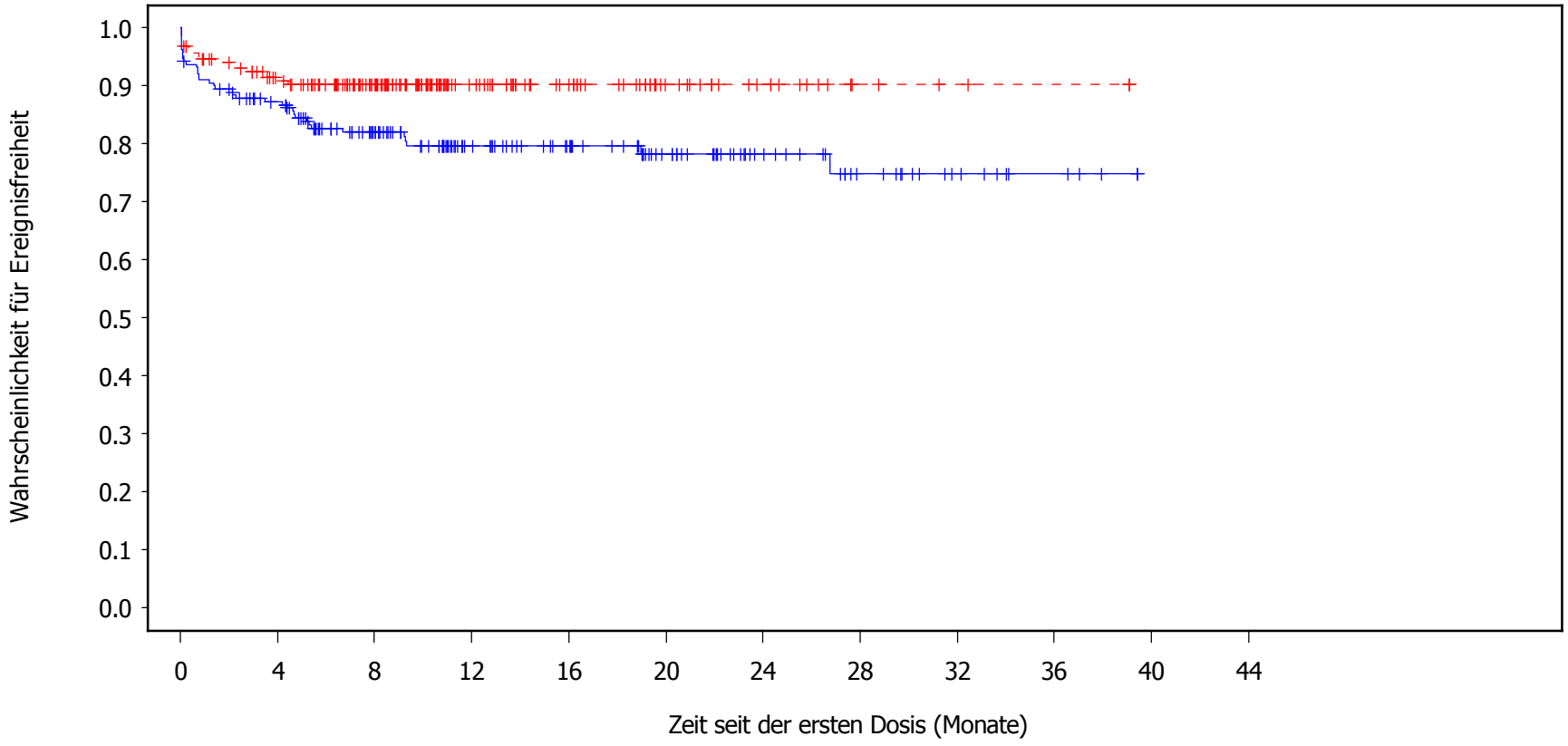
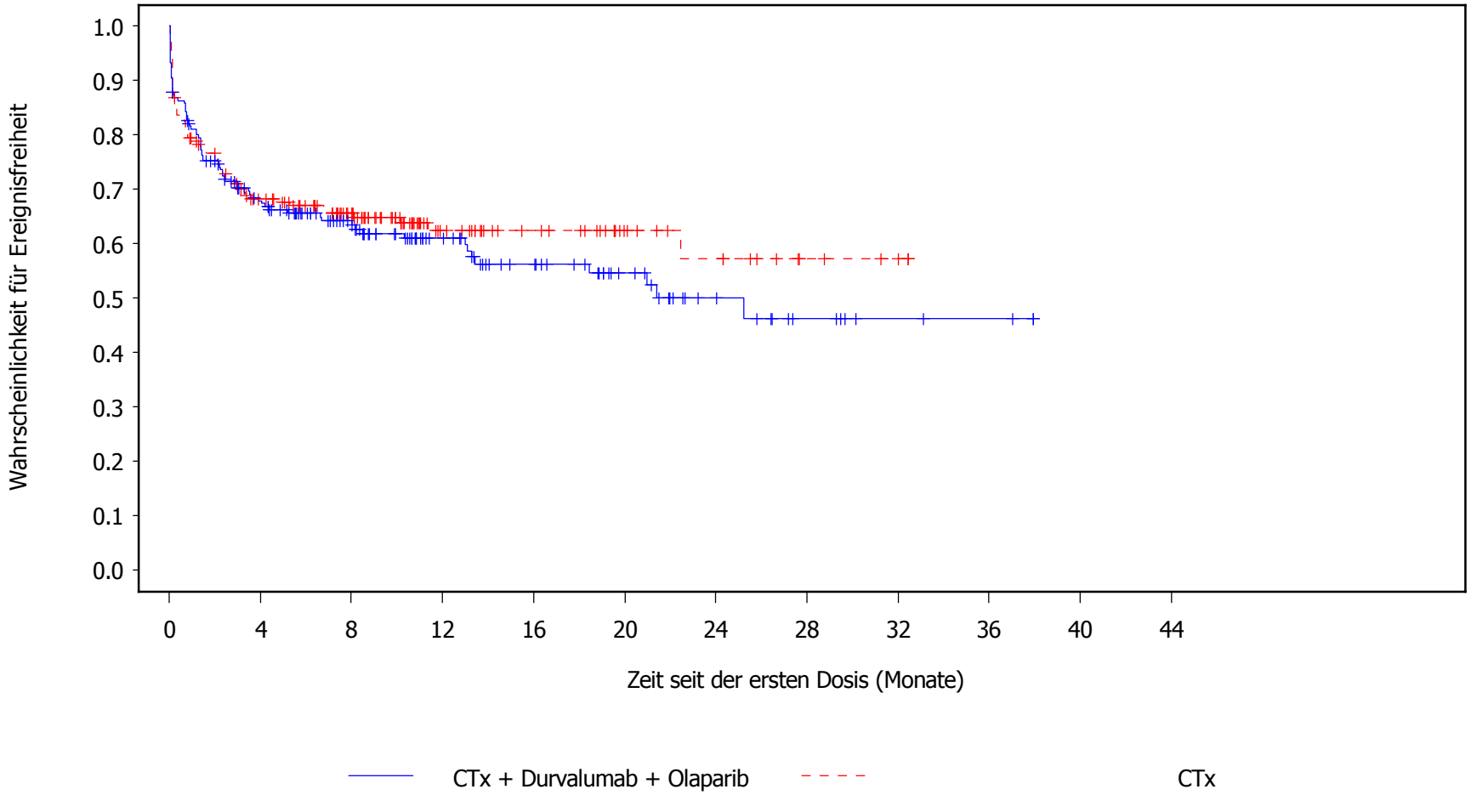
Figure 3.3.2.2D.3 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Asthenie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	156	117	80	65	47	29	17	9	4	0	0	CTx + Durvalumab + Olaparib
190	158	118	63	43	23	14	4	2	1	0	0	CTx

Figure 3.3.2.2D.4 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Ermuedung
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	117	87	56	40	26	14	7	3	2	0	0	CTx + Durvalumab + Olaparib
190	116	85	40	28	16	11	4	2	0	0	0	CTx

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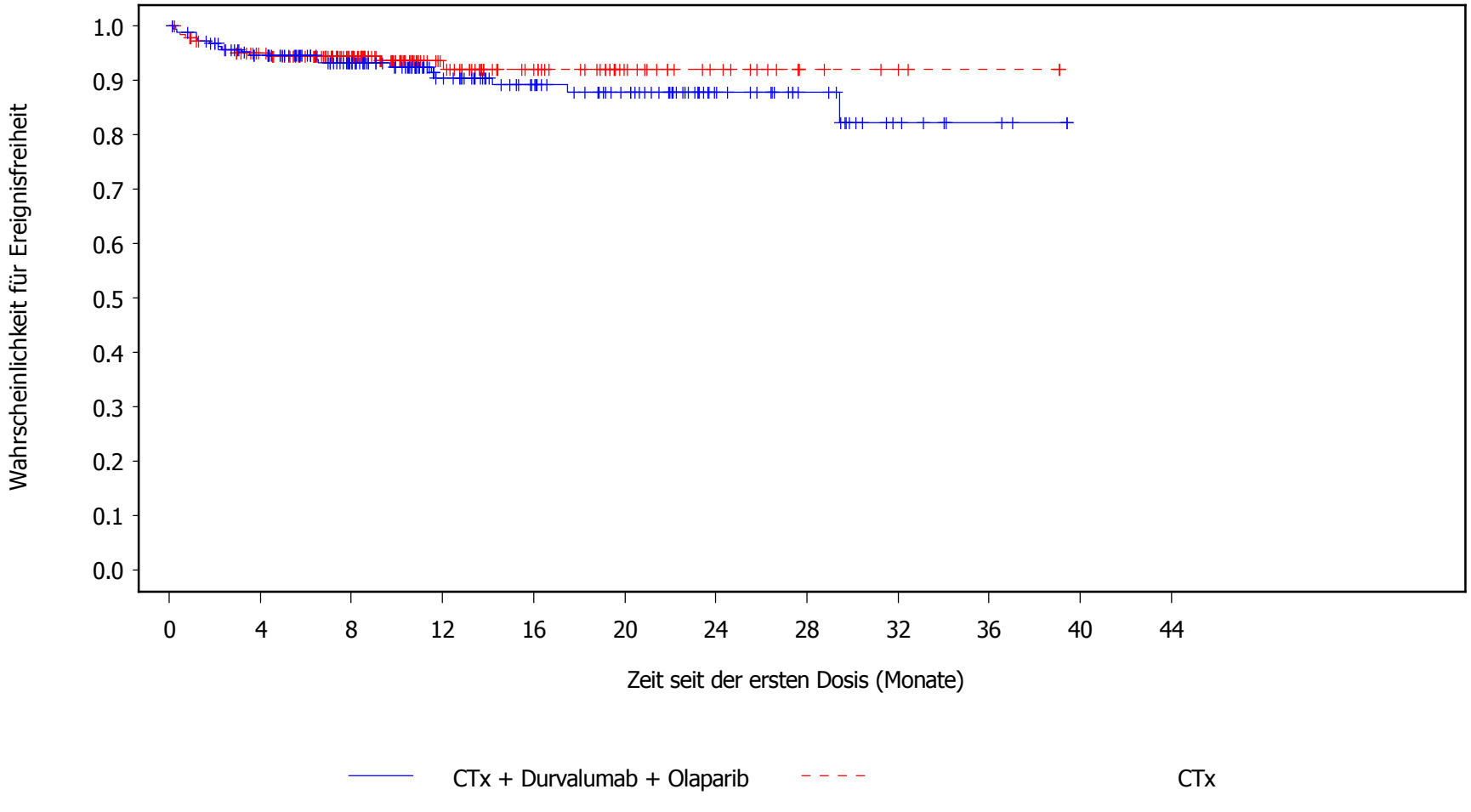
Figure 3.3.2.2D.5 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Fieber
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	167	131	87	66	52	29	18	7	3	0	0	CTx + Durvalumab + Olaparib
190	165	122	65	43	24	14	5	3	1	0	0	CTx

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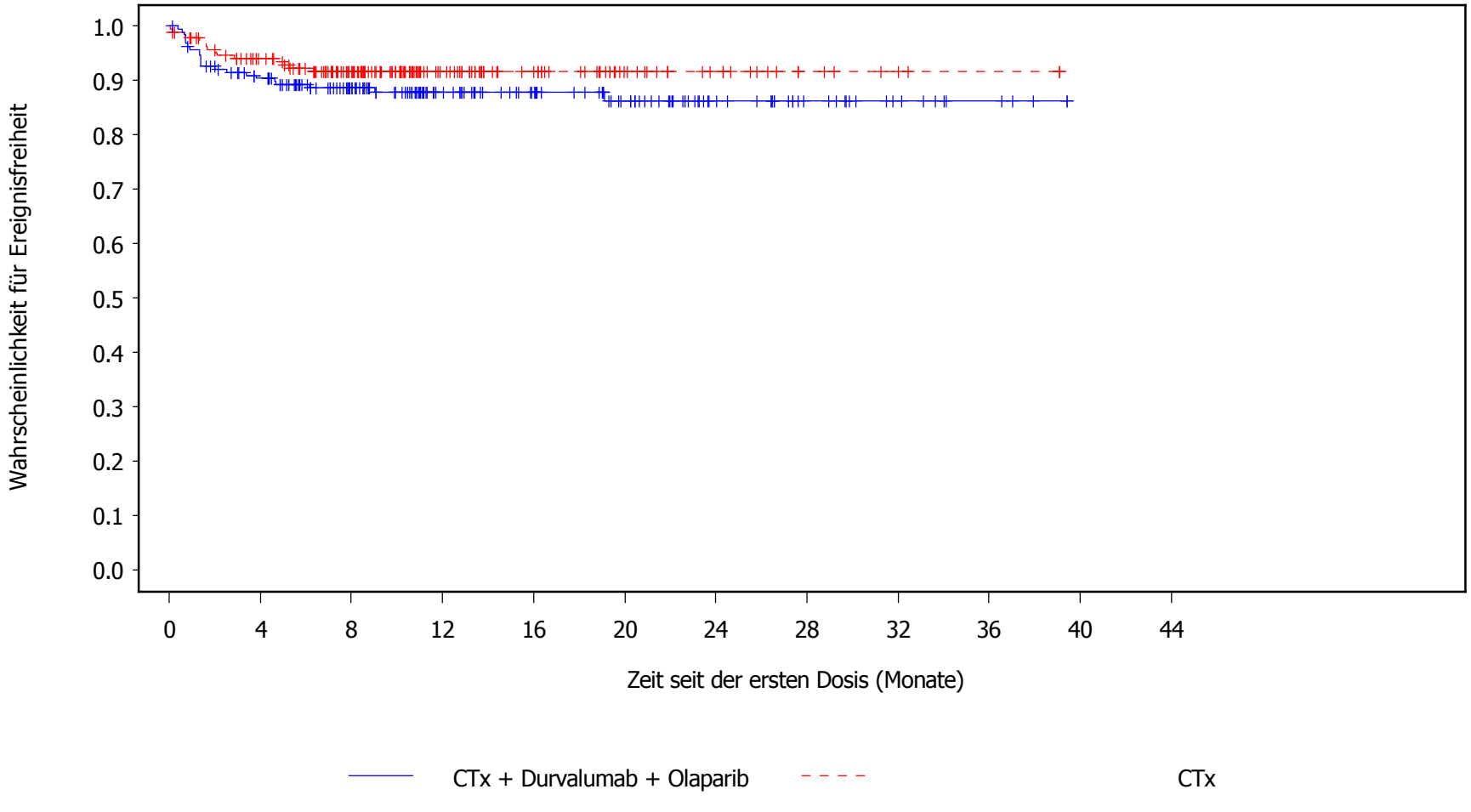
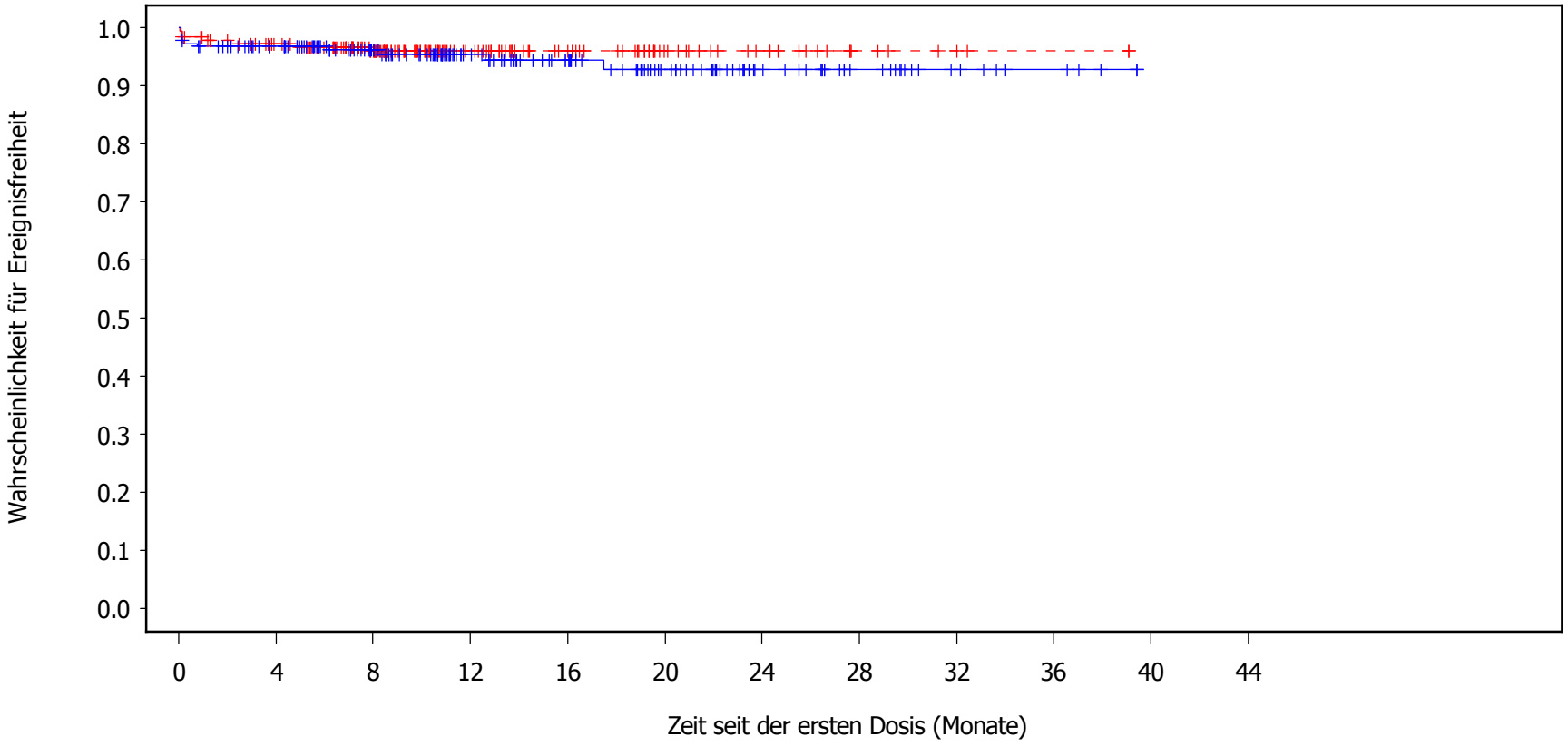
Figure 3.3.2.2D.6 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Oedem peripher
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	161	125	84	67	51	30	17	9	4	0	0	CTx + Durvalumab + Olaparib
190	163	120	65	43	24	15	6	3	1	0	0	CTx

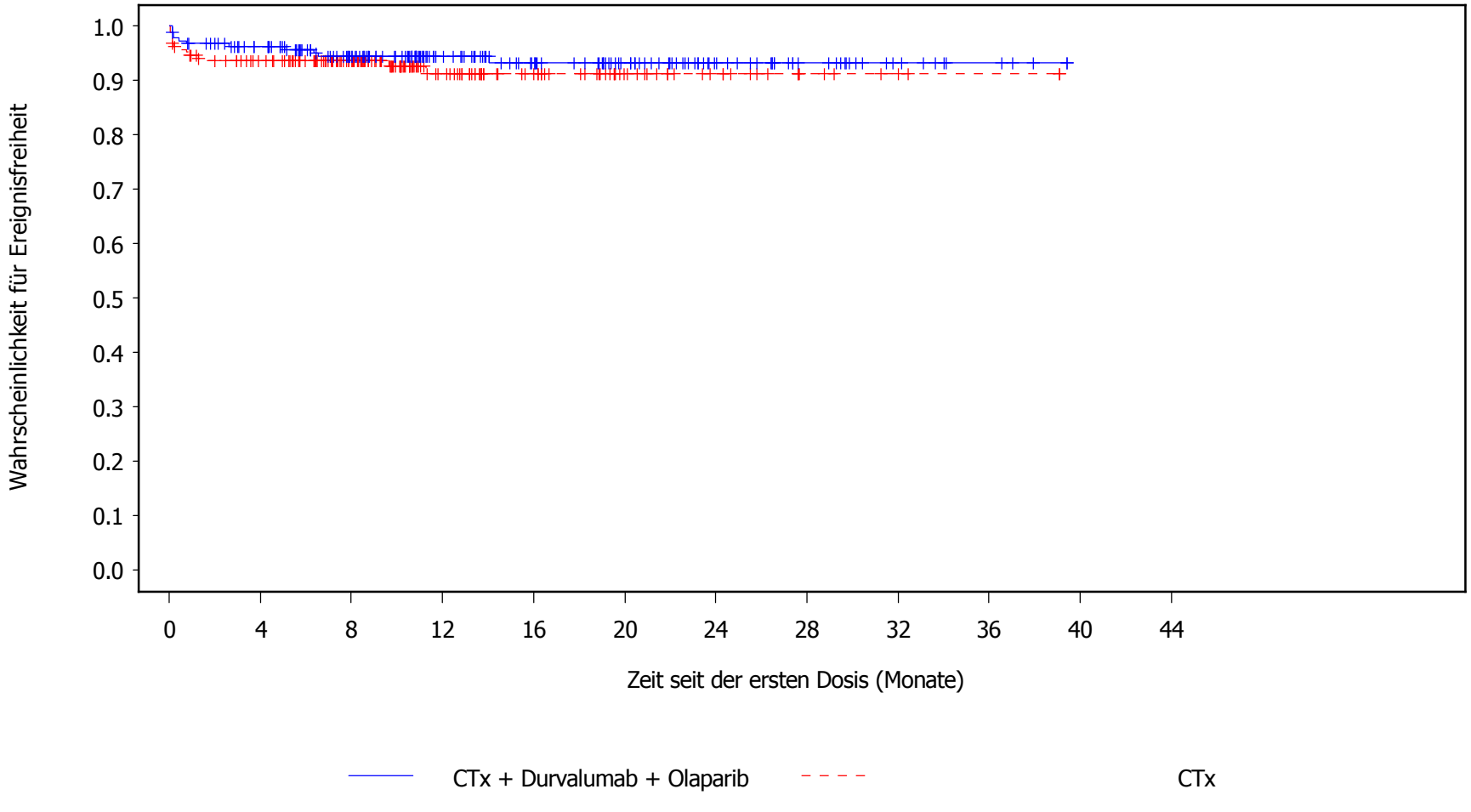
Figure 3.3.2.2D.7 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schmerz
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	170	134	92	72	52	30	17	8	4	0	0	CTx + Durvalumab + Olaparib
190	170	125	68	45	25	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.8 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Unwohlsein
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	169	135	93	73	55	33	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	163	121	66	44	25	15	6	3	1	0	0	CTx

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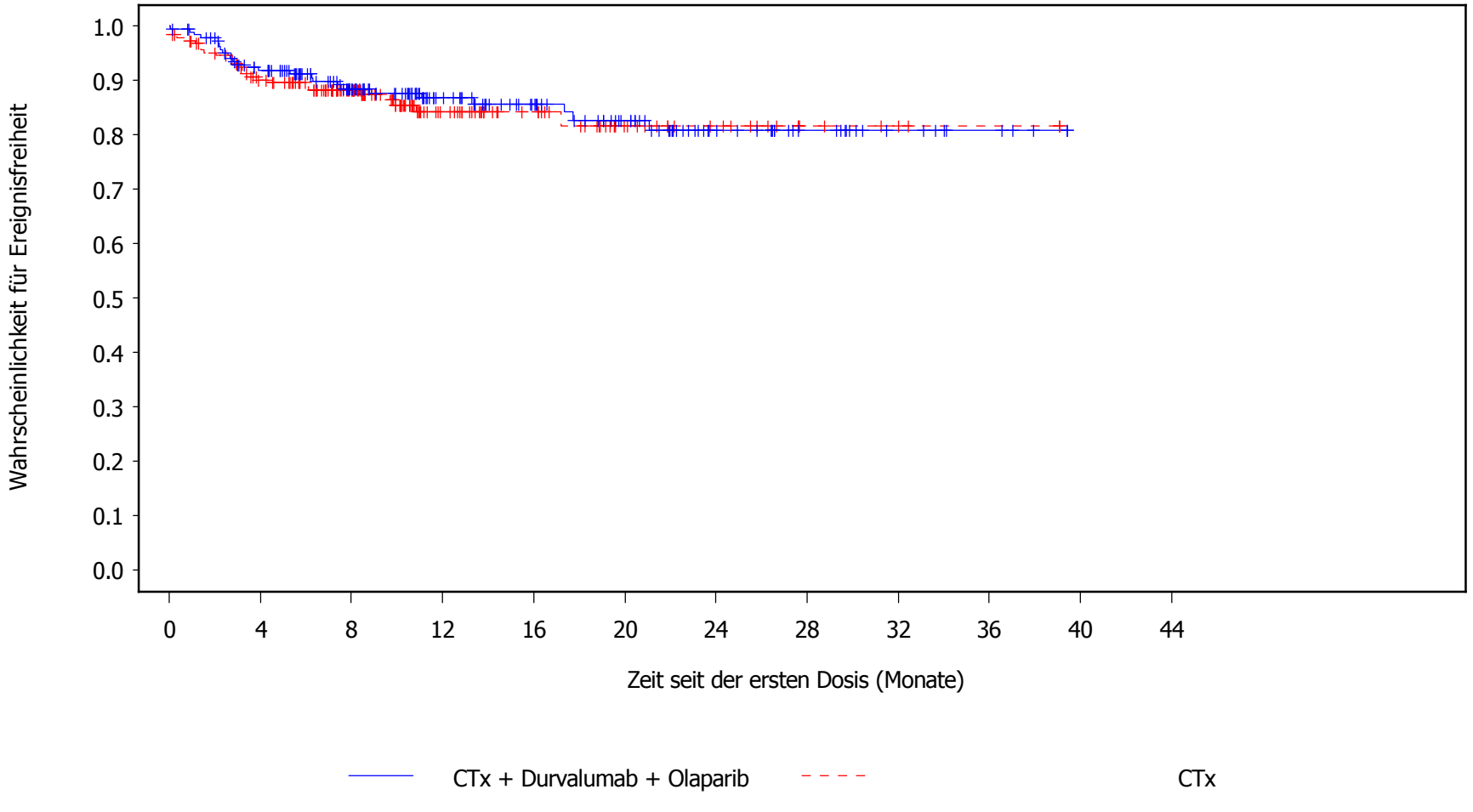
Figure 3.3.2.2D.9 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Augenerkrankungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	161	123	83	64	48	27	16	8	4	0	0	CTx + Durvalumab + Olaparib
190	156	112	57	39	22	14	5	3	1	0	0	CTx

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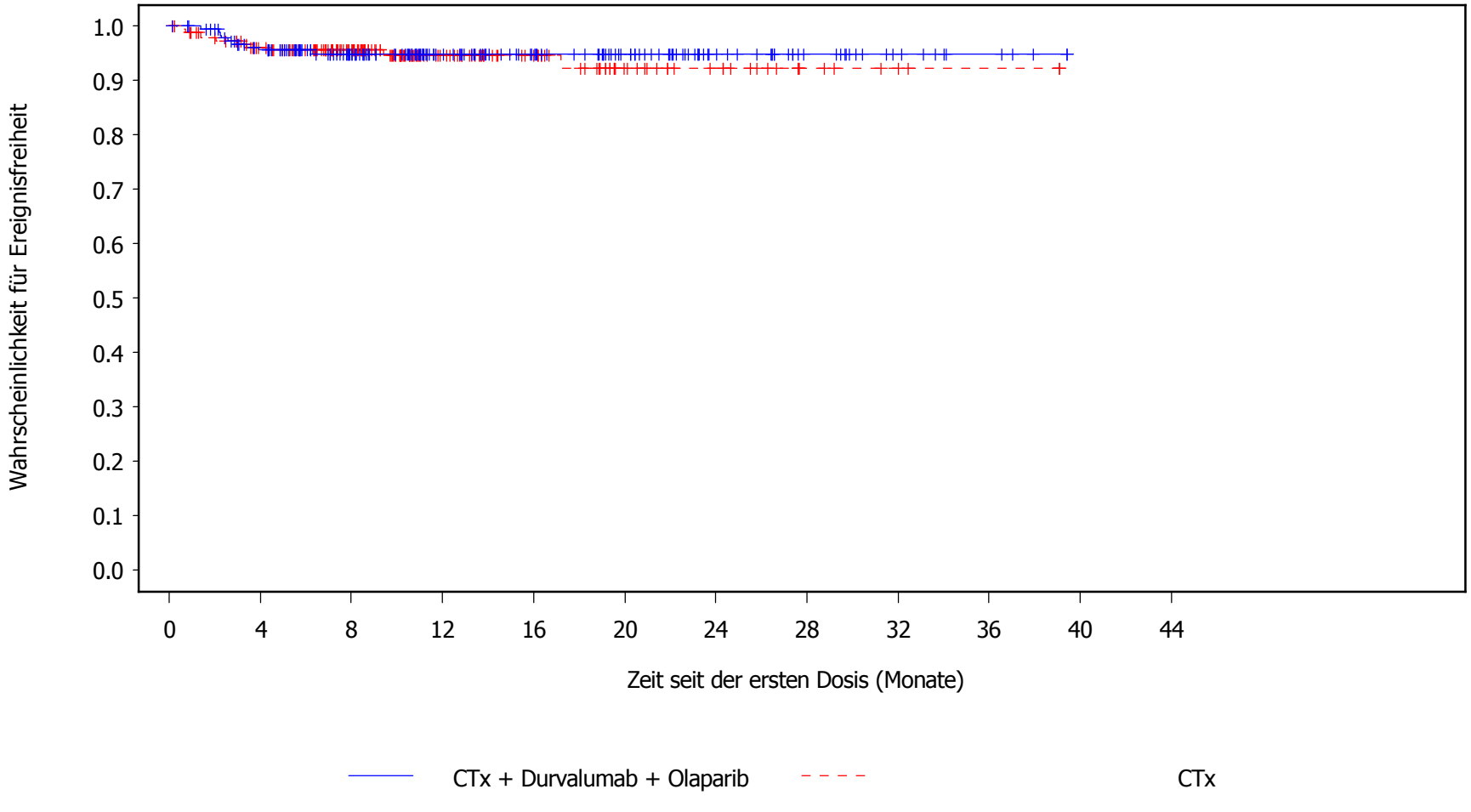
Figure 3.3.2.2D.10 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Sehen verschwommen
Patients with pMMR tumour status, DCO 18OCT2023

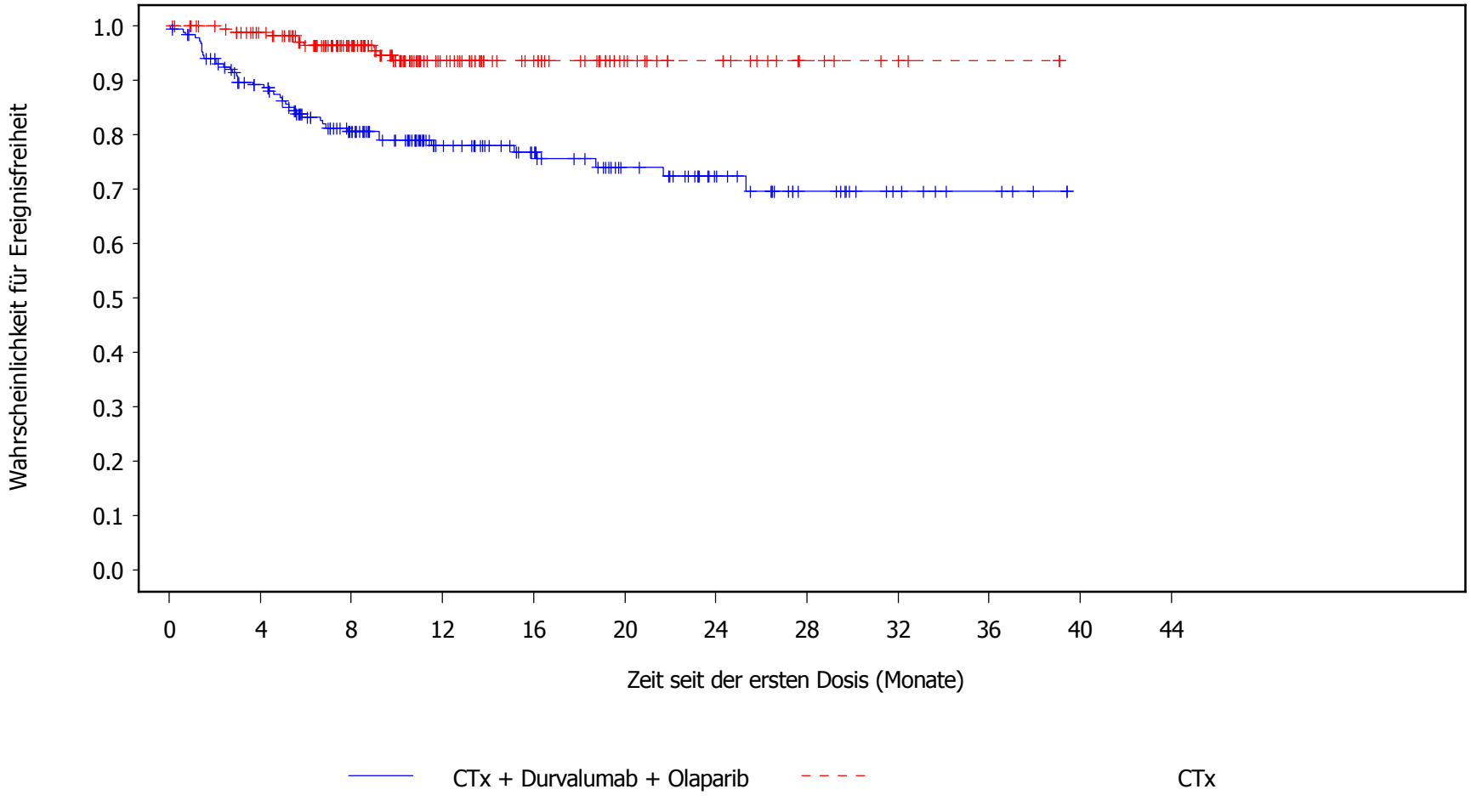


Anzahl an Patienten unter Risiko:

191	168	133	93	73	55	32	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	167	123	66	46	25	16	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebaj 15APR2024:10:33

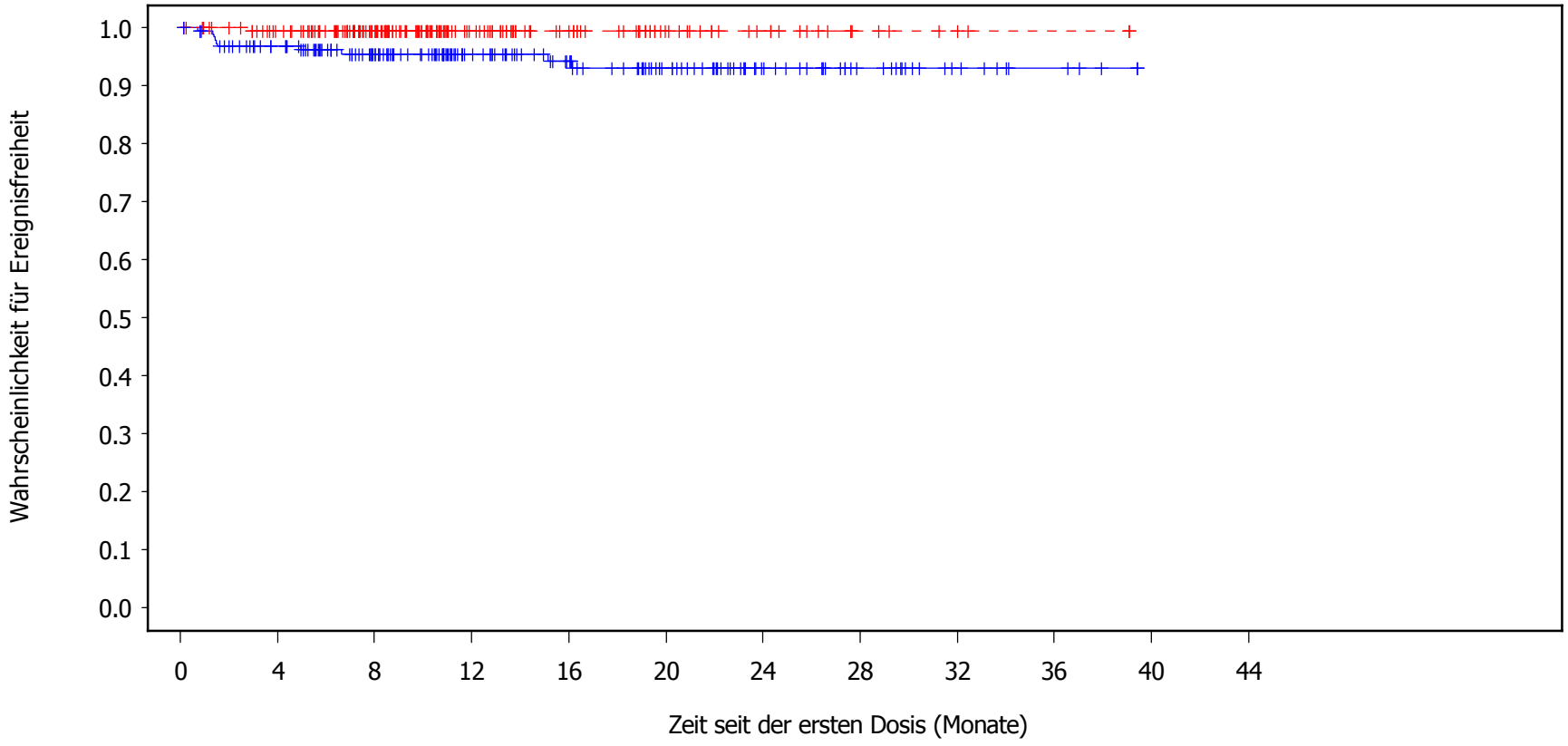
Figure 3.3.2.2D.11 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Endokrine Erkrankungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	156	116	77	60	43	29	16	8	4	0	0	CTx + Durvalumab + Olaparib
190	172	123	64	43	23	16	6	3	1	0	0	CTx

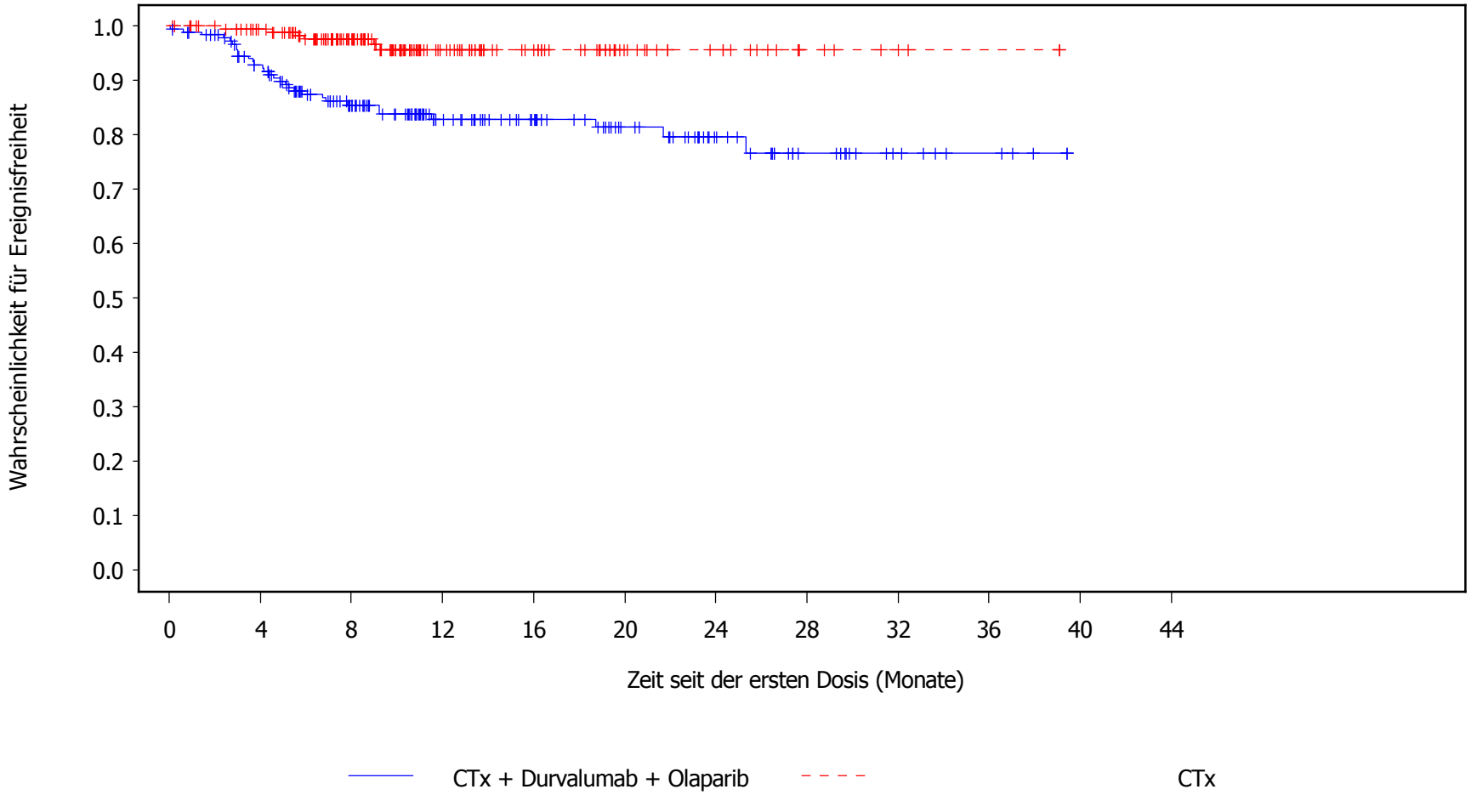
Figure 3.3.2.2D.12 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hyperthyroidismus
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	170	136	95	75	55	33	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	173	128	69	46	26	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.13 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypothyreose
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	163	121	80	63	46	30	16	8	4	0	0	CTx + Durvalumab + Olaparib
190	173	125	67	45	24	16	6	3	1	0	0	CTx

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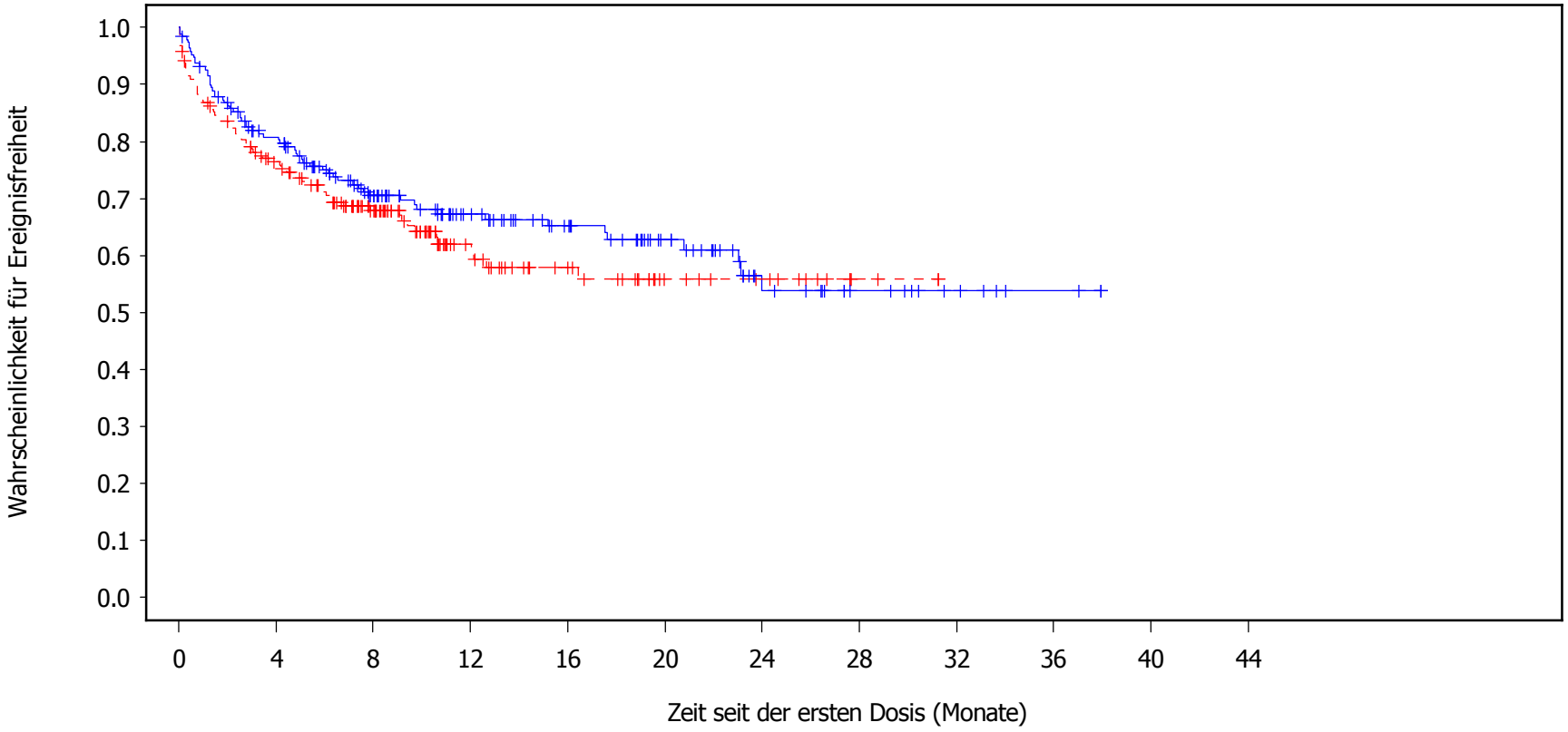
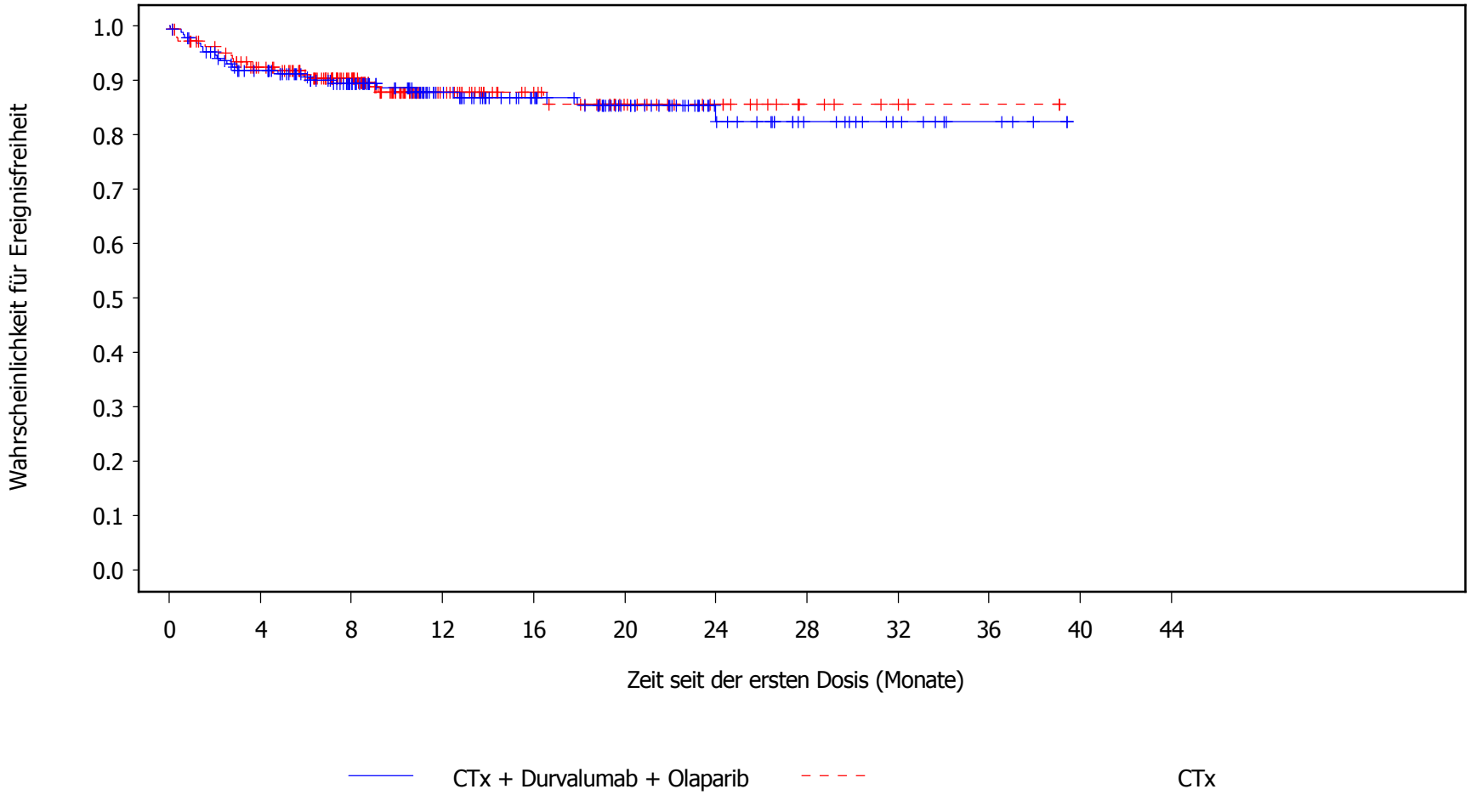
Figure 3.3.2.2D.14 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	144	102	72	55	39	19	11	6	2	0	0	CTx + Durvalumab + Olaparib
190	134	91	45	30	15	11	2	0	0	0	0	CTx

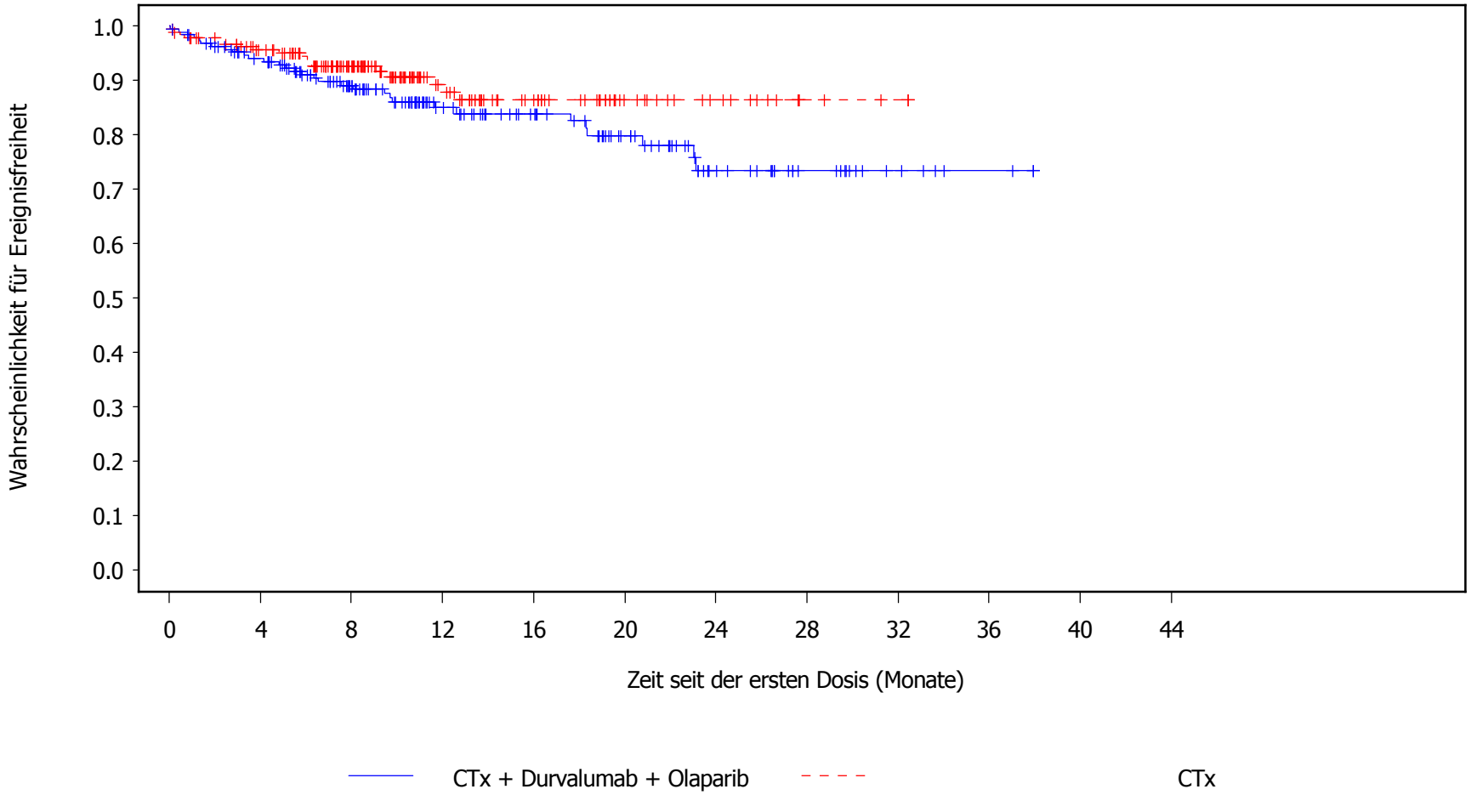
Figure 3.3.2.2D.15 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Dyspnoe
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	162	128	89	69	51	28	16	9	4	0	0	CTx + Durvalumab + Olaparib
190	160	117	61	42	25	16	6	3	1	0	0	CTx

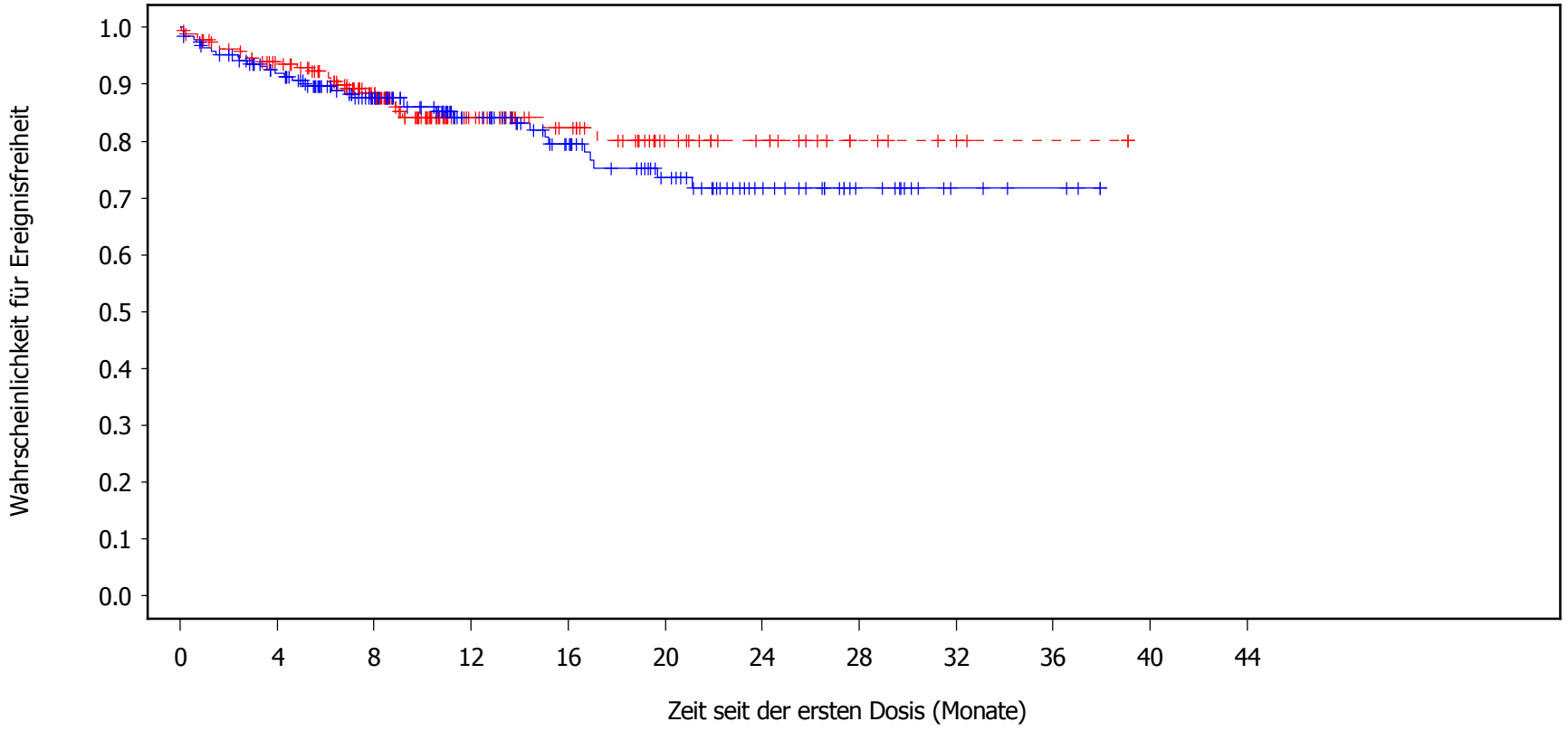
Figure 3.3.2.2D.16 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Husten
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	166	126	83	66	48	27	14	6	2	0	0	CTx + Durvalumab + Olaparib
190	166	119	64	41	20	12	3	1	0	0	0	CTx

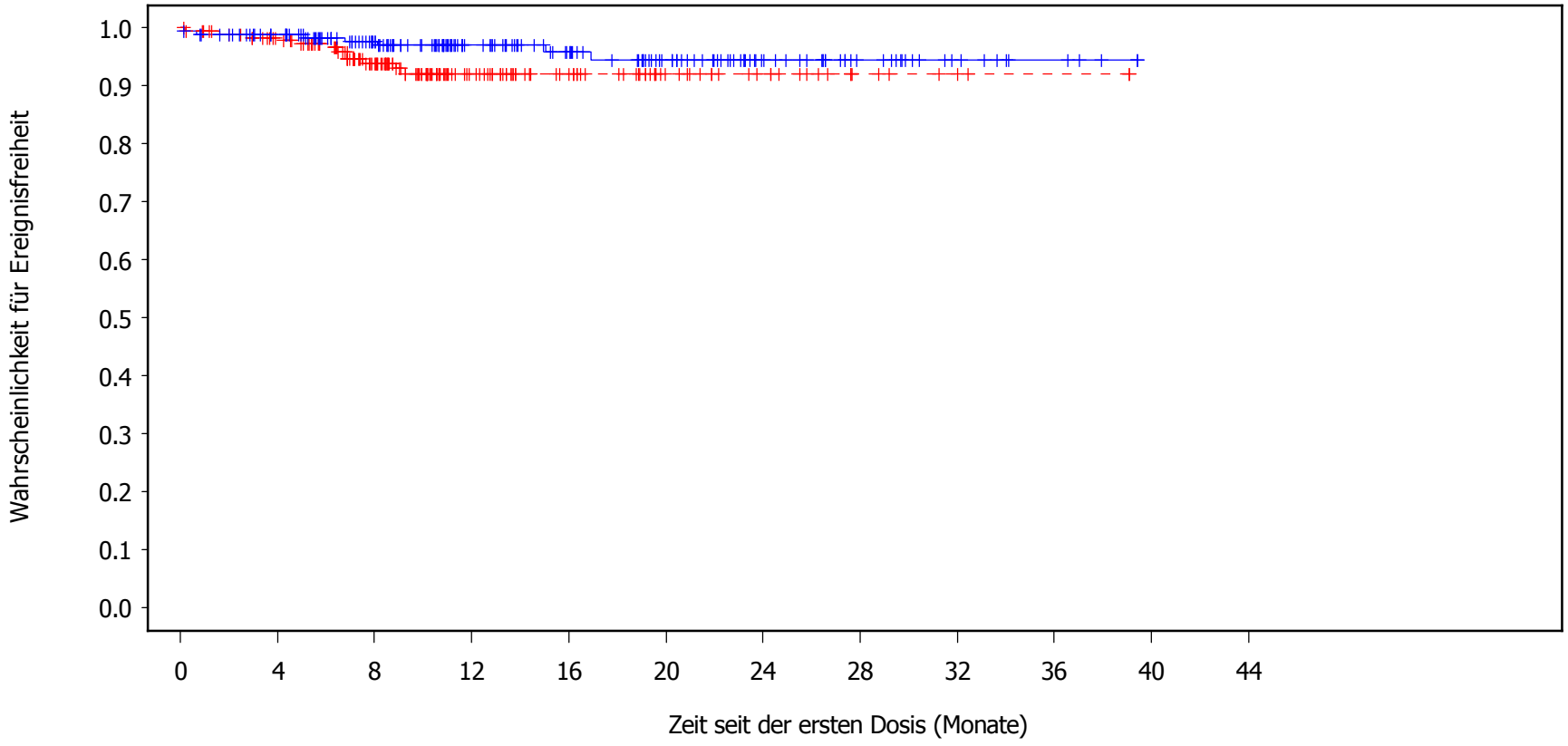
Figure 3.3.2.2D.17 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	162	123	82	61	44	27	14	5	3	0	0	CTx + Durvalumab + Olaparib
190	163	121	62	41	23	15	6	3	1	0	0	CTx

Figure 3.3.2.2D.18 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Vaginale Blutung
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	175	140	96	76	57	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	171	124	67	45	25	16	6	3	1	0	0	CTx

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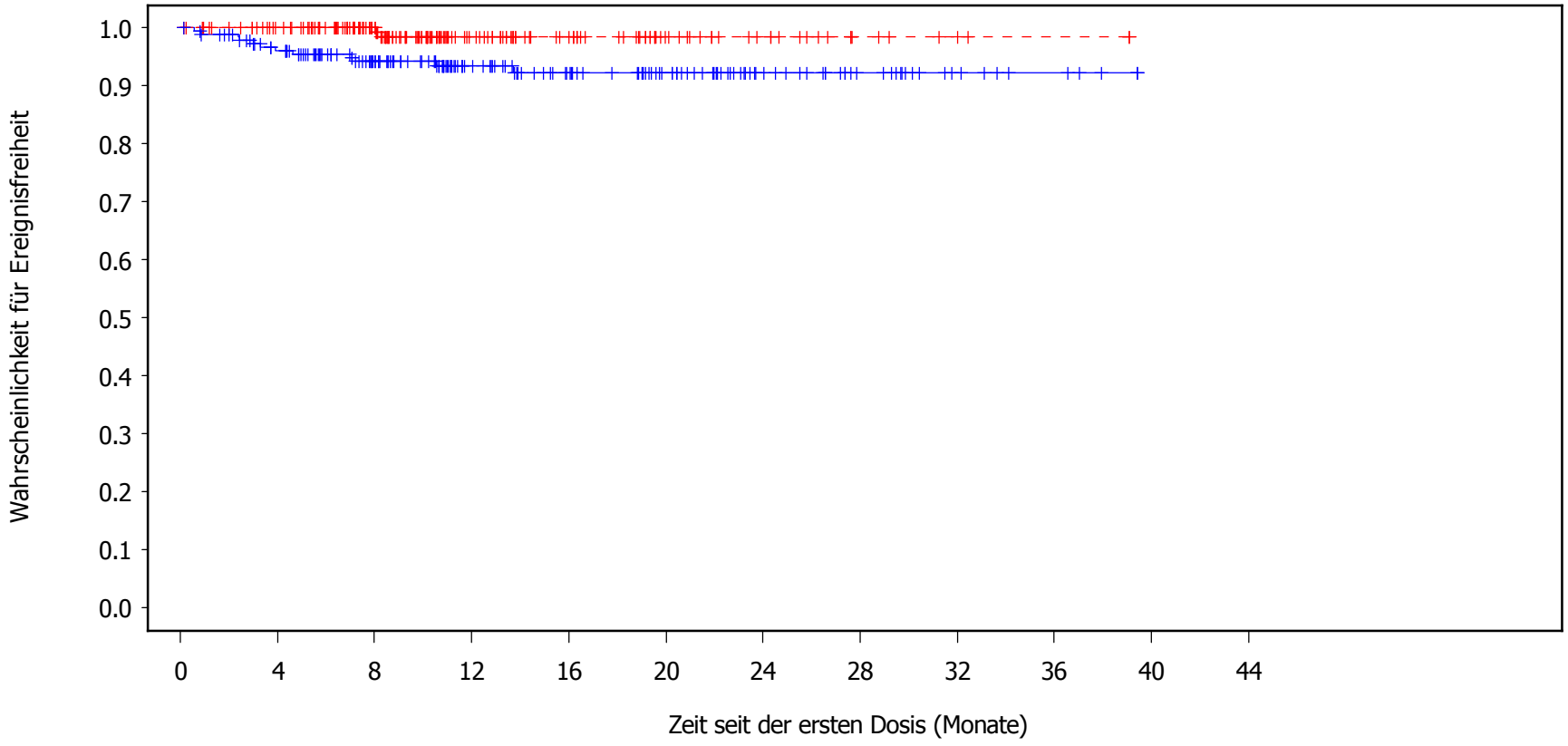
Figure 3.3.2.2D.19 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Vaginaler Ausfluss
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	169	131	89	69	53	31	18	8	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	69	47	26	16	6	3	1	0	0	CTx

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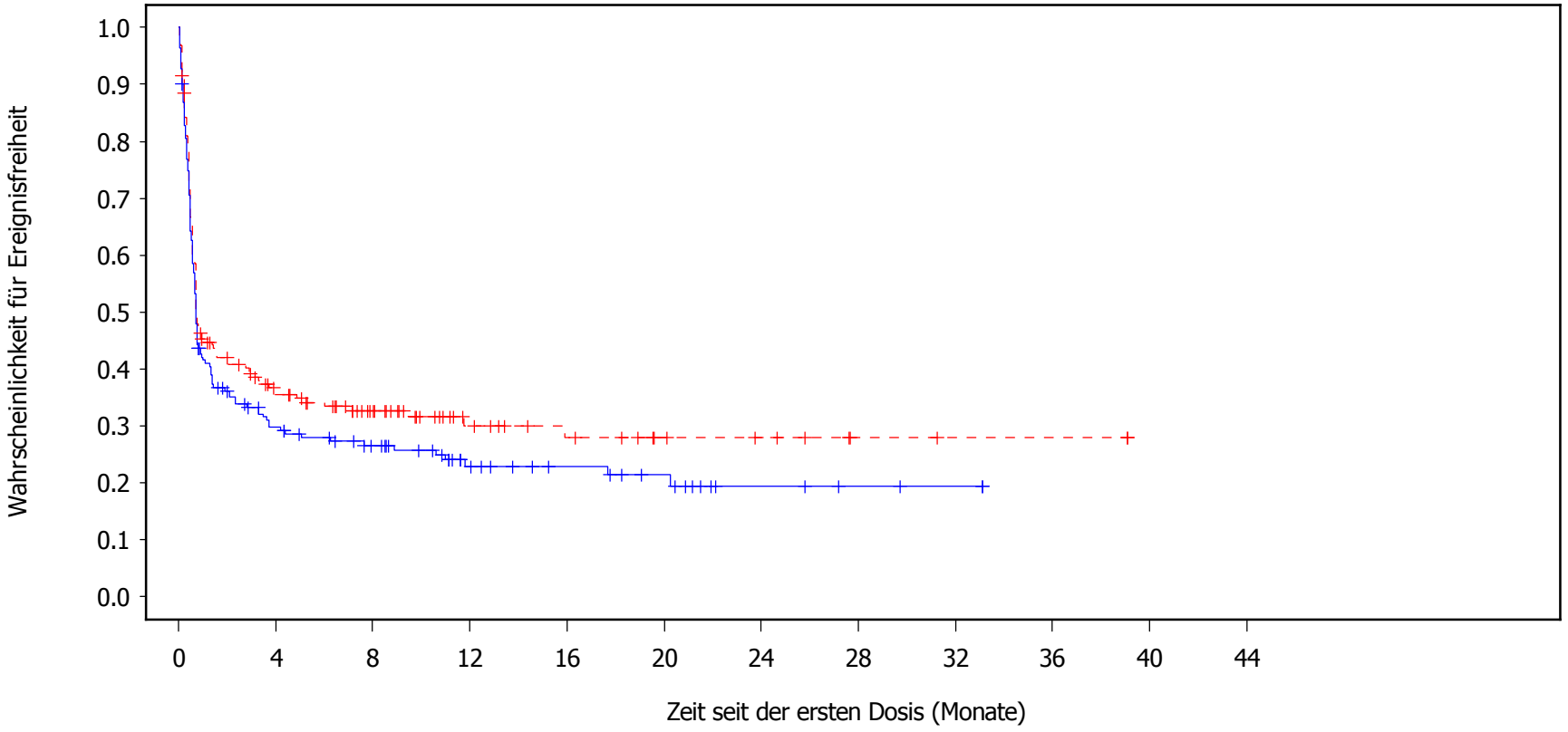
Figure 3.3.2.2D.20 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Haut und des Unterhautgewebes
Patients with pMMR tumour status, DCO 18OCT2023

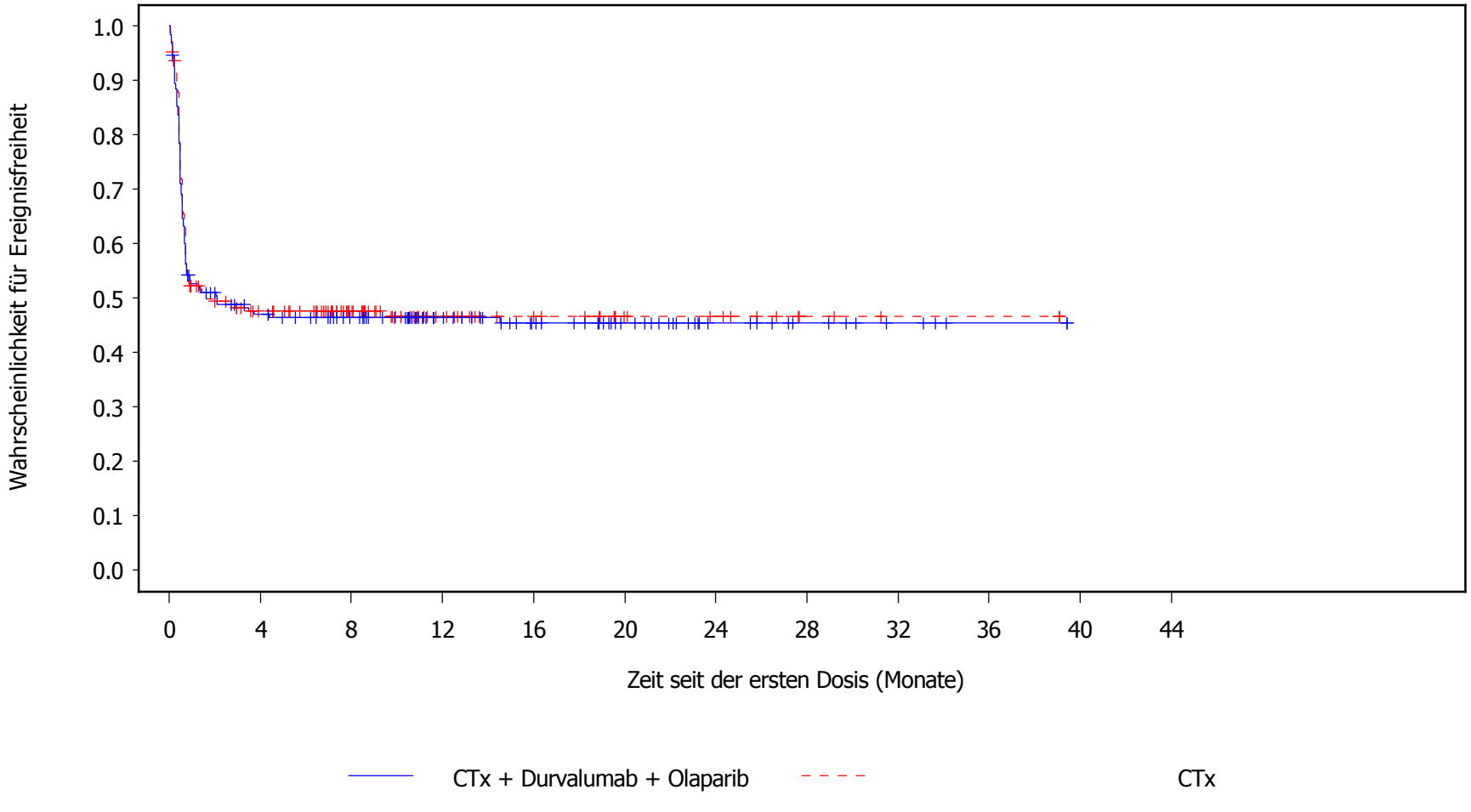


Anzahl an Patienten unter Risiko:

191	50	37	21	15	11	4	2	1	0	0	0	CTx + Durvalumab + Olaparib
190	57	38	19	13	8	6	2	1	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebat 15APR2024:10:33

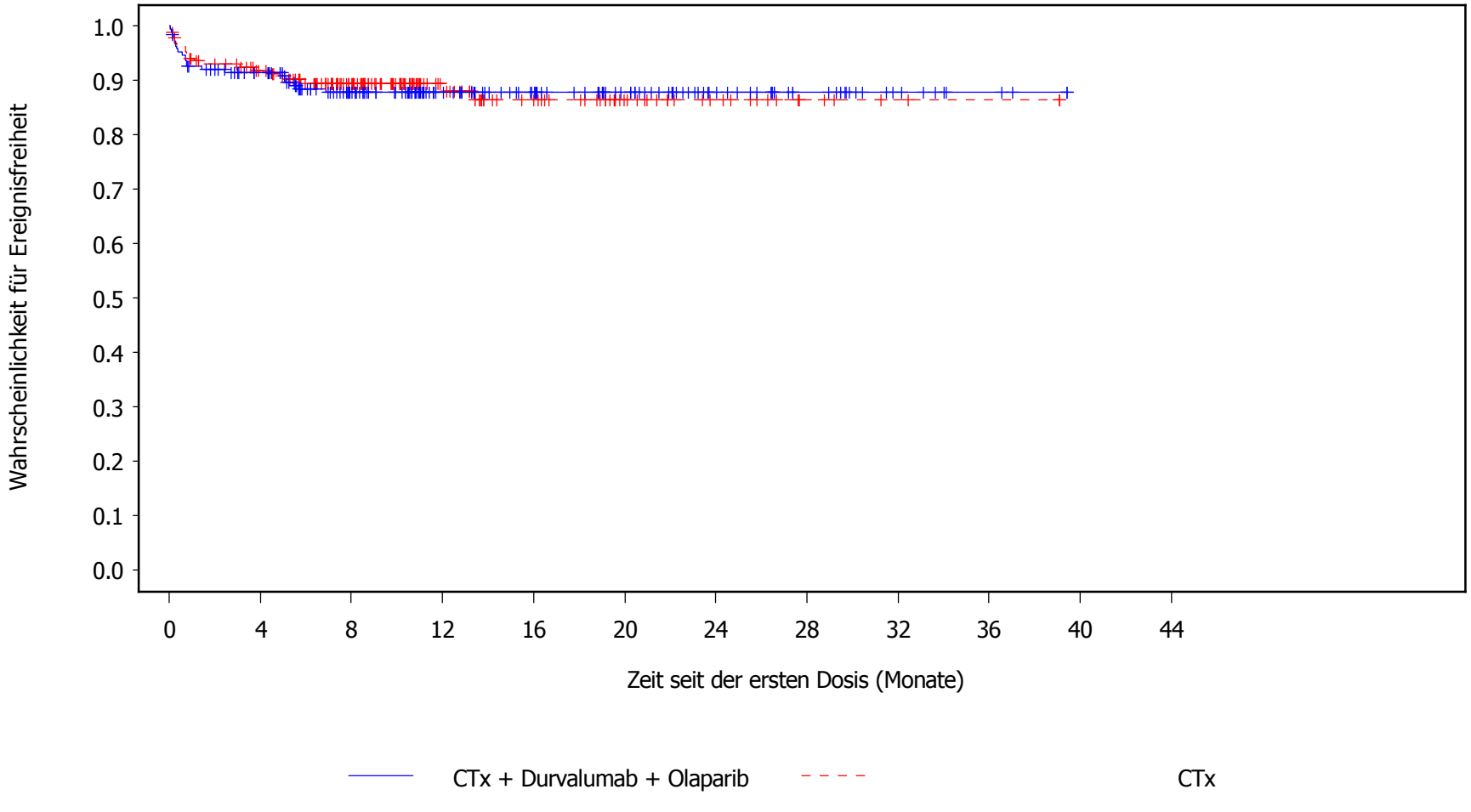
Figure 3.3.2.2D.21 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Alopezie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	82	69	48	36	25	13	8	4	1	0	0	CTx + Durvalumab + Olaparib
190	78	54	29	20	11	9	3	1	1	0	0	CTx

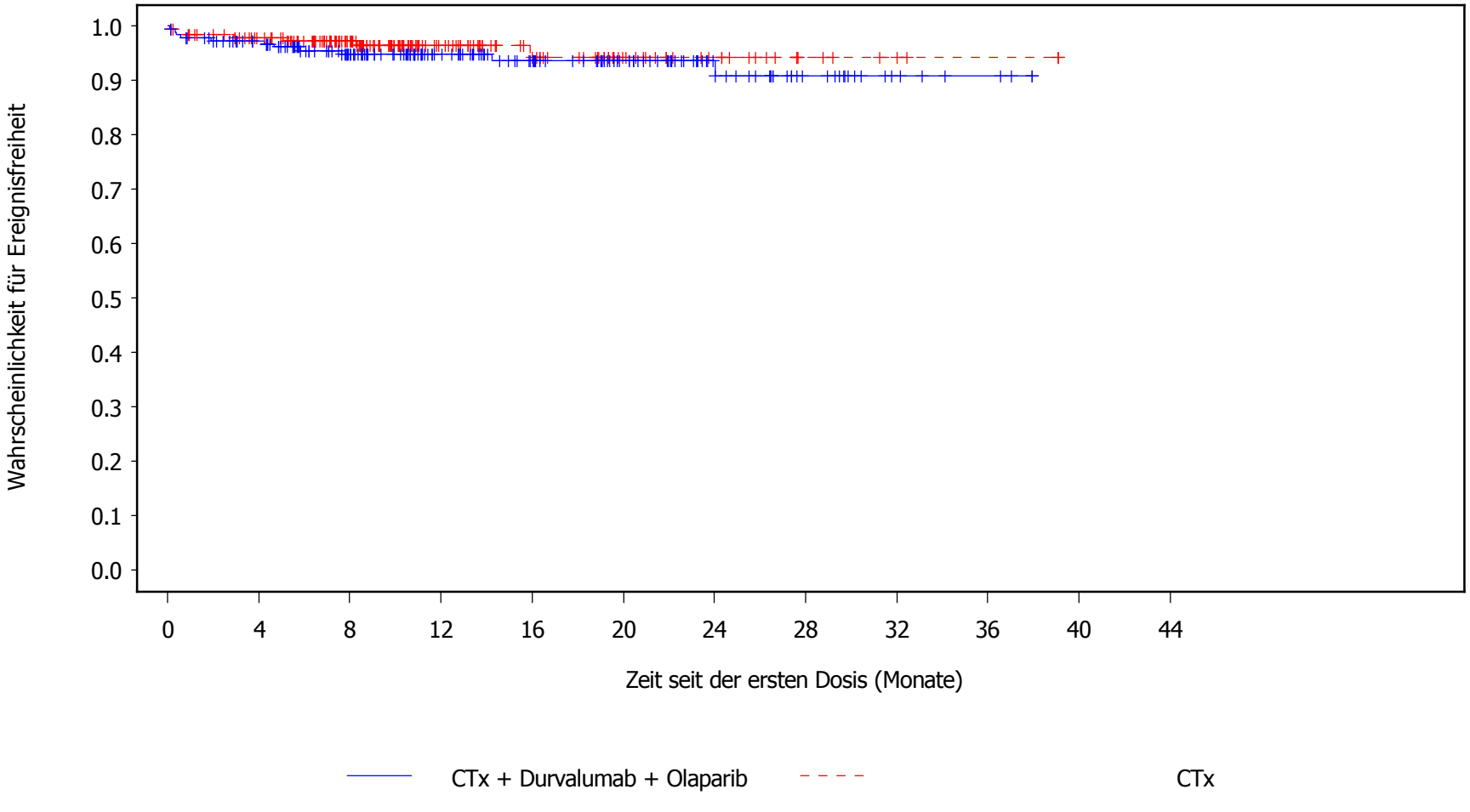
Figure 3.3.2.2D.22 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Ausschlag
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	160	121	83	66	50	31	18	8	3	0	0	CTx + Durvalumab + Olaparib
190	160	115	63	41	24	14	5	2	1	0	0	CTx

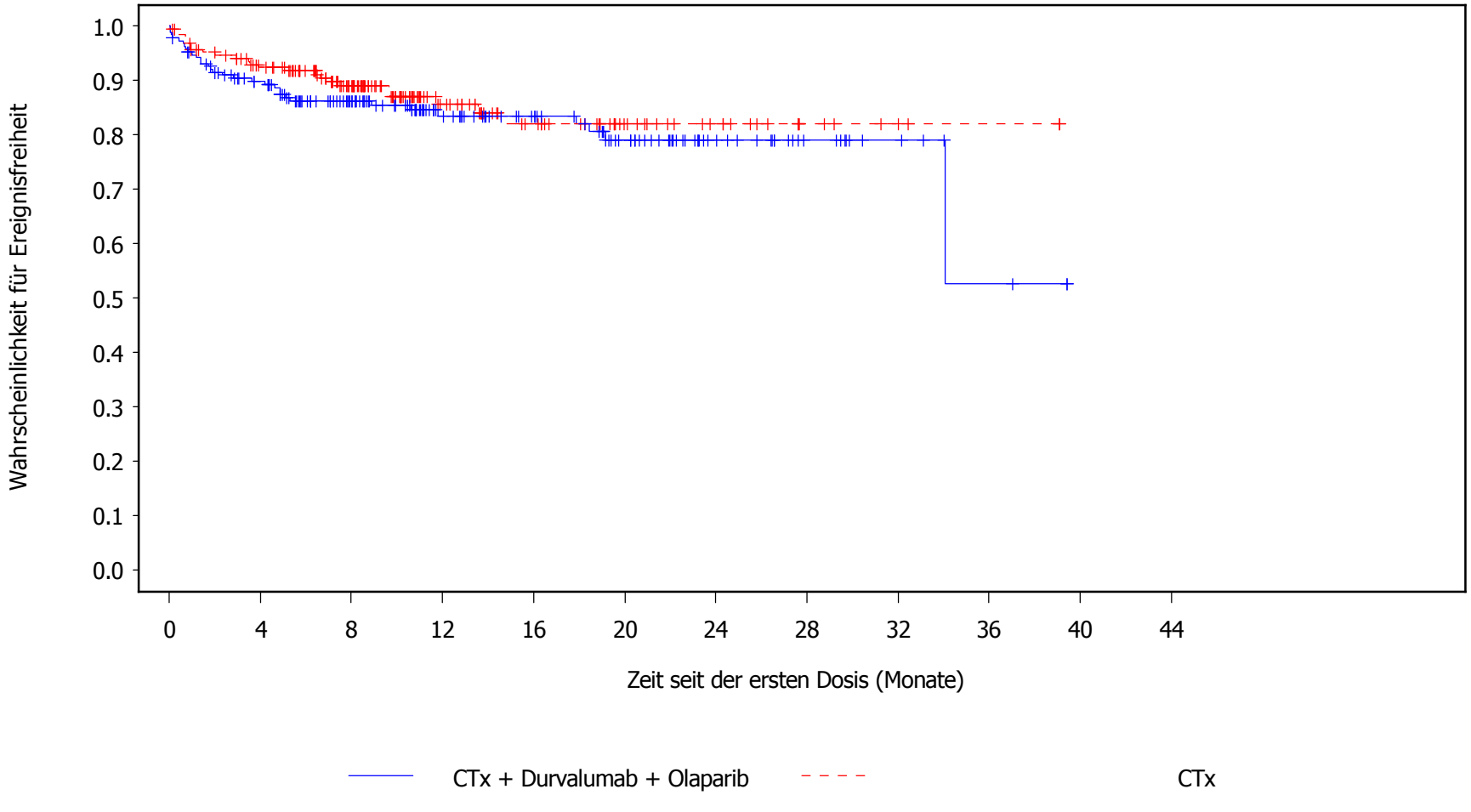
Figure 3.3.2.2D.23 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Ausschlag makulo-papuloes
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	171	134	95	74	55	32	16	6	3	0	0	CTx + Durvalumab + Olaparib
190	170	126	68	45	26	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.24 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Pruritus
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	157	118	78	63	45	24	12	6	2	0	0	CTx + Durvalumab + Olaparib
190	160	114	60	40	24	15	6	3	1	0	0	CTx

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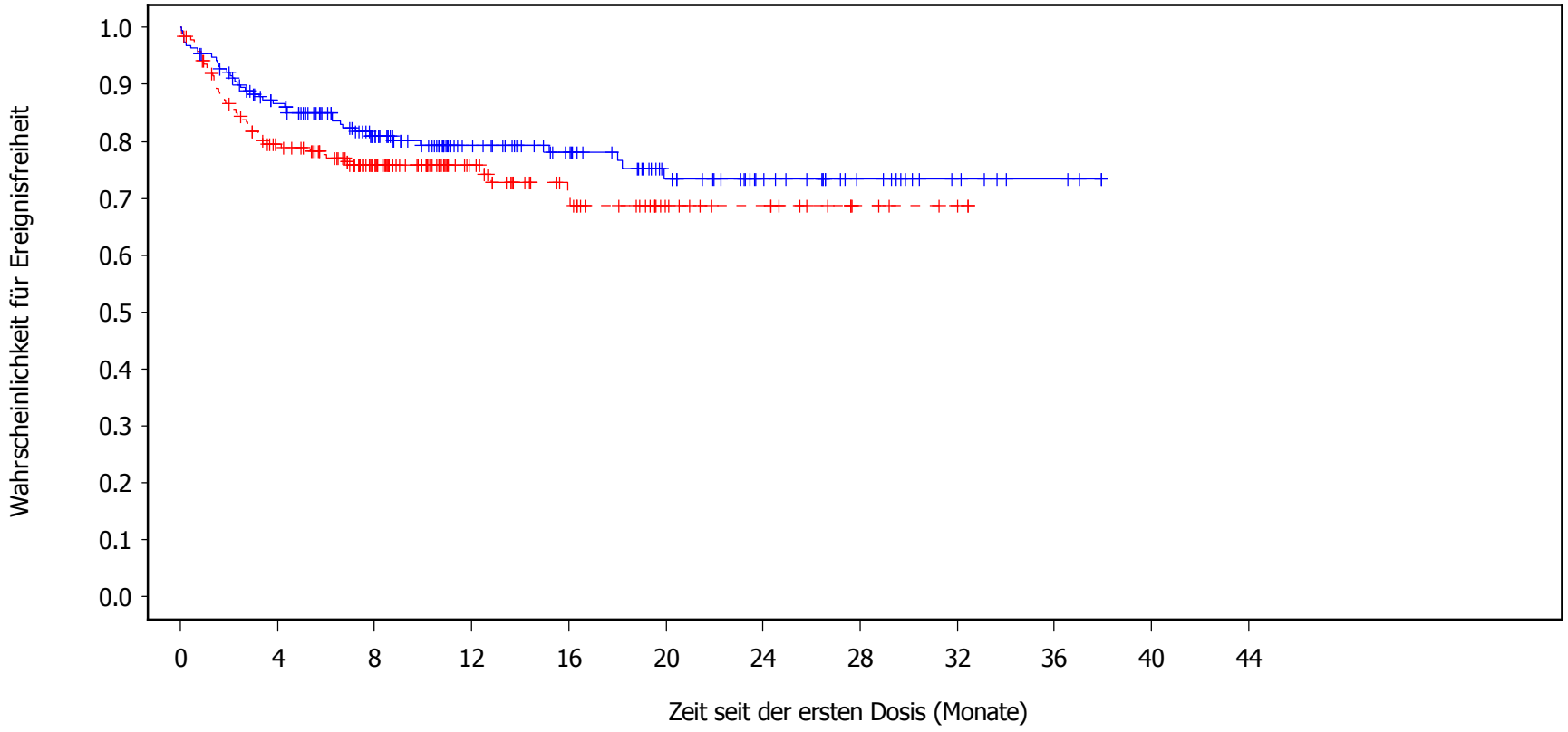
Figure 3.3.2.2D.25 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Nieren und Harnwege
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	153	114	76	59	41	27	15	7	3	0	0	CTx + Durvalumab + Olaparib
190	138	98	54	35	19	14	5	2	0	0	0	CTx

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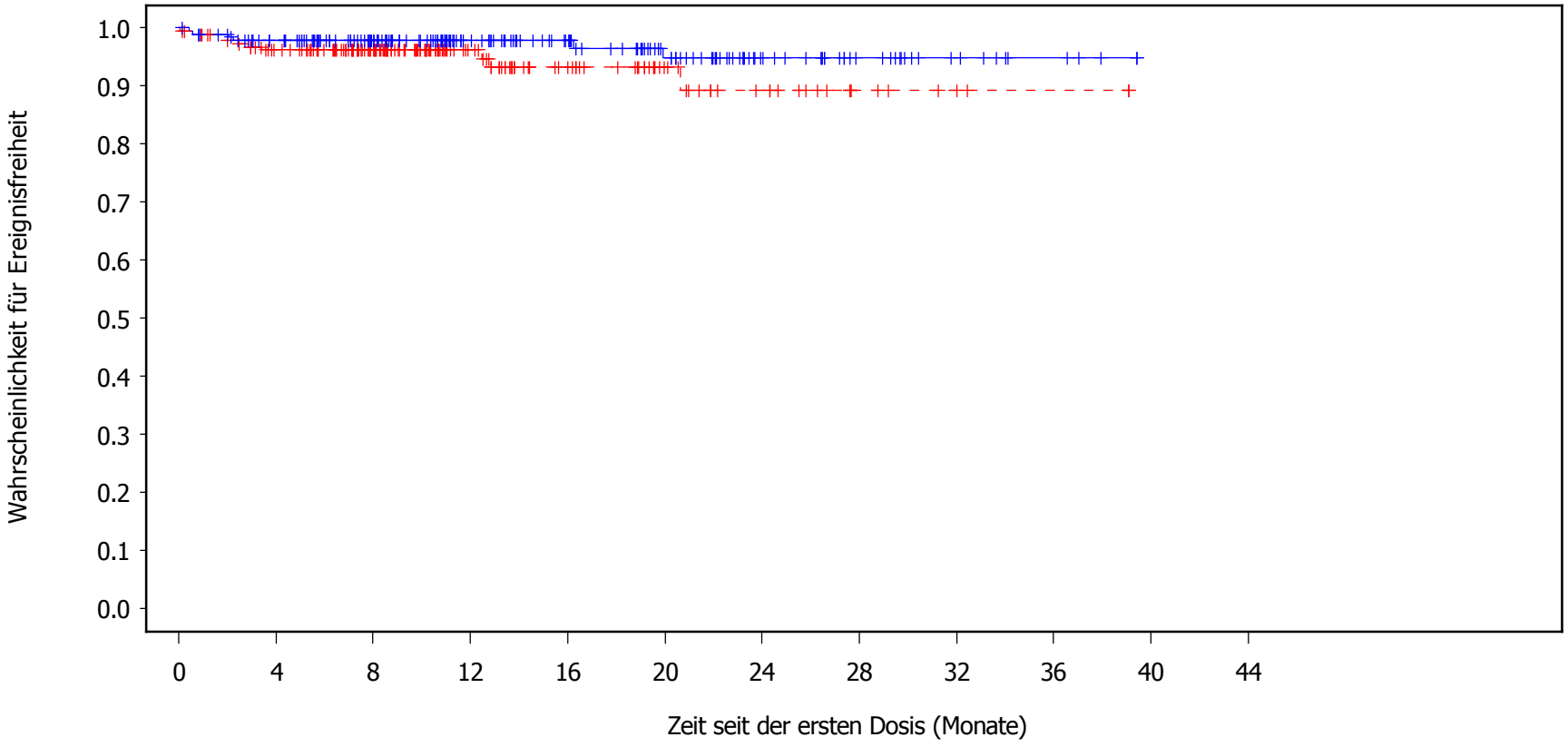
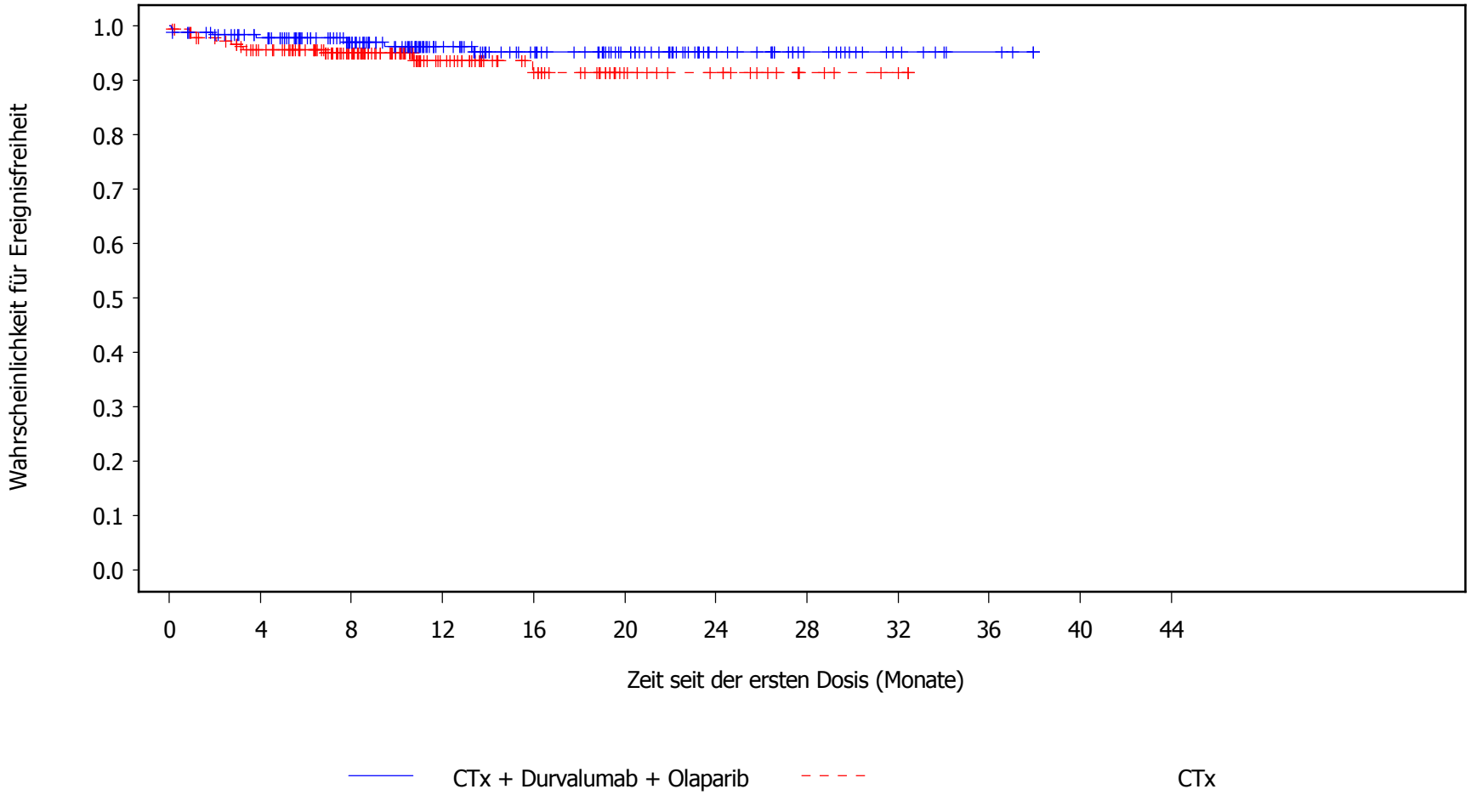
Figure 3.3.2.2D.26 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Haematurie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	173	139	97	77	56	32	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	167	125	69	44	26	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.27 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Pollakisurie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	172	137	92	72	54	31	17	8	3	0	0	CTx + Durvalumab + Olaparib
190	166	121	64	42	21	15	5	2	0	0	0	CTx

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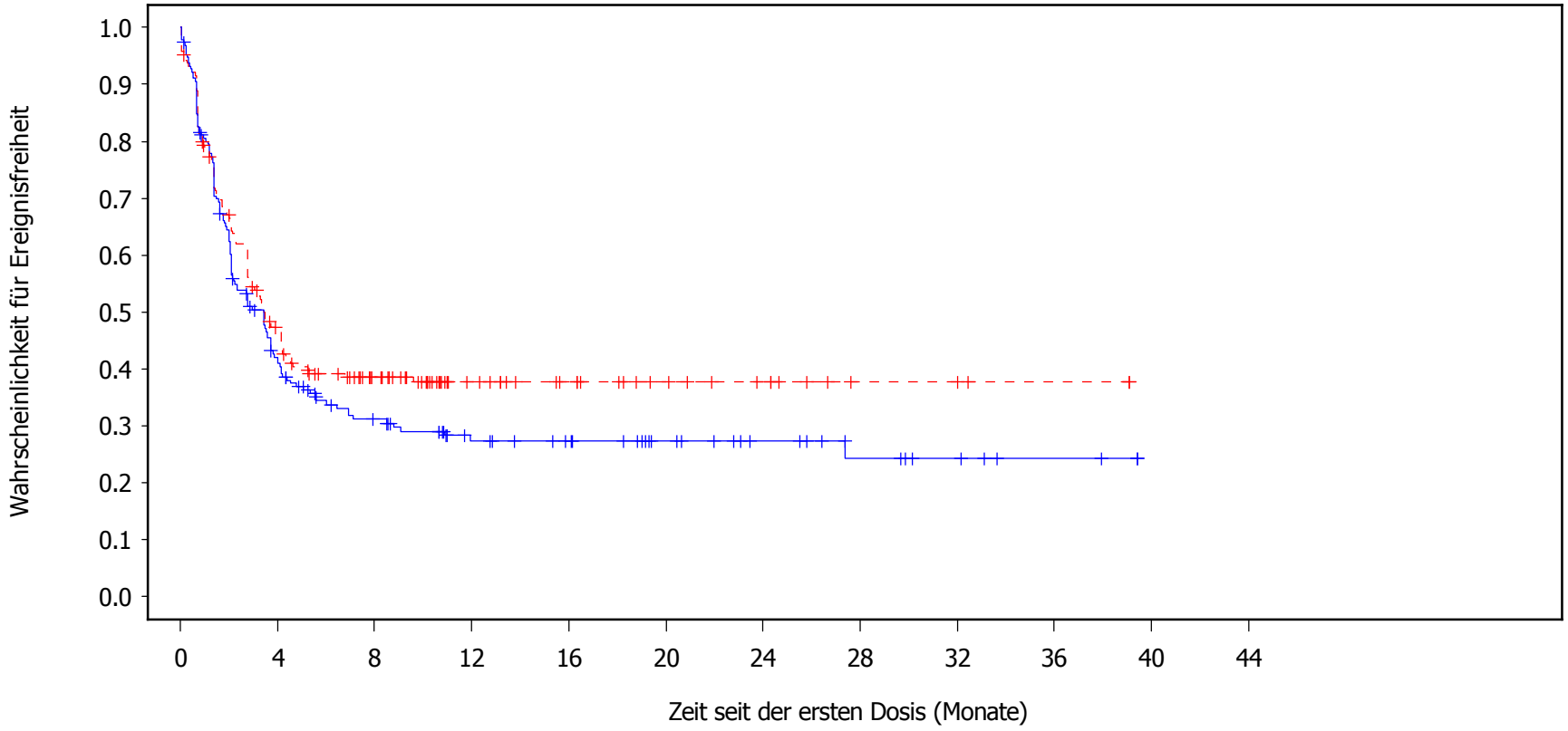
Figure 3.3.2.2D.28 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	74	47	32	27	19	13	8	5	2	0	0	CTx + Durvalumab + Olaparib
190	82	52	28	20	13	9	3	3	1	0	0	CTx

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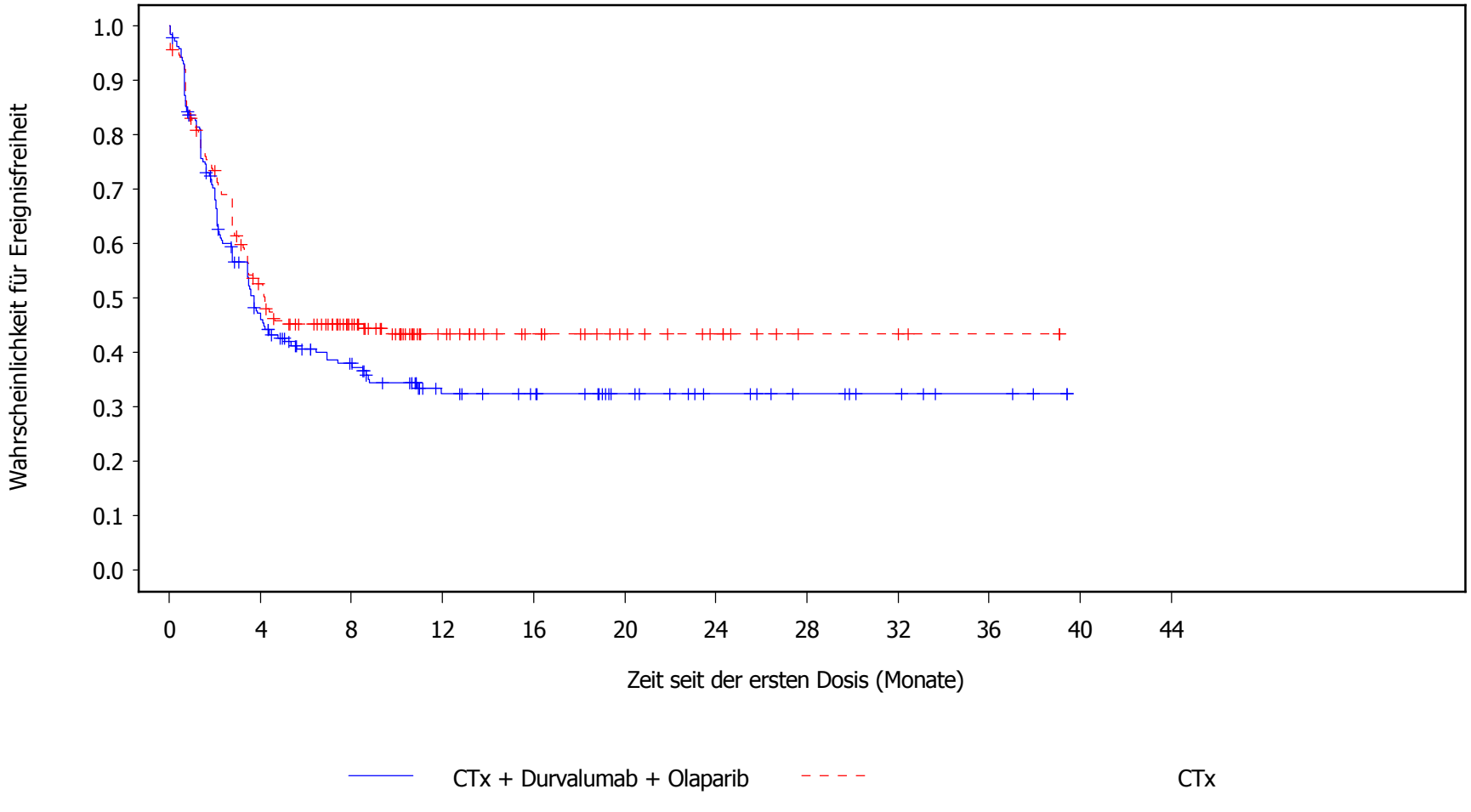
Figure 3.3.2.2D.29 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Anaemie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	83	55	33	28	19	13	9	6	3	0	0	CTx + Durvalumab + Olaparib
190	93	60	32	22	14	9	3	3	1	0	0	CTx

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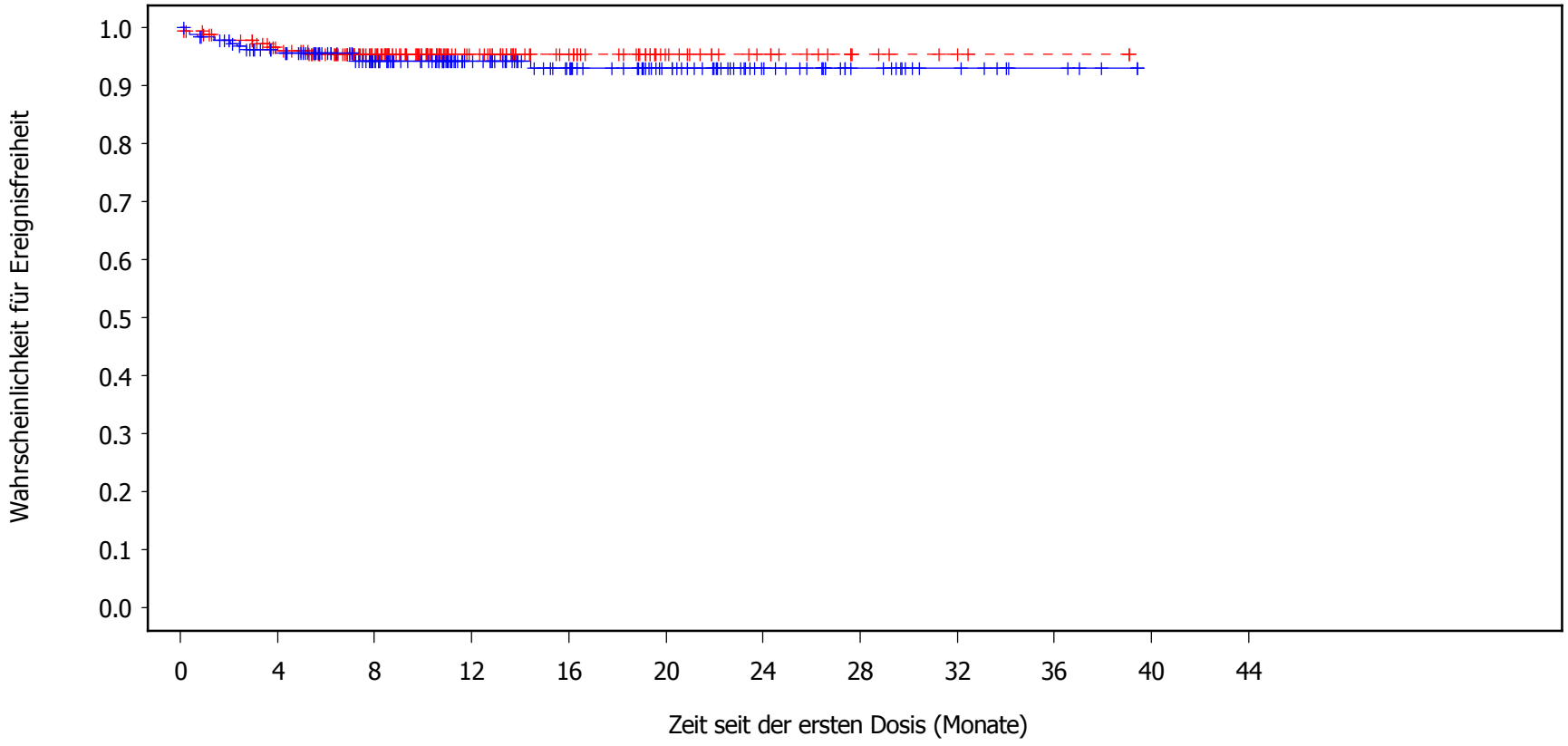
Figure 3.3.2.2D.30 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Leukopenie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	168	133	92	71	52	31	17	9	4	0	0	CTx + Durvalumab + Olaparib
190	168	125	68	46	25	15	6	3	1	0	0	CTx

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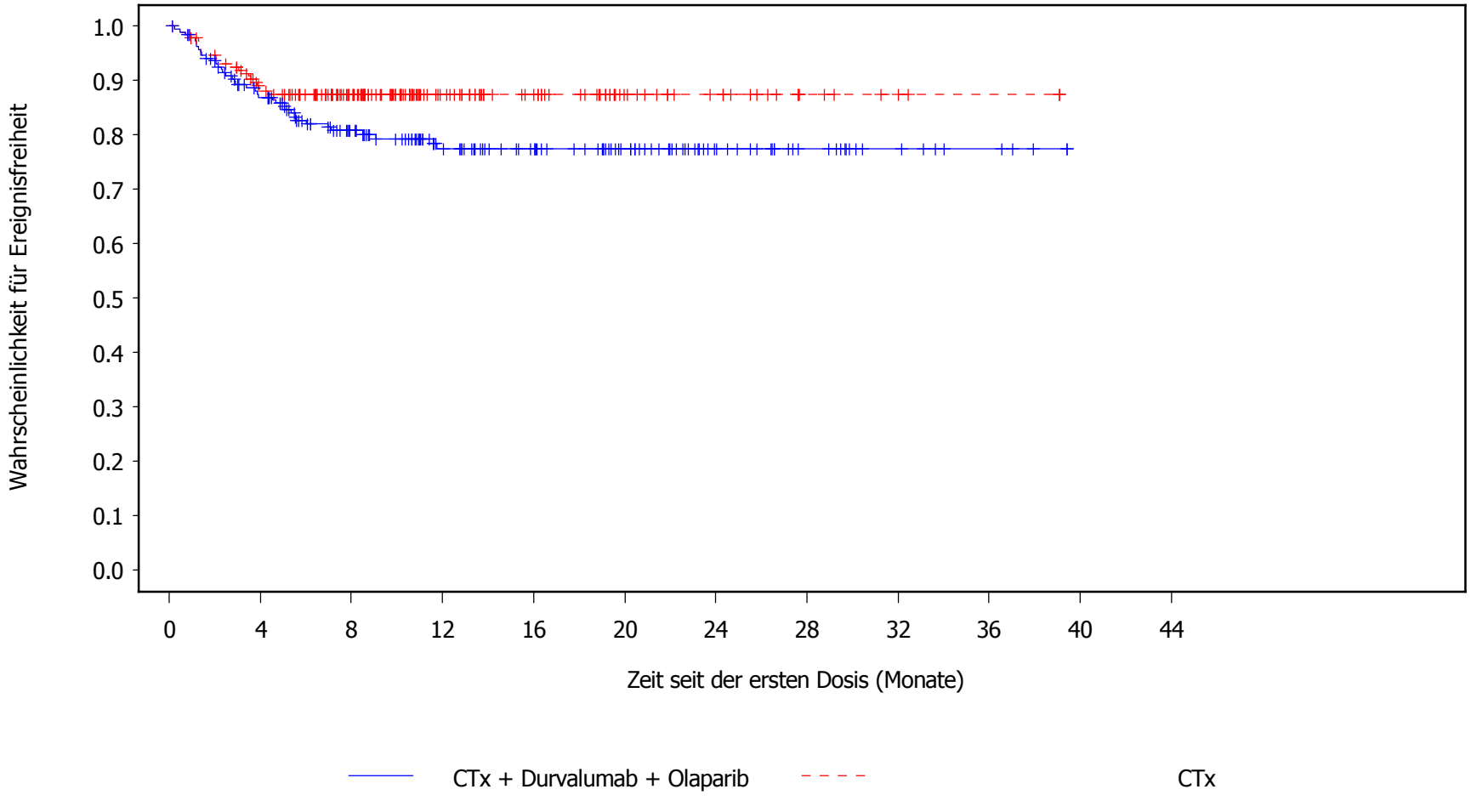
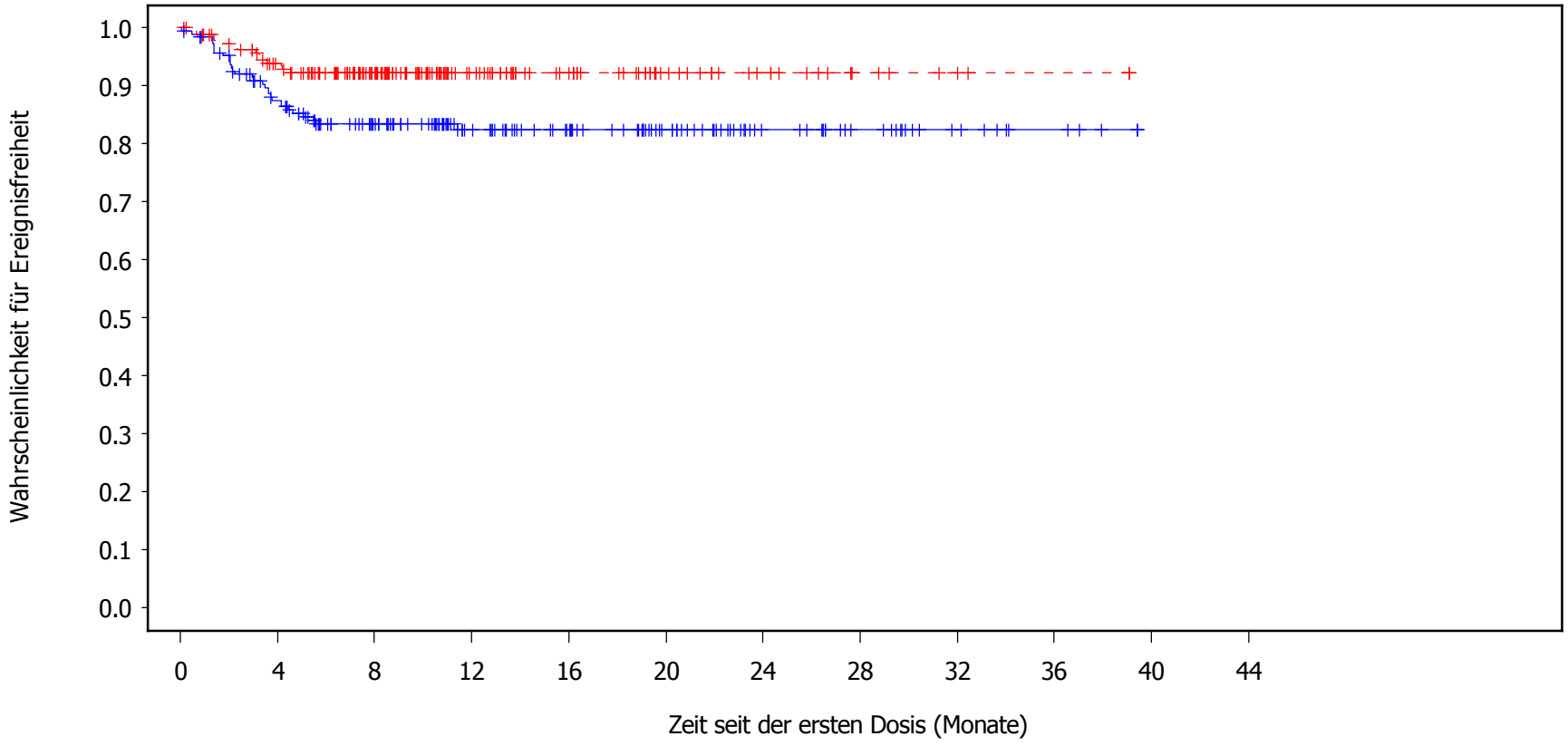
Figure 3.3.2.2D.31 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Neutropenie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	153	115	83	67	49	28	16	8	4	0	0	CTx + Durvalumab + Olaparib
190	155	115	63	45	24	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.32 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Thrombozytopenie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	155	120	85	68	49	28	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	163	117	63	42	24	15	6	3	1	0	0	CTx

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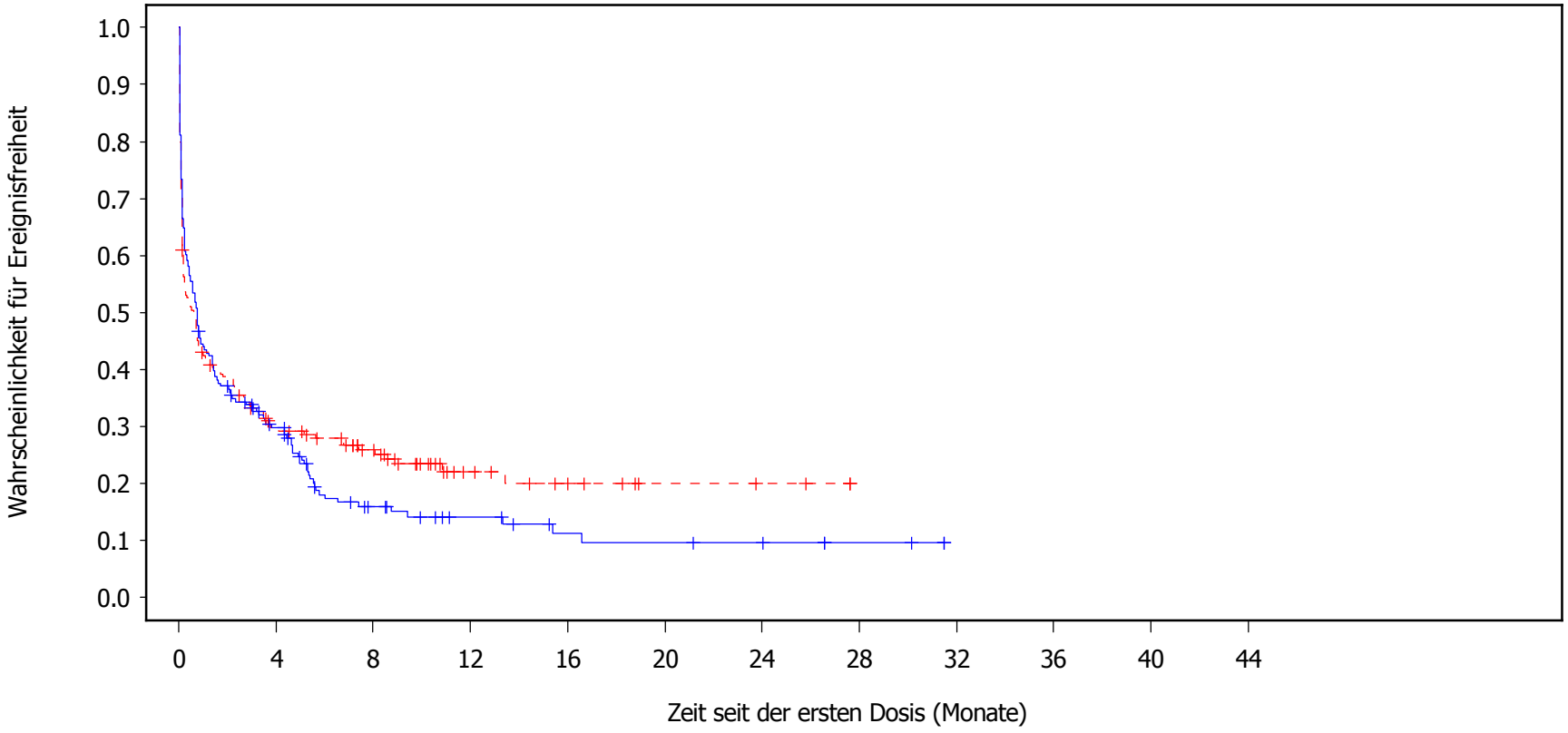
Figure 3.3.2.2D.33 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Gastrointestinaltrakts
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	50	20	12	7	6	5	2	0	0	0	0	CTx + Durvalumab + Olaparib
190	51	34	13	8	3	2	0	0	0	0	0	CTx

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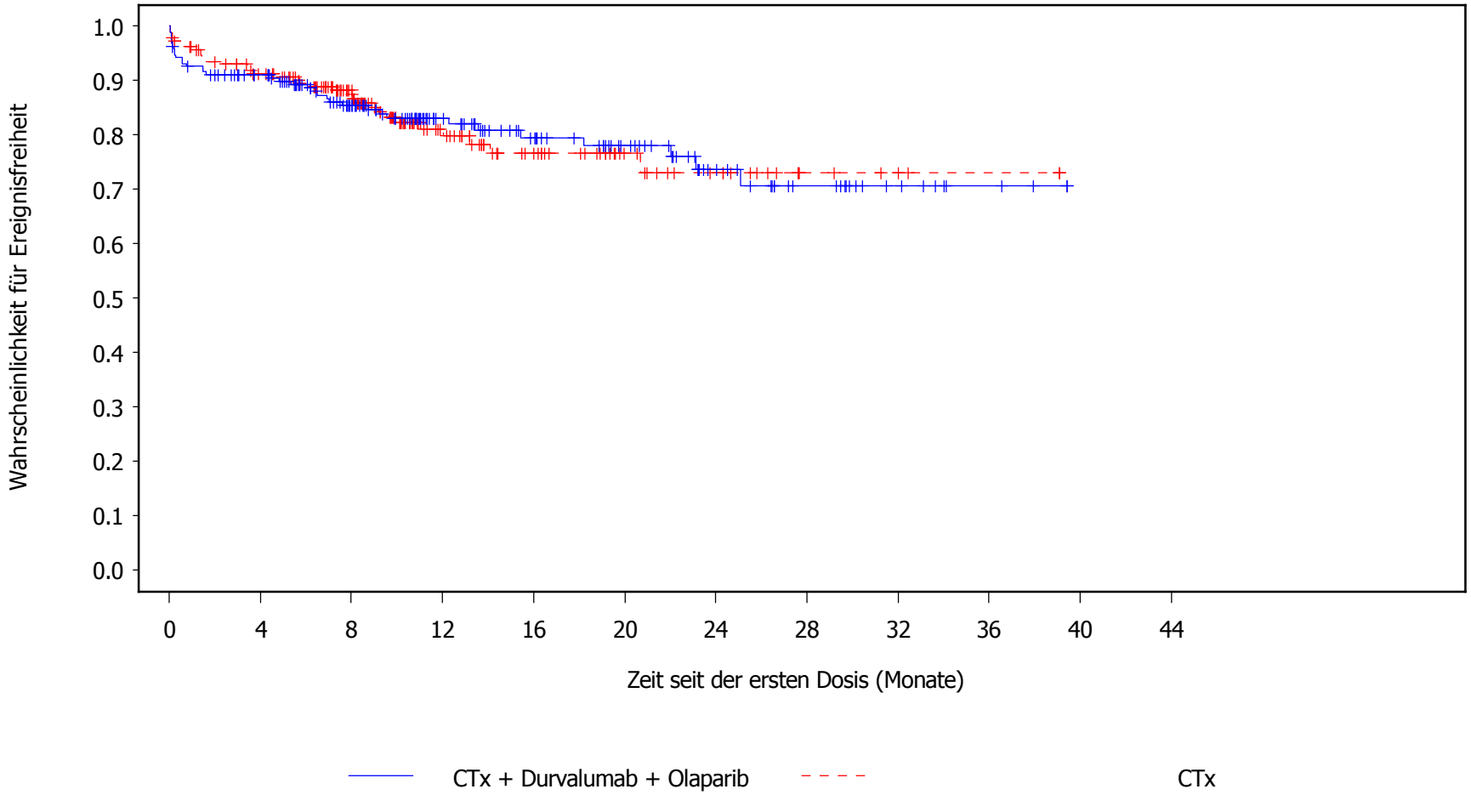
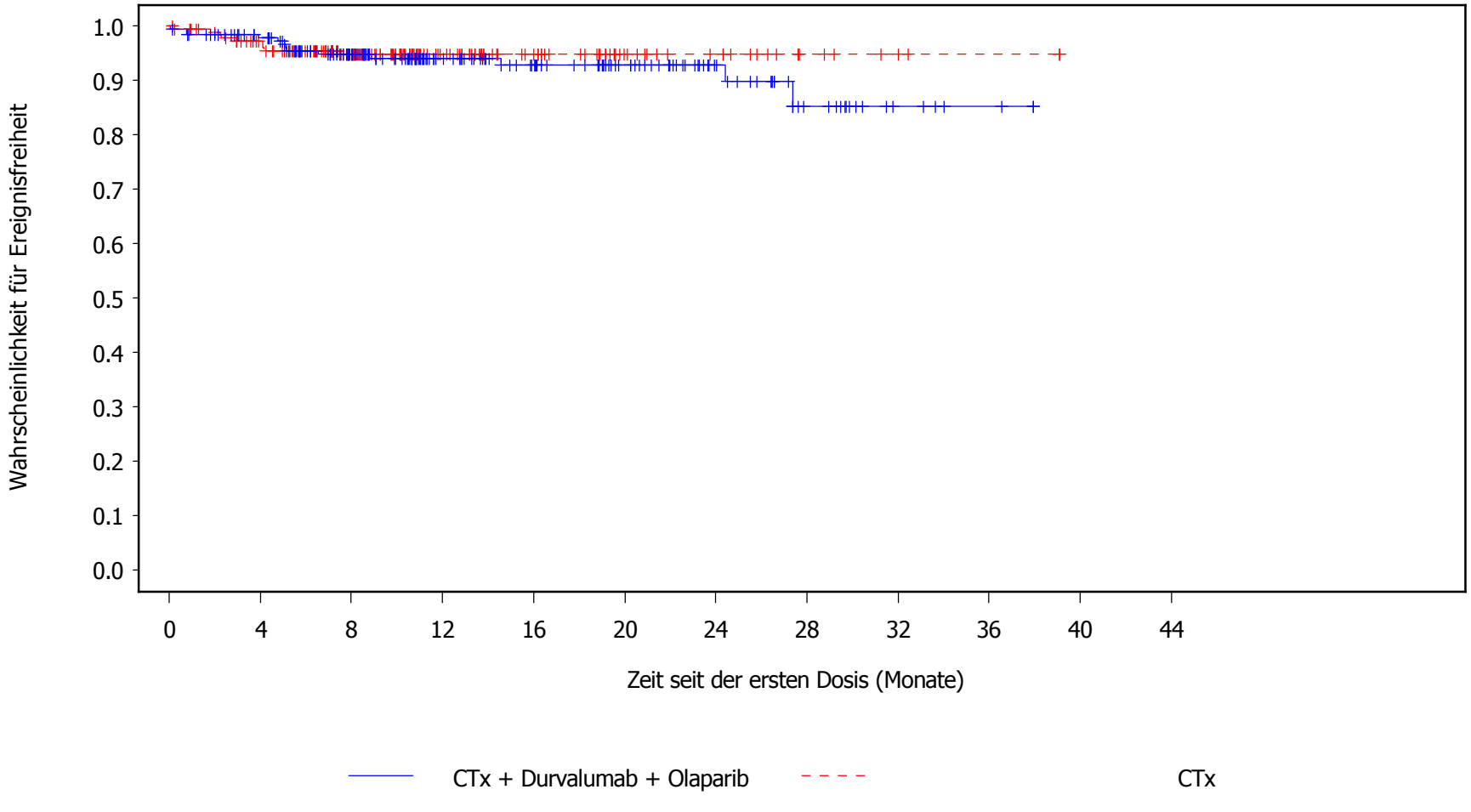
Figure 3.3.2.2D.34 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Abdominalschmerz
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	161	122	79	60	45	27	16	8	3	0	0	CTx + Durvalumab + Olaparib
190	160	118	62	40	23	15	5	3	1	0	0	CTx

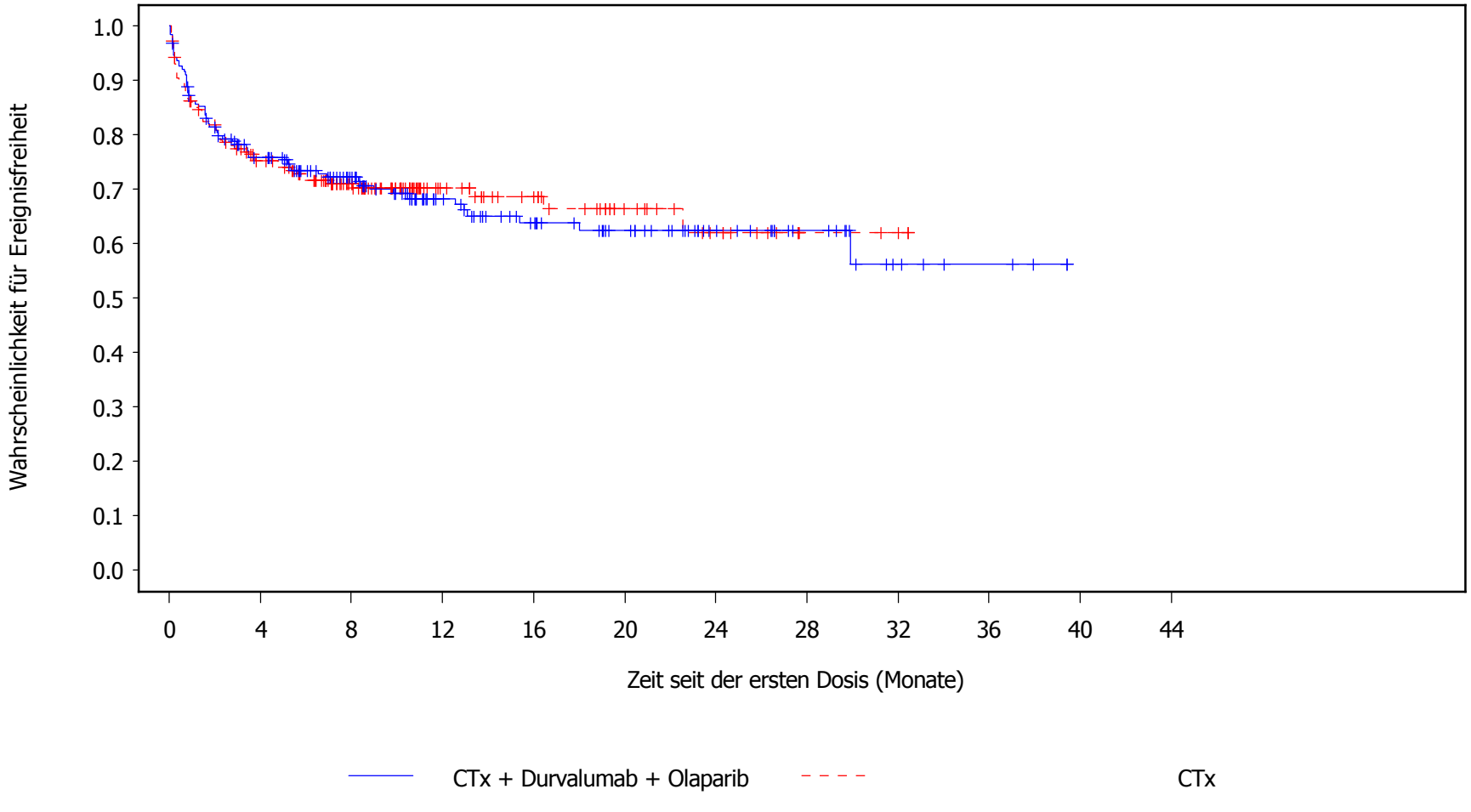
Figure 3.3.2.2D.35 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Bauch aufgetrieben
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	172	133	89	70	52	32	15	5	2	0	0	CTx + Durvalumab + Olaparib
190	169	120	65	43	23	16	6	3	1	0	0	CTx

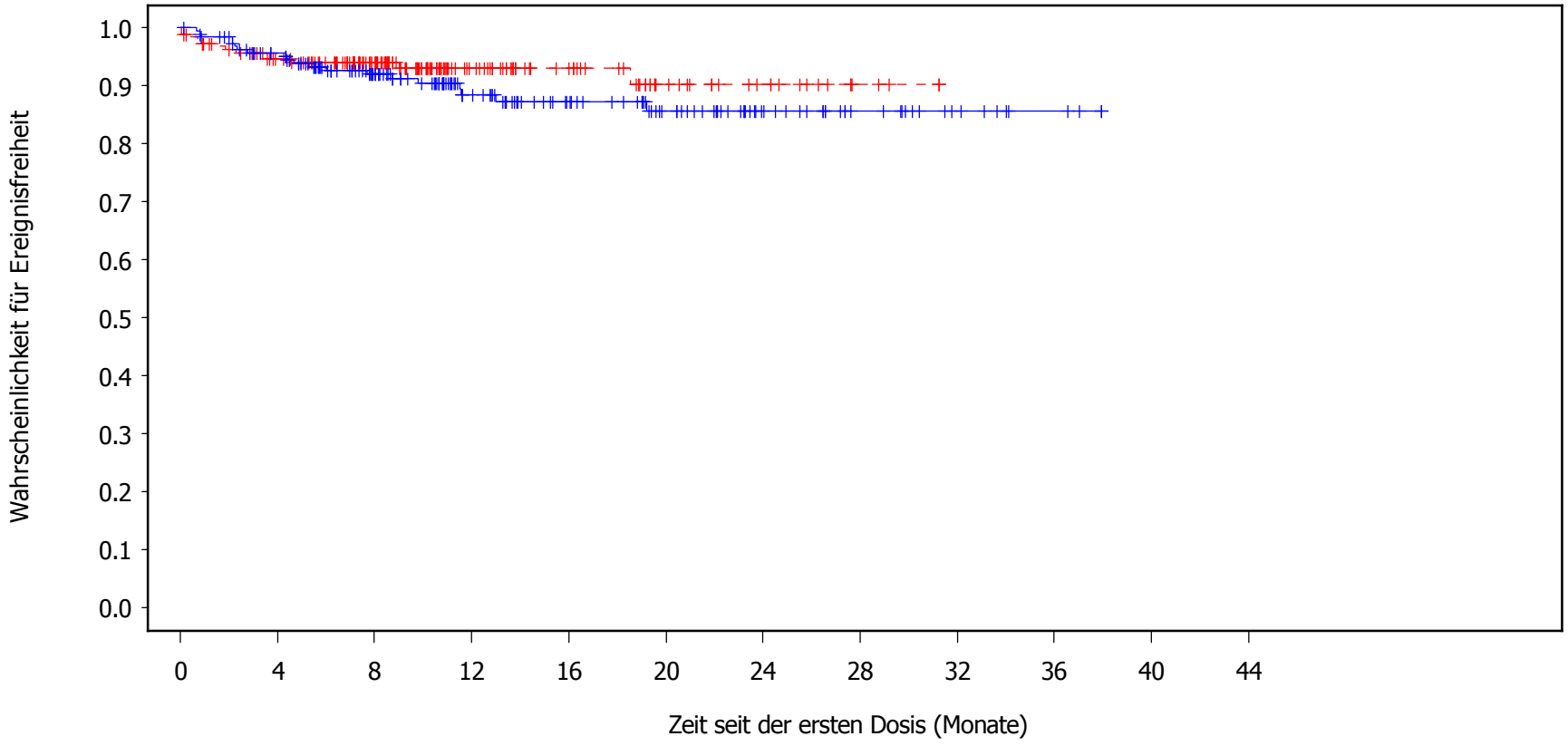
Figure 3.3.2.2D.36 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Diarrhoe
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	133	101	66	50	39	24	15	6	3	0	0	CTx + Durvalumab + Olaparib
190	131	92	48	36	20	12	3	2	0	0	0	CTx

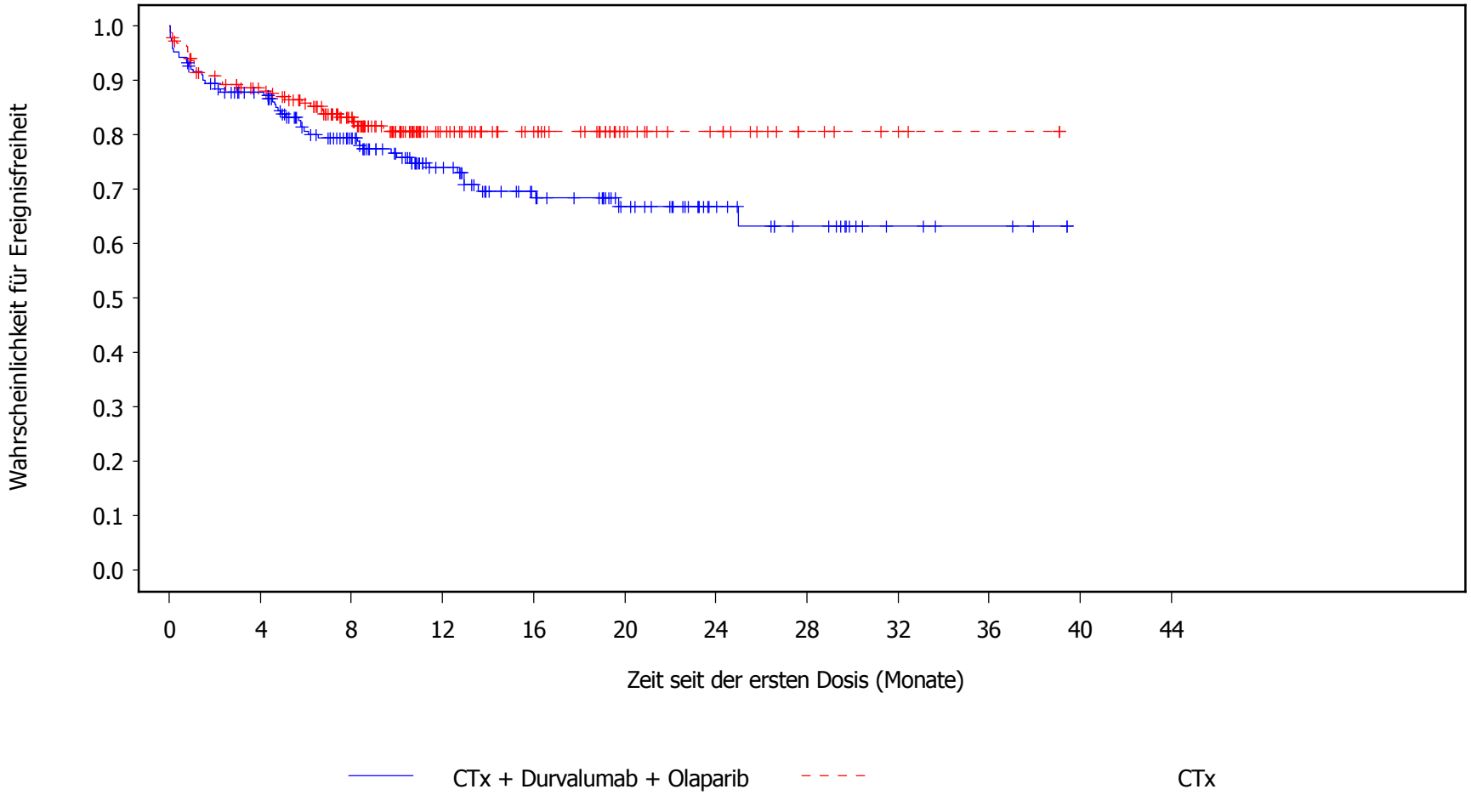
Figure 3.3.2.2D.37 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Dyspepsie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	168	128	86	65	48	29	16	8	3	0	0	CTx + Durvalumab + Olaparib
190	164	121	62	41	22	13	3	0	0	0	0	CTx

Figure 3.3.2.2D.38 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Erbrechen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	156	116	75	54	38	22	14	5	3	0	0	CTx + Durvalumab + Olaparib
190	155	112	59	41	22	15	6	3	1	0	0	CTx

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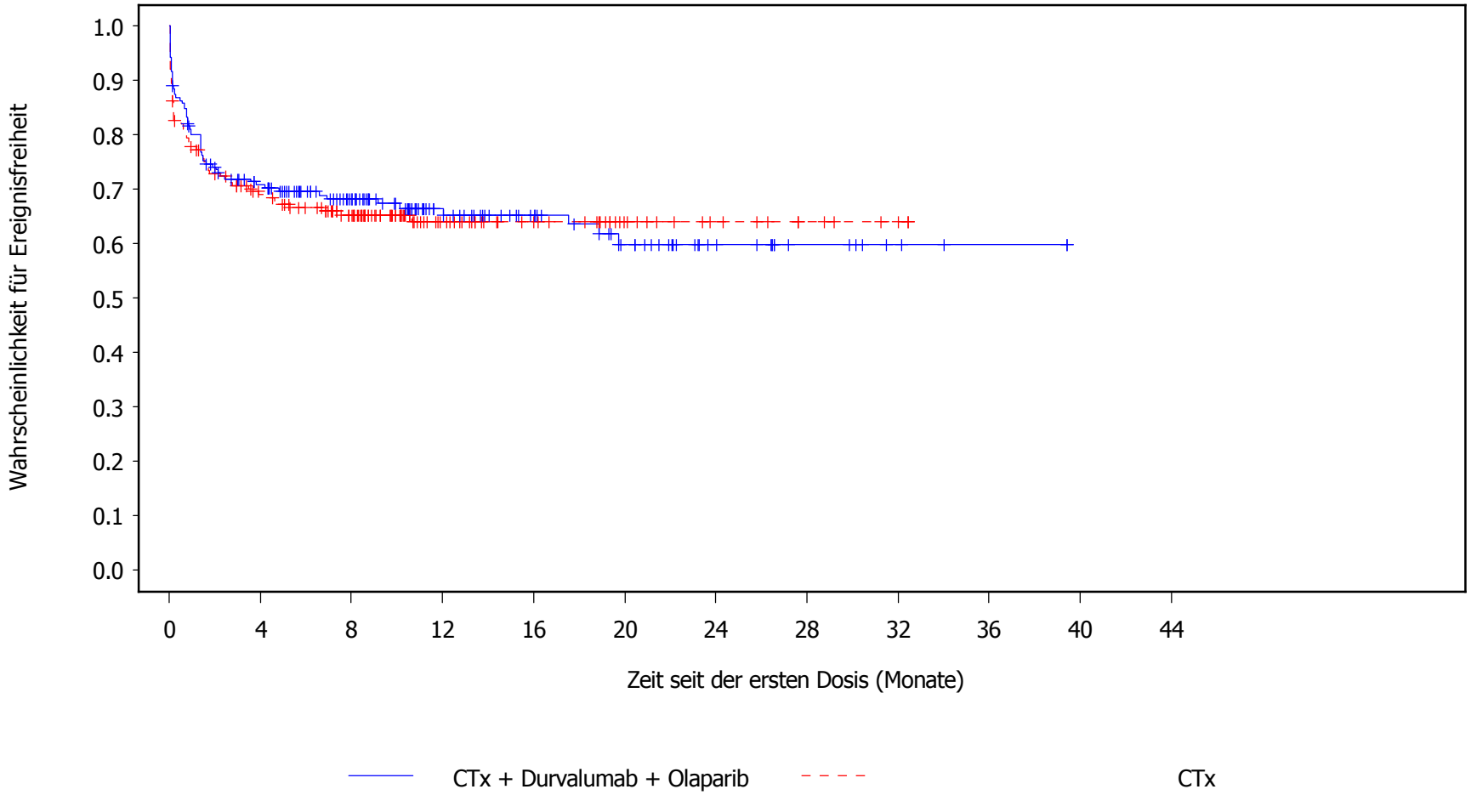
Figure 3.3.2.2D.39 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Obstipation
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	123	92	57	41	28	15	7	3	1	0	0	CTx + Durvalumab + Olaparib
190	118	90	44	30	17	10	5	2	0	0	0	CTx

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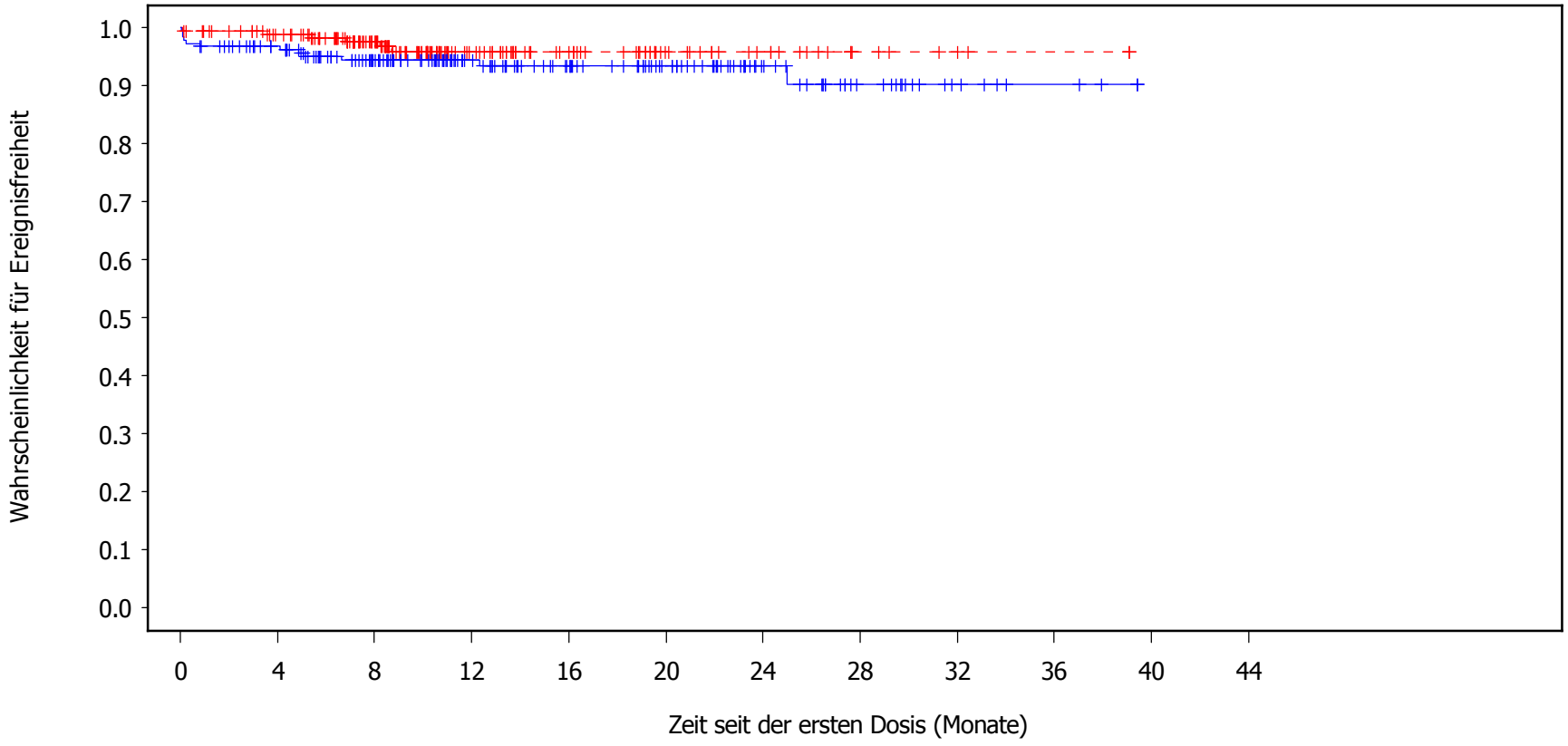
Figure 3.3.2.2D.40 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schmerzen Oberbauch
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	171	136	95	75	57	33	17	7	3	0	0	CTx + Durvalumab + Olaparib
190	172	125	66	44	25	16	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebbn 15APR2024:10:33

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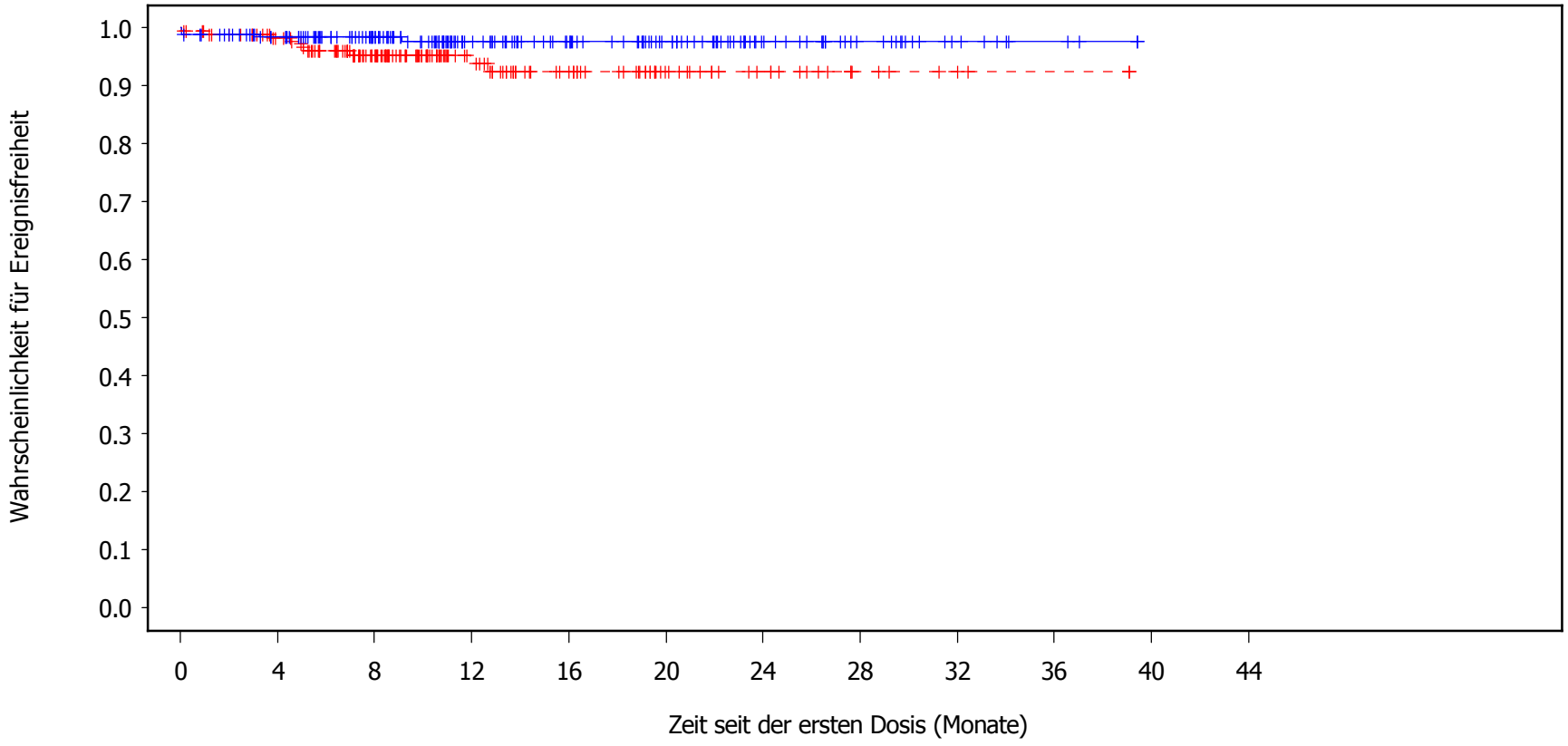
Figure 3.3.2.2D.41 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schmerzen Unterbauch
Patients with pMMR tumour status, DCO 18OCT2023

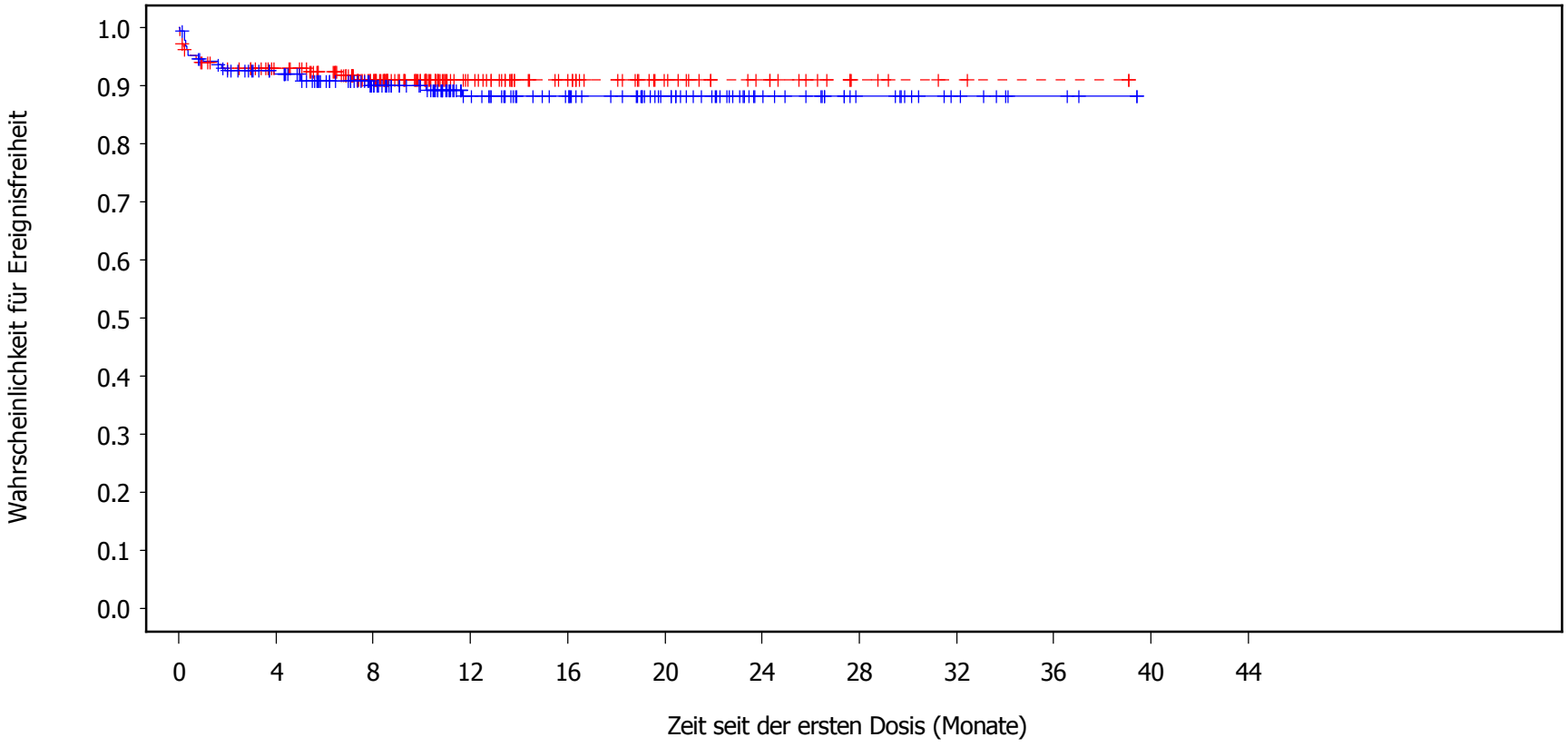


Anzahl an Patienten unter Risiko:

191	173	139	95	75	56	32	18	8	3	0	0	CTx + Durvalumab + Olaparib
190	171	124	69	47	26	16	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebbo 15APR2024:10:33

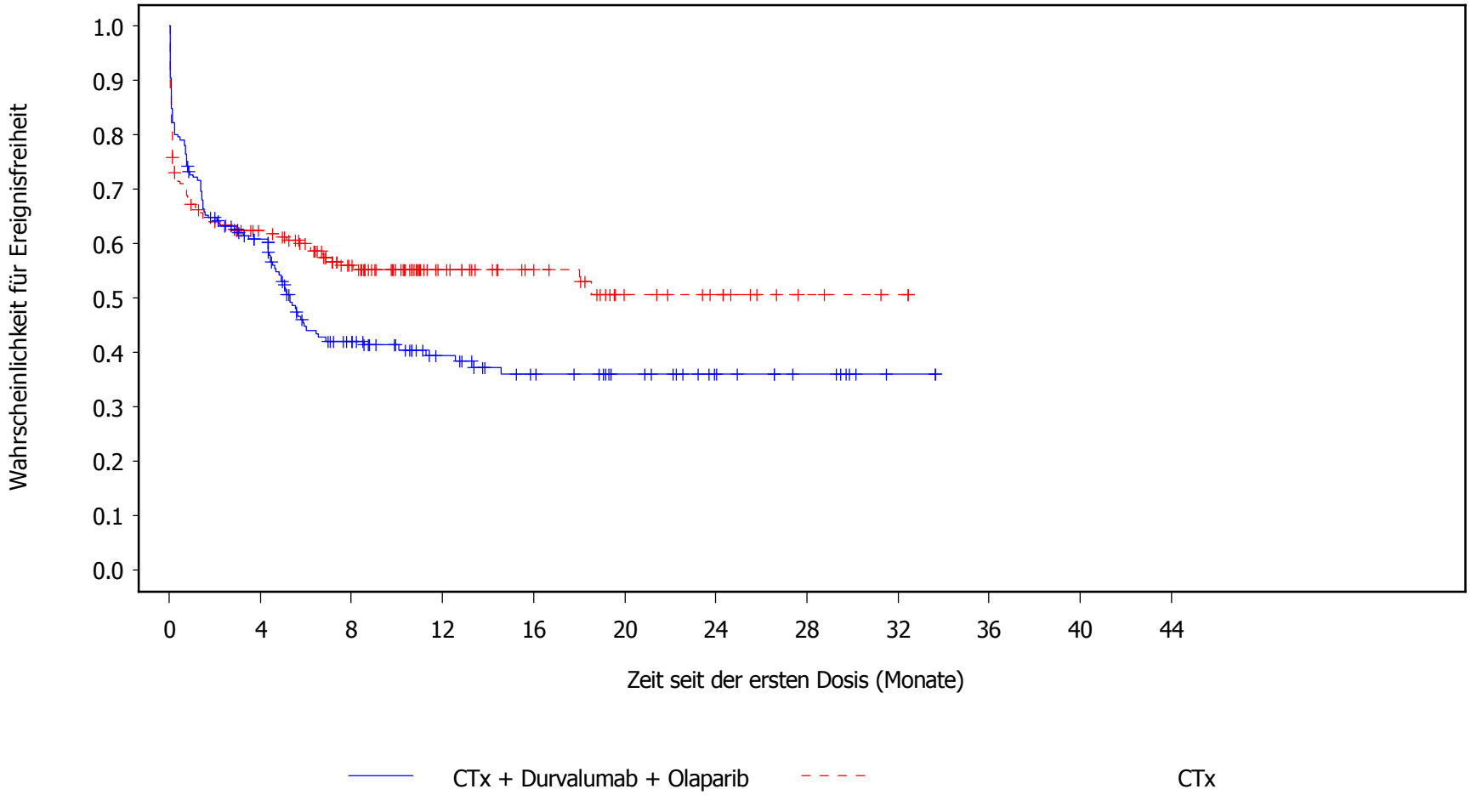
Figure 3.3.2.2D.42 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Stomatitis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	161	126	83	67	49	28	16	8	3	0	0	CTx + Durvalumab + Olaparib
190	161	118	60	40	24	15	5	2	1	0	0	CTx

Figure 3.3.2.2D.43 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Uebelkeit
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	104	59	38	27	20	12	7	1	0	0	0	CTx + Durvalumab + Olaparib
190	107	73	39	27	14	10	3	1	0	0	0	CTx

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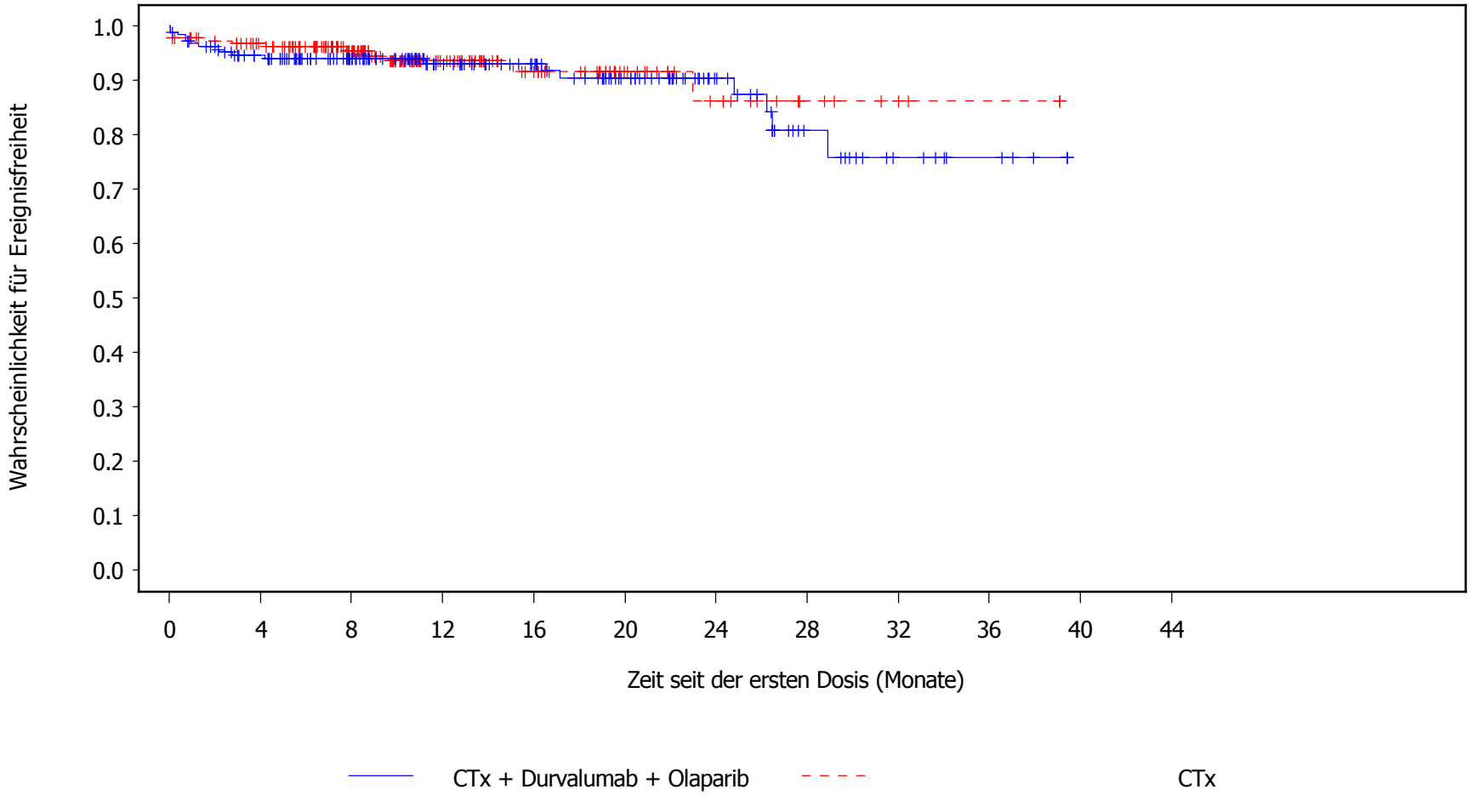
Figure 3.3.2.2D.44 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Immunsystems
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	166	131	90	74	55	33	16	8	4	0	0	CTx + Durvalumab + Olaparib
190	169	124	69	45	25	15	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebbr 15APR2024:10:33

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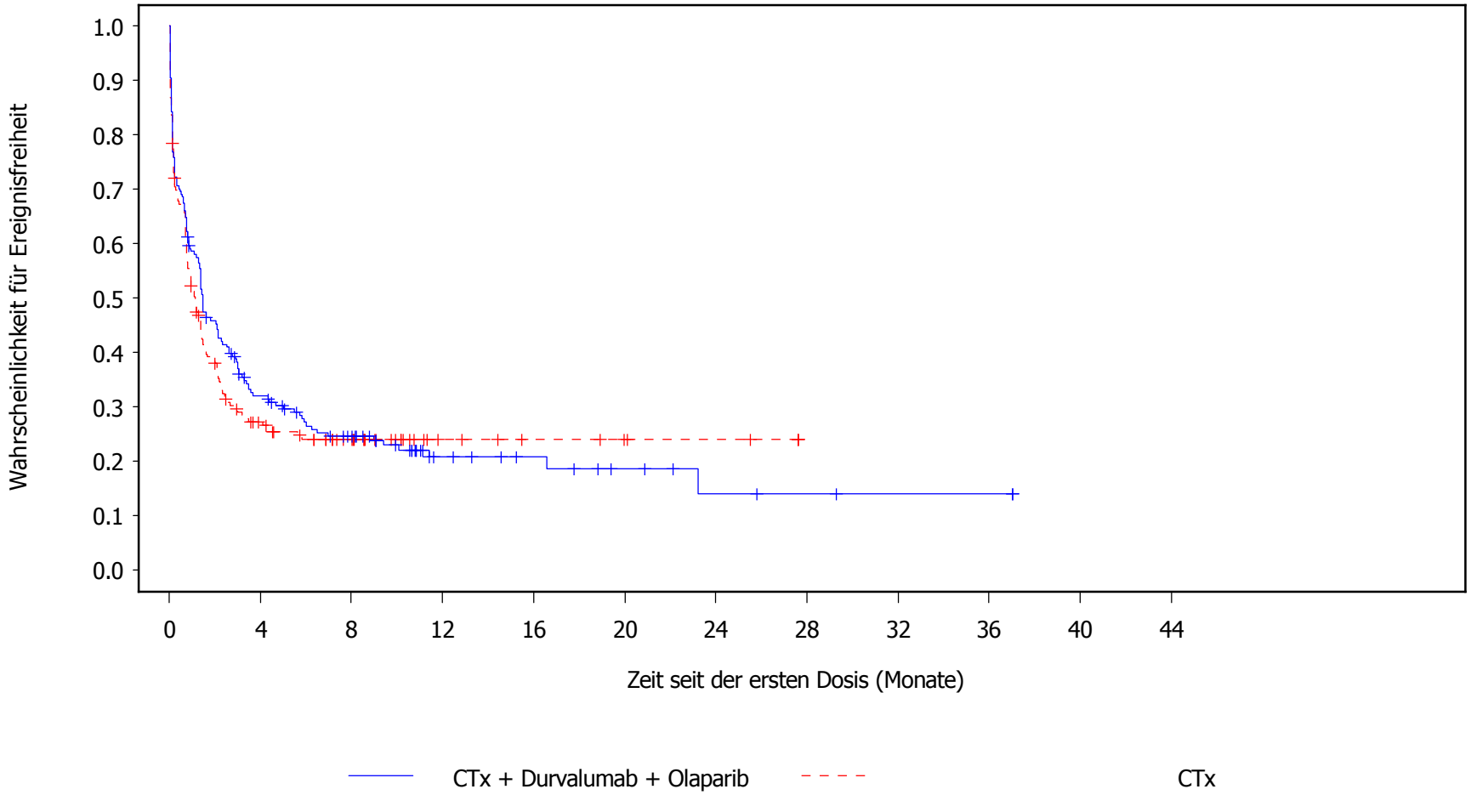
Figure 3.3.2.2D.45 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Nervensystems
Patients with pMMR tumour status, DCO 18OCT2023

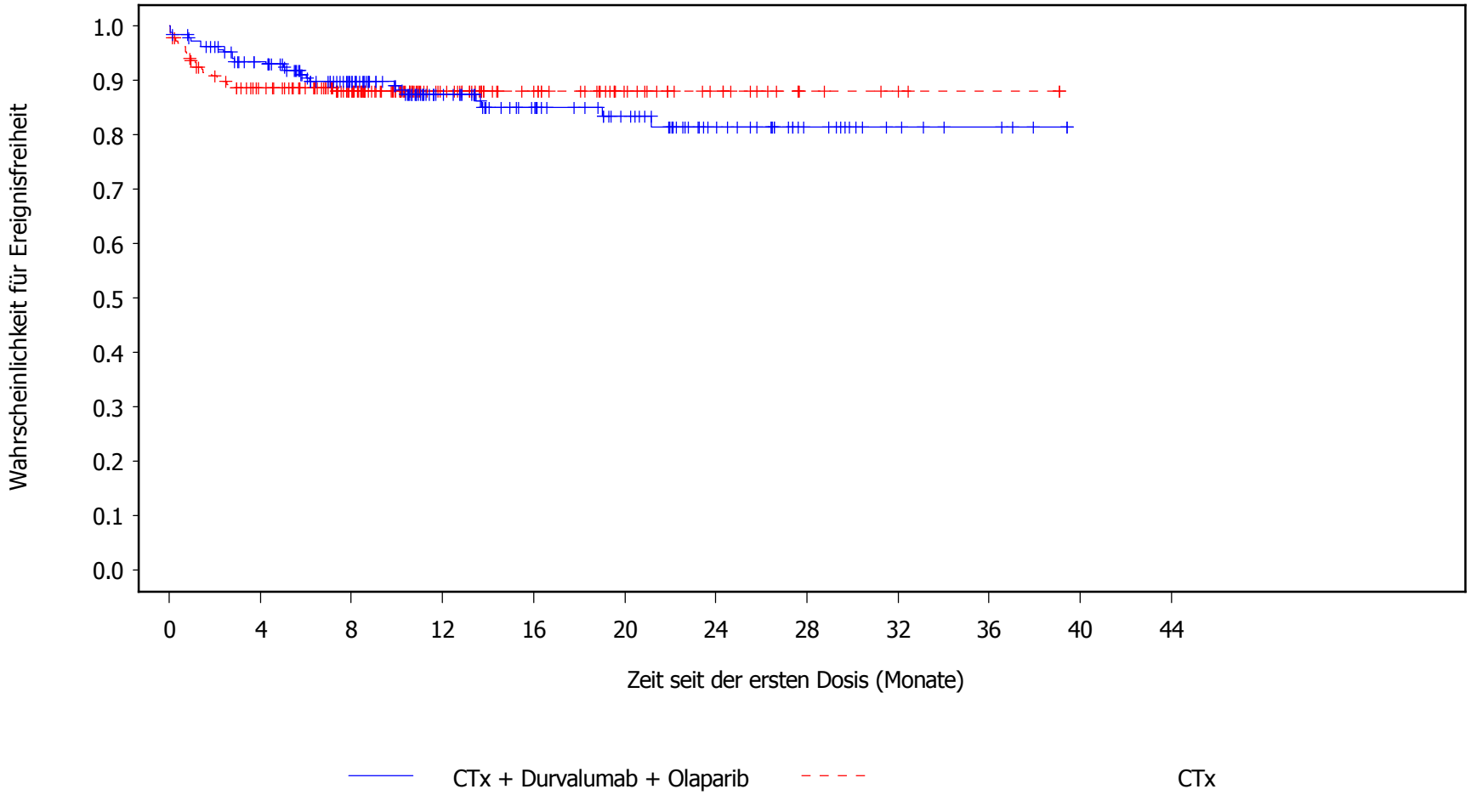


Anzahl an Patienten unter Risiko:

191	56	36	14	10	6	3	2	1	1	0	0	CTx + Durvalumab + Olaparib
190	44	27	9	6	4	3	0	0	0	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebbs 15APR2024:10:33

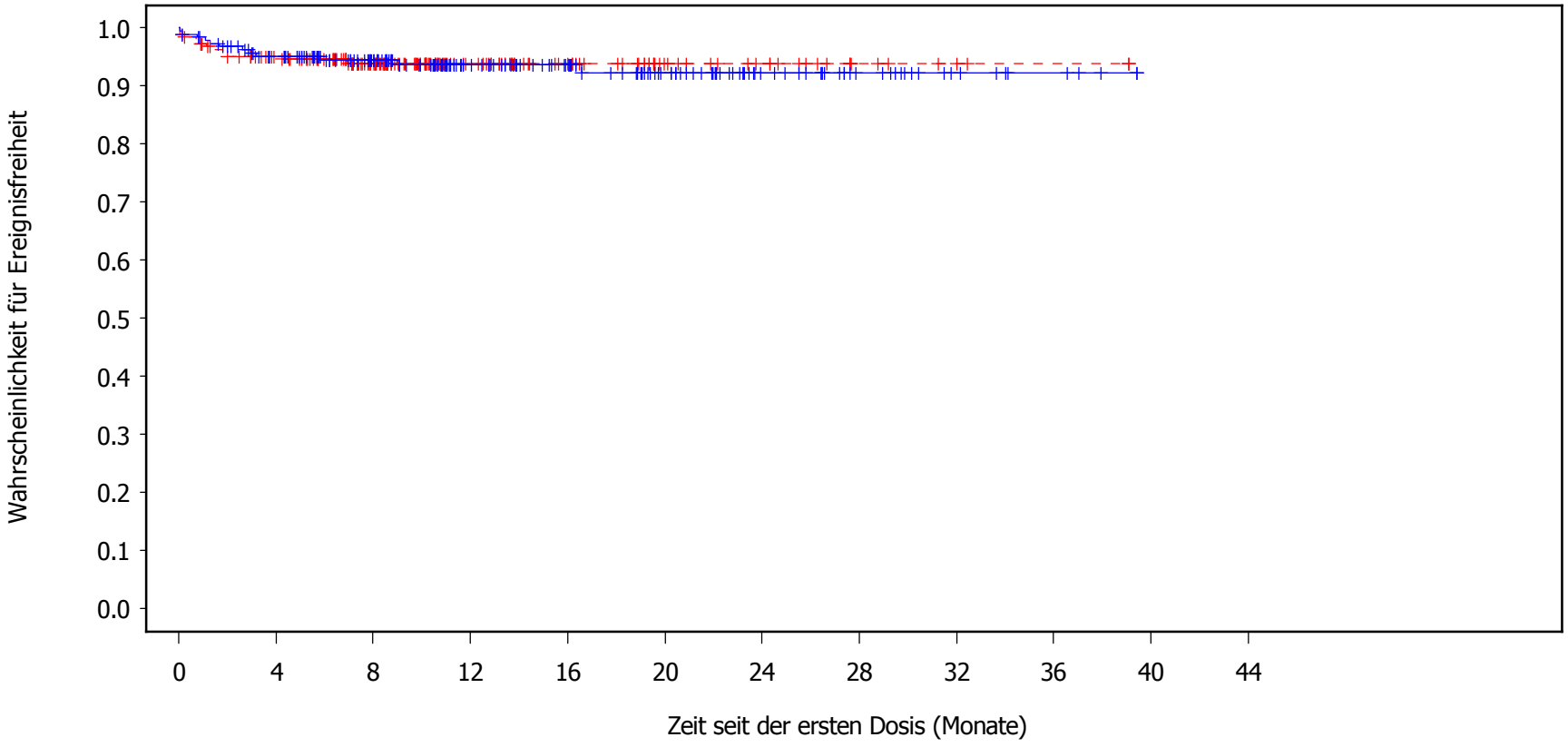
Figure 3.3.2.2D.46 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Dysgeusie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	164	126	82	62	48	30	15	7	4	0	0	CTx + Durvalumab + Olaparib
190	153	115	63	42	25	15	5	3	1	0	0	CTx

Figure 3.3.2.2D.47 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypoaesthesie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	167	132	90	72	53	30	17	8	4	0	0	CTx + Durvalumab + Olaparib
190	165	119	64	42	23	16	6	3	1	0	0	CTx

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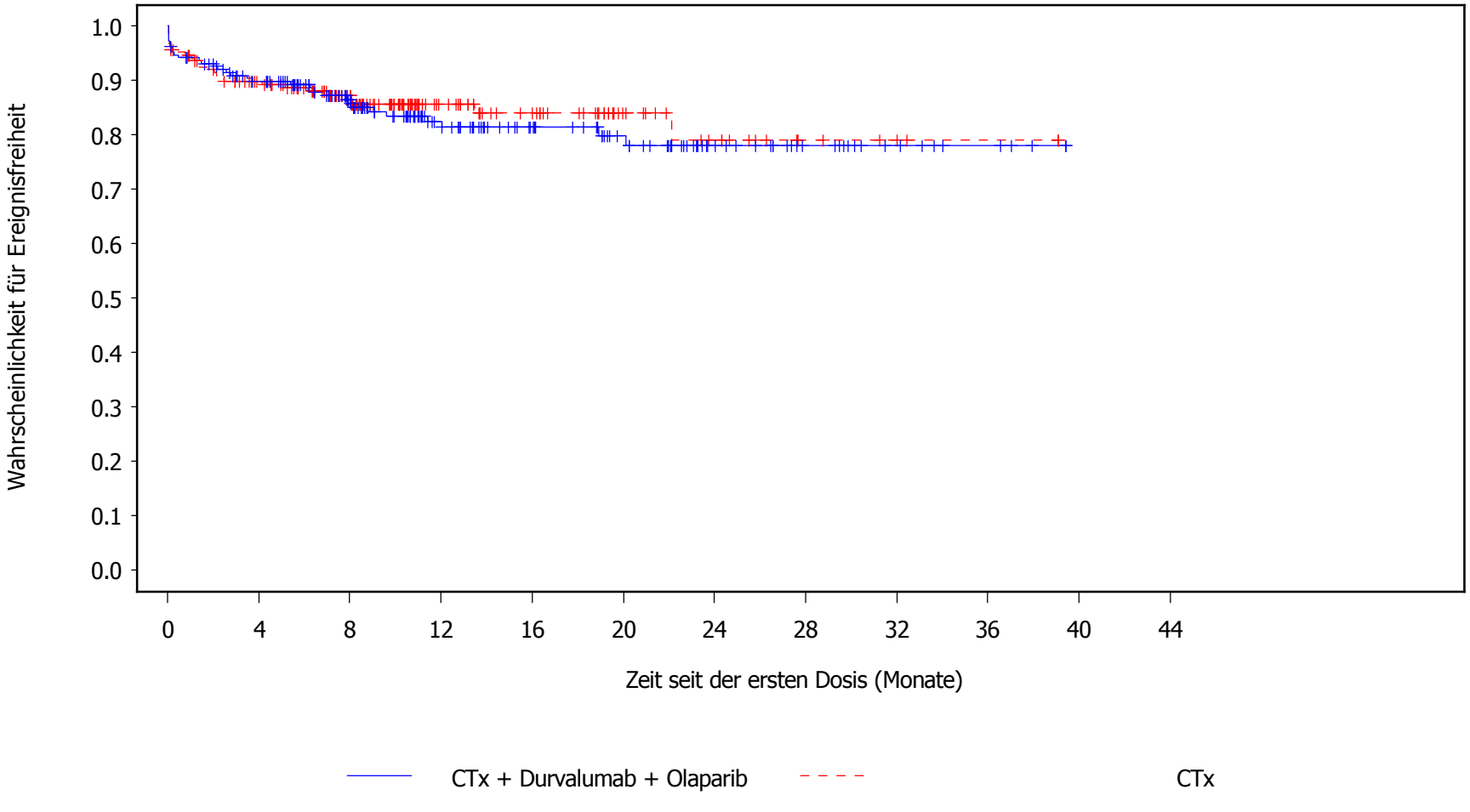
Figure 3.3.2.2D.48 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Kopfschmerzen
Patients with pMMR tumour status, DCO 18OCT2023

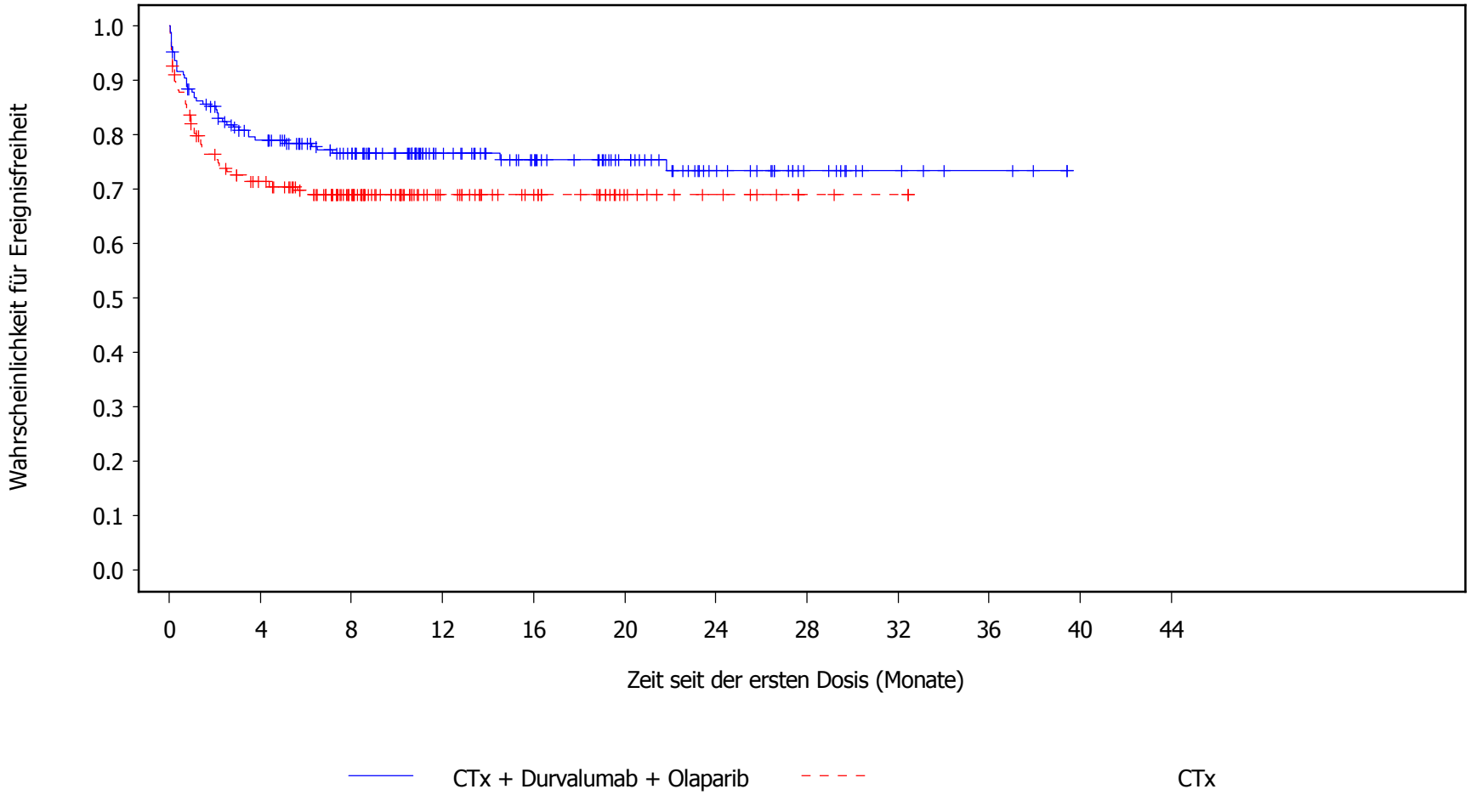


Anzahl an Patienten unter Risiko:

191	158	120	79	59	45	26	15	8	4	0	0	CTx + Durvalumab + Olaparib
190	155	113	59	42	22	14	5	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebbv 15APR2024:10:33

Figure 3.3.2.2D.49 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Periphere Neuropathie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	140	113	76	59	43	26	13	6	3	0	0	CTx + Durvalumab + Olaparib
190	124	85	43	30	14	8	2	1	0	0	0	CTx

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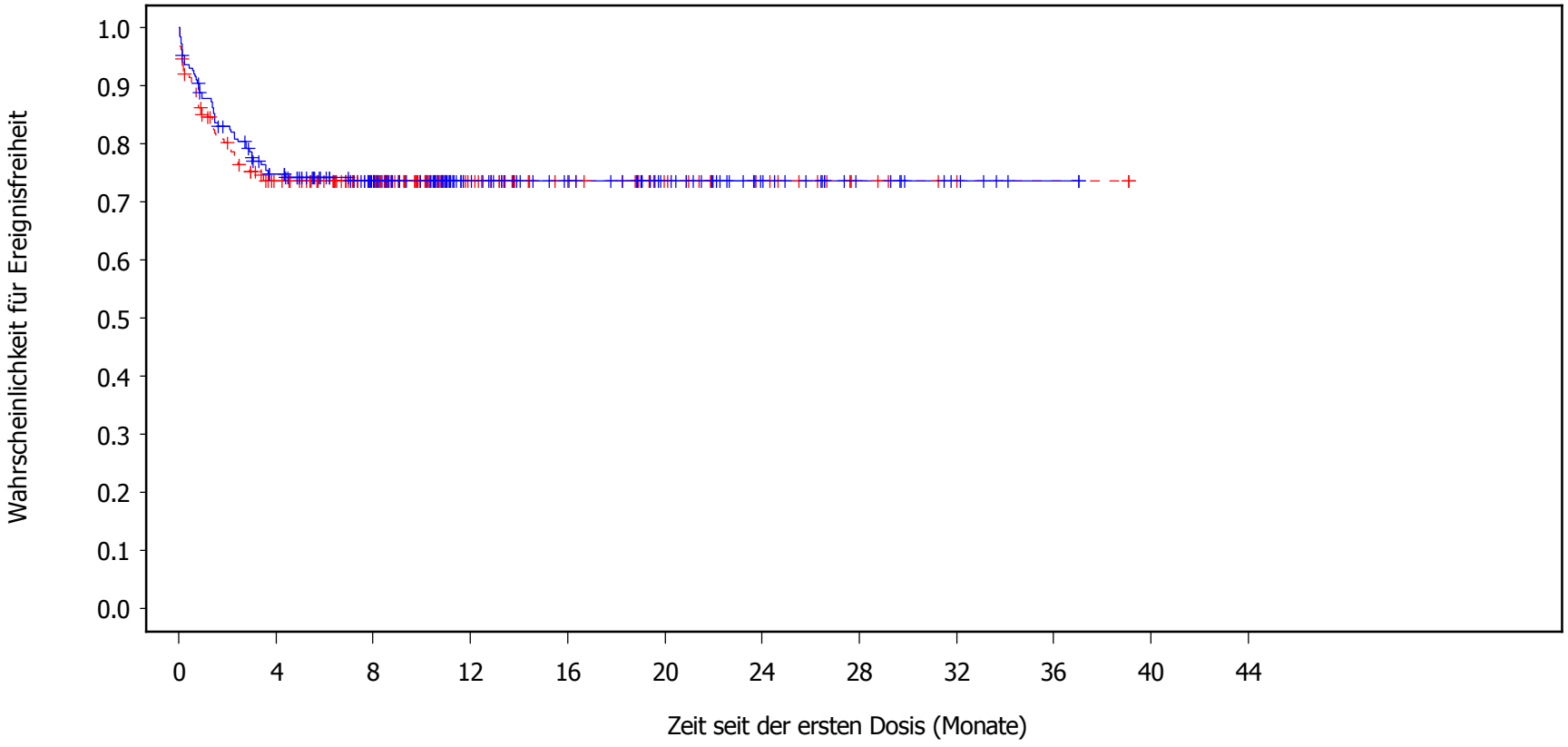
Figure 3.3.2.2D.50 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Periphere sensorische Neuropathie
Patients with pMMR tumour status, DCO 18OCT2023

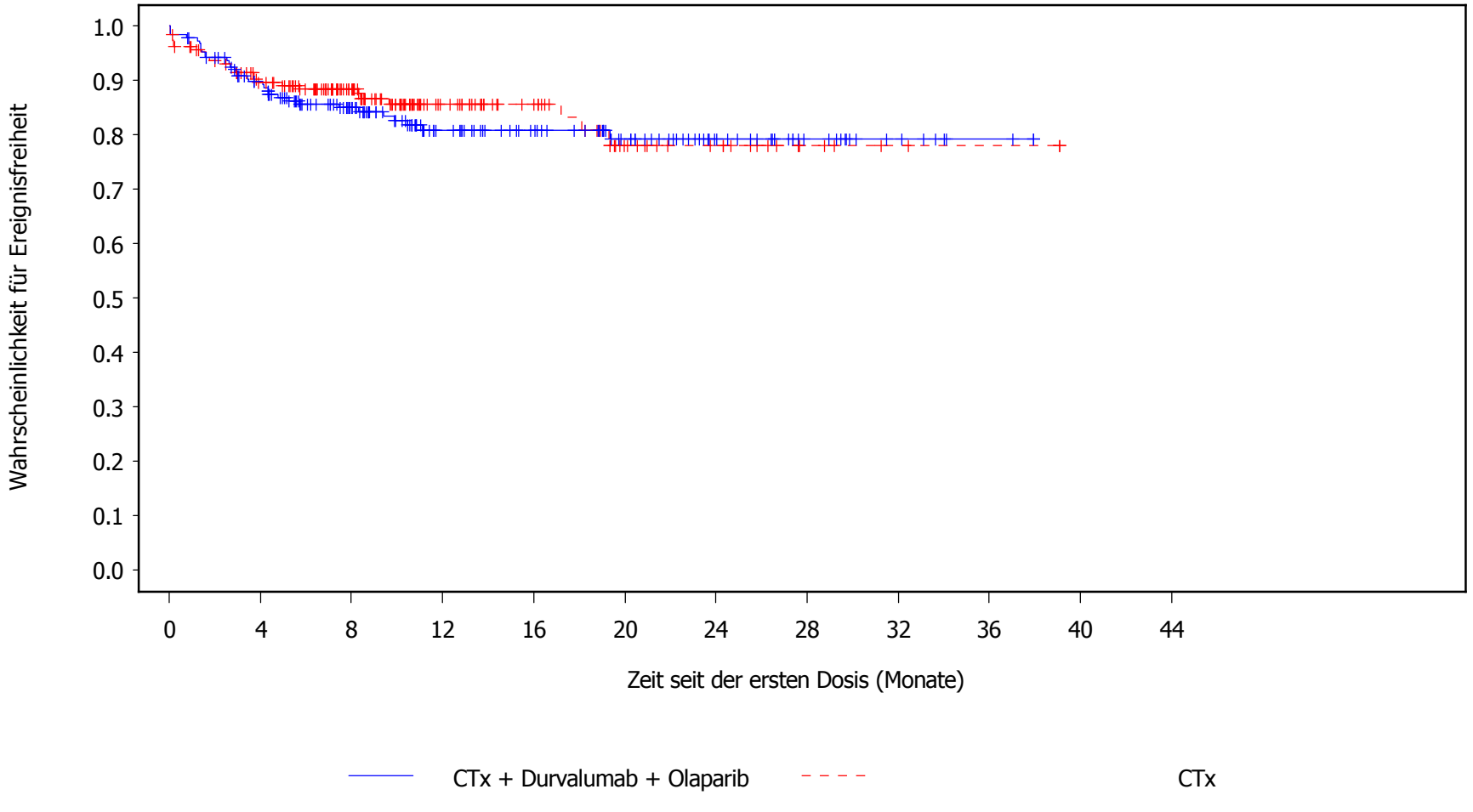


Anzahl an Patienten unter Risiko:

191	132	100	61	48	36	21	11	5	1	0	0	CTx + Durvalumab + Olaparib
190	125	94	45	30	20	13	5	2	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebbx 15APR2024:10:33

Figure 3.3.2.2D.51 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schwindelgefuehl
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	159	120	78	63	47	29	15	7	2	0	0	CTx + Durvalumab + Olaparib
190	155	111	59	41	22	15	5	2	1	0	0	CTx

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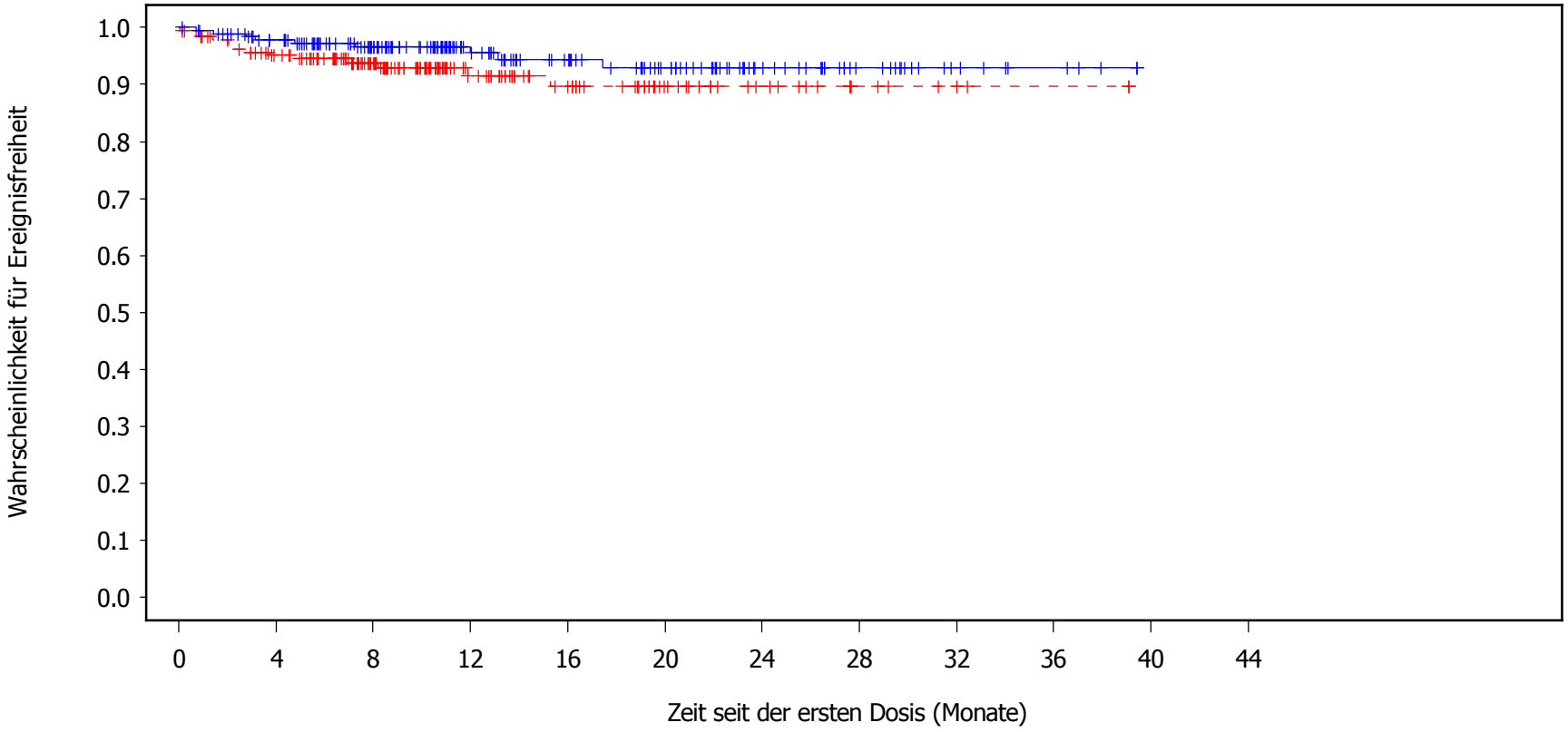
Figure 3.3.2.2D.52 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Ohrs und des Labyrinths
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	172	135	90	72	55	33	18	8	4	0	0	CTx + Durvalumab + Olaparib
190	165	120	64	44	24	14	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebbz 15APR2024:10:33

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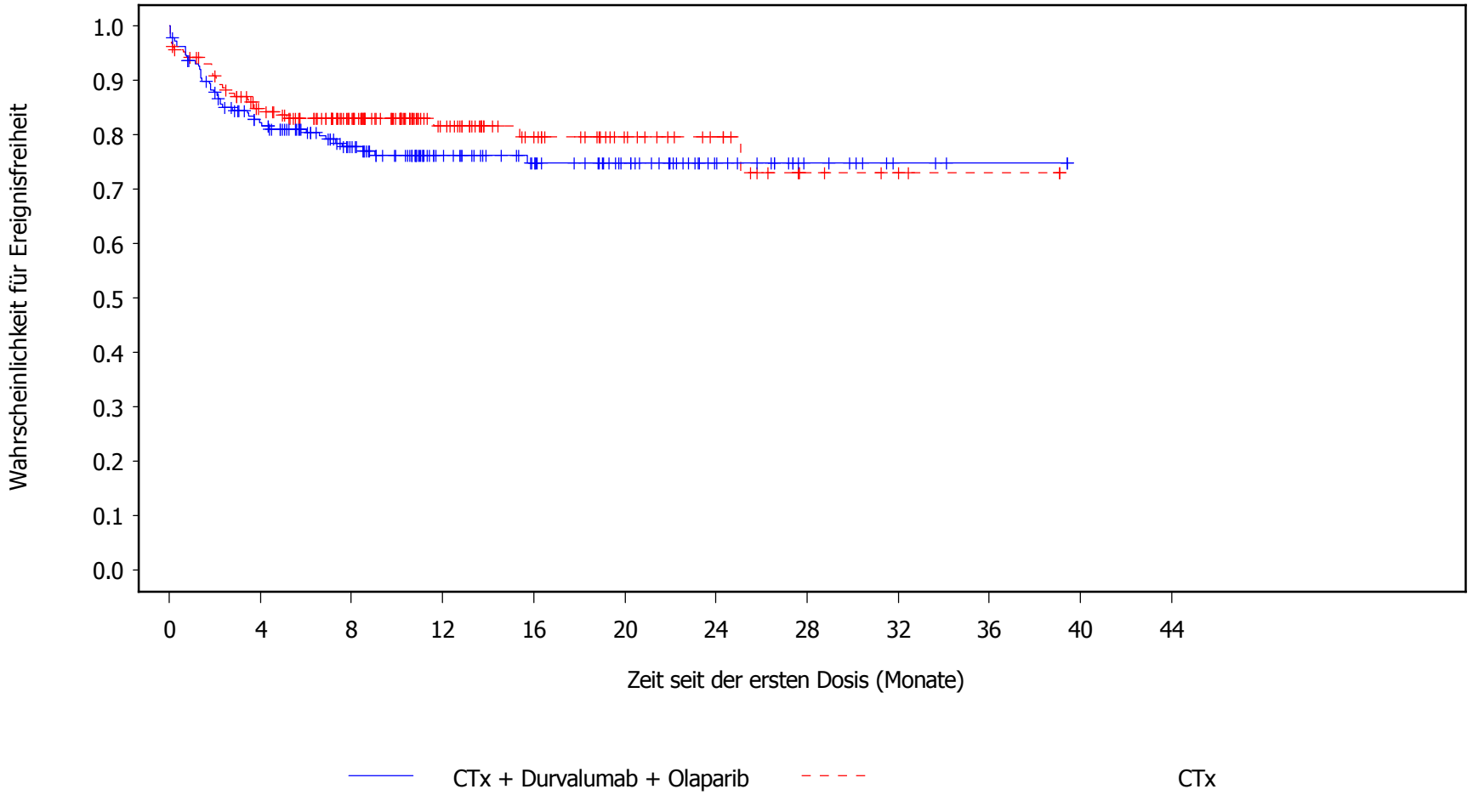
Figure 3.3.2.2D.53 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Gefaesserkrankungen
Patients with pMMR tumour status, DCO 18OCT2023

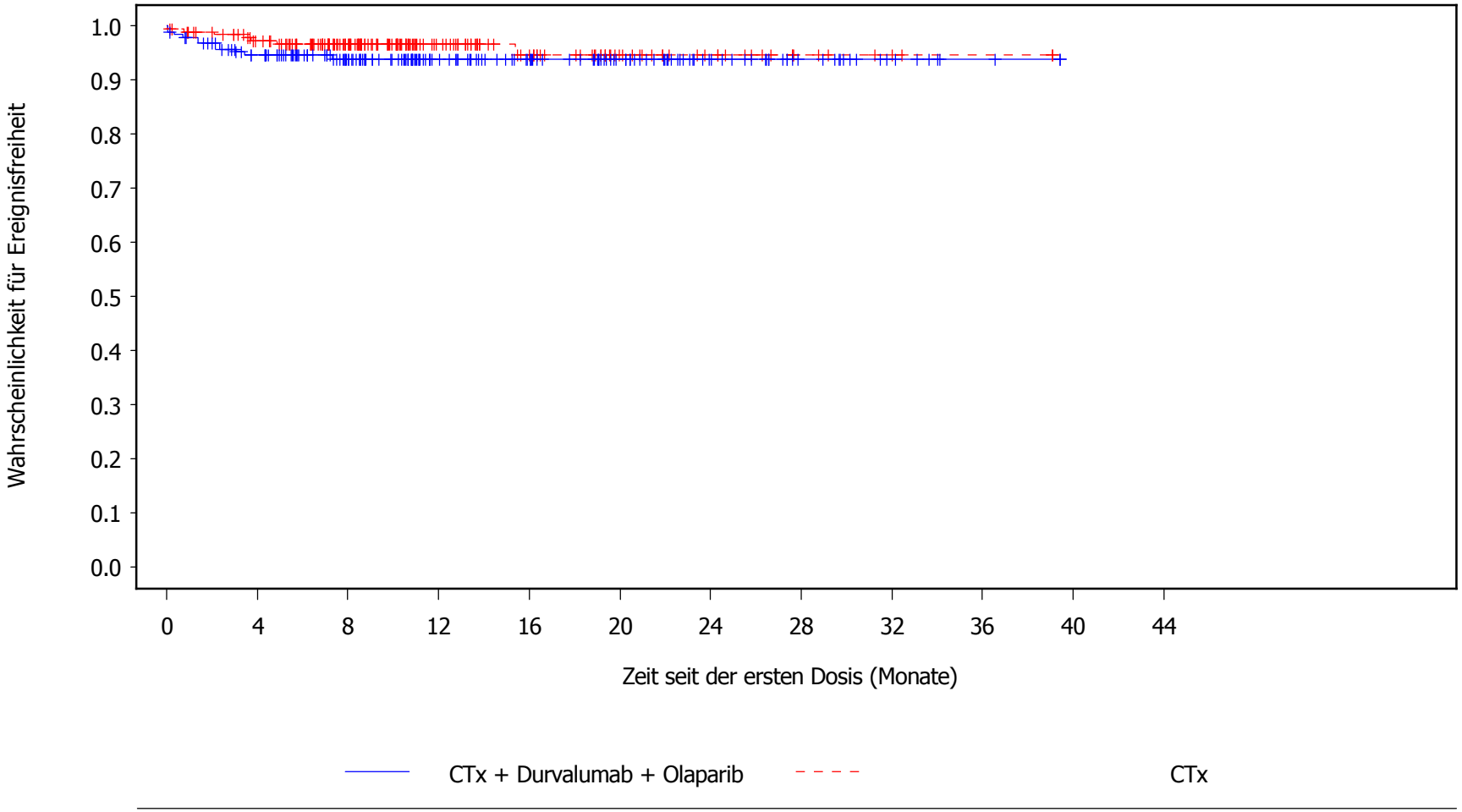


Anzahl an Patienten unter Risiko:

191	144	107	69	53	38	21	9	3	1	0	0	CTx + Durvalumab + Olaparib
190	146	109	59	37	23	15	5	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebca 15APR2024:10:33

Figure 3.3.2.2D.54 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypertonie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	166	130	88	70	51	30	16	7	2	0	0	CTx + Durvalumab + Olaparib
190	169	125	69	46	26	16	6	3	1	0	0	CTx

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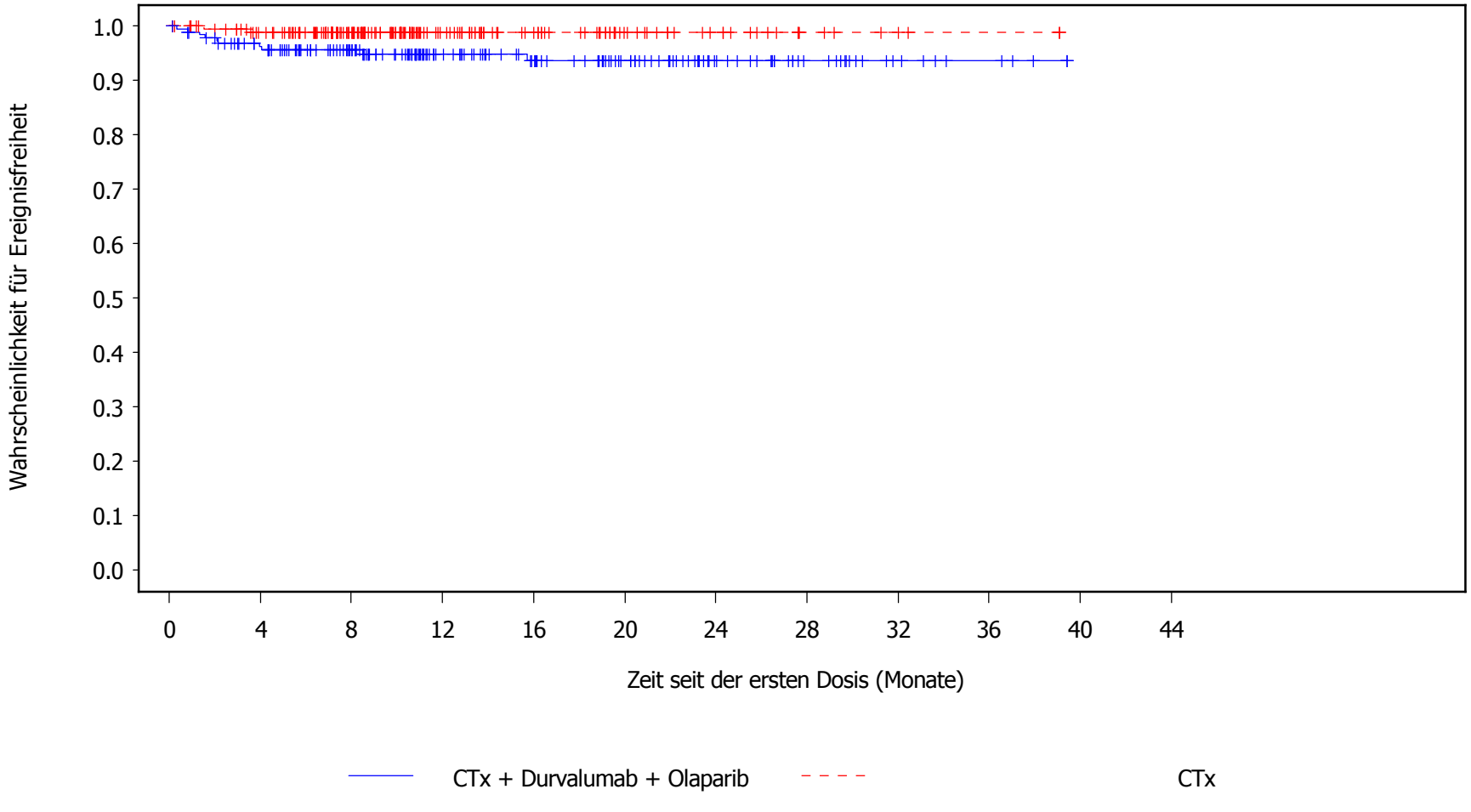
Figure 3.3.2.2D.55 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypotonie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	170	137	92	73	55	33	18	8	4	0	0	CTx + Durvalumab + Olaparib
190	172	127	70	47	26	16	6	3	1	0	0	CTx

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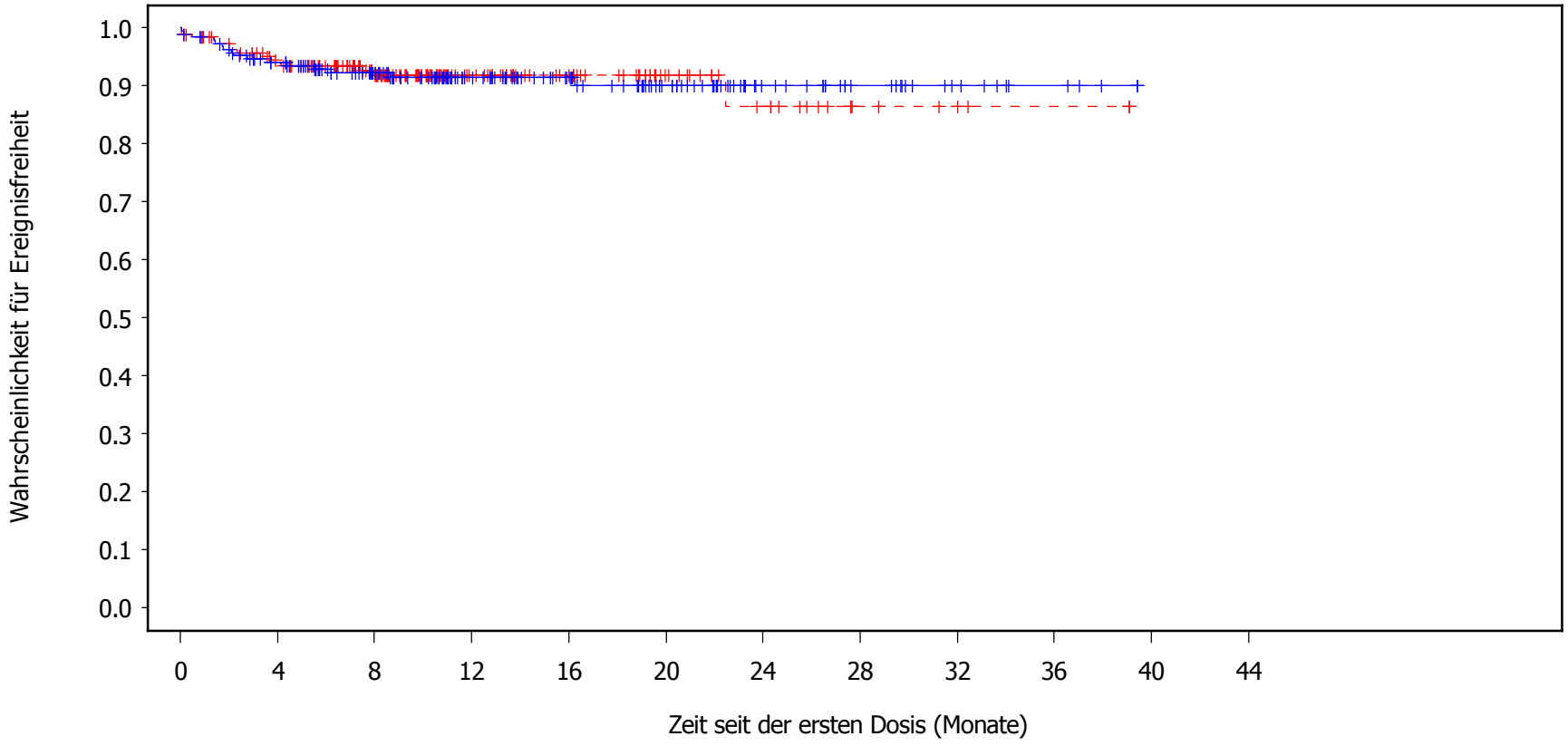
Figure 3.3.2.2D.56 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Herzerkrankungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	166	133	90	70	51	28	17	9	4	0	0	CTx + Durvalumab + Olaparib
190	164	119	64	45	25	15	5	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebcd 15APR2024:10:33

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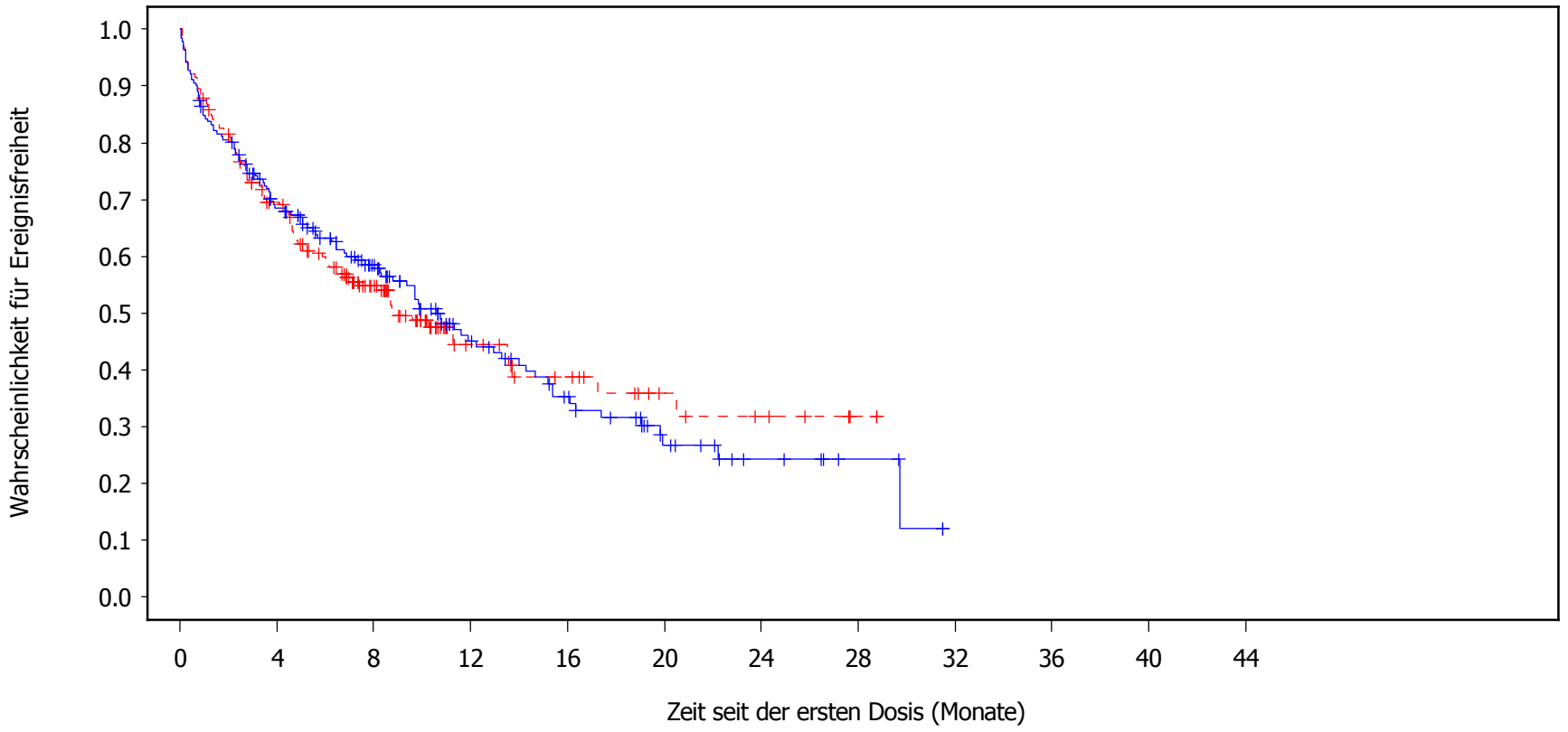
Figure 3.3.2.2D.57 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Infektionen und parasitaere Erkrankungen
Patients with pMMR tumour status, DCO 18OCT2023

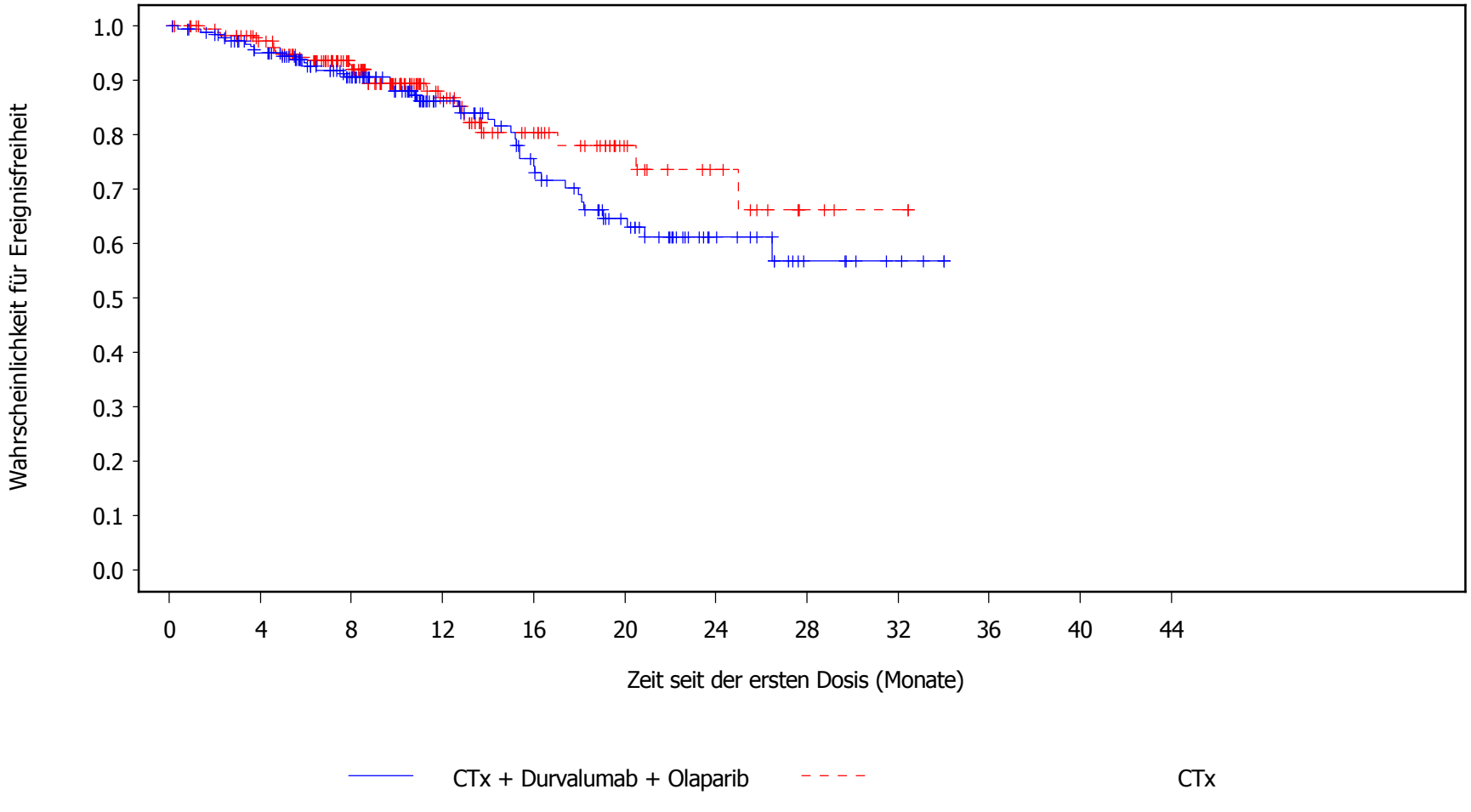


Anzahl an Patienten unter Risiko:

191	121	83	45	30	15	7	3	0	0	0	0	CTx + Durvalumab + Olaparib
190	124	72	26	17	9	6	1	0	0	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebce 15APR2024:10:33

Figure 3.3.2.2D.58 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: COVID-19
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	168	129	81	59	39	19	7	3	0	0	0	CTx + Durvalumab + Olaparib
190	169	121	62	39	19	11	3	1	0	0	0	CTx

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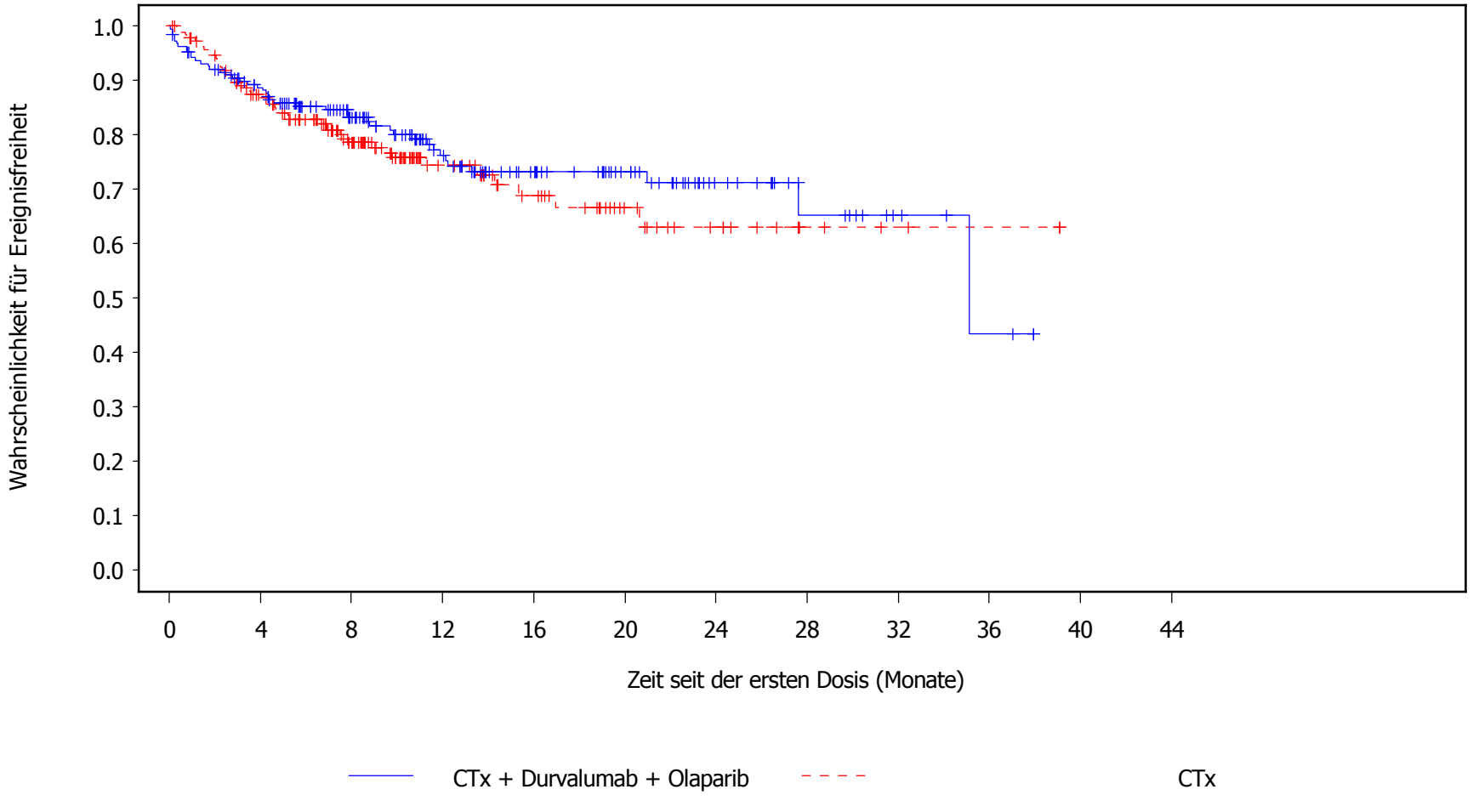
Figure 3.3.2.2D.59 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Harnwegsinfektion
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	157	118	77	56	40	21	11	5	2	0	0	CTx + Durvalumab + Olaparib
190	152	103	51	34	20	12	4	2	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebcg 15APR2024:10:33

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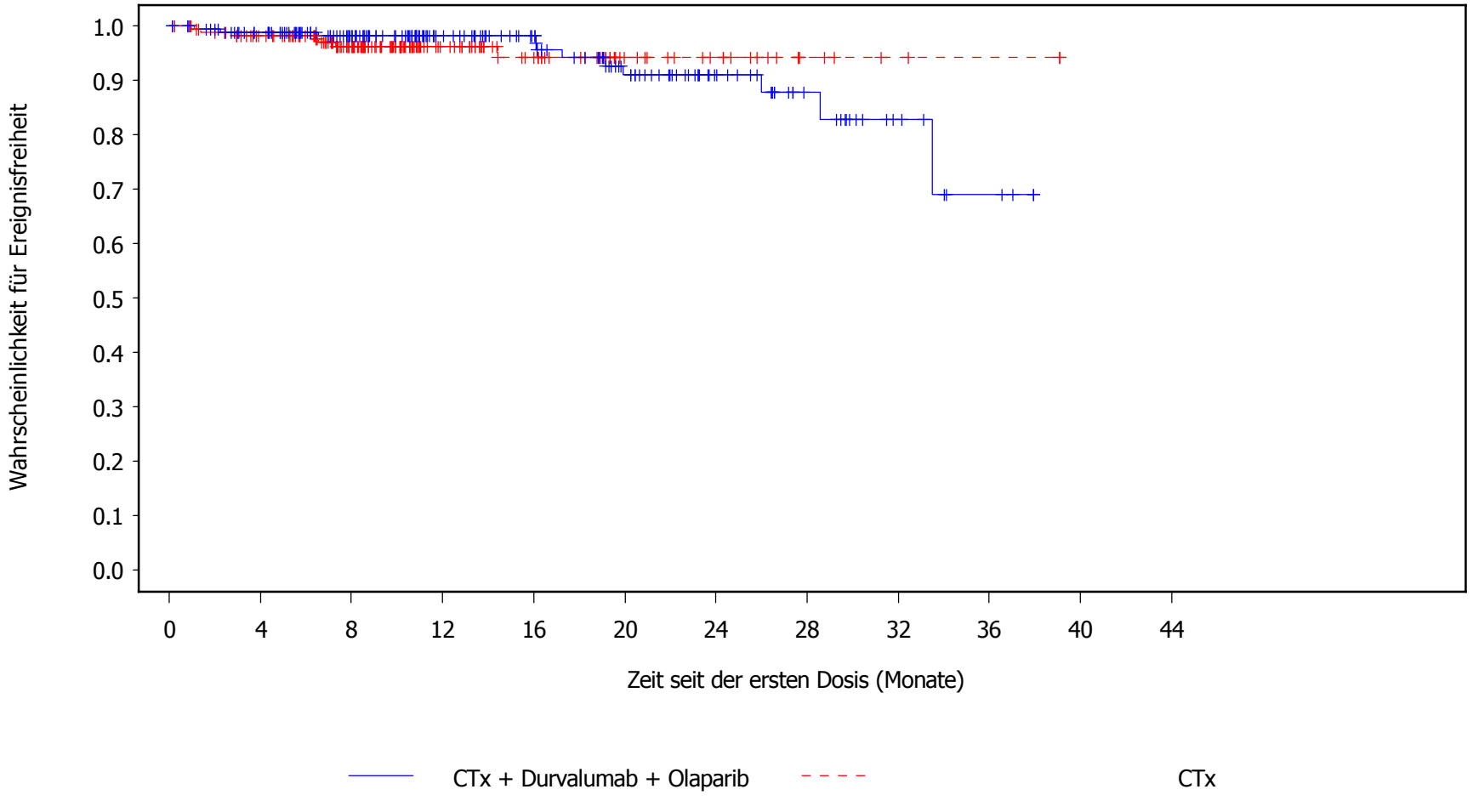
Figure 3.3.2.2D.60 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Infektion der oberen Atemwege
Patients with pMMR tumour status, DCO 18OCT2023

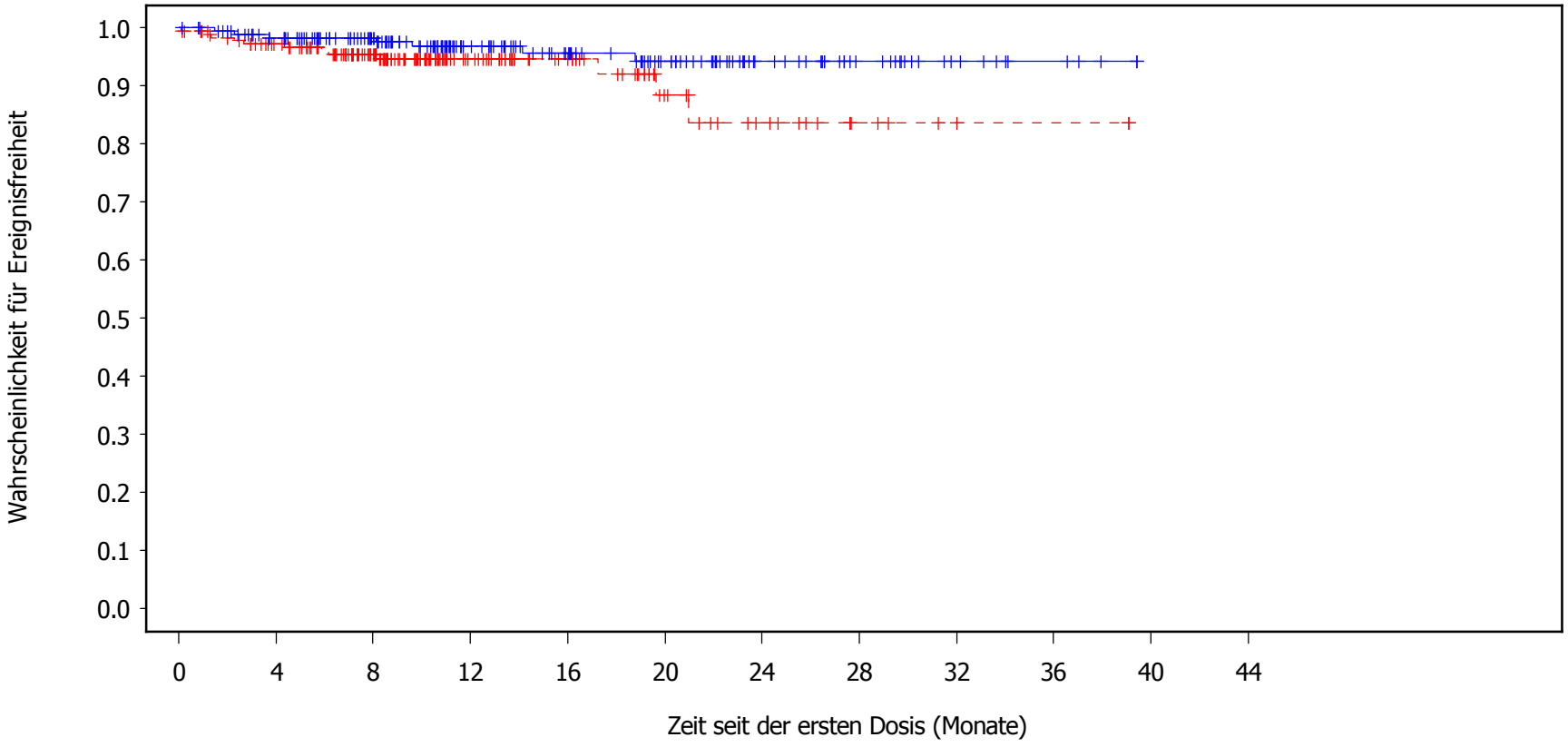


Anzahl an Patienten unter Risiko:

191	174	139	96	78	54	33	18	8	3	0	0	CTx + Durvalumab + Olaparib
190	171	123	64	43	22	15	5	2	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebch 15APR2024:10:33

Figure 3.3.2.2D.61 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Nasopharyngitis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	173	139	94	74	56	33	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	169	125	65	44	22	13	5	2	1	0	0	CTx

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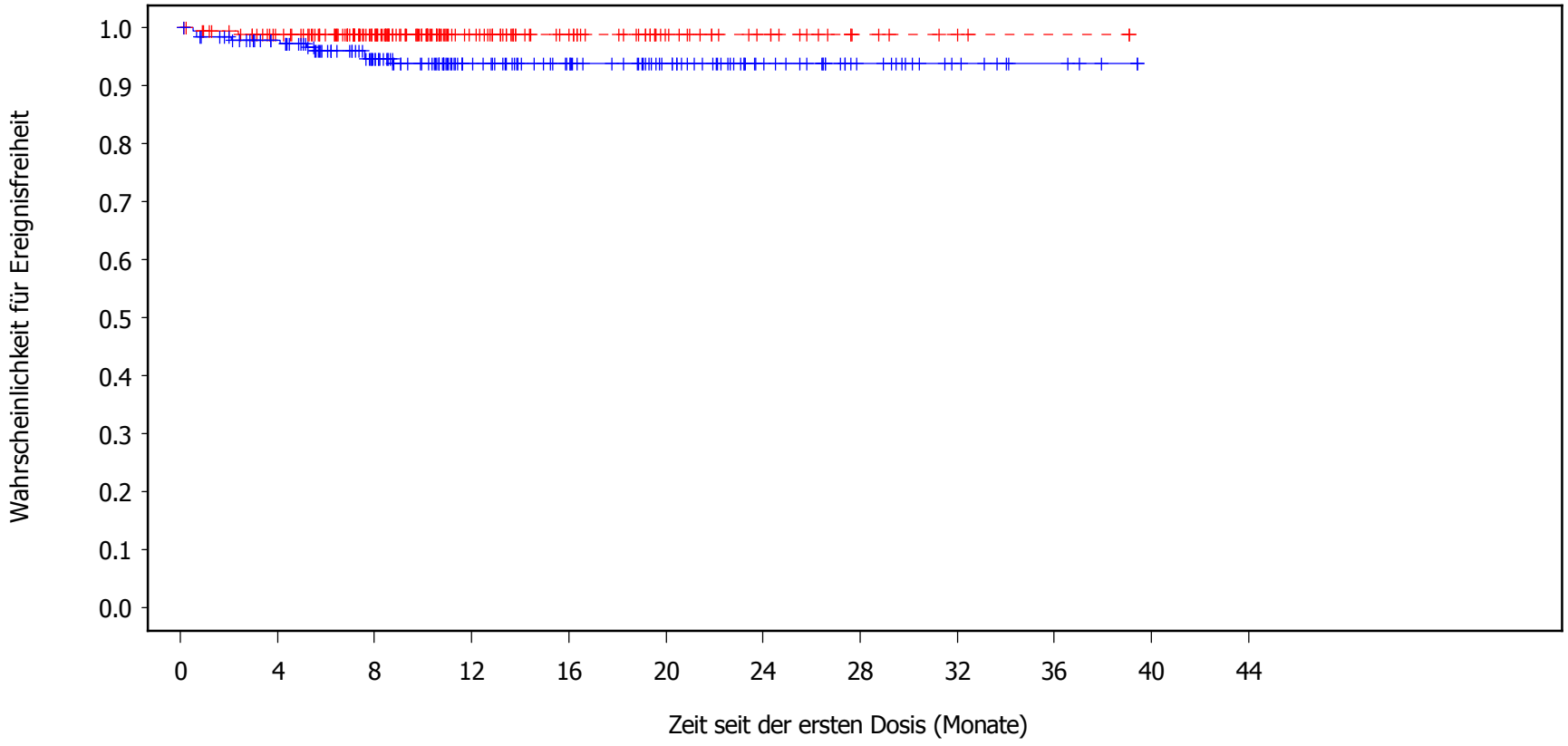
Figure 3.3.2.2D.62 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Leber- und Gallenerkrankungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	172	133	91	72	54	33	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	172	127	69	46	26	16	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebcj 15APR2024:10:33

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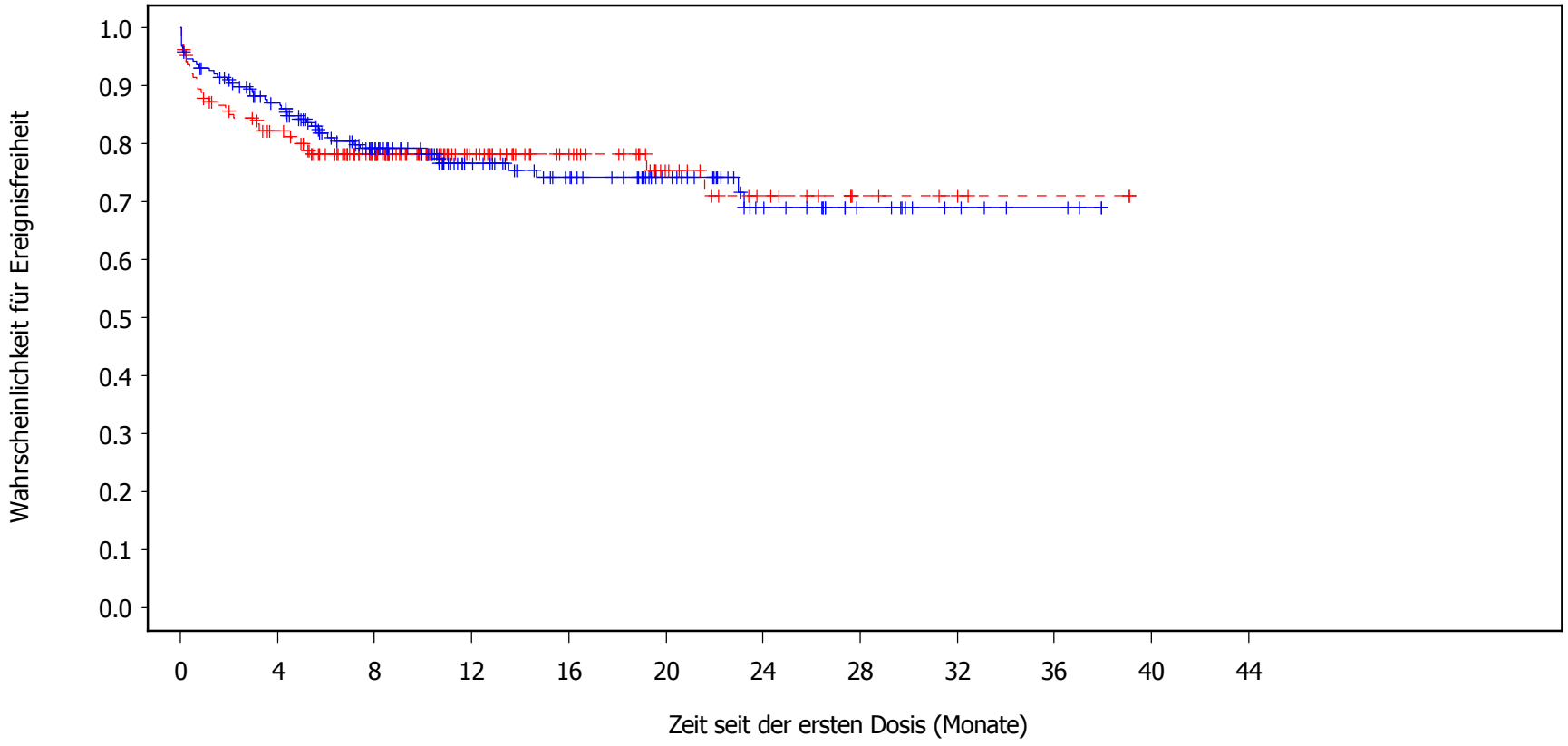
Figure 3.3.2.2D.63 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Psychiatrische Erkrankungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	153	111	73	56	41	23	12	6	3	0	0	CTx + Durvalumab + Olaparib
190	146	106	58	39	21	12	5	3	1	0	0	CTx

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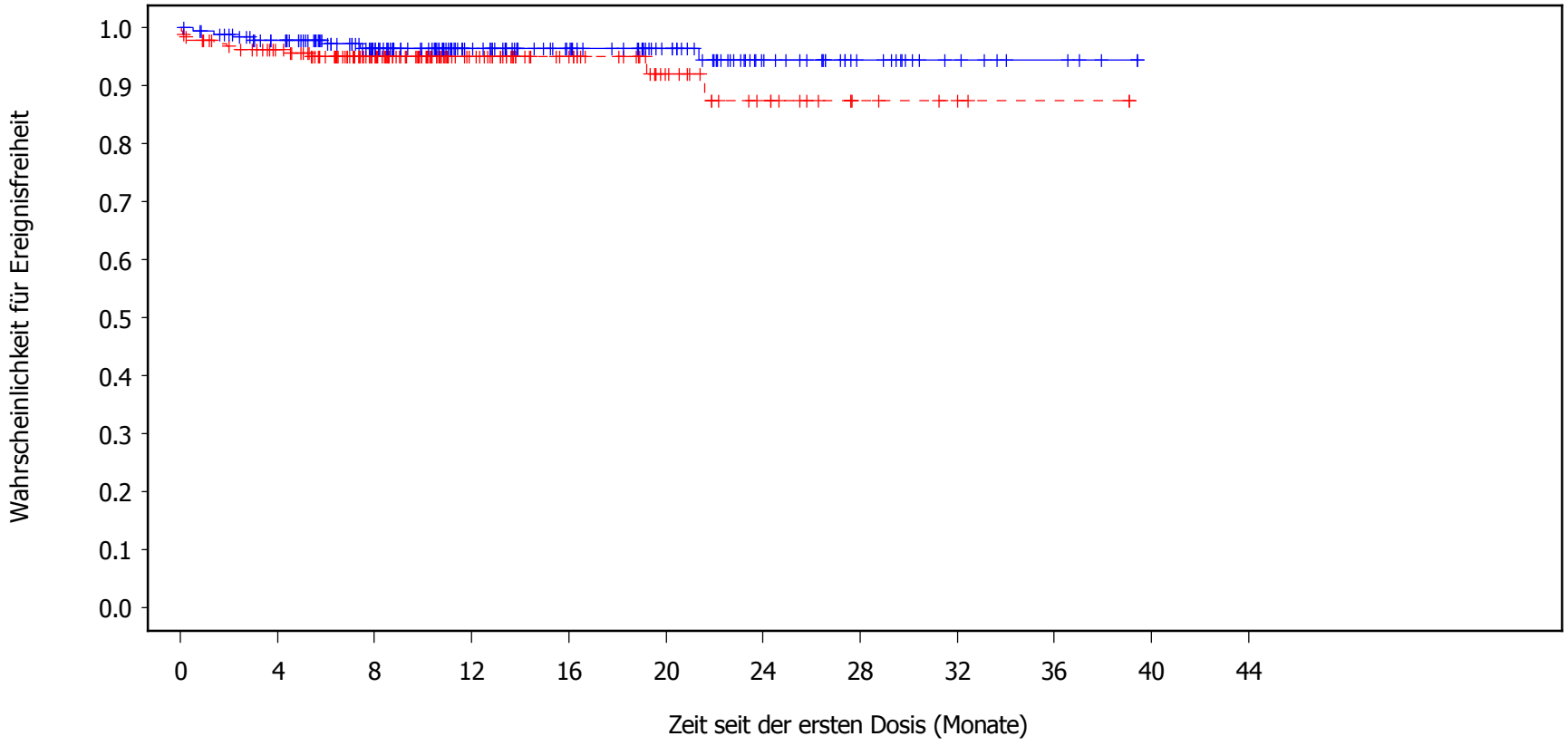
Figure 3.3.2.2D.64 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Angst
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	172	135	92	73	56	32	17	8	4	0	0	CTx + Durvalumab + Olaparib
190	168	123	68	45	25	14	5	3	1	0	0	CTx

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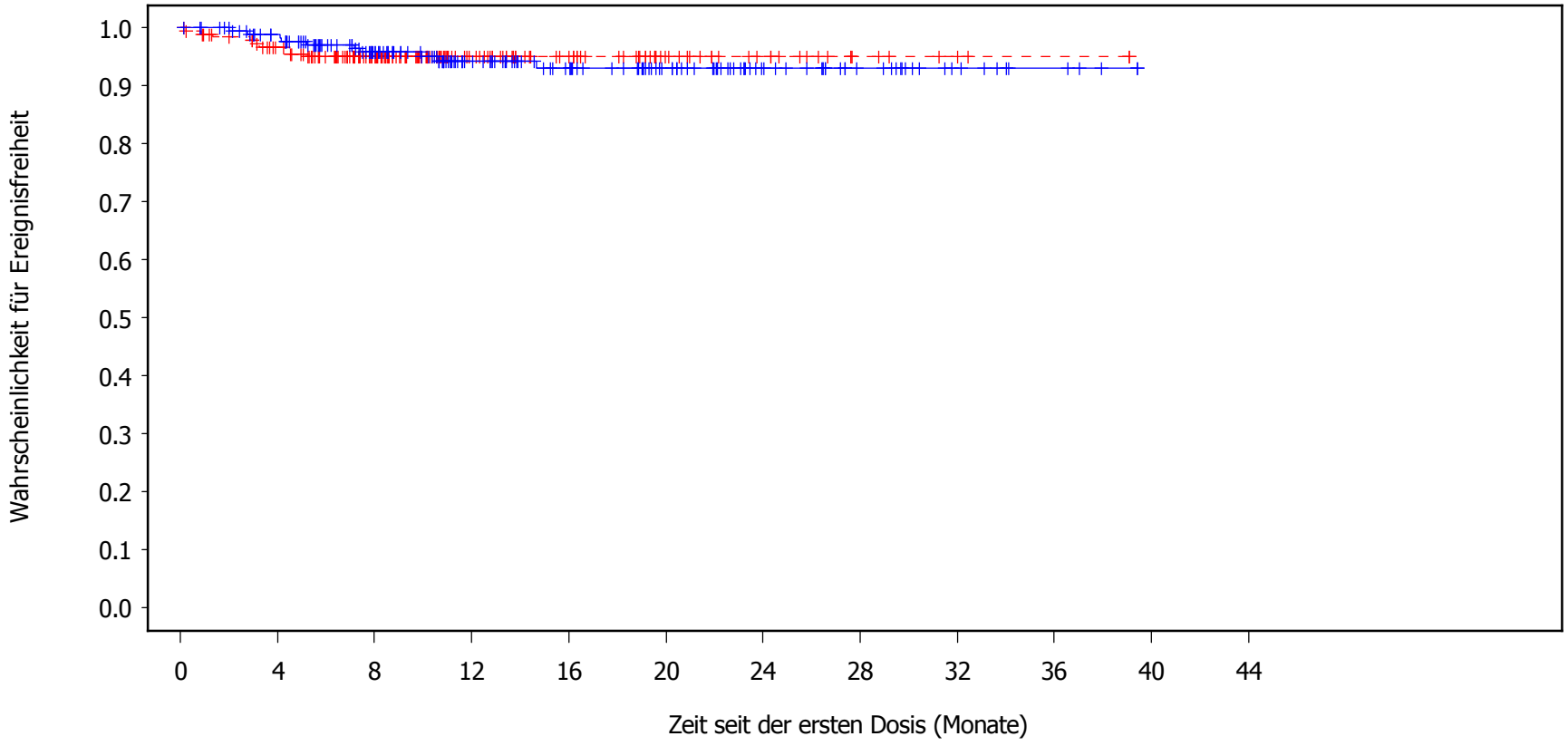
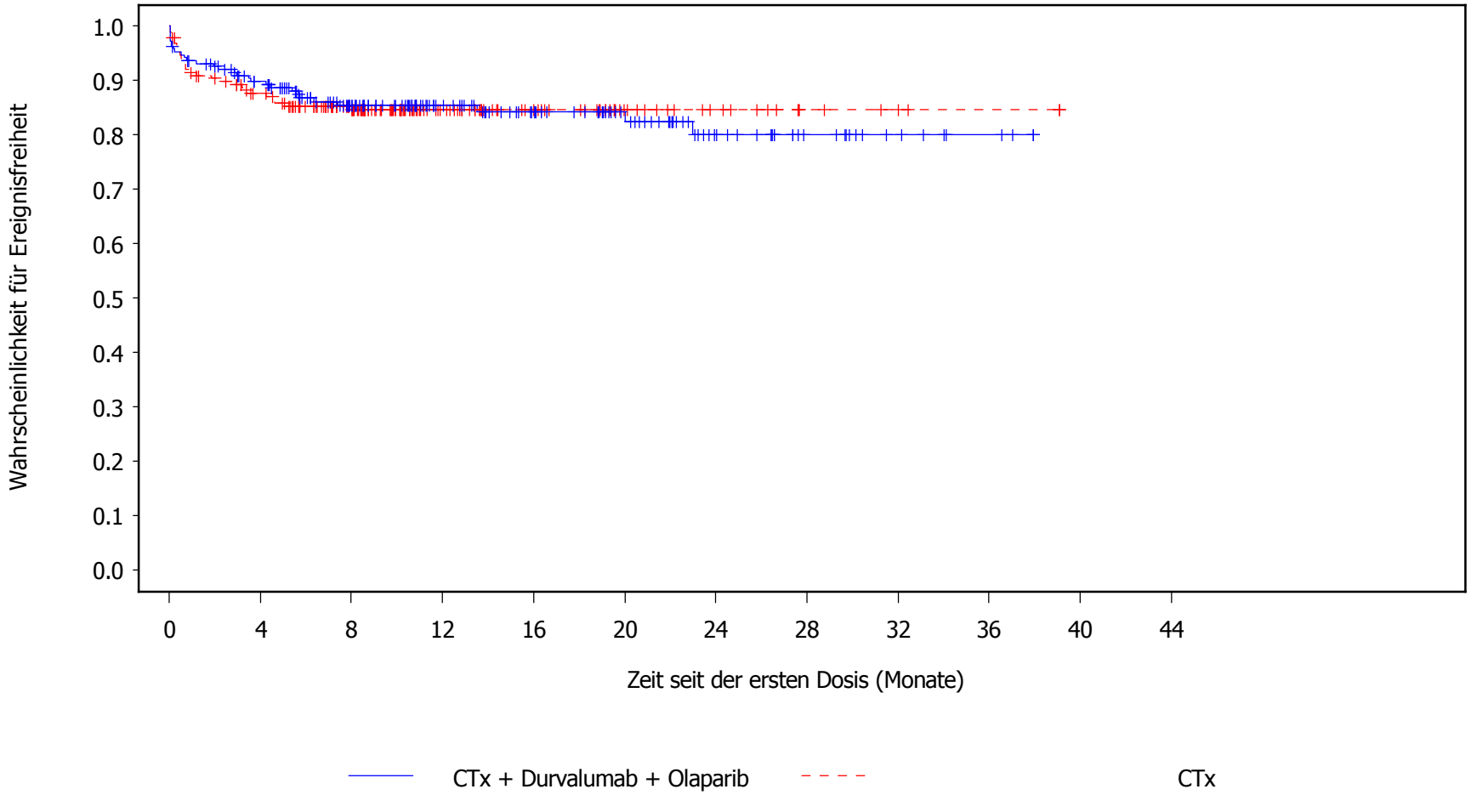
Figure 3.3.2.2D.65 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Depression
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	174	136	93	73	54	32	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	169	124	67	46	26	16	6	3	1	0	0	CTx

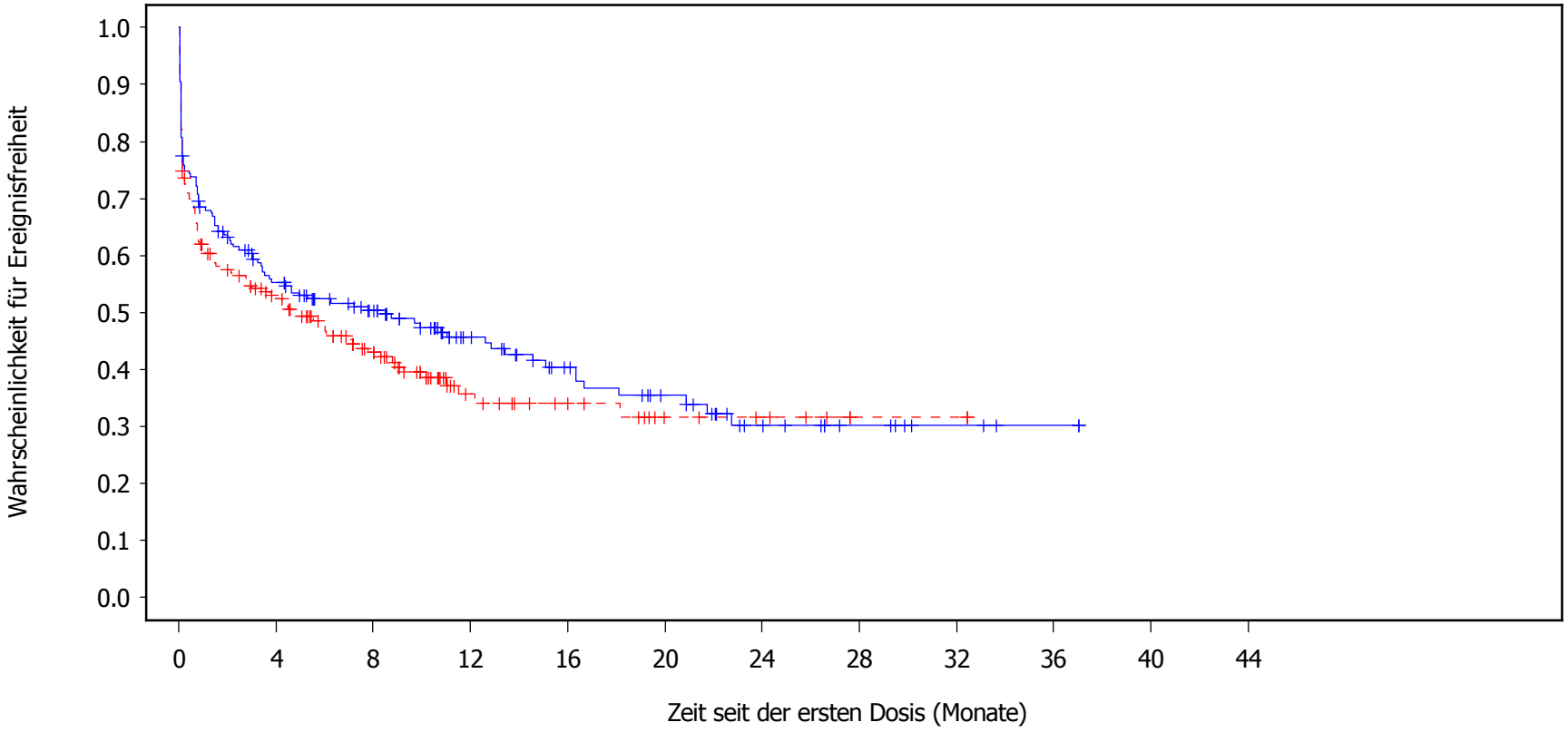
Figure 3.3.2.2D.66 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schlaflosigkeit
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	157	118	81	63	47	27	14	7	3	0	0	CTx + Durvalumab + Olaparib
190	154	113	59	39	21	13	5	3	1	0	0	CTx

Figure 3.3.2.2D.67 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	97	74	47	33	24	13	7	3	1	0	0	CTx + Durvalumab + Olaparib
190	87	55	23	16	8	6	1	1	0	0	0	CTx

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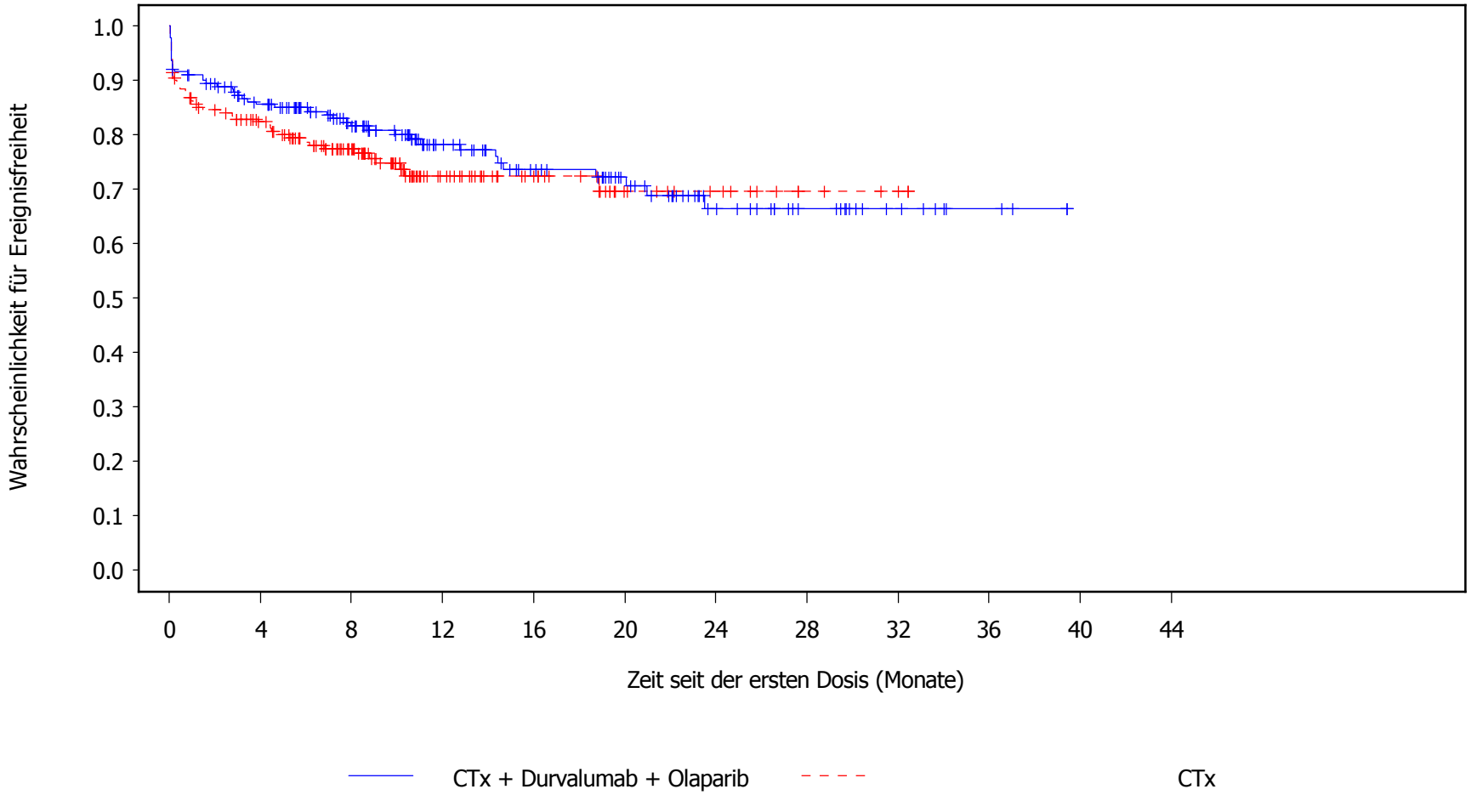
Figure 3.3.2.2D.68 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Arthralgie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	150	116	75	57	44	26	16	8	3	0	0	CTx + Durvalumab + Olaparib
190	141	100	48	32	16	11	4	2	0	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebcp 15APR2024:10:33

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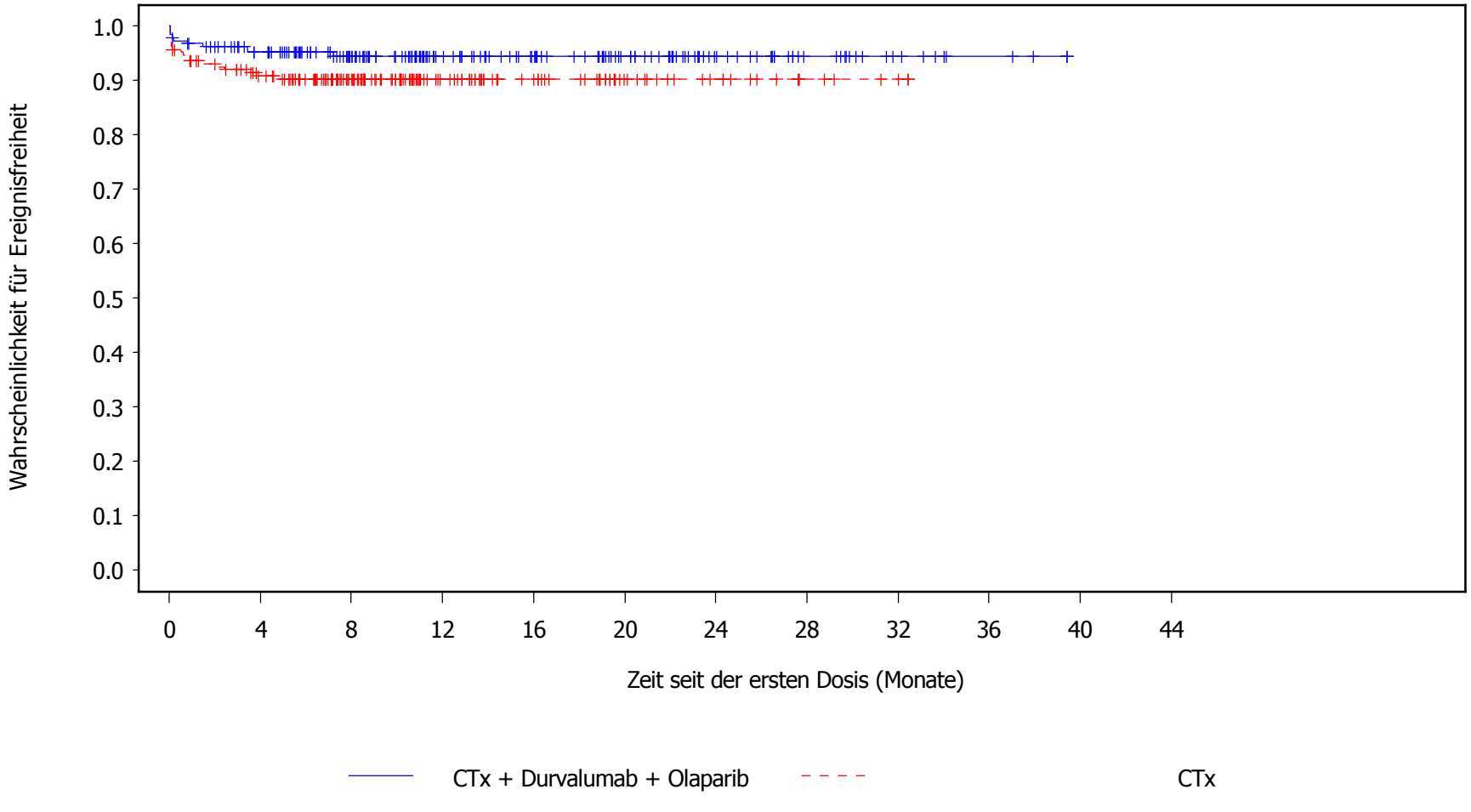
Figure 3.3.2.2D.69 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Knochenschmerzen
Patients with pMMR tumour status, DCO 18OCT2023

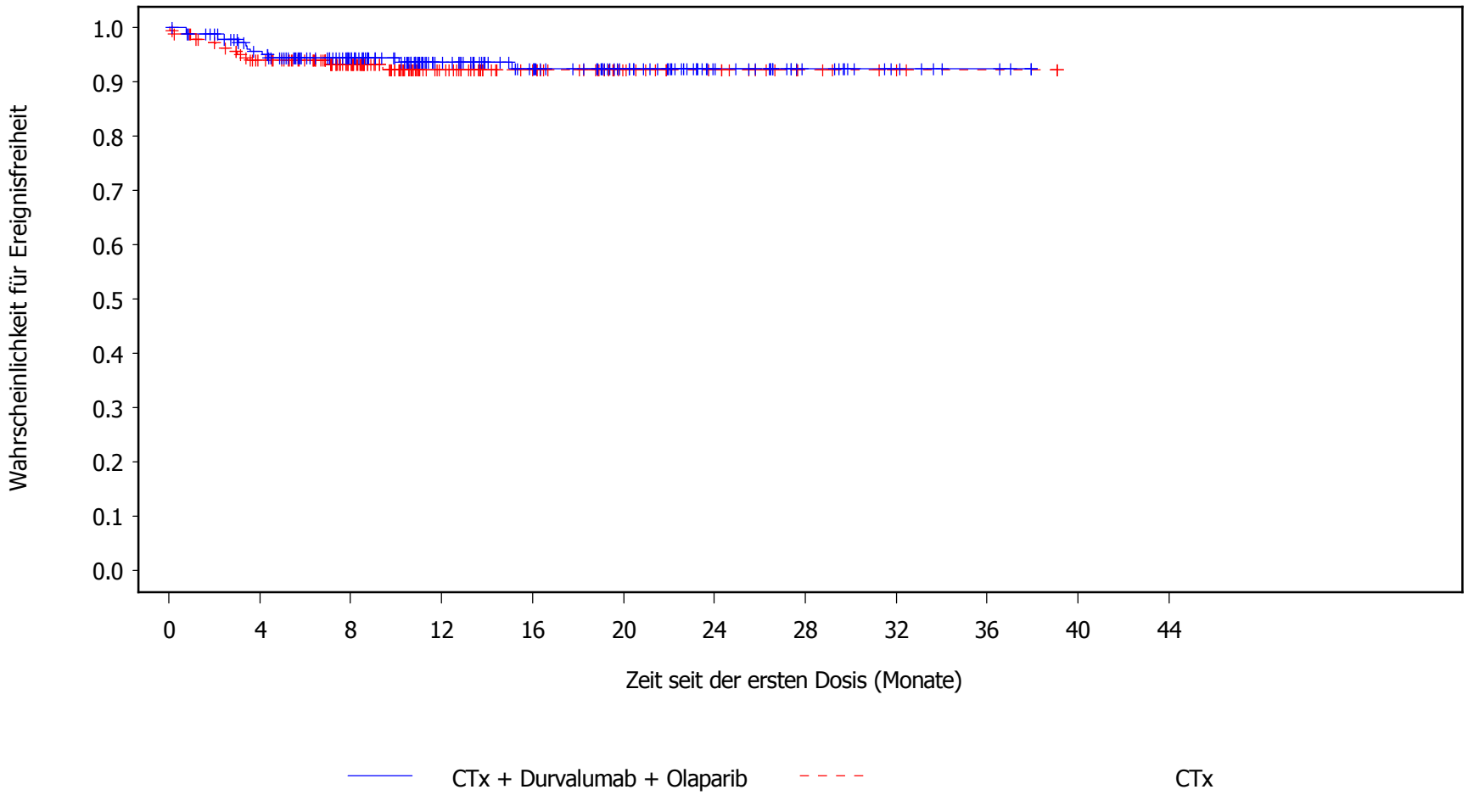


Anzahl an Patienten unter Risiko:

191	167	131	90	73	54	32	17	8	3	0	0	CTx + Durvalumab + Olaparib
190	157	113	63	43	23	14	5	2	0	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebcq 15APR2024:10:33

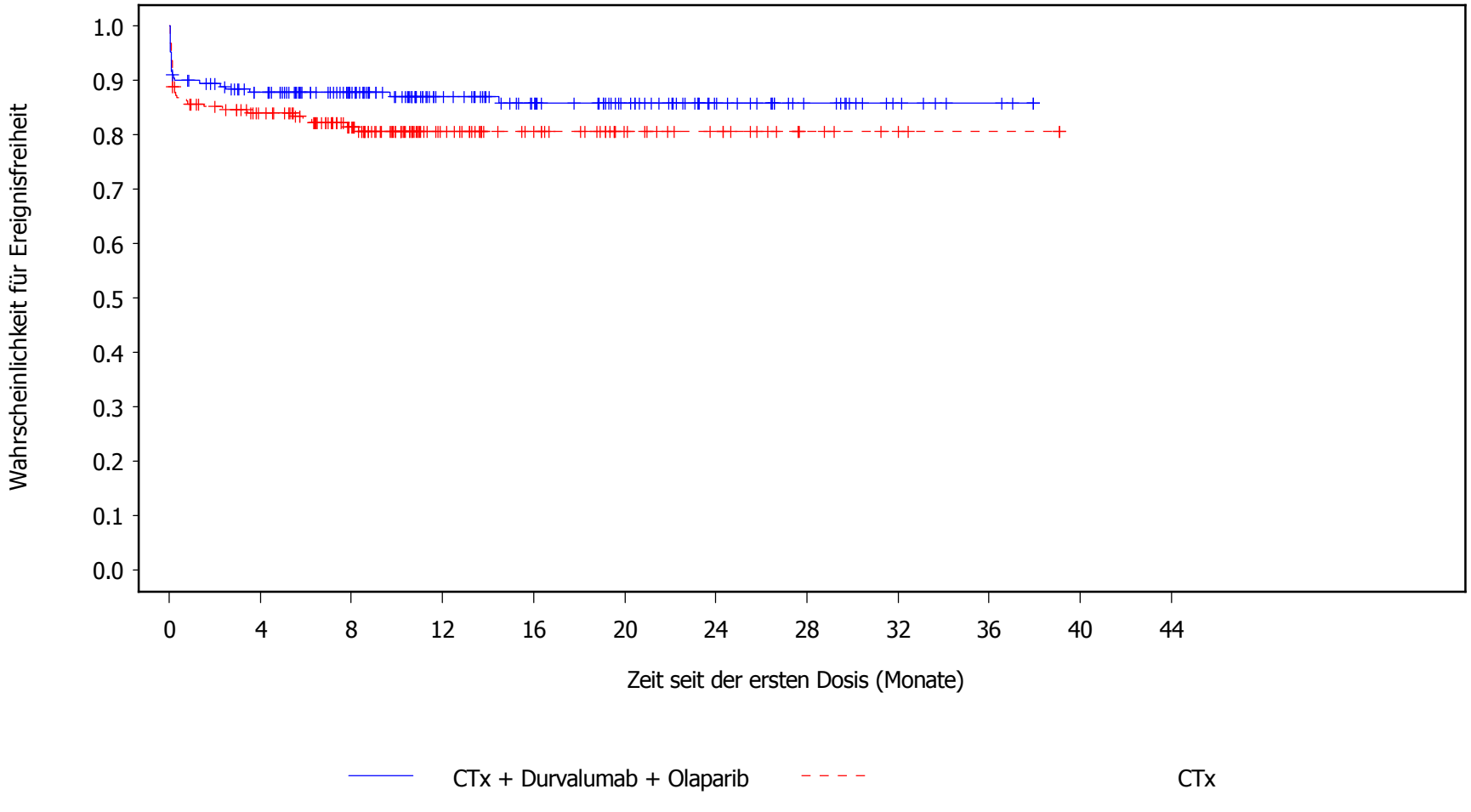
Figure 3.3.2.2D.70 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Muskulaere Schwaeche
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	169	135	91	71	52	29	15	7	3	0	0	CTx + Durvalumab + Olaparib
190	163	123	65	44	23	16	6	3	1	0	0	CTx

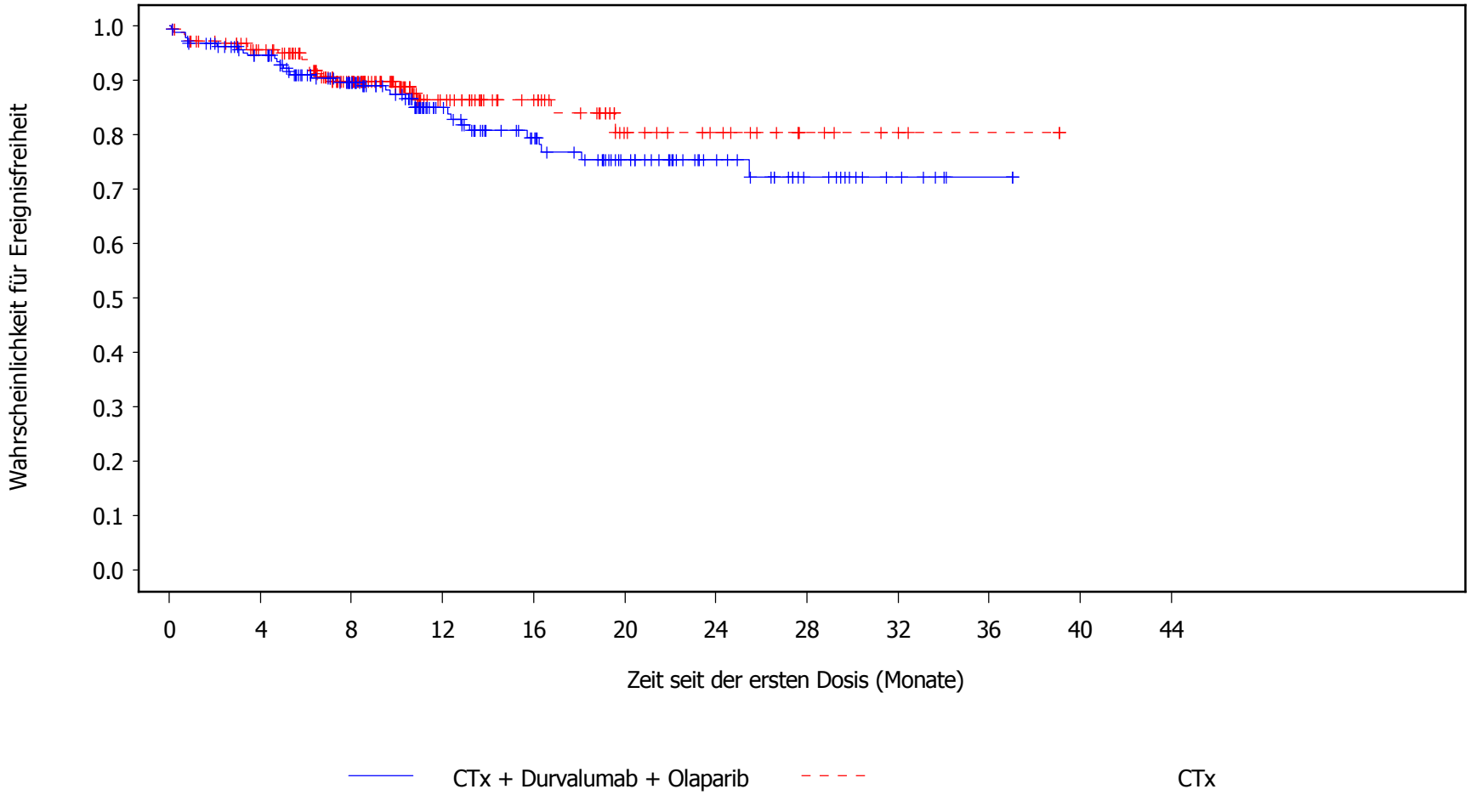
Figure 3.3.2.2D.71 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Myalgie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	154	122	83	65	49	29	16	7	3	0	0	CTx + Durvalumab + Olaparib
190	144	106	55	39	23	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.72 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Rueckenschmerzen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	167	128	84	62	43	27	14	6	1	0	0	CTx + Durvalumab + Olaparib
190	166	118	59	41	20	14	6	3	1	0	0	CTx

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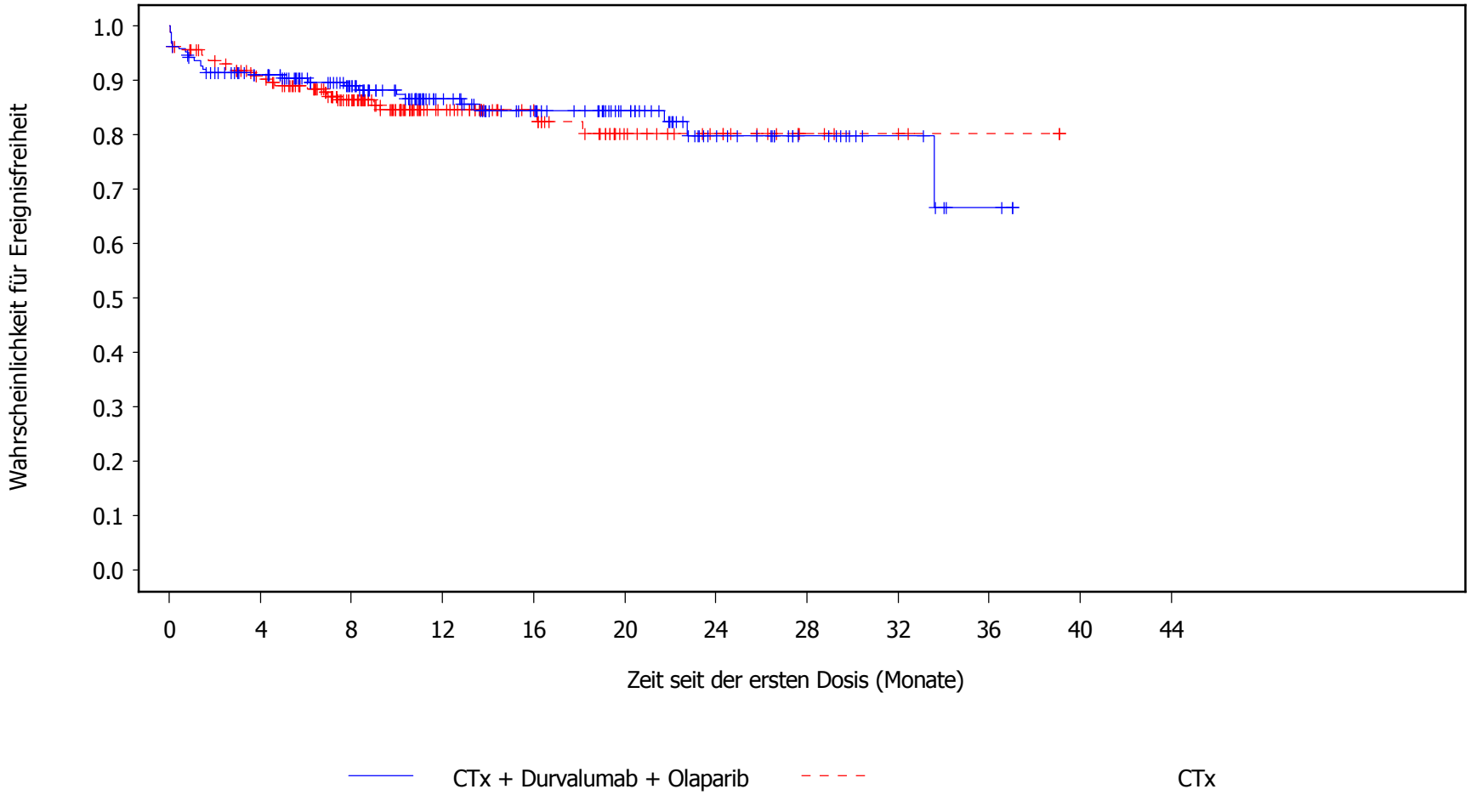
Figure 3.3.2.2D.73 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Schmerz in einer Extremitaet
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	159	126	85	66	48	26	14	7	2	0	0	CTx + Durvalumab + Olaparib
190	158	112	61	43	22	14	5	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebcu 15APR2024:10:33

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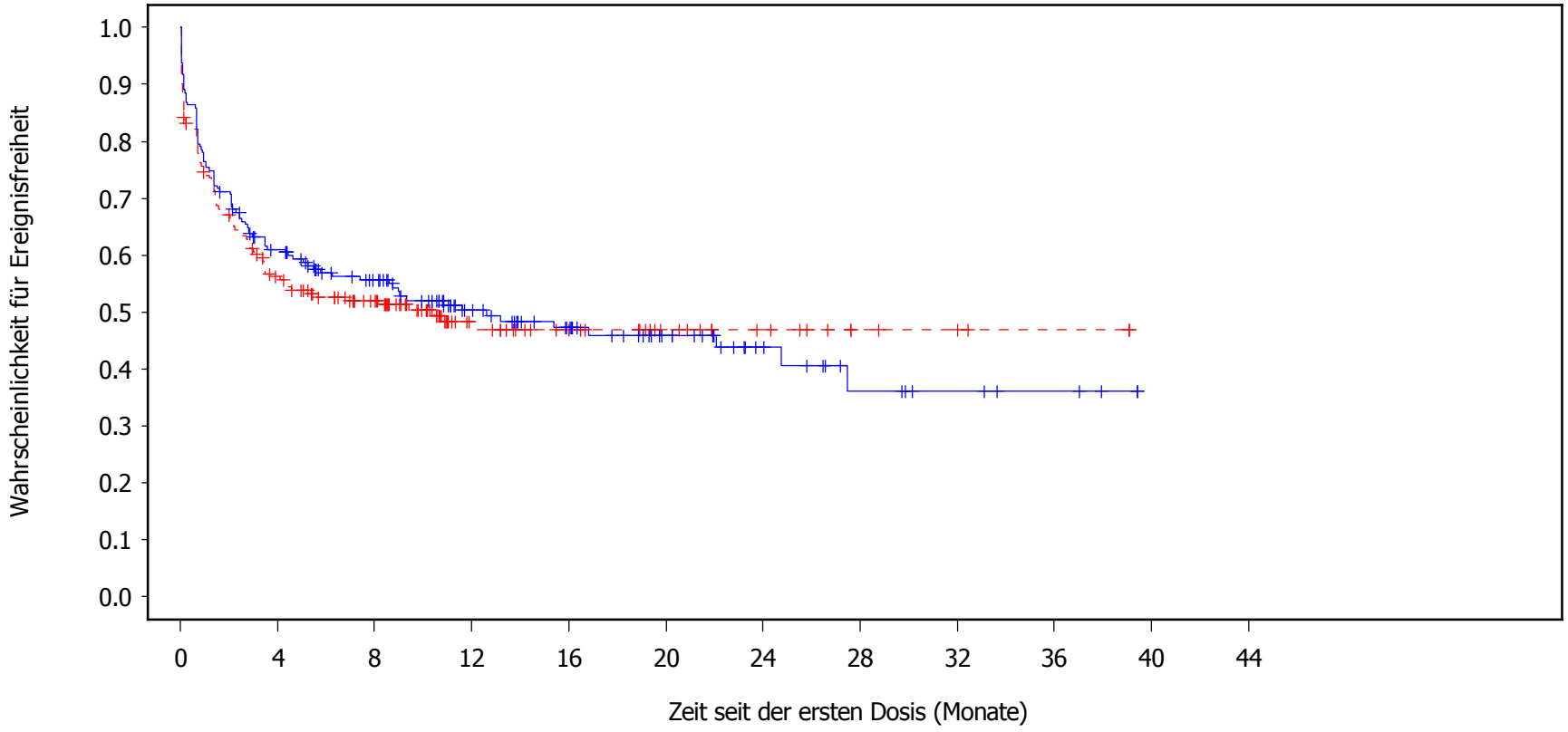
Figure 3.3.2.2D.74 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Stoffwechsel- und Ernaehrungsstoerungen
Patients with pMMR tumour status, DCO 18OCT2023

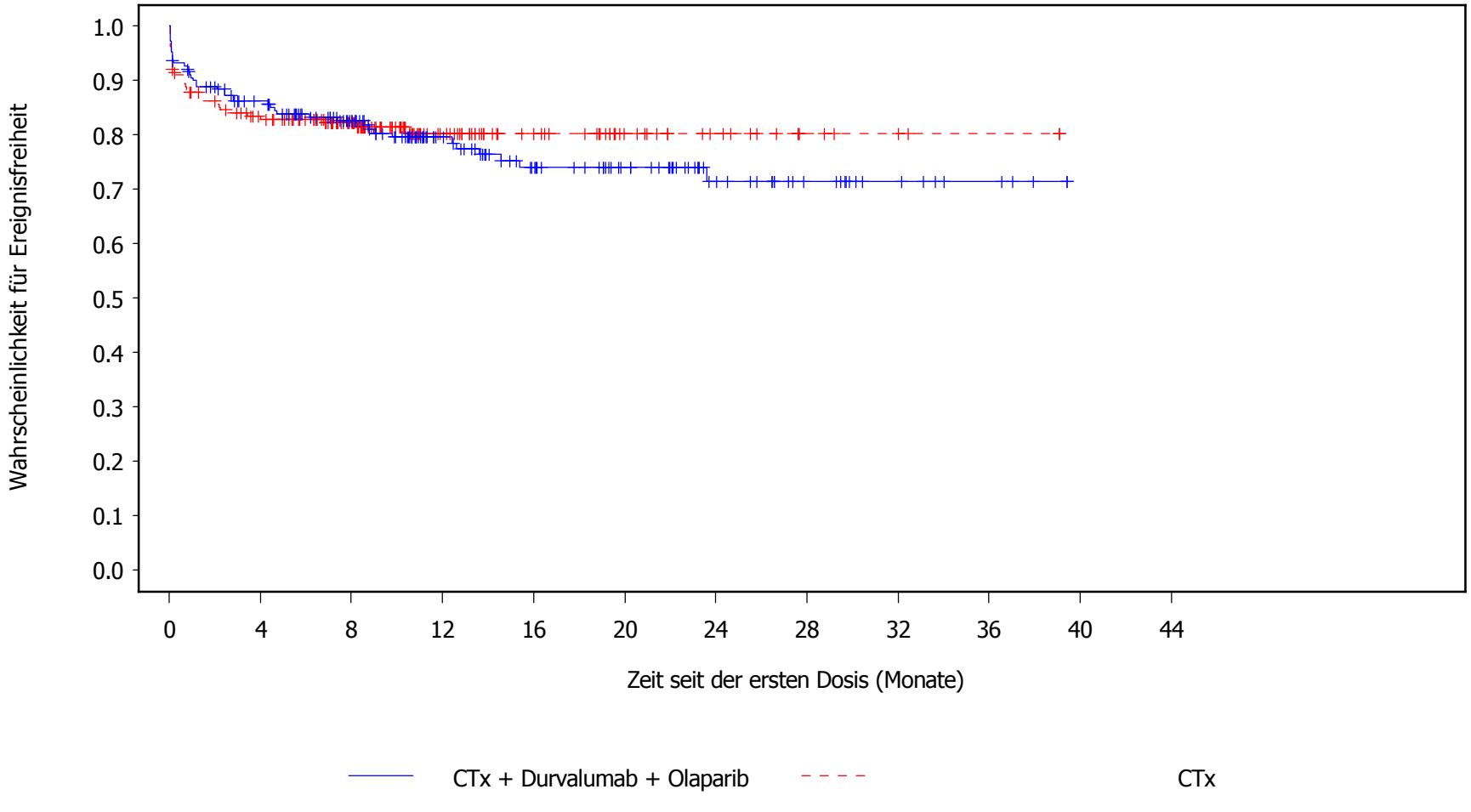


Anzahl an Patienten unter Risiko:

191	110	84	54	40	27	15	8	5	3	0	0	CTx + Durvalumab + Olaparib
190	99	74	35	25	16	10	4	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebcv 15APR2024:10:33

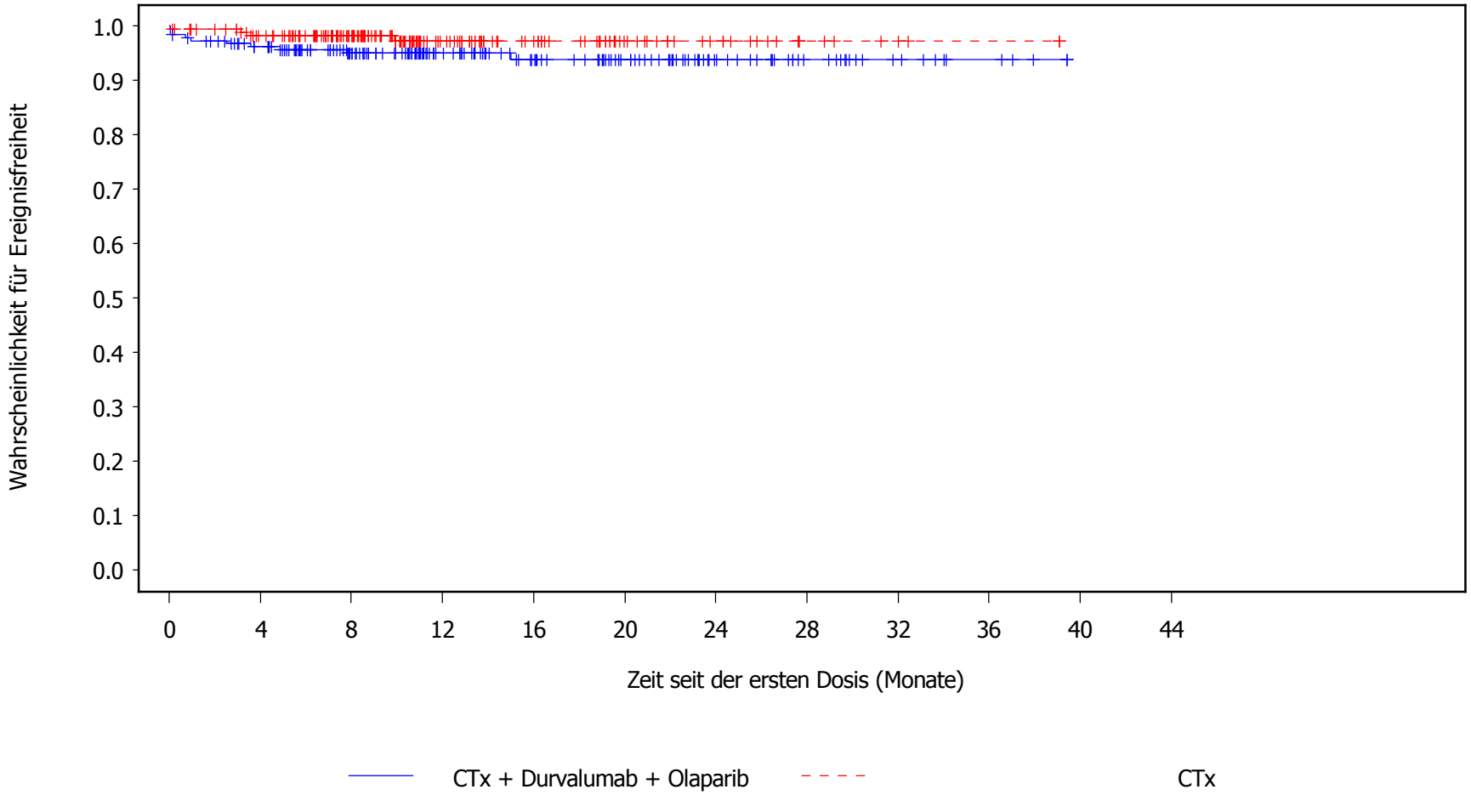
Figure 3.3.2.2D.75 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Appetit vermindert
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	151	120	79	58	44	26	15	8	4	0	0	CTx + Durvalumab + Olaparib
190	146	107	57	37	21	13	5	3	1	0	0	CTx

Figure 3.3.2.2D.76 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypalbuminaemie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	171	136	94	73	55	32	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	172	127	70	47	26	16	6	3	1	0	0	CTx

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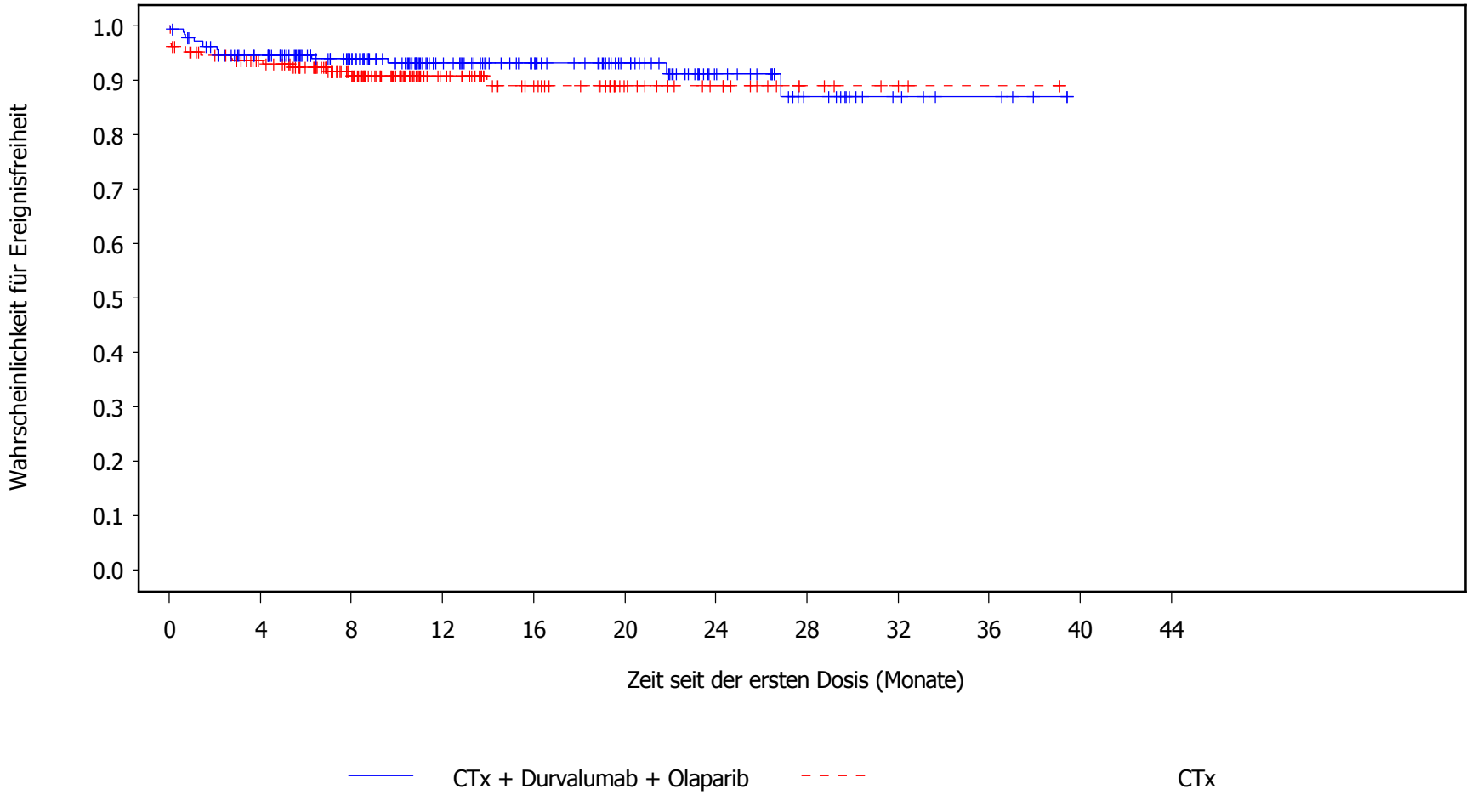
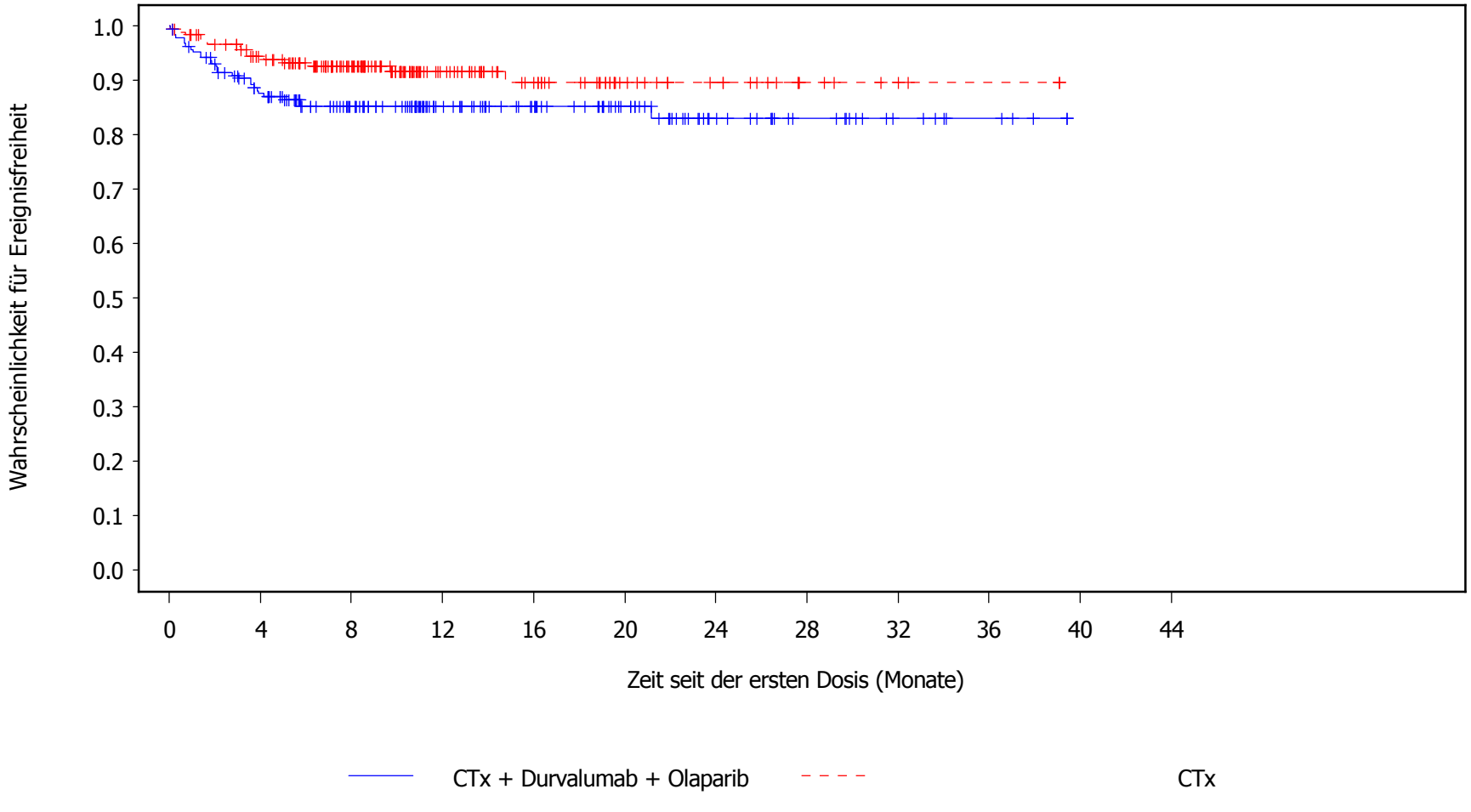
Figure 3.3.2.2D.77 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hyperglykaemie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	167	135	92	73	55	32	16	7	4	0	0	CTx + Durvalumab + Olaparib
190	162	117	62	42	25	16	6	3	1	0	0	CTx

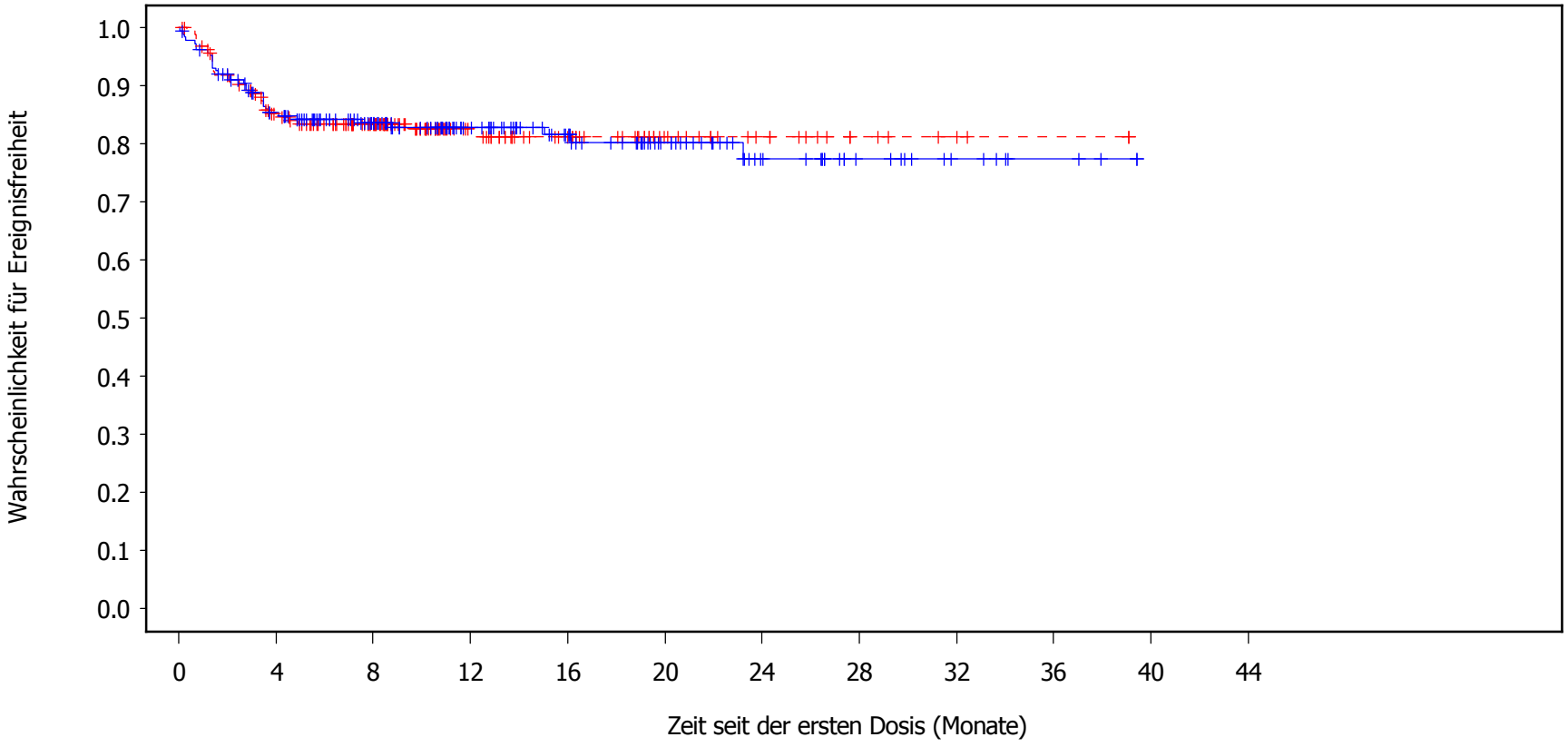
Figure 3.3.2.2D.78 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypokaliaemie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	155	120	82	65	47	26	16	8	4	0	0	CTx + Durvalumab + Olaparib
190	164	120	64	42	22	15	6	3	1	0	0	CTx

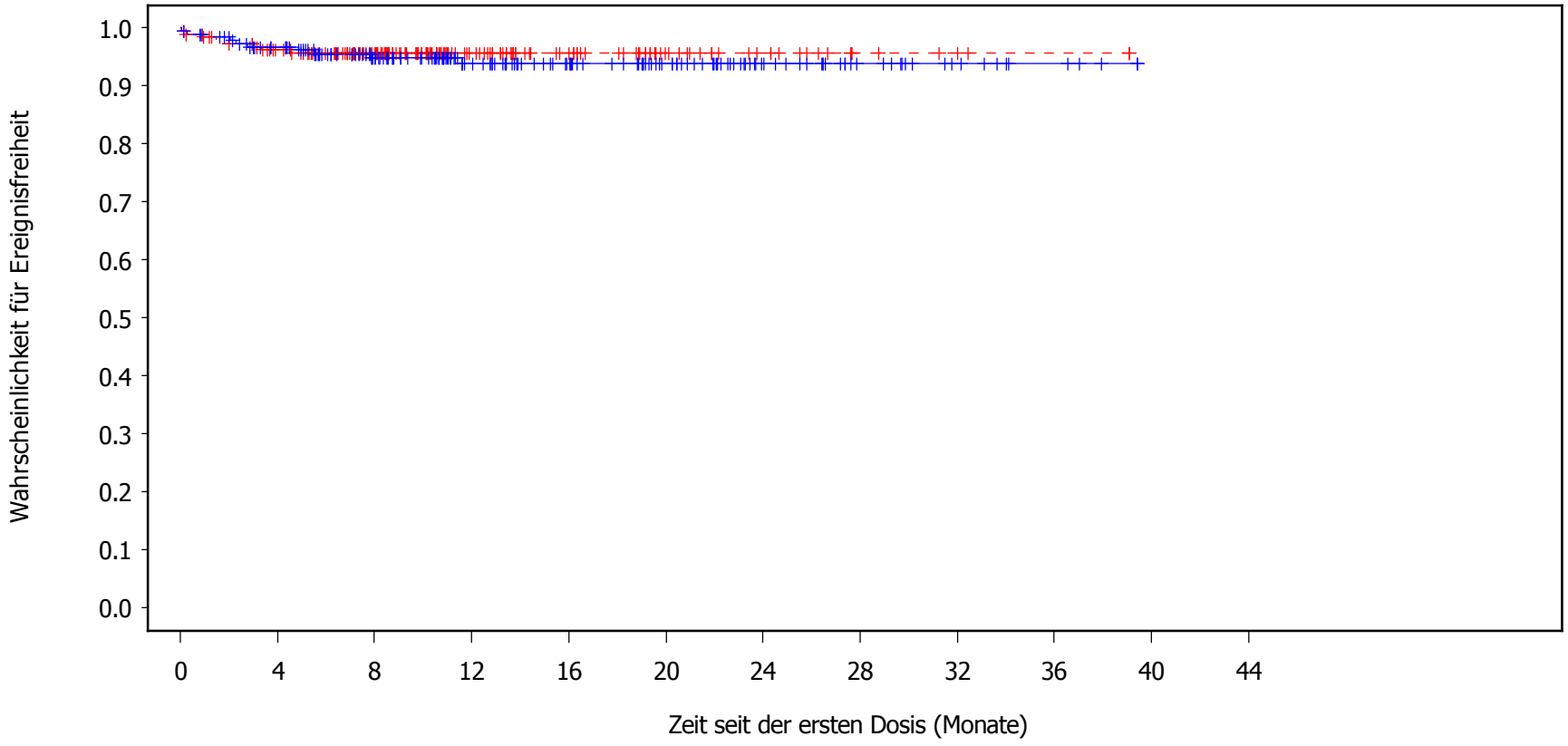
Figure 3.3.2.2D.79 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hypomagnesiaemie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	151	118	82	62	42	24	13	7	3	0	0	CTx + Durvalumab + Olaparib
190	148	113	61	43	23	14	6	3	1	0	0	CTx

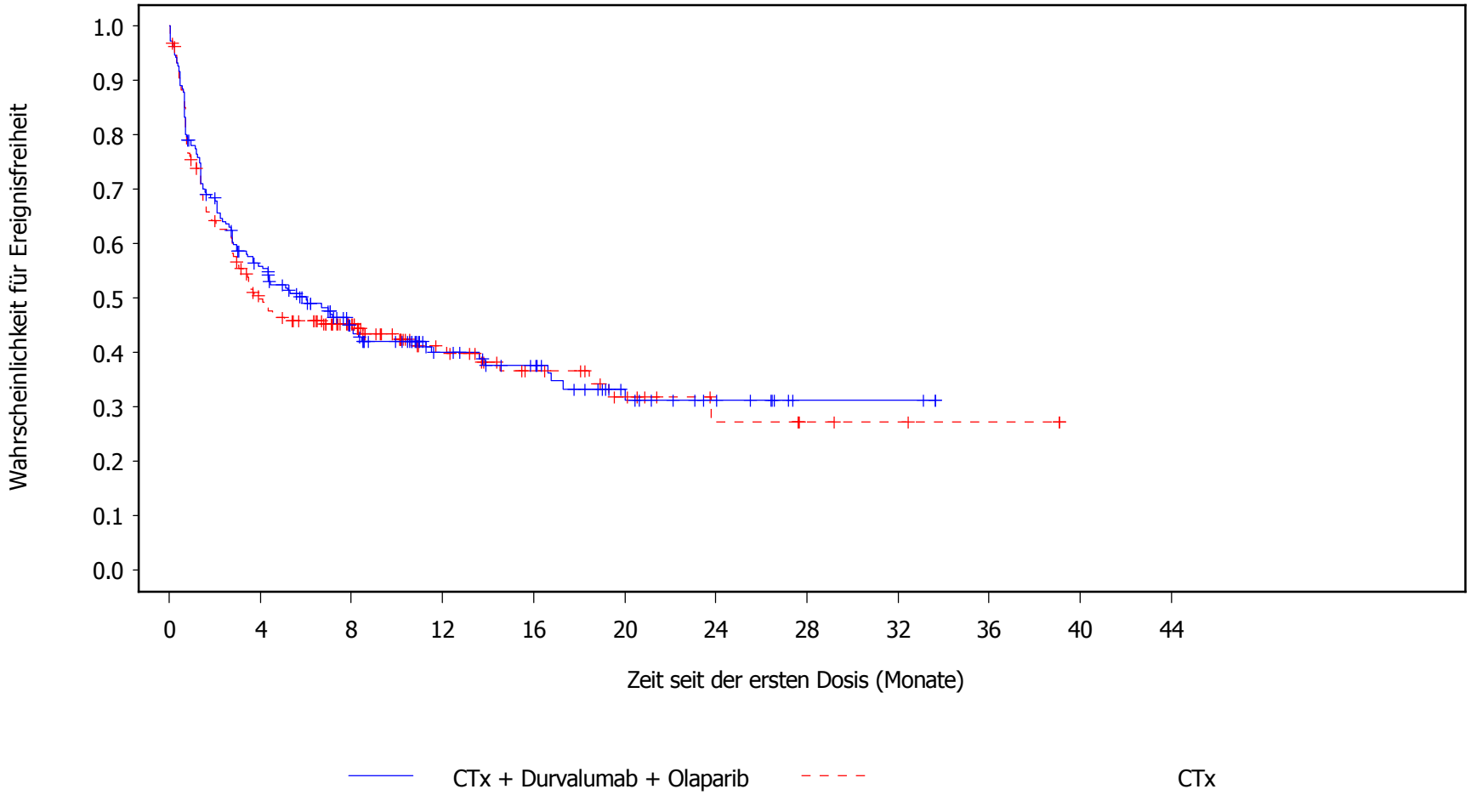
Figure 3.3.2.2D.80 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Hyponatriaemie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	170	135	93	73	54	31	17	9	4	0	0	CTx + Durvalumab + Olaparib
190	168	125	68	45	25	15	5	3	1	0	0	CTx

Figure 3.3.2.2D.81 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Untersuchungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	100	62	37	29	16	9	2	2	0	0	0	CTx + Durvalumab + Olaparib
190	87	58	30	19	12	6	3	2	1	0	0	CTx

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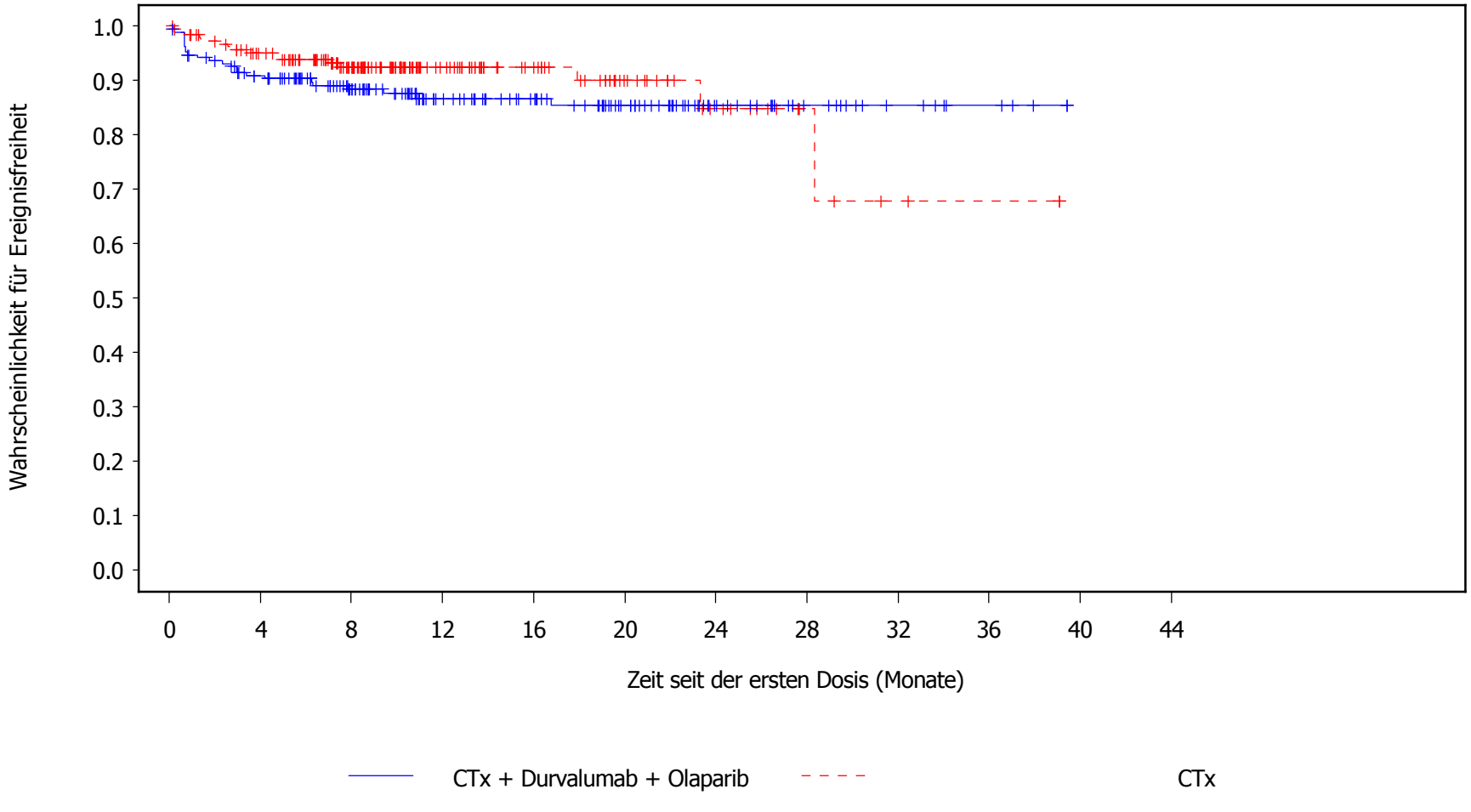
Figure 3.3.2.2D.82 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Alaninaminotransferase erhoeht
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	162	125	86	71	52	29	15	8	4	0	0	CTx + Durvalumab + Olaparib
190	165	119	66	44	25	14	5	2	1	0	0	CTx

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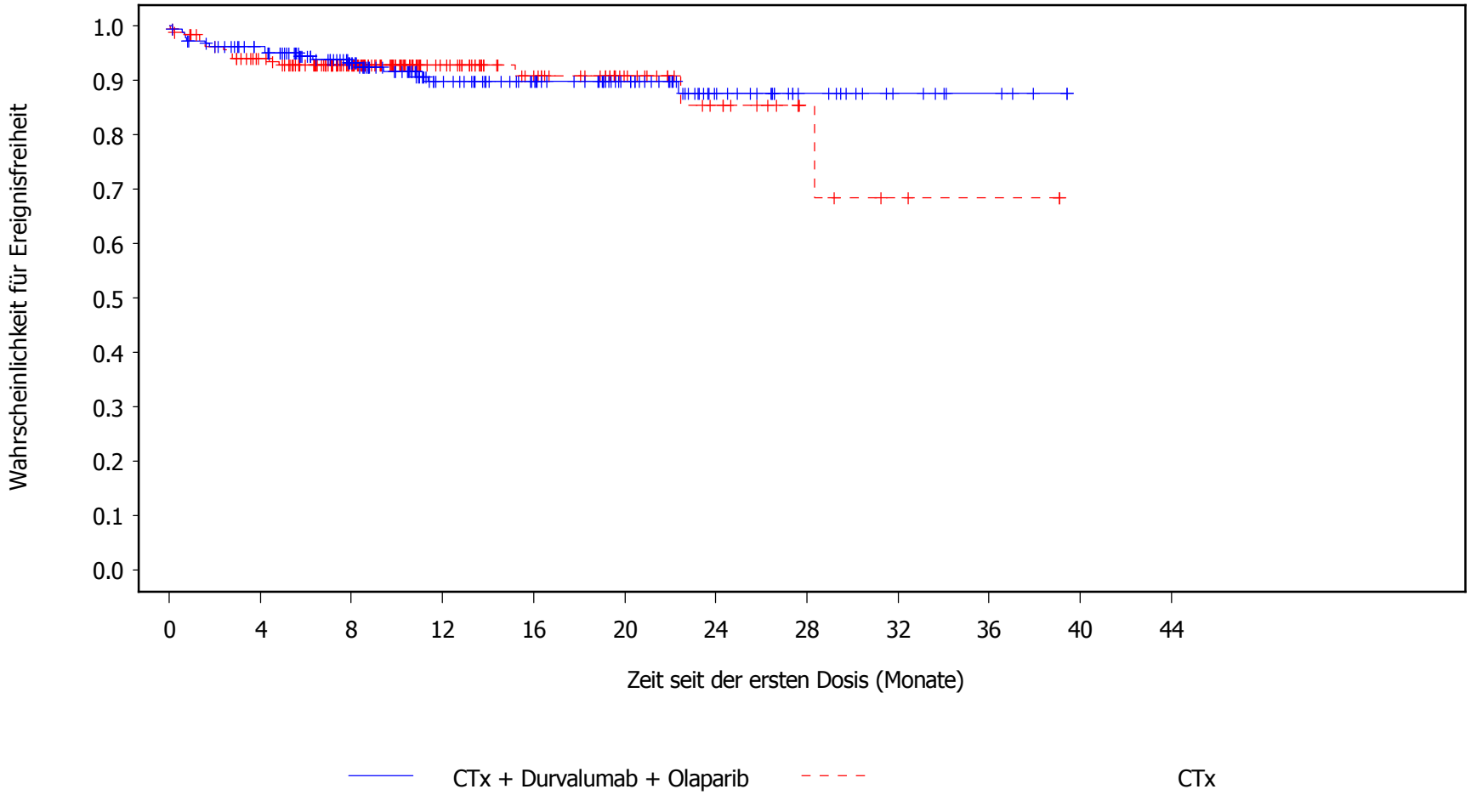
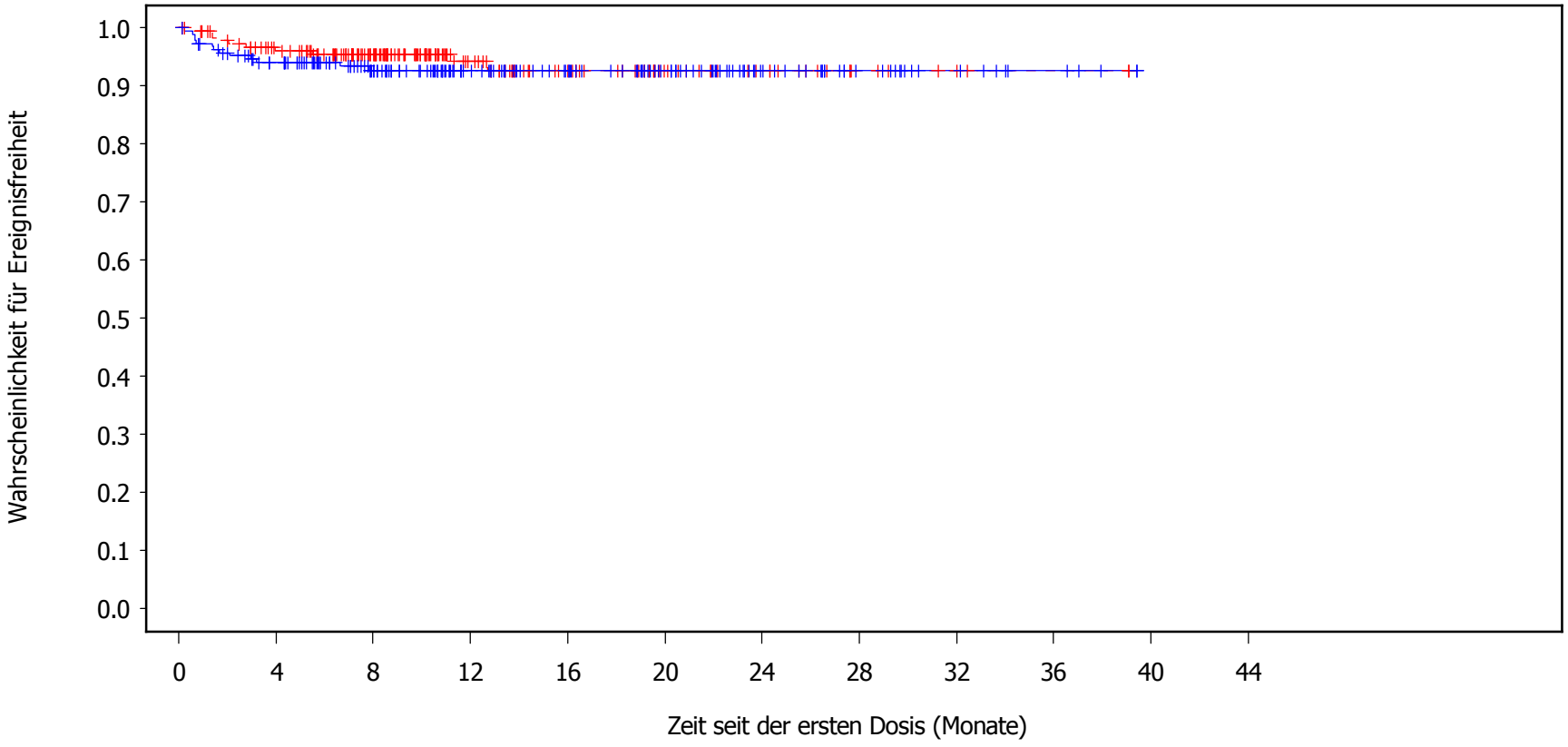
Figure 3.3.2.2D.83 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Aspartataminotransferase erhoeht
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	170	131	89	72	54	30	16	8	4	0	0	CTx + Durvalumab + Olaparib
190	165	120	65	43	25	14	5	2	1	0	0	CTx

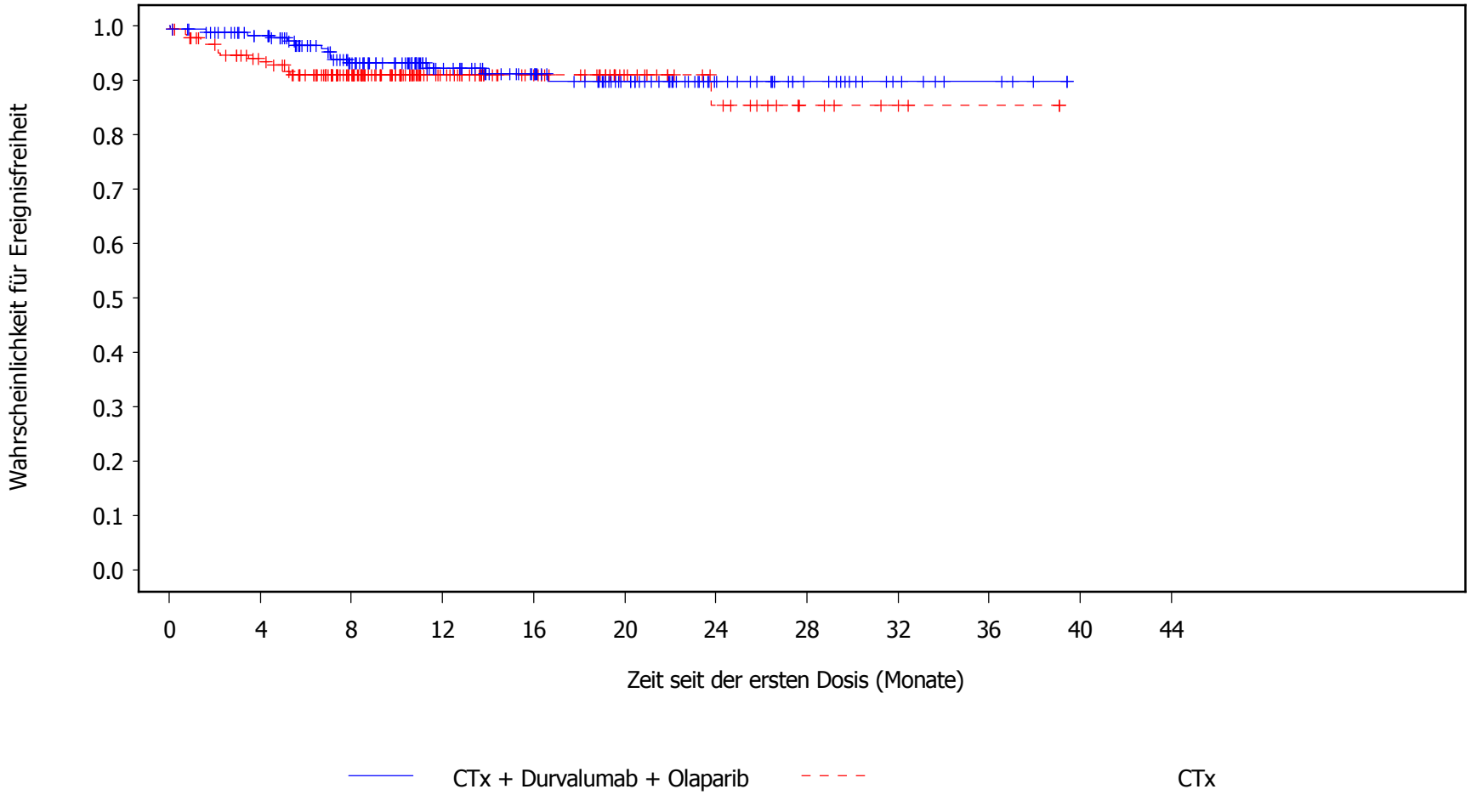
Figure 3.3.2.2D.84 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Gamma-Glutamyltransferase erhoeht
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	166	130	91	73	54	31	17	9	4	0	0	CTx + Durvalumab + Olaparib
190	167	124	66	45	25	16	6	3	1	0	0	CTx

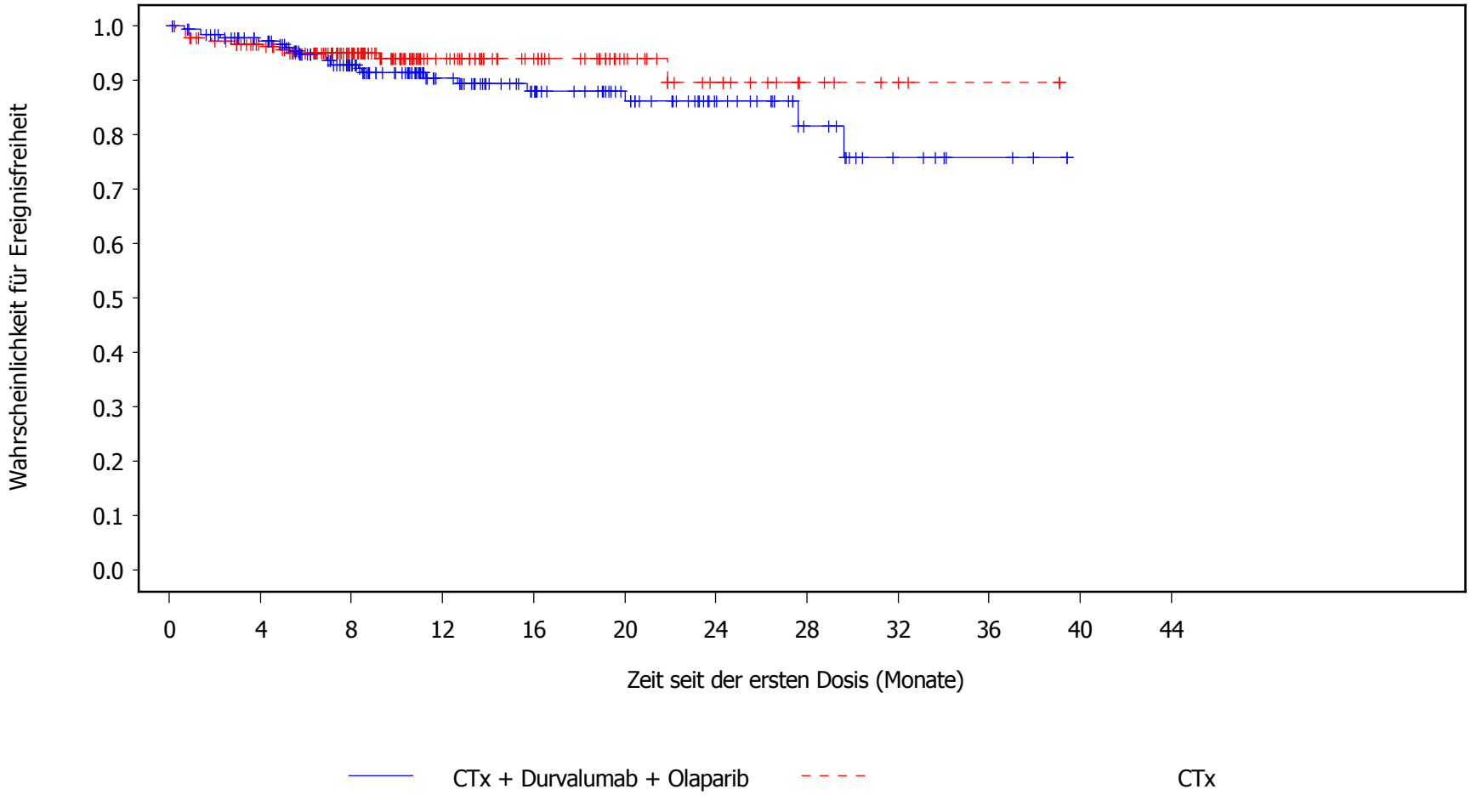
Figure 3.3.2.2D.85 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Gewicht erniedrigt
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	173	133	91	72	53	31	17	8	4	0	0	CTx + Durvalumab + Olaparib
190	164	121	66	45	26	15	6	3	1	0	0	CTx

Figure 3.3.2.2D.86 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Kreatinin im Blut erhoeht
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	171	131	86	65	49	31	16	7	3	0	0	CTx + Durvalumab + Olaparib
190	168	125	68	46	26	15	6	3	1	0	0	CTx

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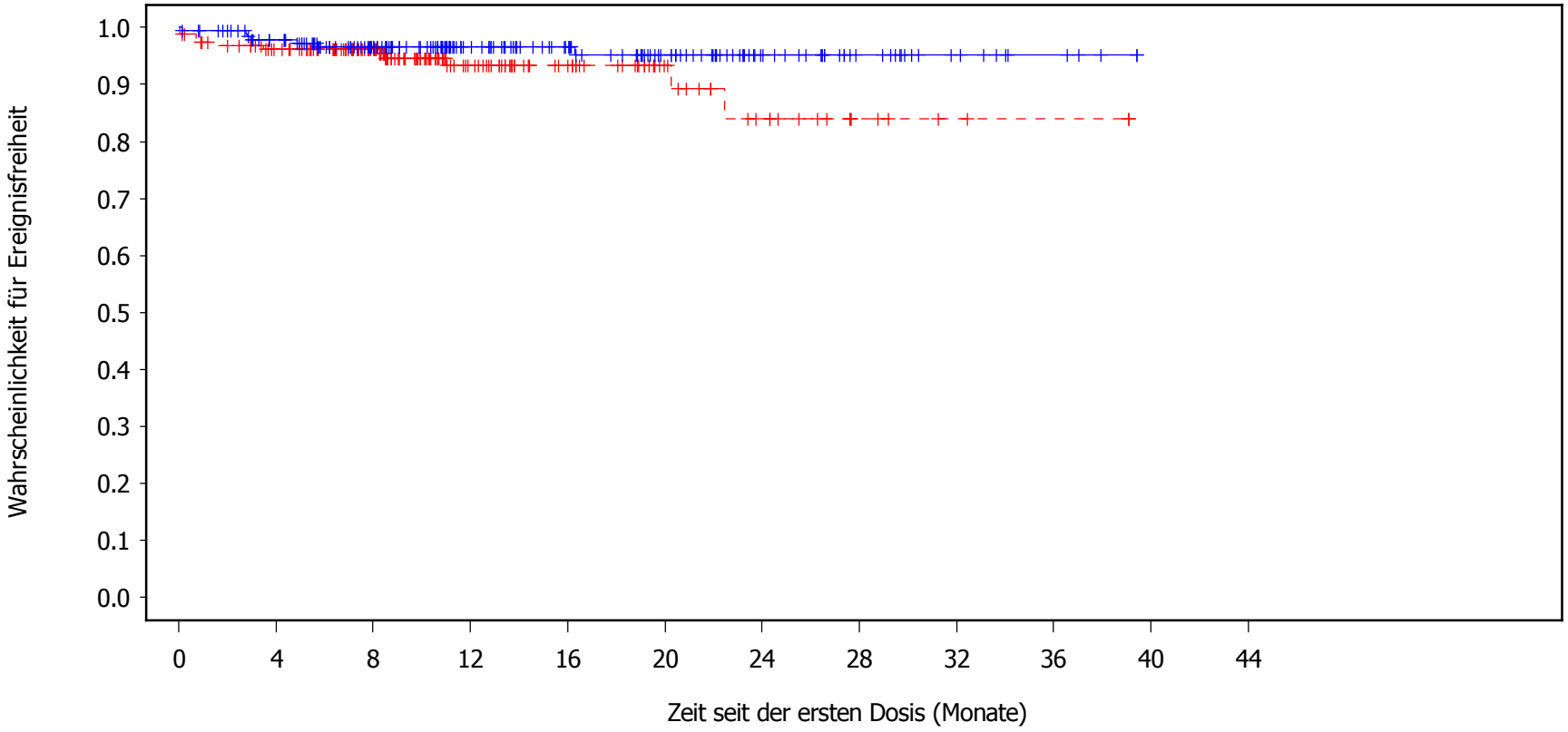
Figure 3.3.2.2D.87 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Laktatdehydrogenase im Blut erhoeht
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	172	137	96	76	56	33	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	168	124	66	44	24	14	5	2	1	0	0	CTx

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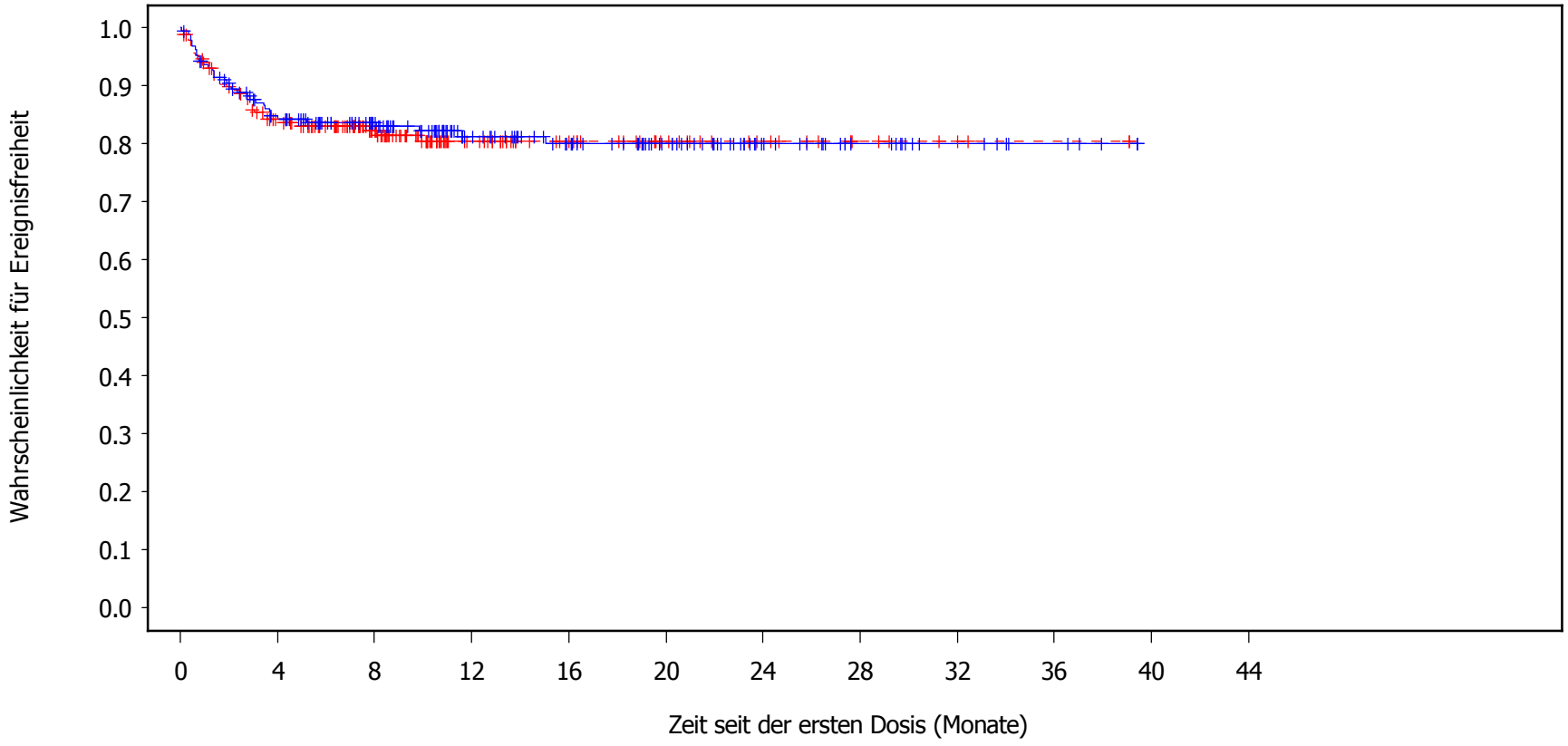
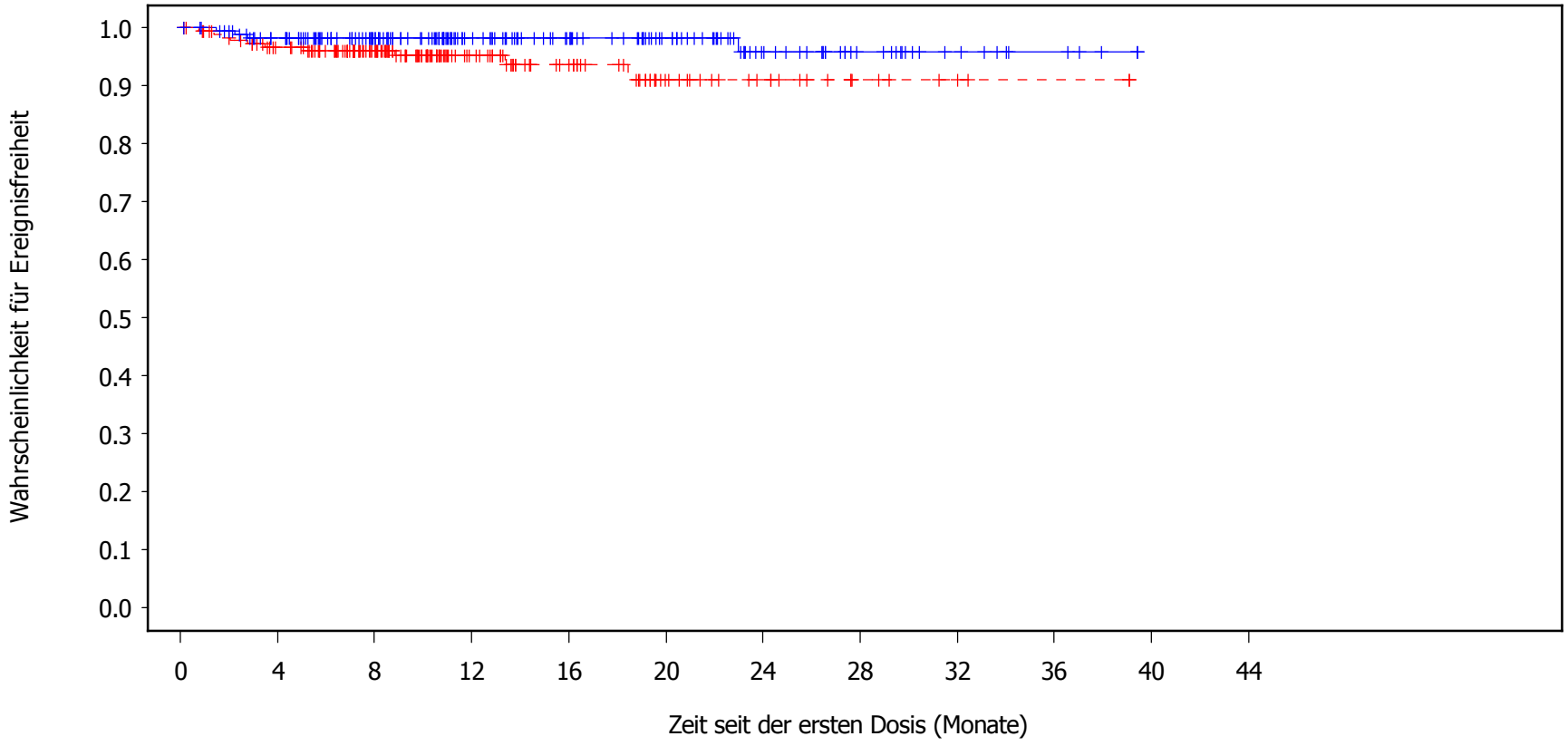
Figure 3.3.2.2D.88 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Leukozytenzahl erniedrigt
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	149	118	79	62	46	26	15	8	4	0	0	CTx + Durvalumab + Olaparib
190	145	100	51	34	21	13	6	3	1	0	0	CTx

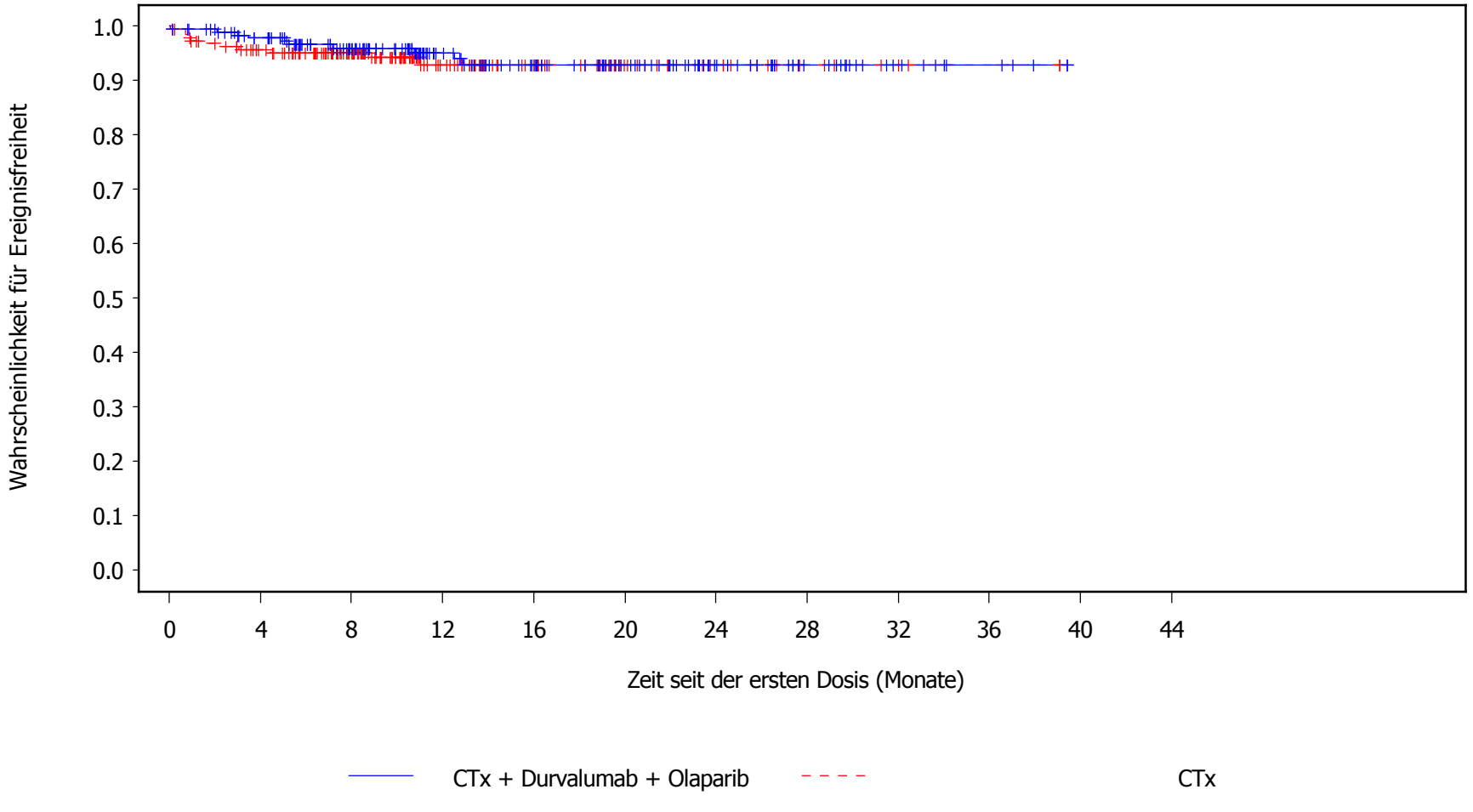
Figure 3.3.2.2D.89 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Lipase erhoeht
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	173	138	96	76	57	33	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	168	125	68	46	24	15	6	3	1	0	0	CTx

Figure 3.3.2.2D.90 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Lymphozytenzahl erniedrigt
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	172	136	91	72	54	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	166	123	65	44	24	16	6	3	1	0	0	CTx

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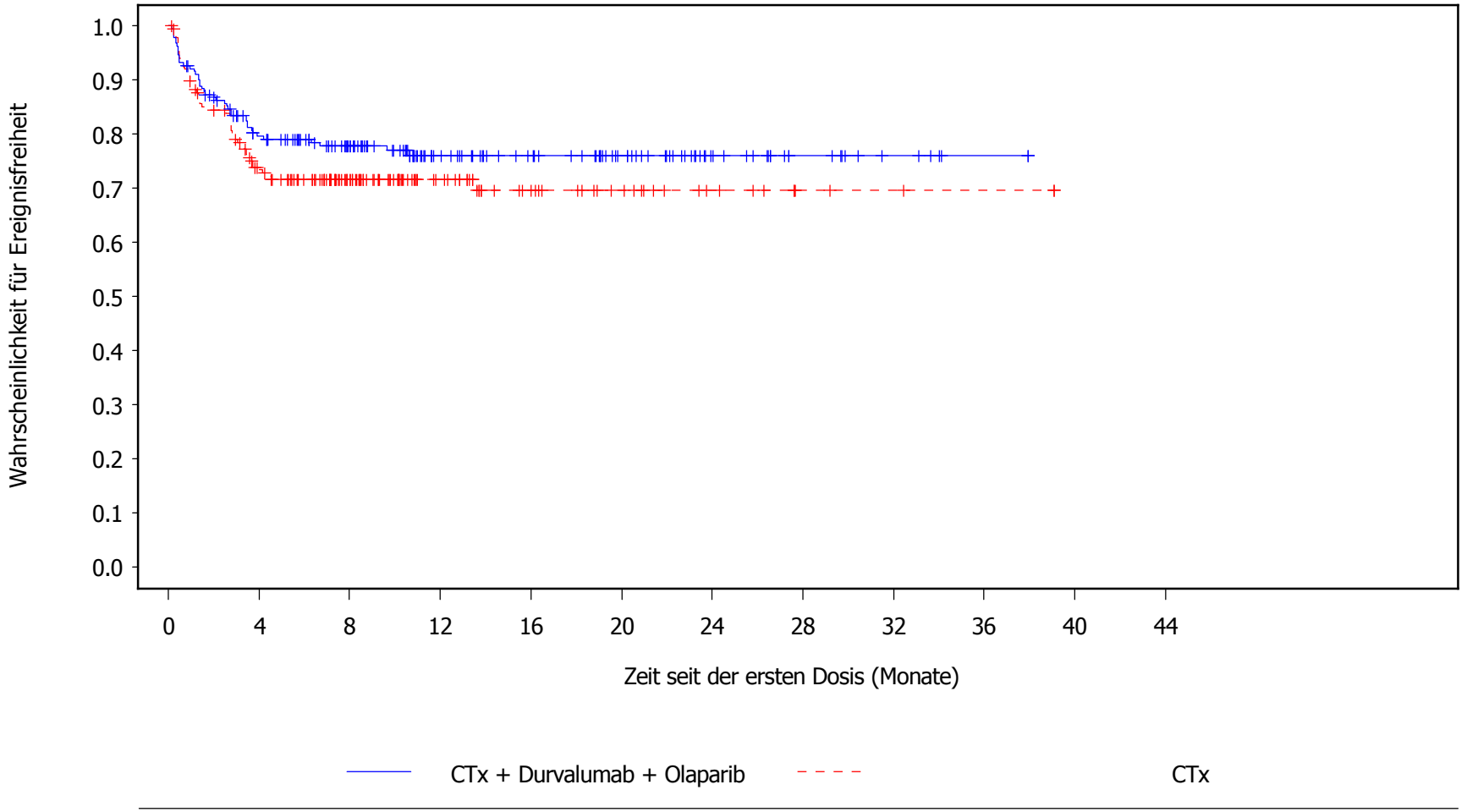
Figure 3.3.2.2D.91 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Neutrophilenzahl erniedrigt
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	140	109	70	56	41	22	11	5	1	0	0	CTx + Durvalumab + Olaparib
190	127	84	45	26	17	9	3	2	1	0	0	CTx

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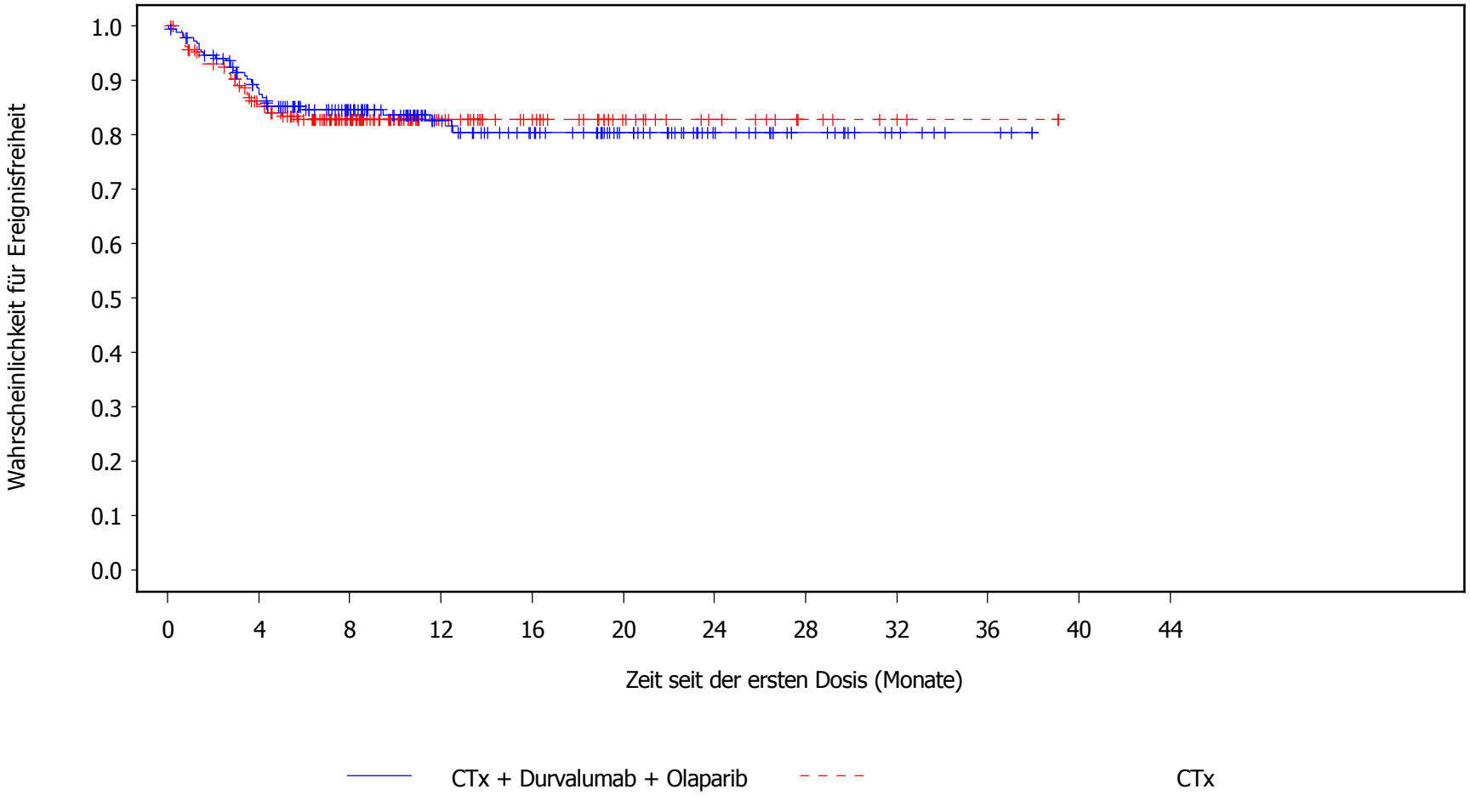
Figure 3.3.2.2D.92 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Thrombozytenzahl vermindert
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	157	118	76	60	43	26	15	7	3	0	0	CTx + Durvalumab + Olaparib
190	148	103	54	38	22	14	6	3	1	0	0	CTx

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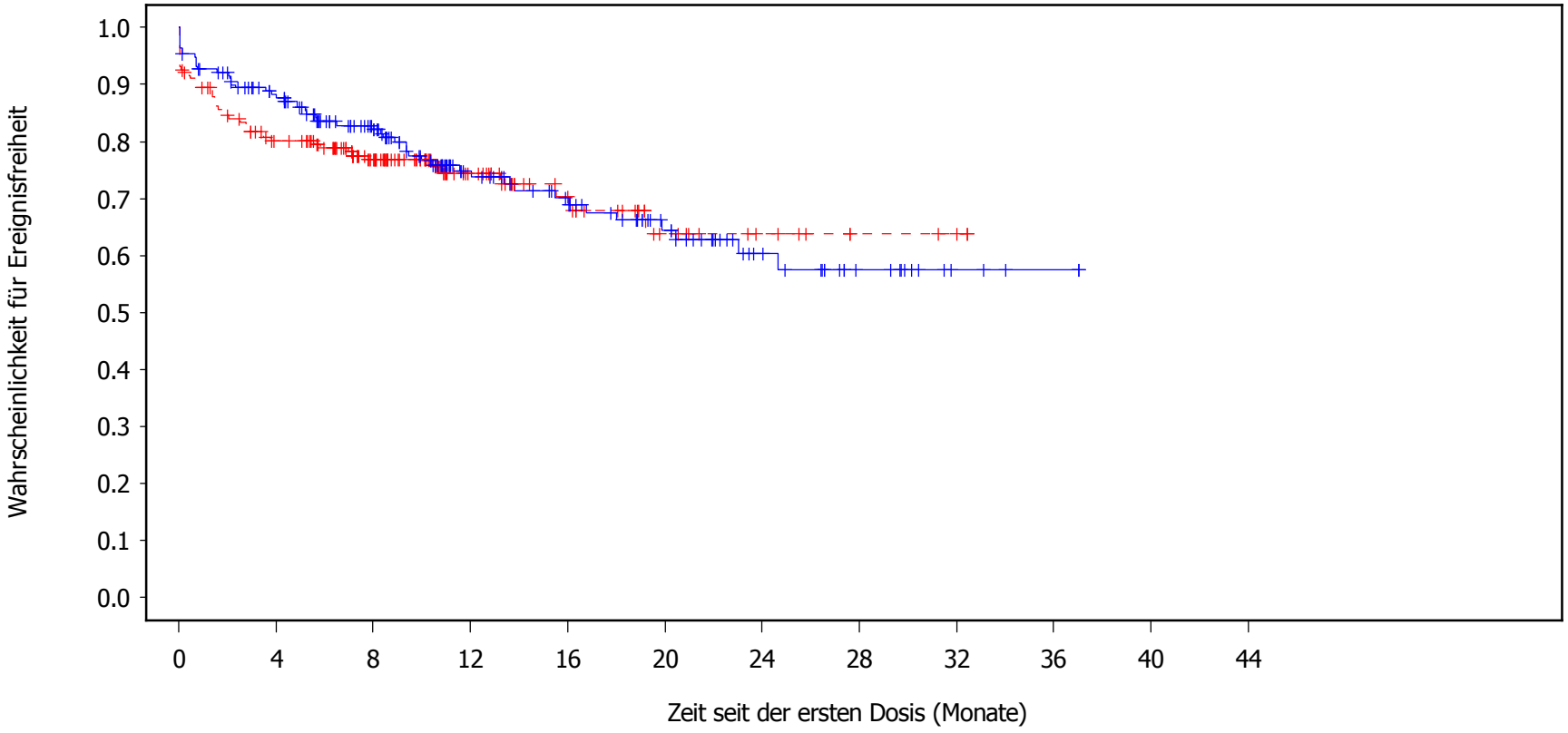
Figure 3.3.2.2D.93 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	154	116	70	56	39	22	11	3	1	0	0	CTx + Durvalumab + Olaparib
190	139	99	50	30	14	8	3	2	0	0	0	CTx

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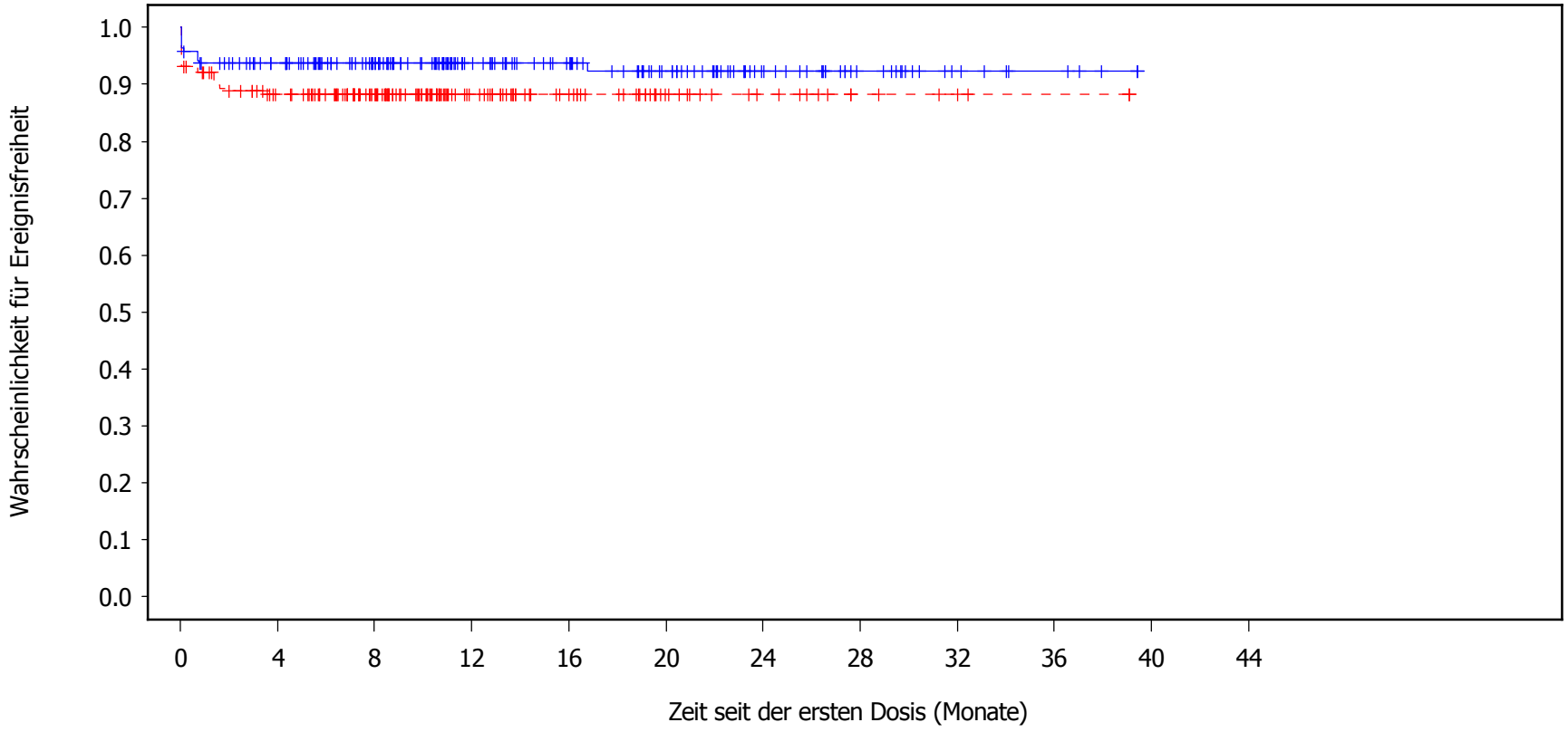
Figure 3.3.2.2D.94 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Reaktion im Zusammenhang mit einer Infusion
Patients with pMMR tumour status, DCO 18OCT2023

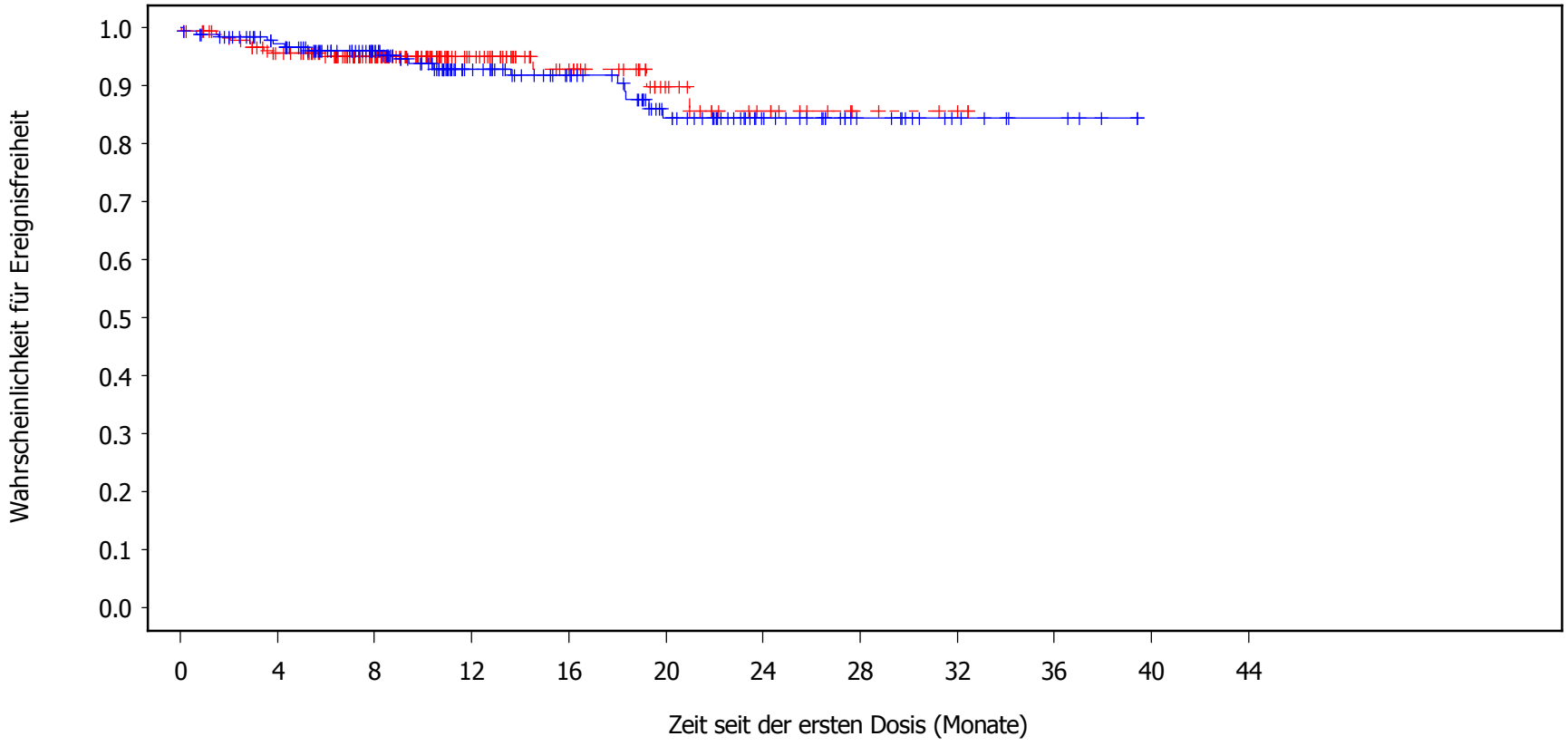


Anzahl an Patienten unter Risiko:

191	164	133	90	73	55	33	18	8	4	0	0	CTx + Durvalumab + Olaparib
190	152	113	60	39	20	12	5	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebdp 15APR2024:10:33

Figure 3.3.2.2D.95 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of PT: Sturz
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	171	135	90	72	50	30	16	8	4	0	0	CTx + Durvalumab + Olaparib
190	167	125	68	44	24	13	4	2	0	0	0	CTx

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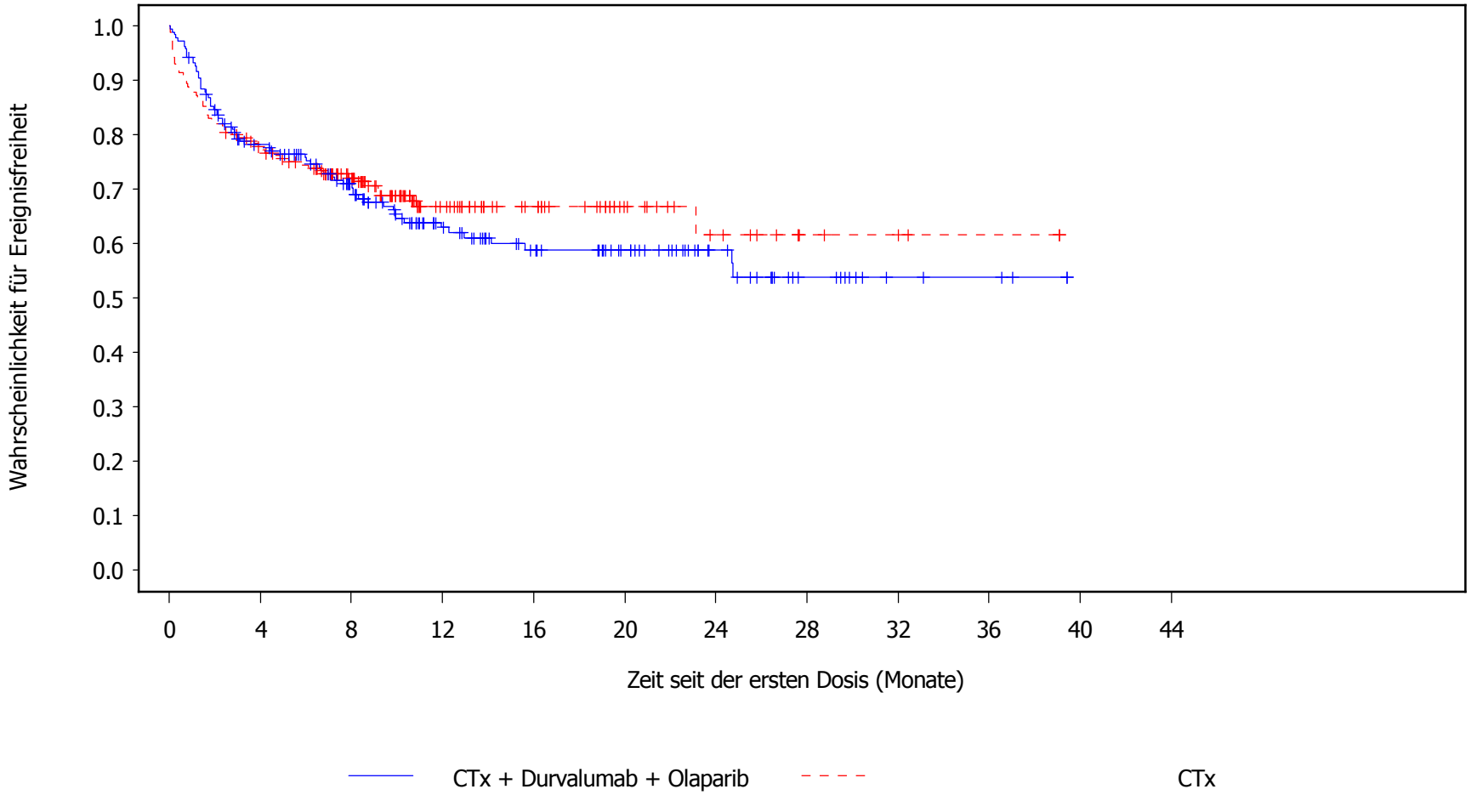
Figure 3.3.2.2D.96 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUE
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	139	107	69	52	41	24	11	4	3	0	0	CTx + Durvalumab + Olaparib
190	143	104	54	36	19	11	4	3	1	0	0	CTx

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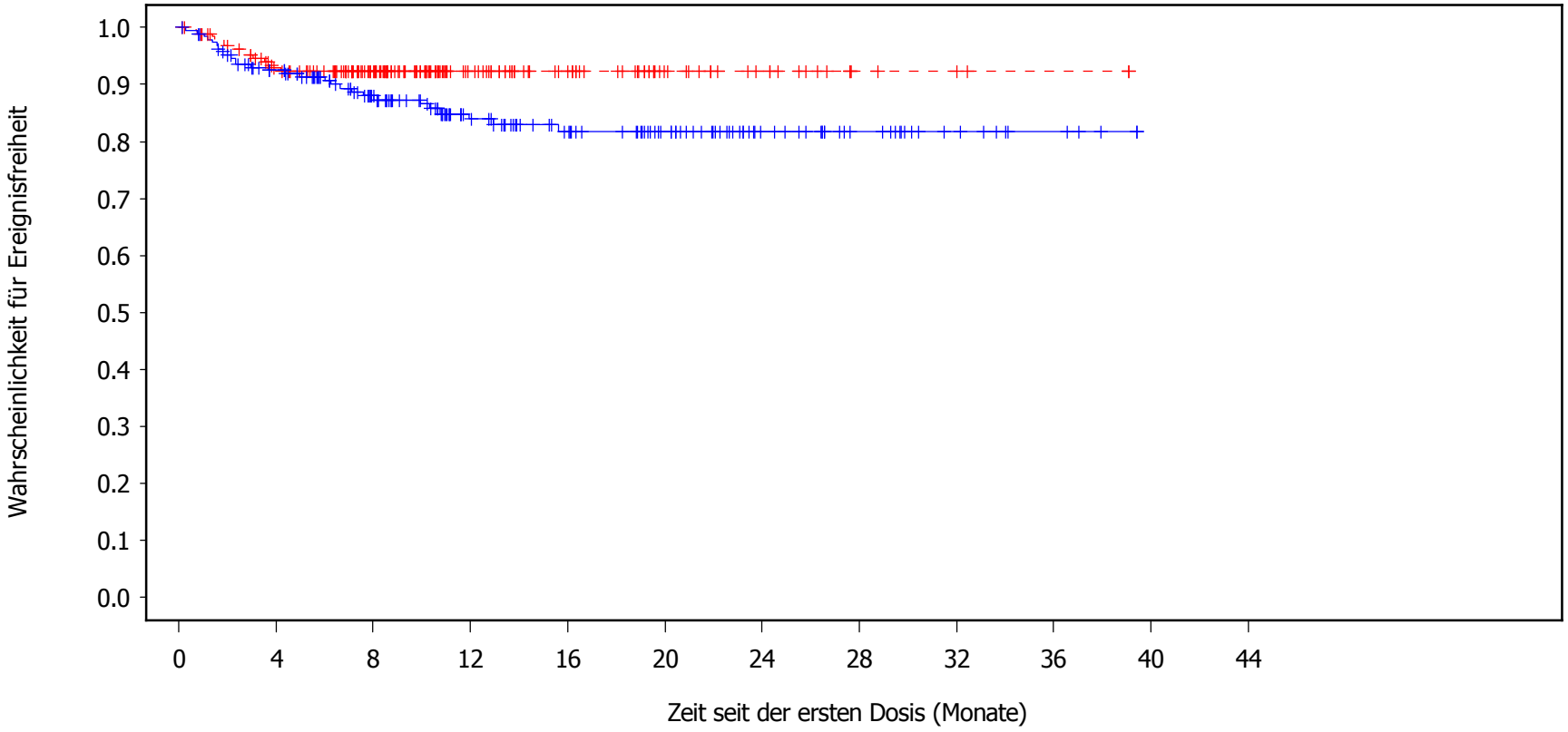
Figure 3.3.2.2D.97 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	162	125	86	68	52	30	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	161	121	65	44	23	14	4	3	1	0	0	CTx

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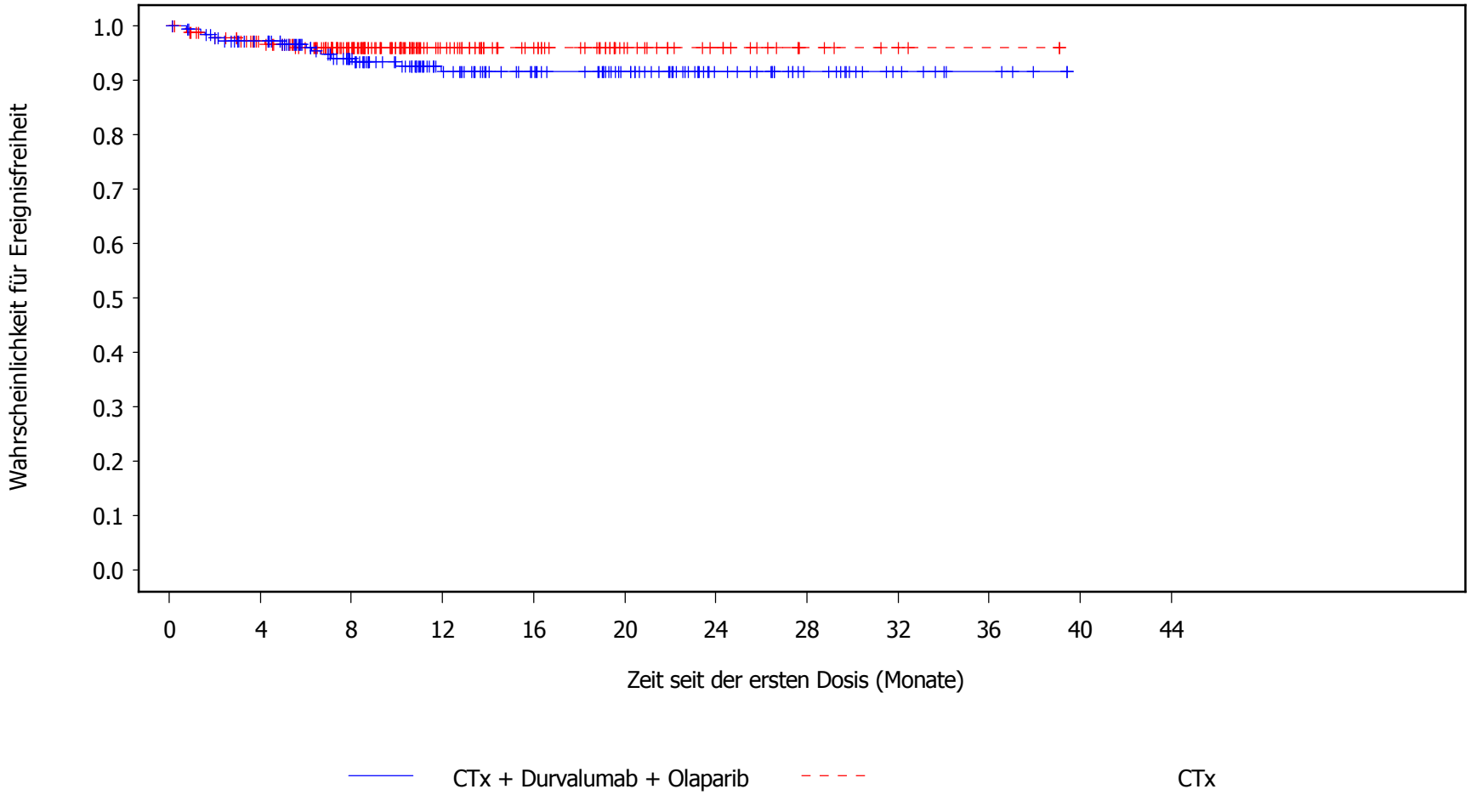
Figure 3.3.2.2D.98 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUE PT: Anaemie
Patients with pMMR tumour status, DCO 18OCT2023

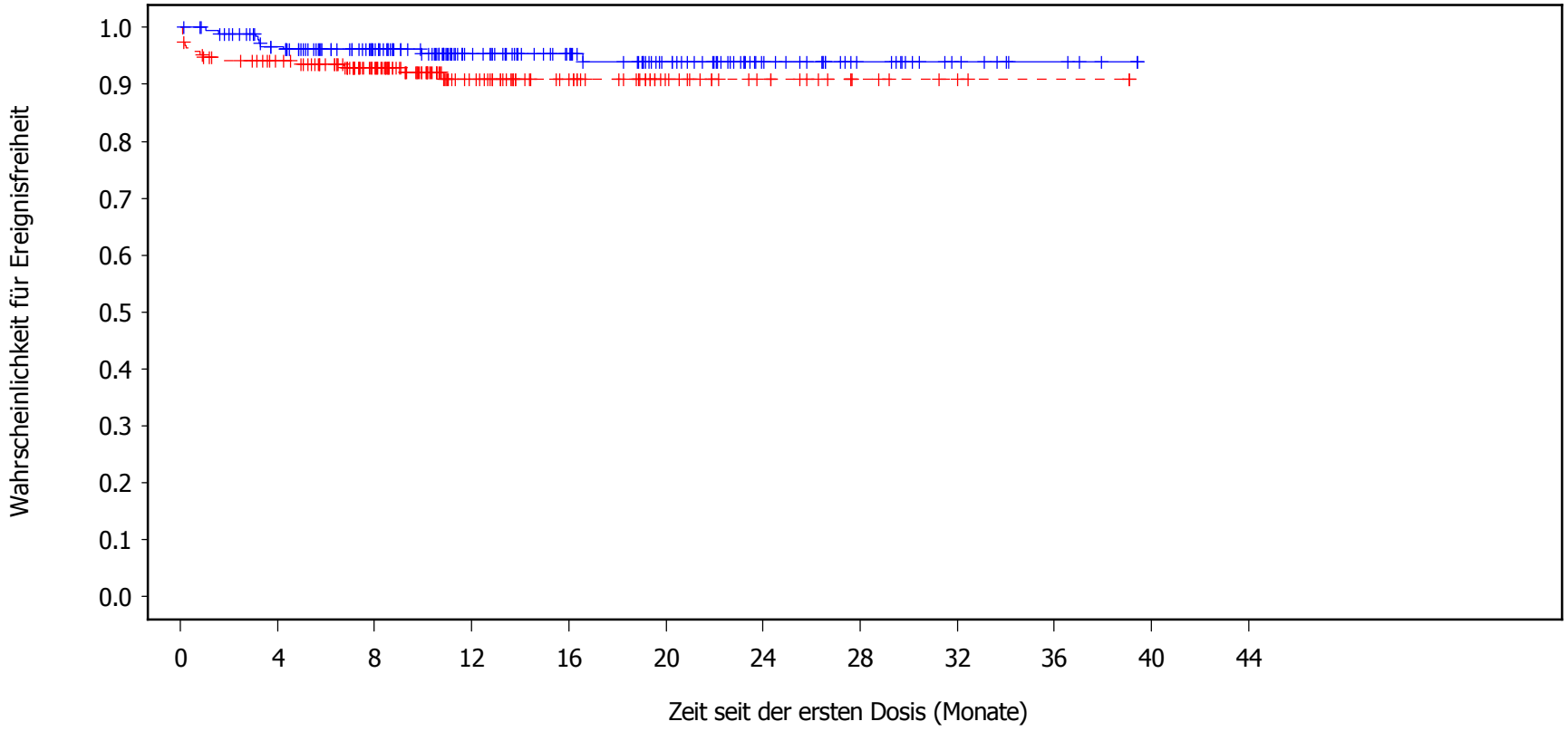


Anzahl an Patienten unter Risiko:

191	171	134	93	74	57	33	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	169	126	69	47	26	16	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebdt 15APR2024:10:33

Figure 3.3.2.2D.99 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Gastrointestinaltrakts
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	170	138	94	74	55	32	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	167	125	67	45	25	15	6	3	1	0	0	CTx

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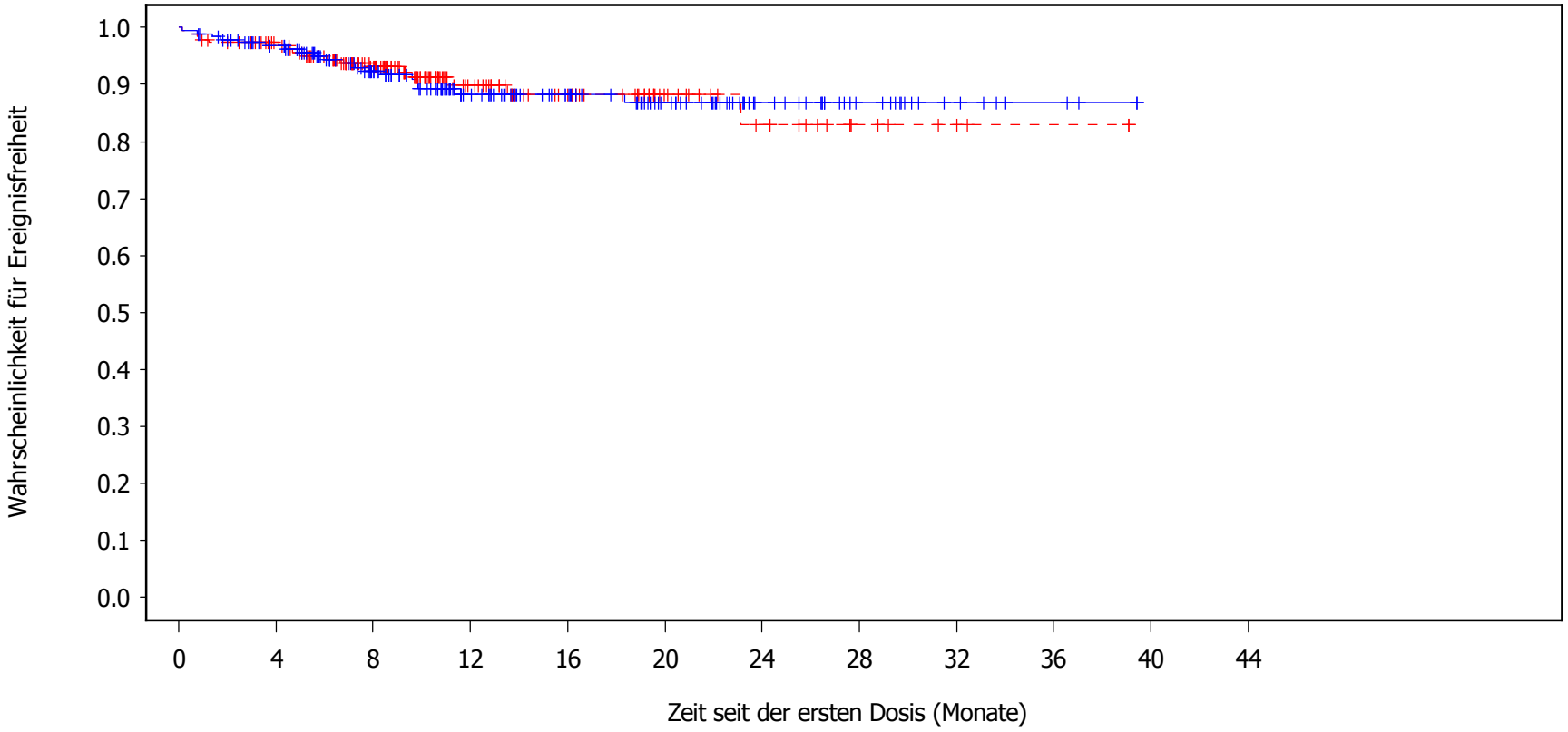
Figure 3.3.2.2D.100 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUE SOC: Infektionen und parasitaere Erkrankungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	171	130	87	68	51	29	16	7	3	0	0	CTx + Durvalumab + Olaparib
190	173	123	64	44	24	15	6	3	1	0	0	CTx

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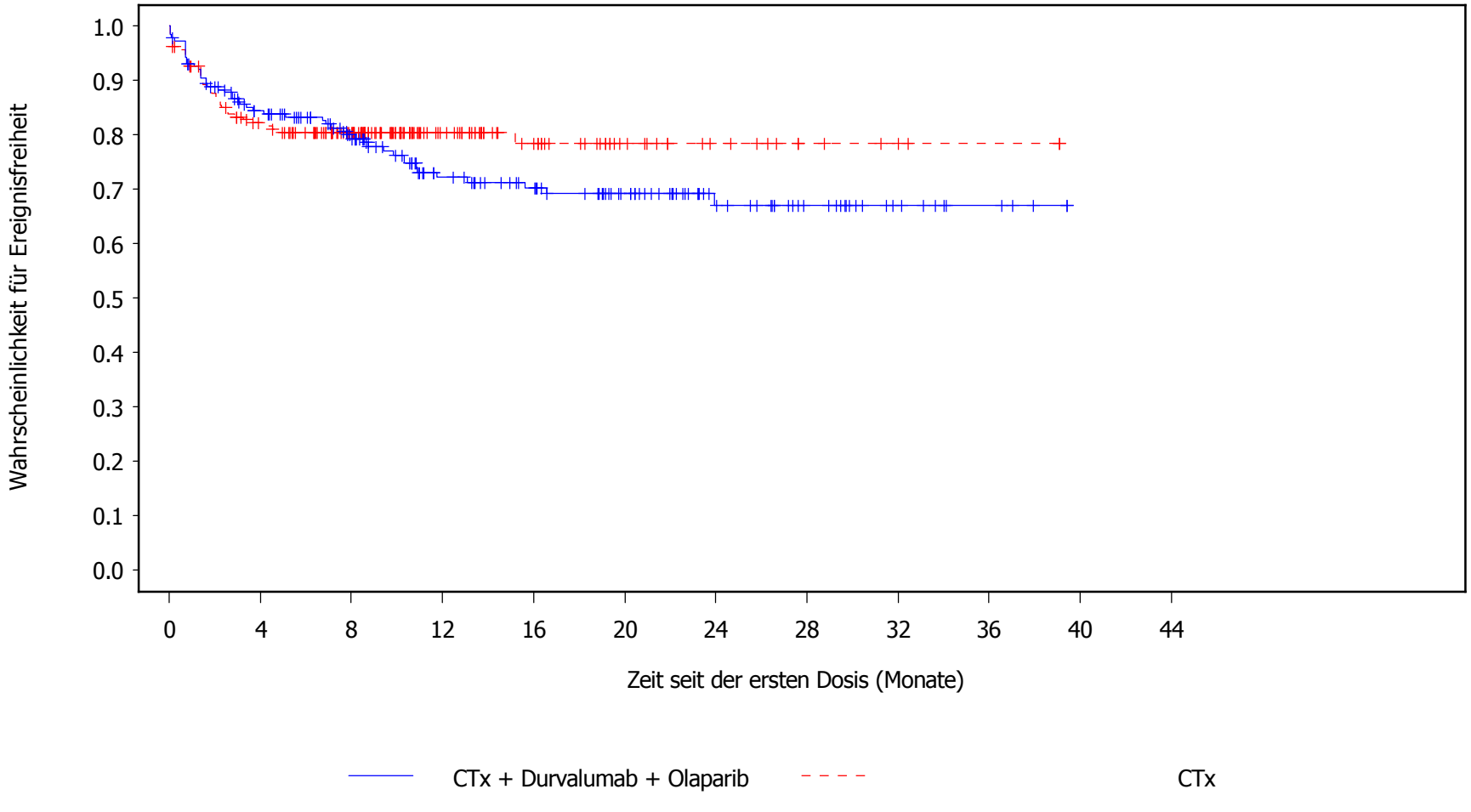
Figure 3.3.2.2D.101 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of Therapieabbruch aufgrund von UE
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	147	118	81	68	52	31	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	145	112	58	36	19	11	5	3	1	0	0	CTx

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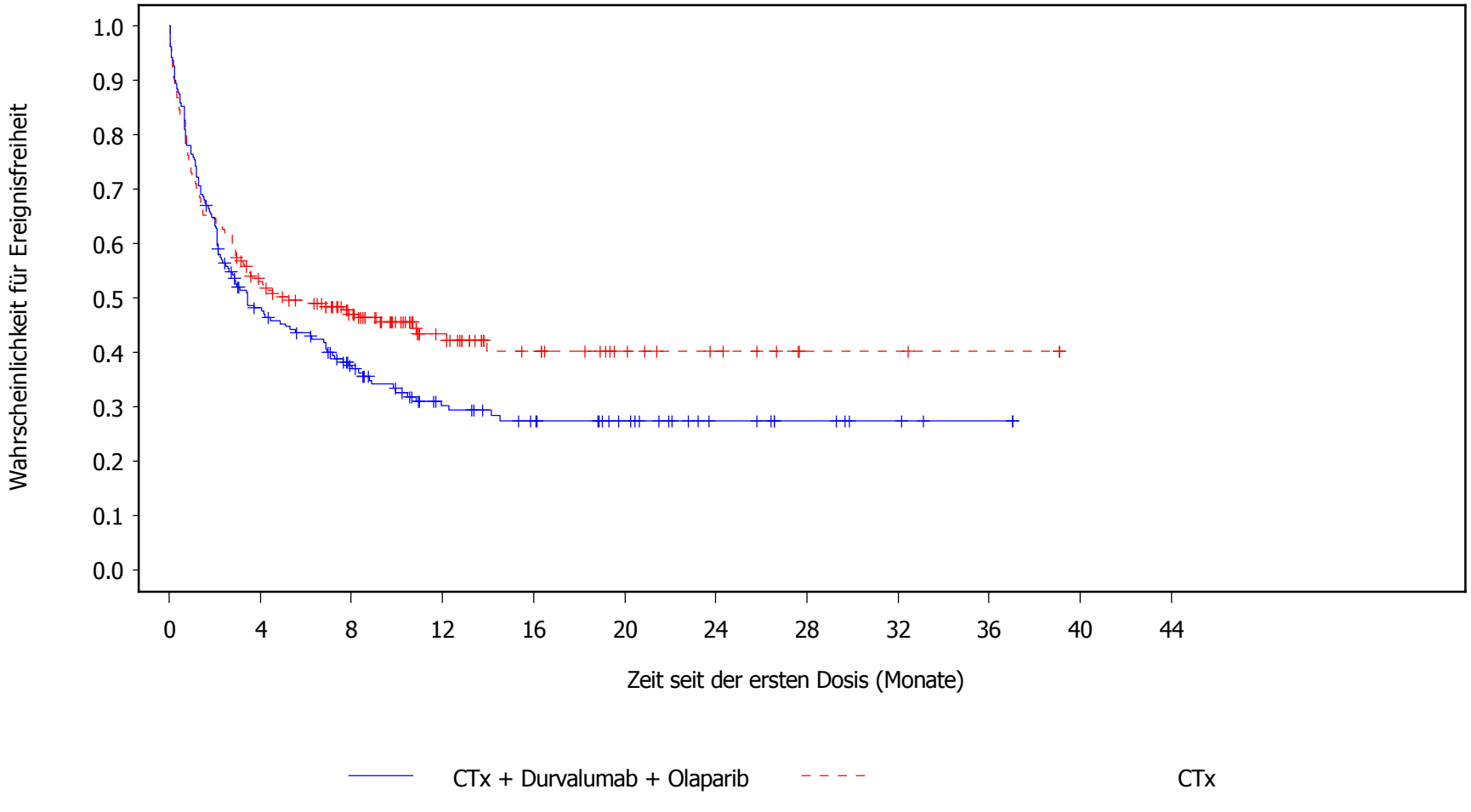
Figure 3.3.2.2D.102 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UE mit CTCAE Grad >=3
Patients with pMMR tumour status, DCO 18OCT2023

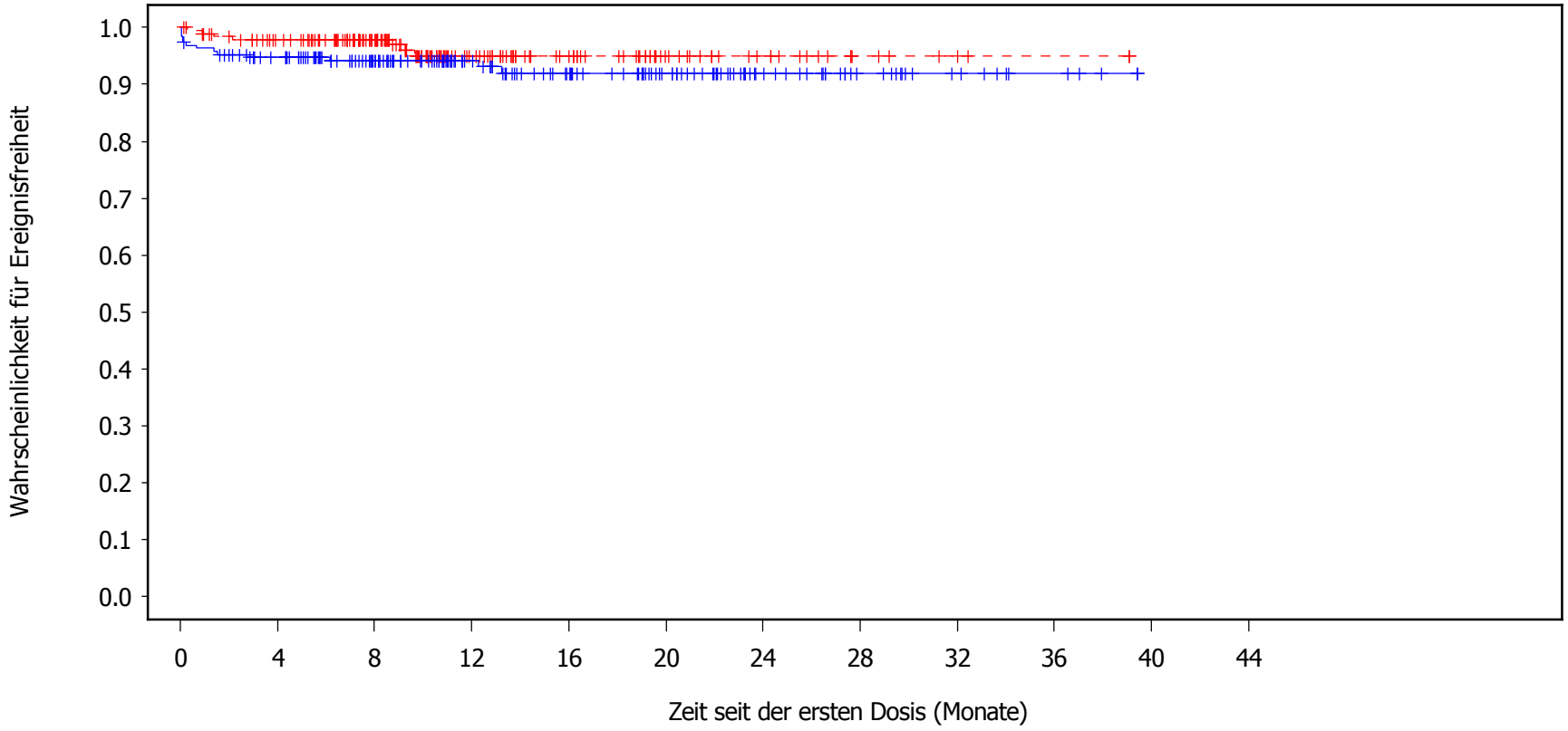


Anzahl an Patienten unter Risiko:

191	85	57	34	26	19	10	6	3	1	0	0	CTx + Durvalumab + Olaparib
190	96	67	35	19	11	7	2	2	1	0	0	CTx

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.2.2D.103 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	169	134	93	73	54	31	17	9	4	0	0	CTx + Durvalumab + Olaparib
190	170	127	69	47	26	16	6	3	1	0	0	CTx

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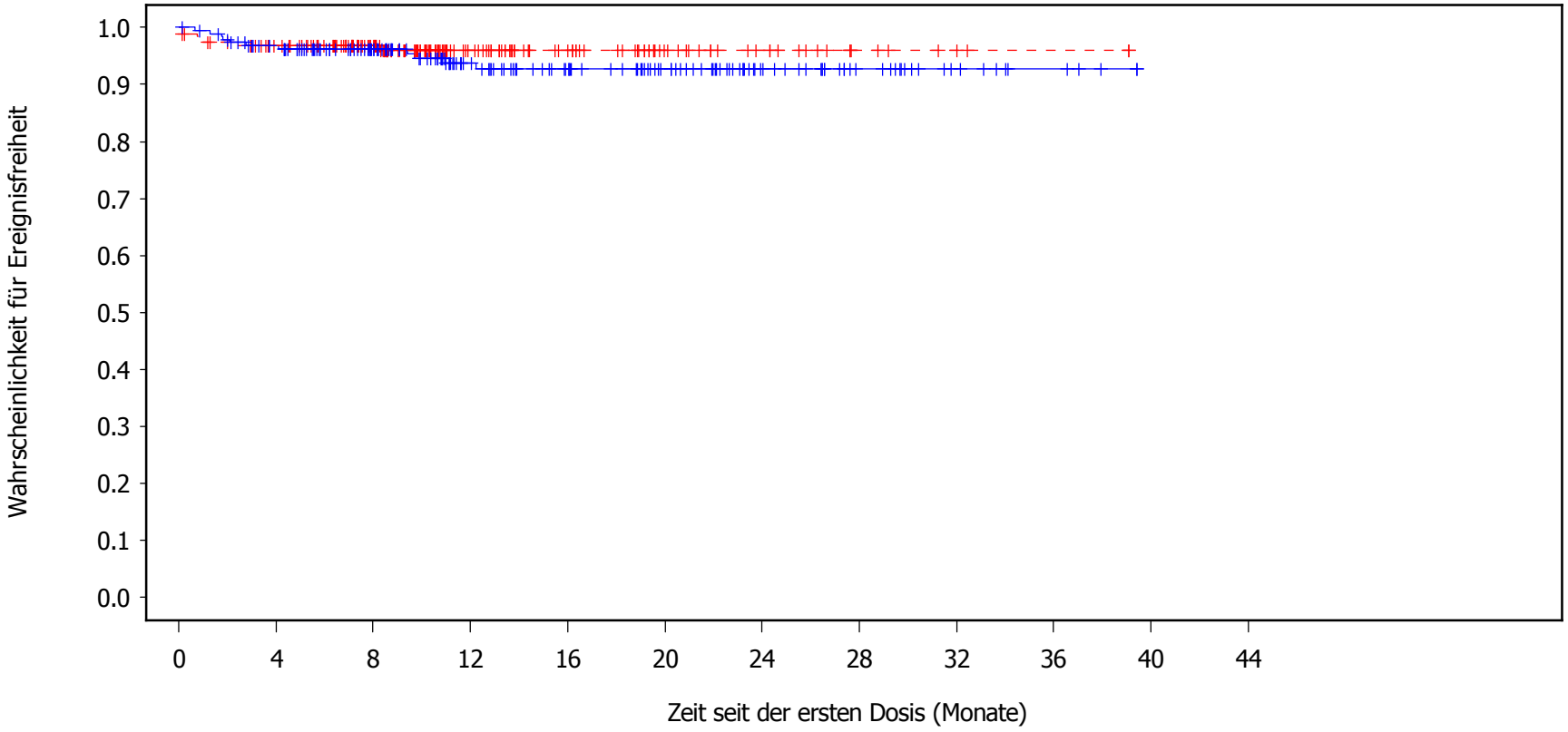
Figure 3.3.2.2D.104 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	172	137	93	74	57	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	172	128	70	47	26	16	6	3	1	0	0	CTx

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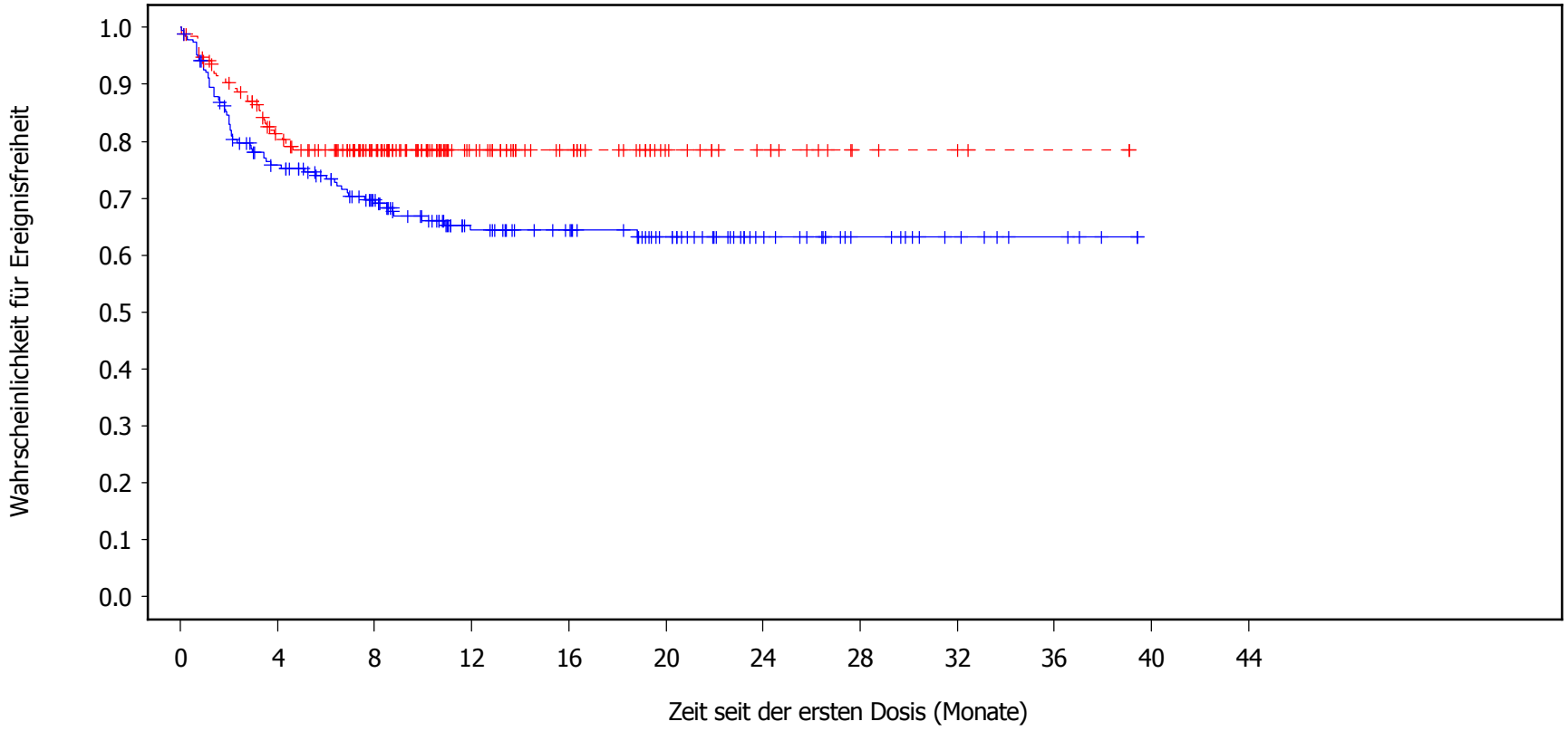
Figure 3.3.2.2D.105 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with pMMR tumour status, DCO 18OCT2023

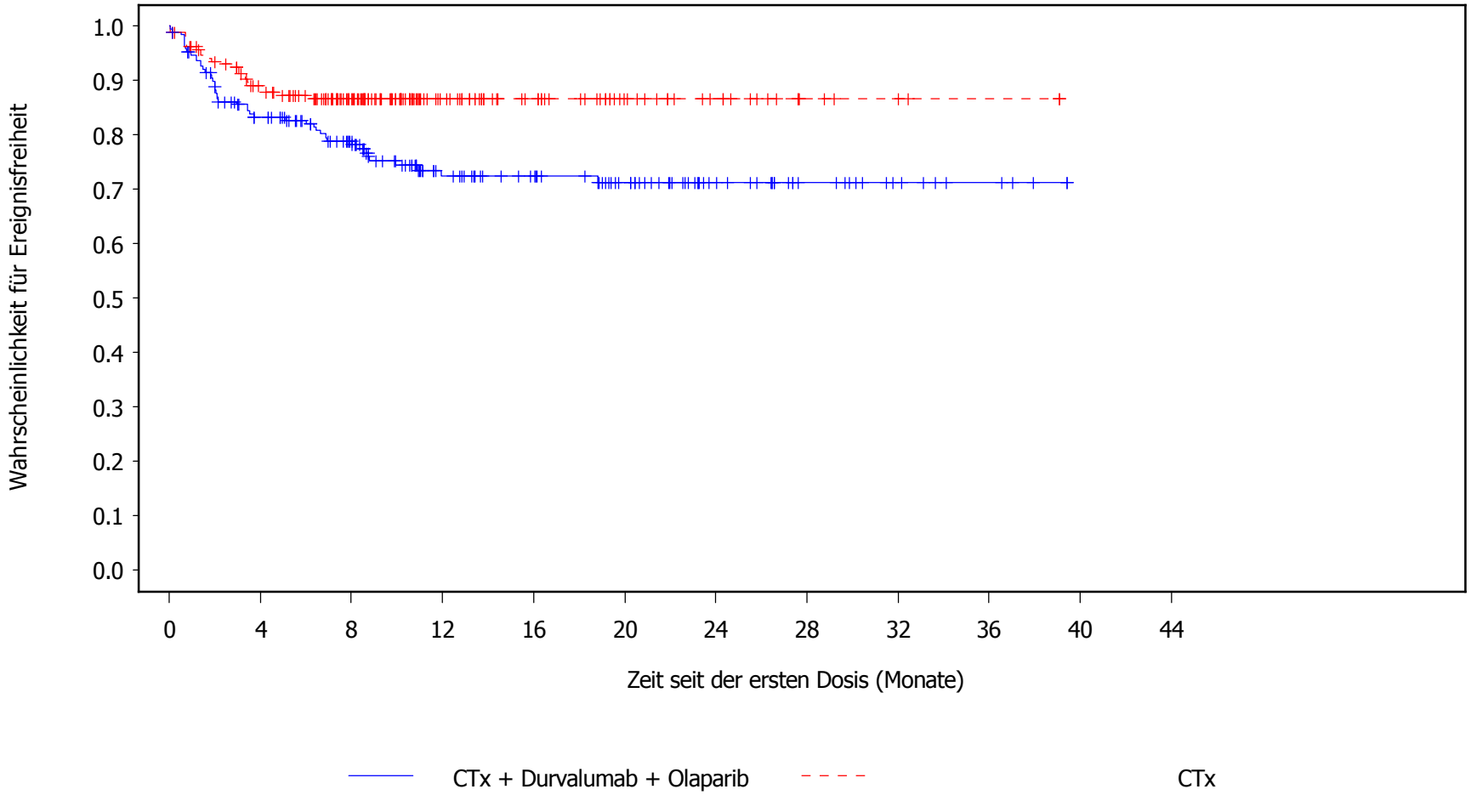


Anzahl an Patienten unter Risiko:

191	134	104	69	58	44	25	14	8	4	0	0	CTx + Durvalumab + Olaparib
190	140	103	55	36	19	12	4	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebea 15APR2024:10:33

Figure 3.3.2.2D.106 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Anaemie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	146	115	74	62	48	28	15	8	4	0	0	CTx + Durvalumab + Olaparib
190	155	115	61	41	24	15	5	3	1	0	0	CTx

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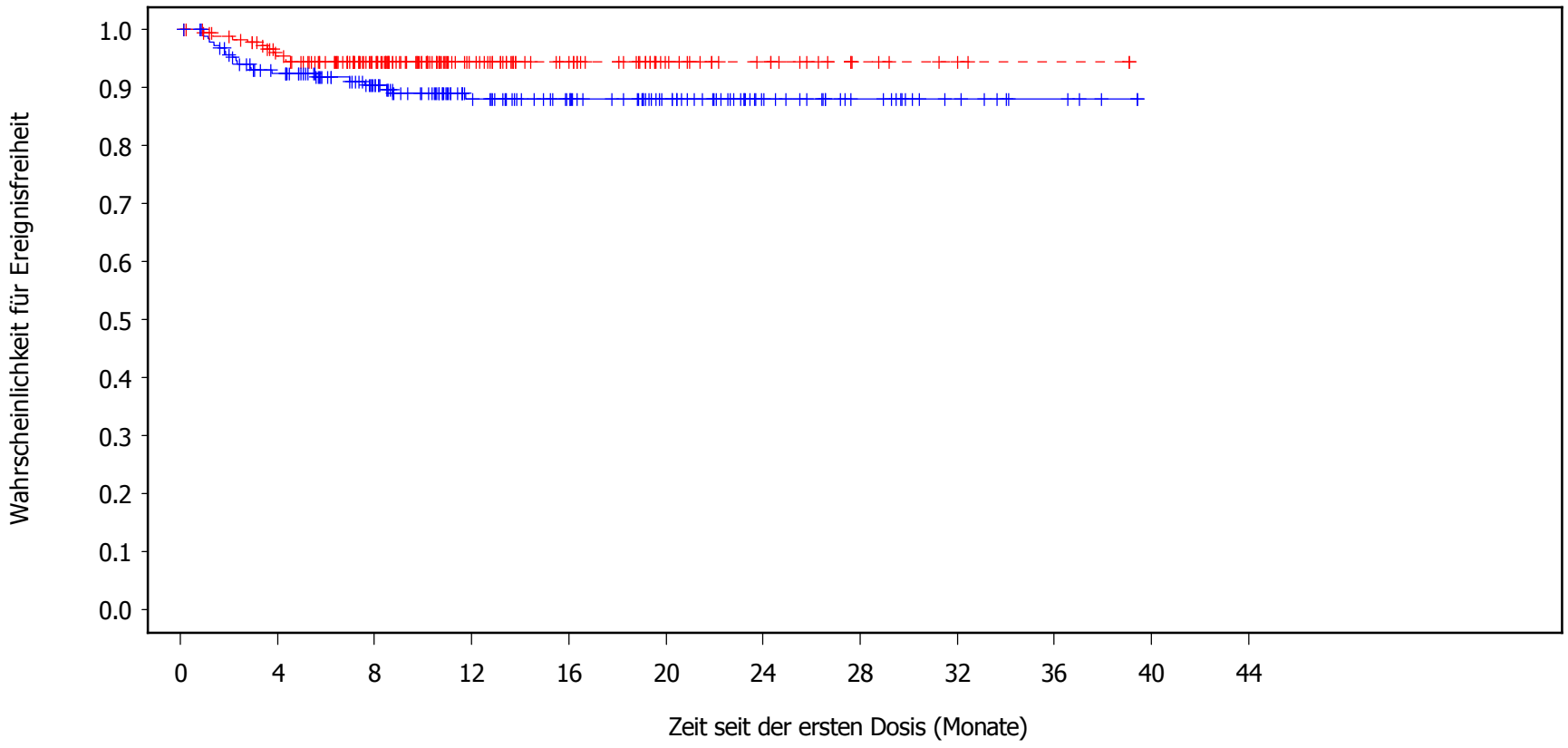
Figure 3.3.2.2D.107 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Neutropenie
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	163	129	90	72	53	30	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	166	122	68	46	25	16	6	3	1	0	0	CTx

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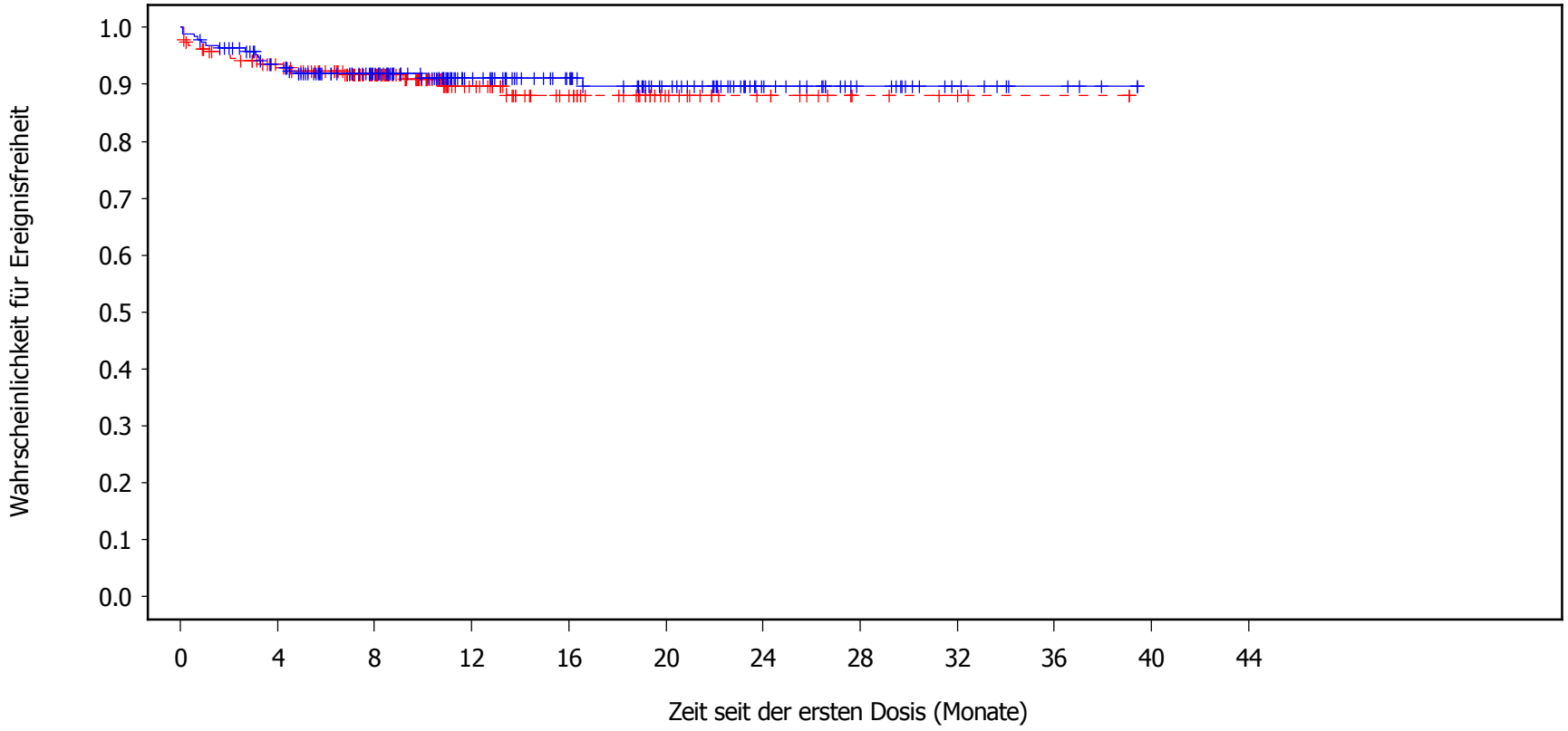
Figure 3.3.2.2D.108 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Gastrointestinaltrakts
Patients with pMMR tumour status, DCO 18OCT2023

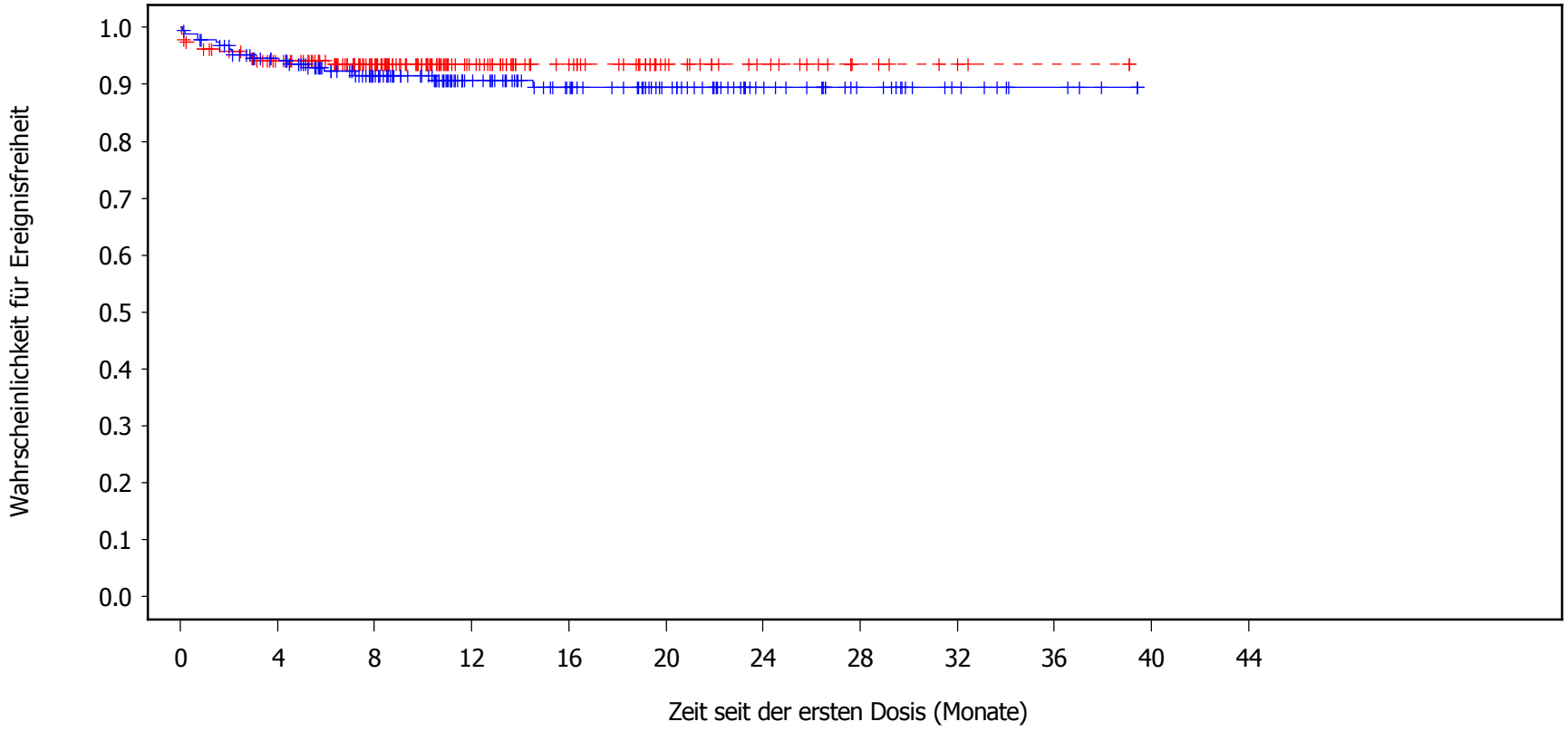


Anzahl an Patienten unter Risiko:

191	166	133	90	71	53	31	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	163	121	64	43	23	14	5	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebed 15APR2024:10:33

Figure 3.3.2.2D.109 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Nervensystems
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	166	130	88	67	50	30	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	164	121	66	44	24	15	6	3	1	0	0	CTx

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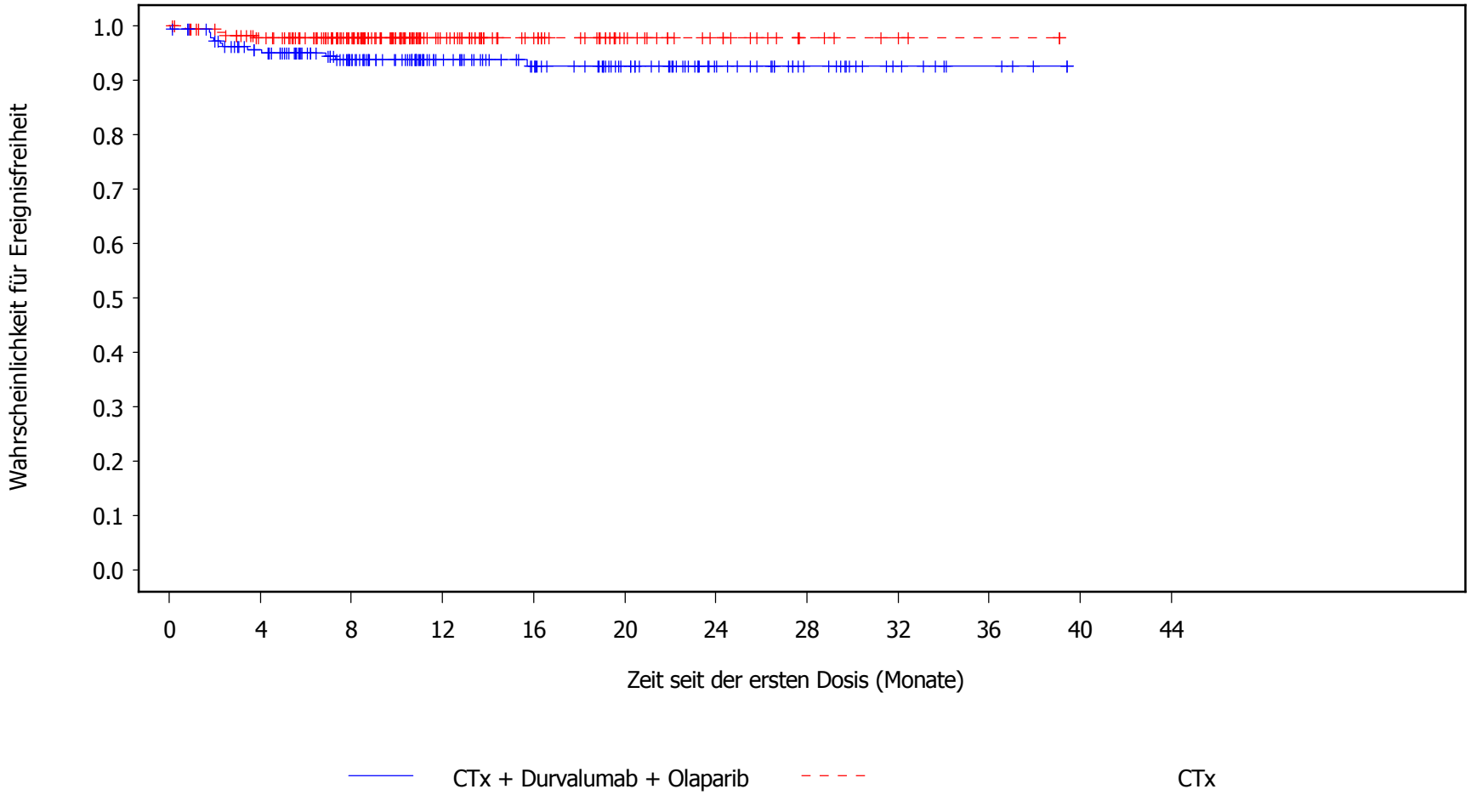
Figure 3.3.2.2D.110 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Gefaesserkrankungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	169	132	92	74	55	33	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	170	128	70	47	26	16	6	3	1	0	0	CTx

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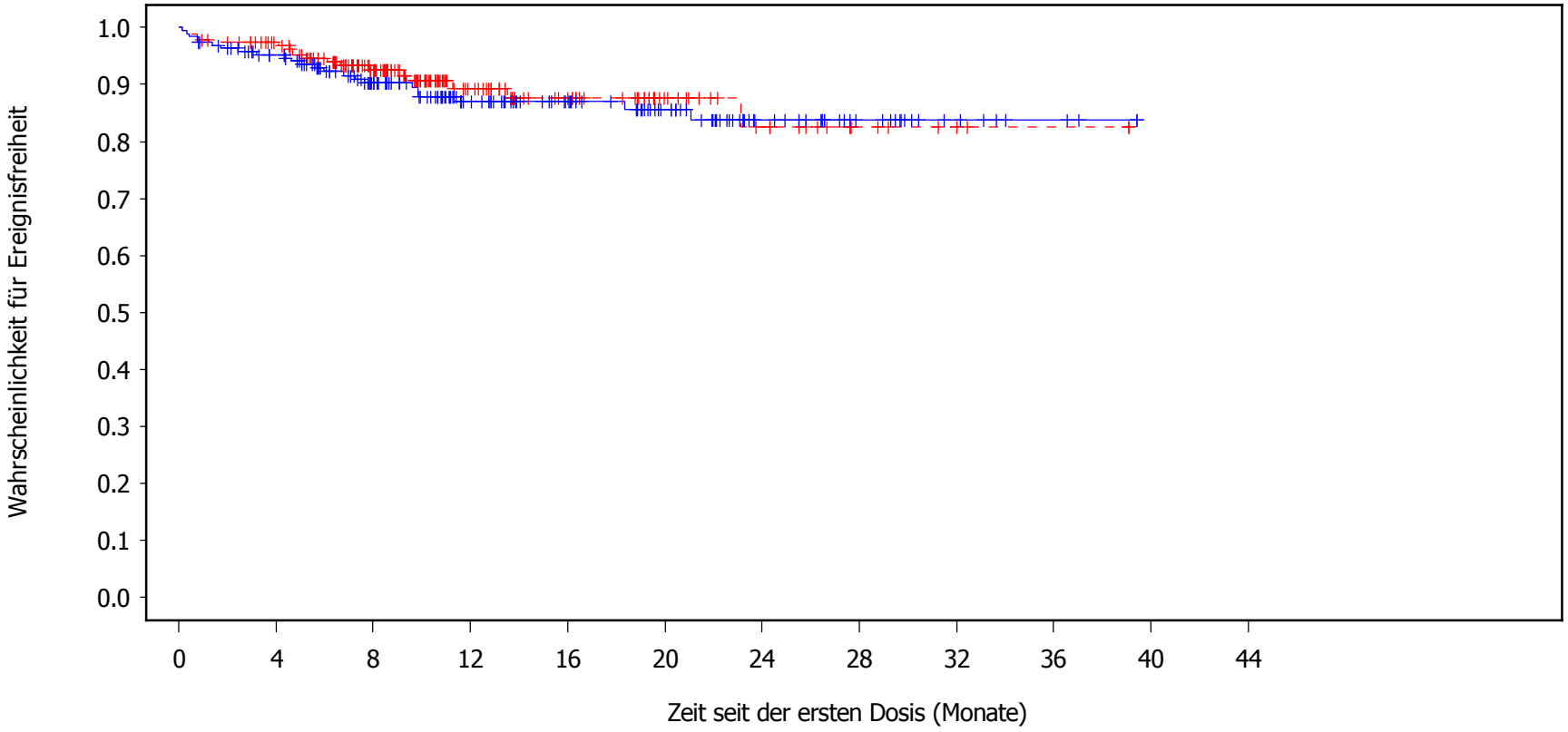
Figure 3.3.2.2D.111 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Infektionen und parasitaere Erkrankungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	169	129	88	69	52	29	16	7	3	0	0	CTx + Durvalumab + Olaparib
190	173	122	64	44	24	15	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebeg 15APR2024:10:33

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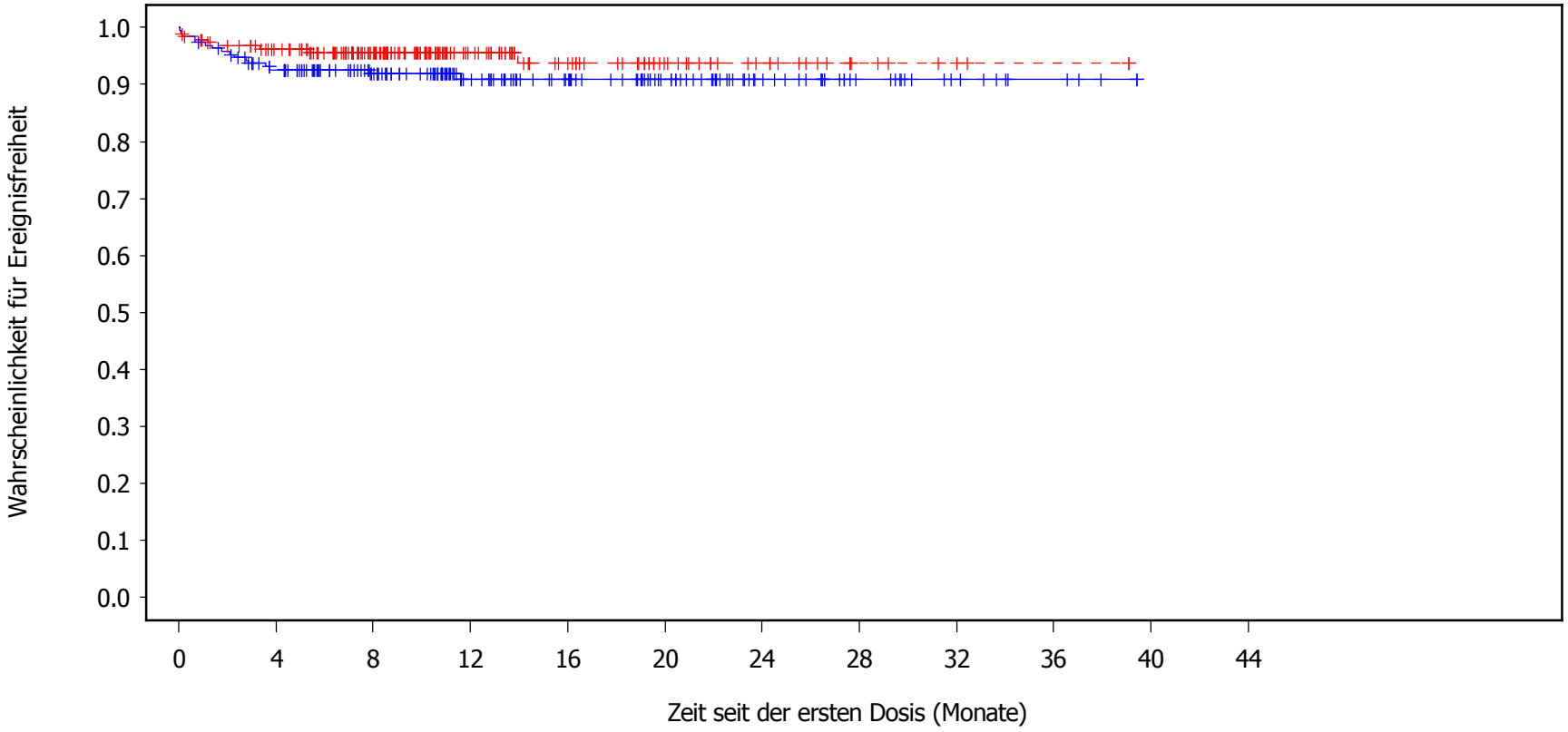
Figure 3.3.2.2D.112 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Stoffwechsel- und Ernaehrungsstoerungen
Patients with pMMR tumour status, DCO 18OCT2023

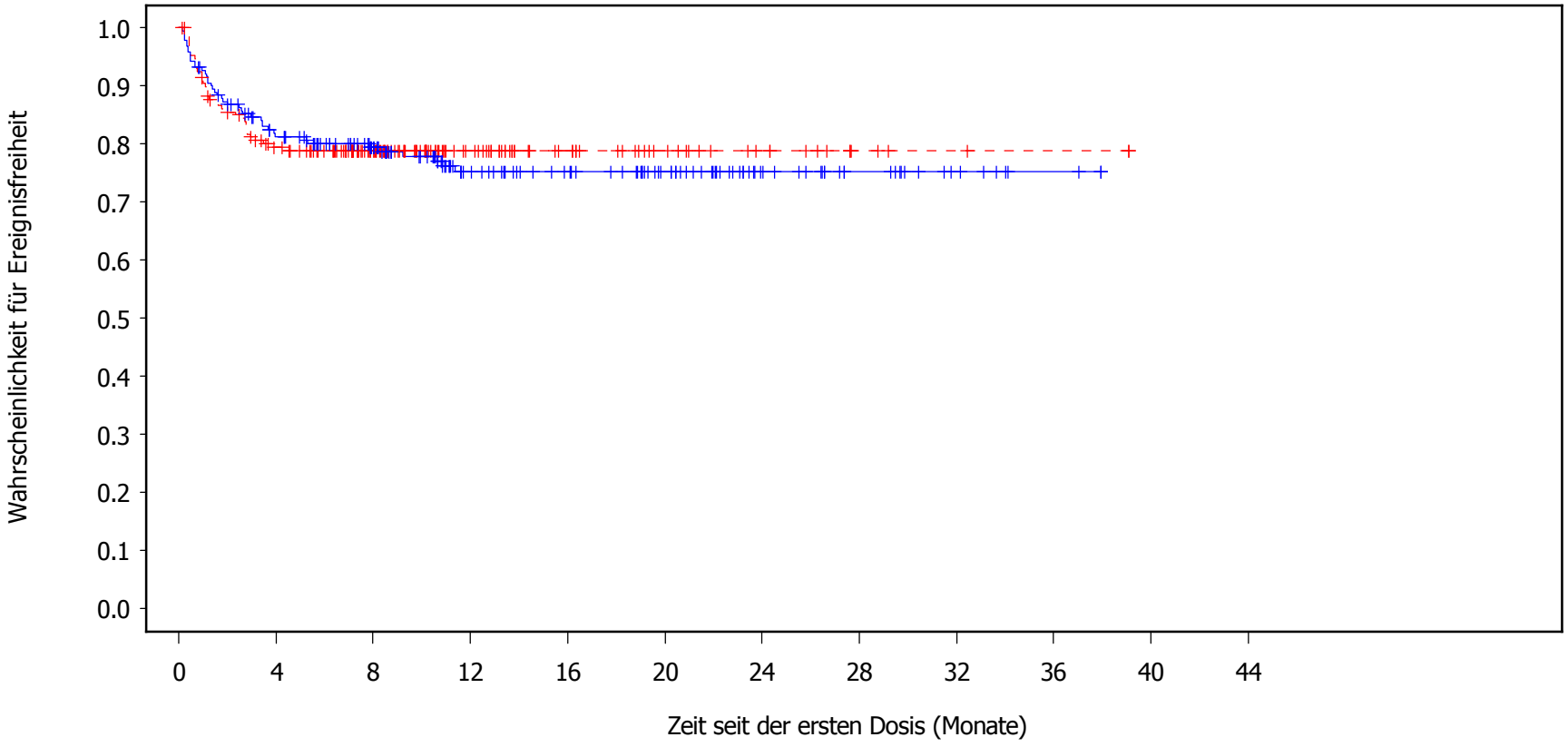


Anzahl an Patienten unter Risiko:

191	166	132	91	72	53	32	17	9	4	0	0	CTx + Durvalumab + Olaparib
190	167	125	67	44	26	16	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebeh 15APR2024:10:33

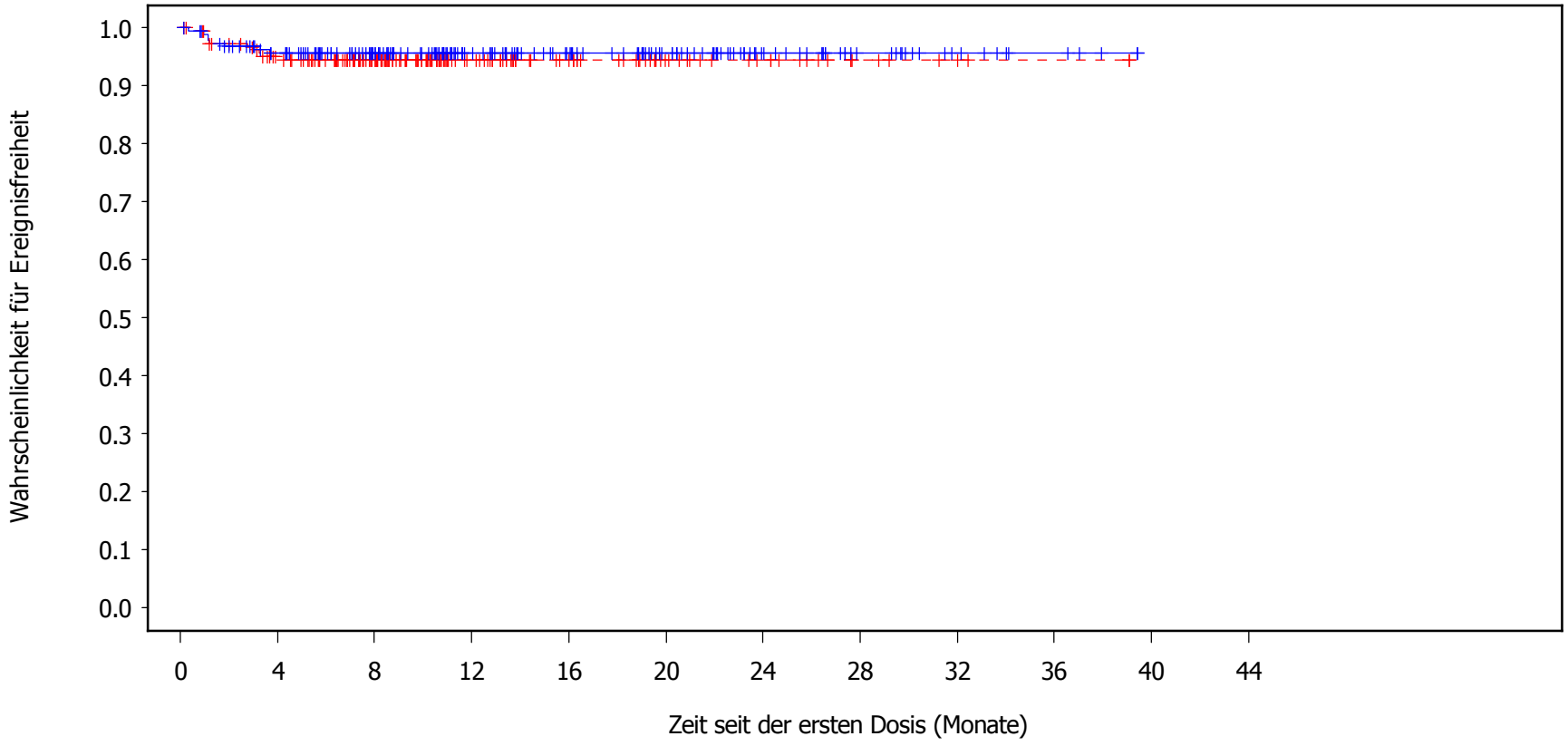
Figure 3.3.2.2D.113 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Untersuchungen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	144	115	76	63	48	26	15	7	2	0	0	CTx + Durvalumab + Olaparib
190	139	97	53	32	20	12	4	2	1	0	0	CTx

Figure 3.3.2.2D.114 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Leukozytenzahl erniedrigt
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	168	136	94	74	56	33	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	165	120	64	42	24	16	6	3	1	0	0	CTx

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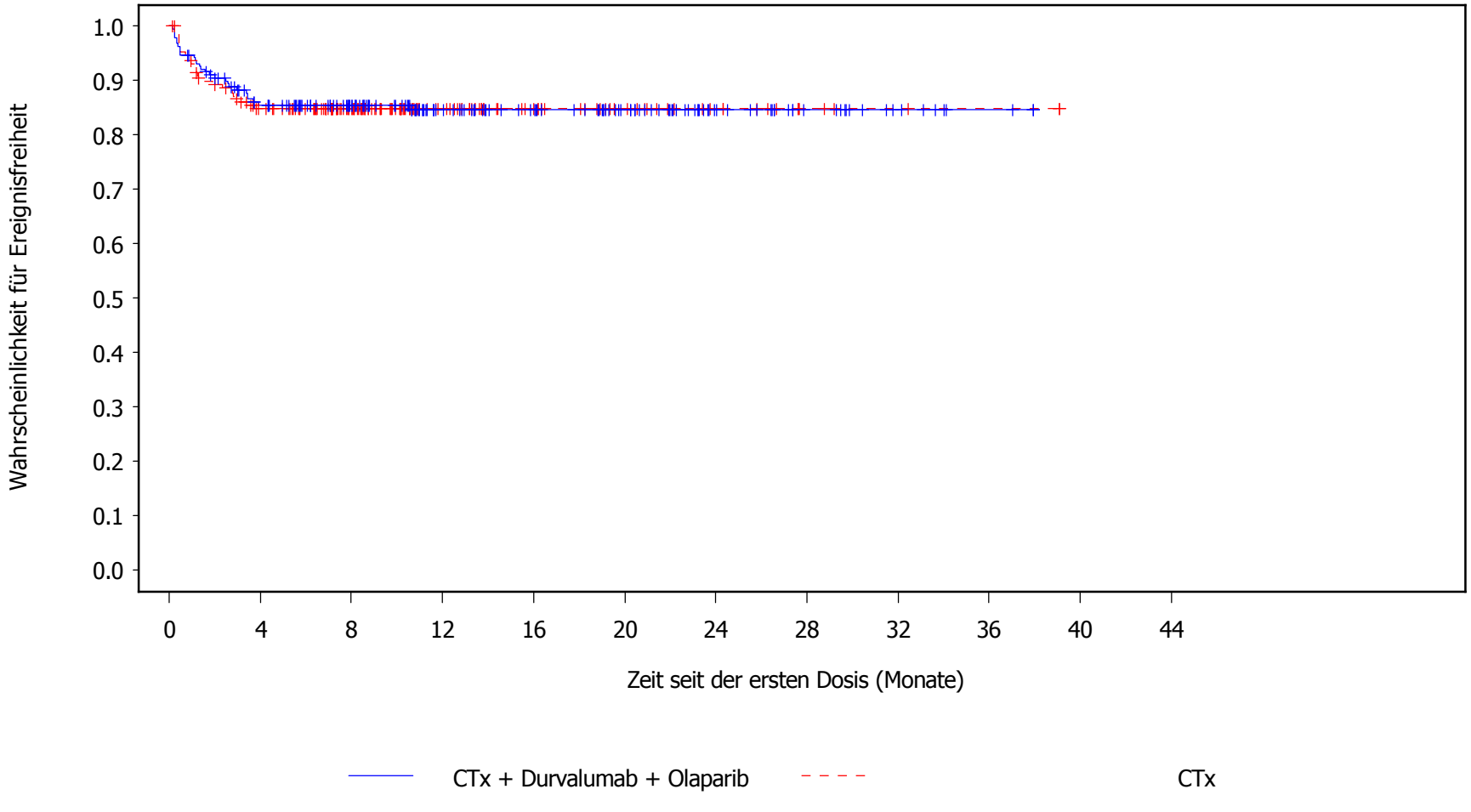
Figure 3.3.2.2D.115 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Neutrophilenzahl erniedrigt
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	150	121	81	66	50	27	15	7	2	0	0	CTx + Durvalumab + Olaparib
190	148	104	55	34	21	12	4	2	1	0	0	CTx

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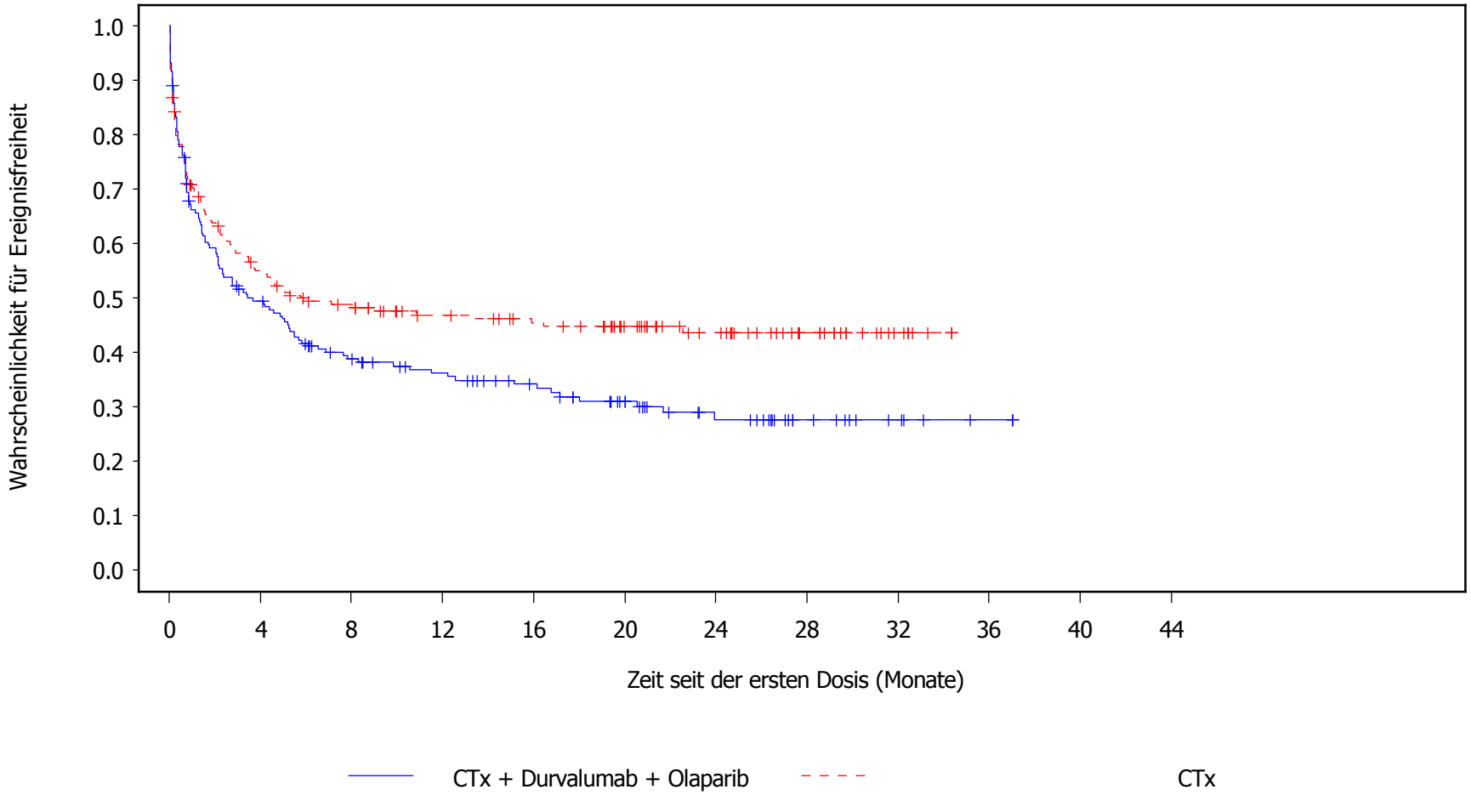
Figure 3.3.2.2D.116 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	90	65	55	45	34	22	11	5	1	0	0	CTx + Durvalumab + Olaparib
190	99	83	70	63	48	35	20	6	0	0	0	CTx

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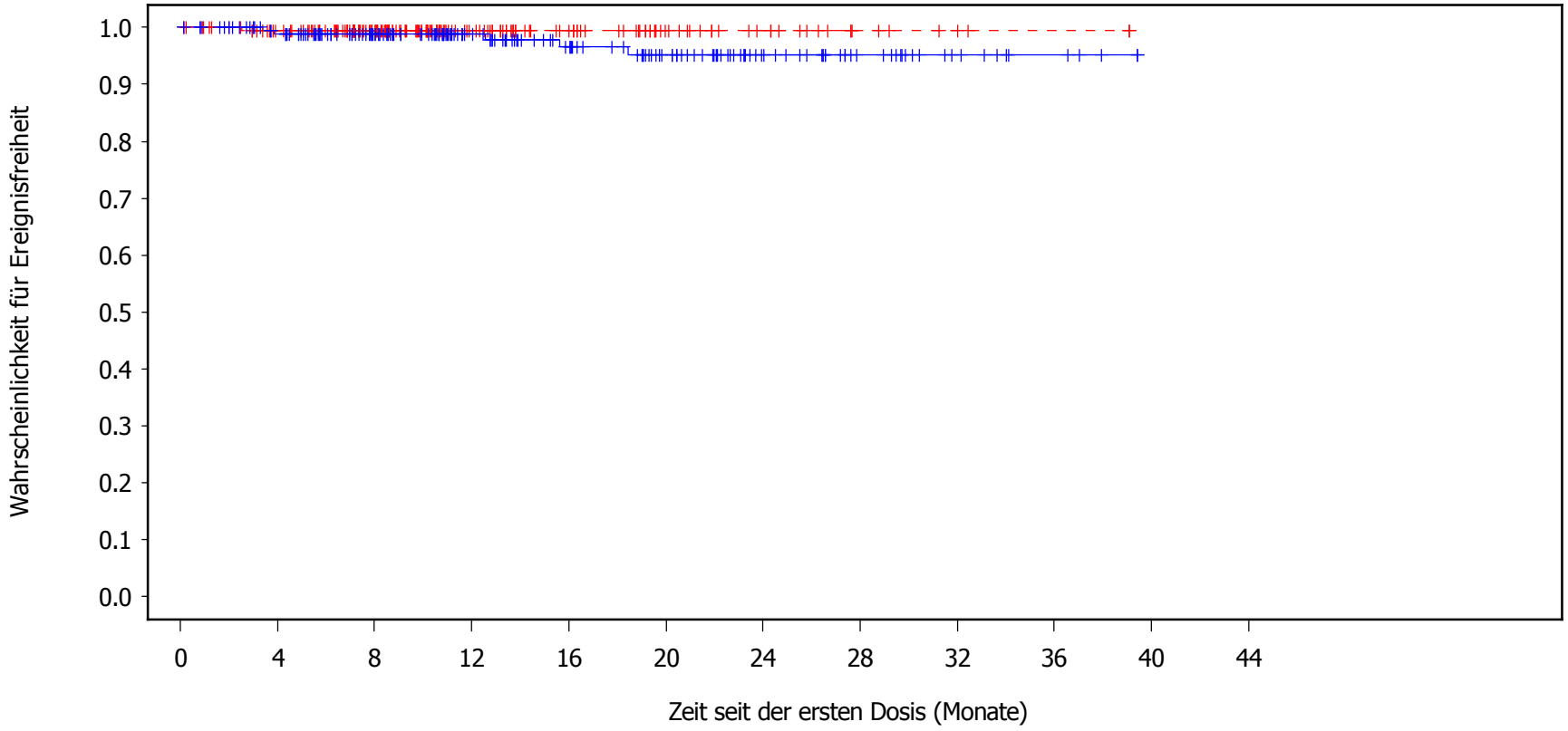
Figure 3.3.2.2D.117 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Andere seltene/sonstige Ereignisse
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	174	139	97	76	57	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	173	128	70	47	26	16	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebem 15APR2024:10:33

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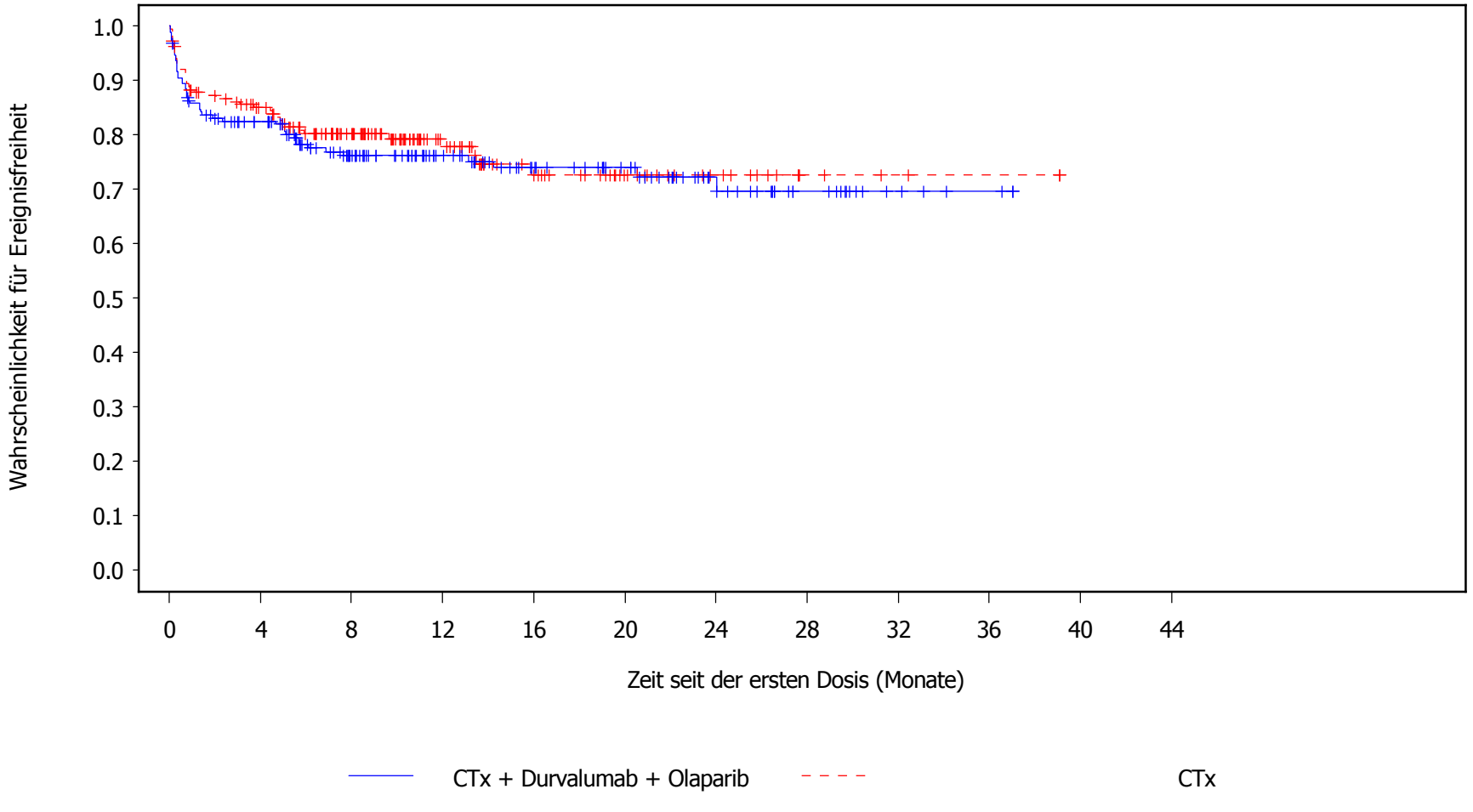
Figure 3.3.2.2D.118 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Dermatitis/Hautausschlag
Patients with pMMR tumour status, DCO 18OCT2023

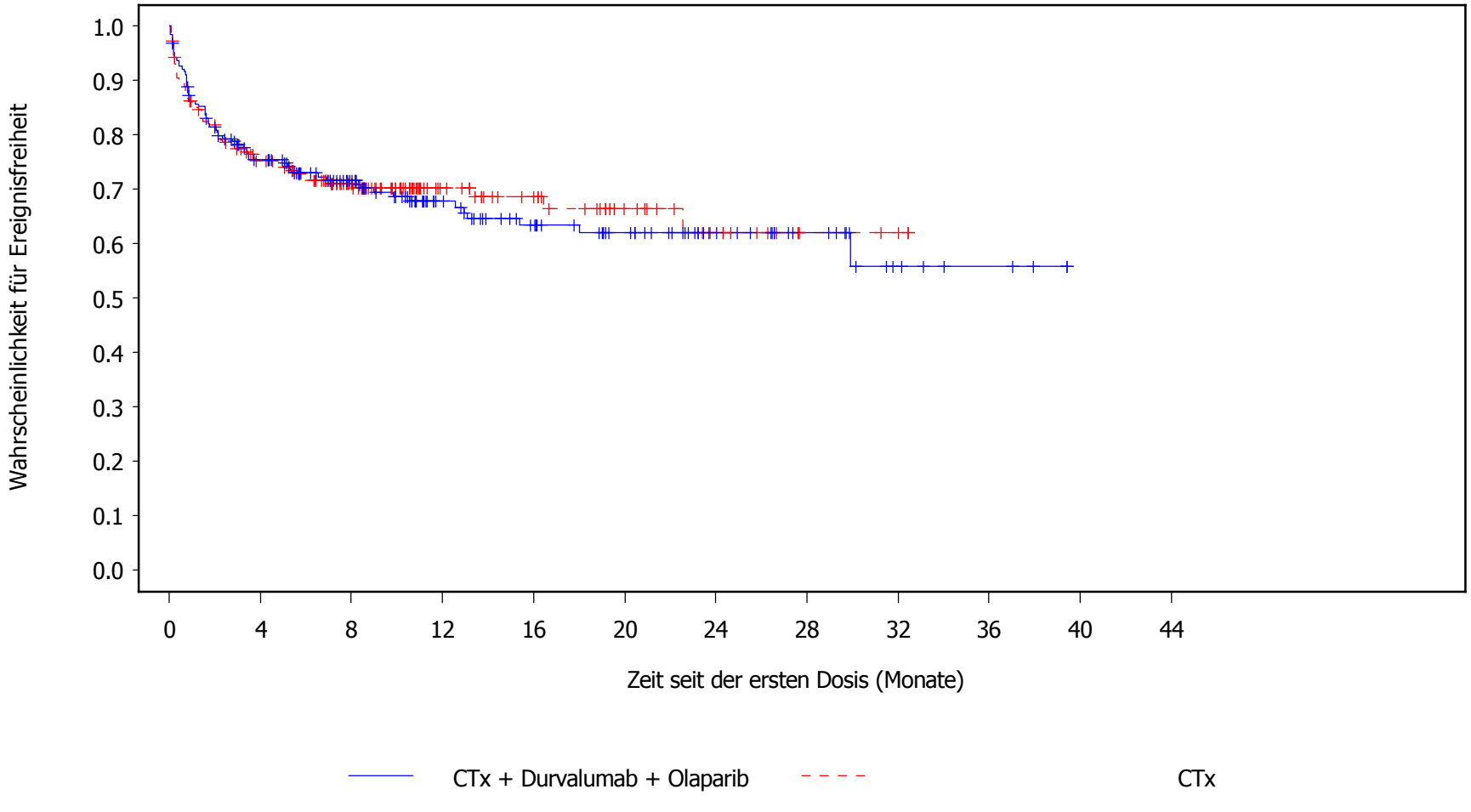


Anzahl an Patienten unter Risiko:

191	143	104	75	57	46	28	14	5	2	0	0	CTx + Durvalumab + Olaparib
190	147	105	59	36	22	13	4	2	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaeben 15APR2024:10:33

Figure 3.3.2.2D.119 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Diarrhö/Kolitis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	132	101	66	50	39	24	15	6	3	0	0	CTx + Durvalumab + Olaparib
190	131	92	48	36	20	12	3	2	0	0	0	CTx

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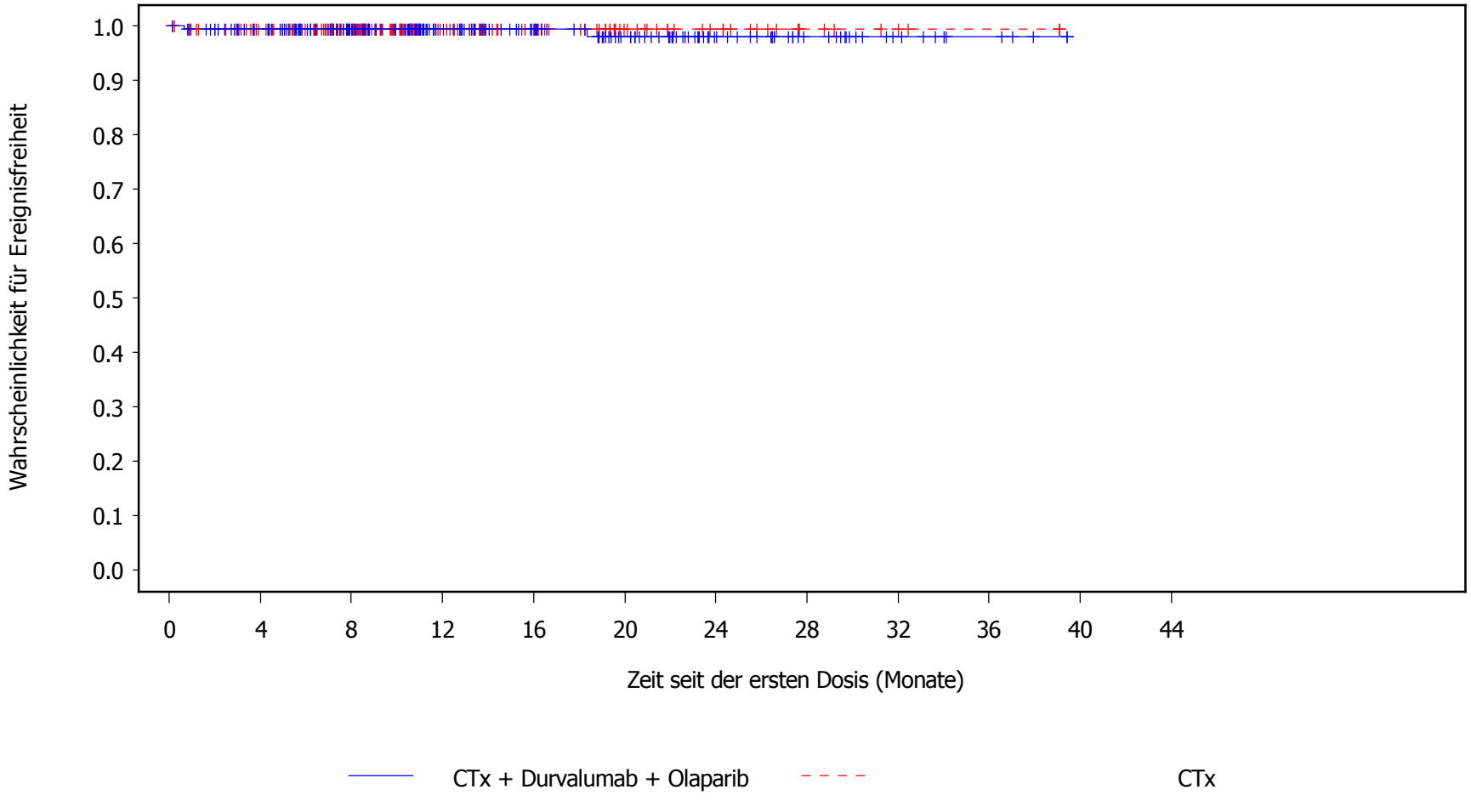
Figure 3.3.2.2D.120 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Hepatische Ereignisse
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	175	141	97	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	173	128	69	46	26	16	6	3	1	0	0	CTx

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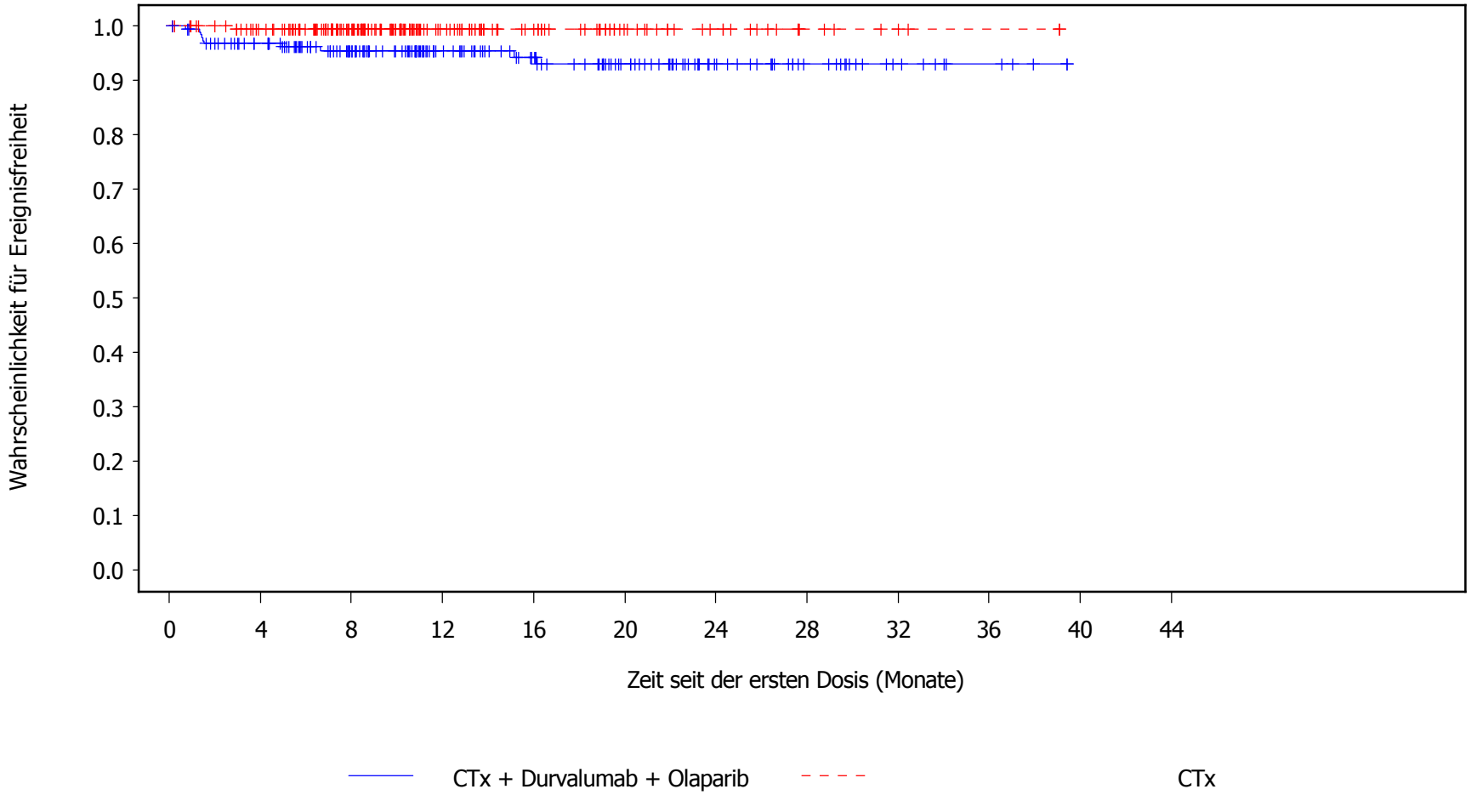
Figure 3.3.2.2D.121 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Hyperthyreose Ereignisse
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	170	136	95	75	55	33	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	173	128	69	46	26	16	6	3	1	0	0	CTx

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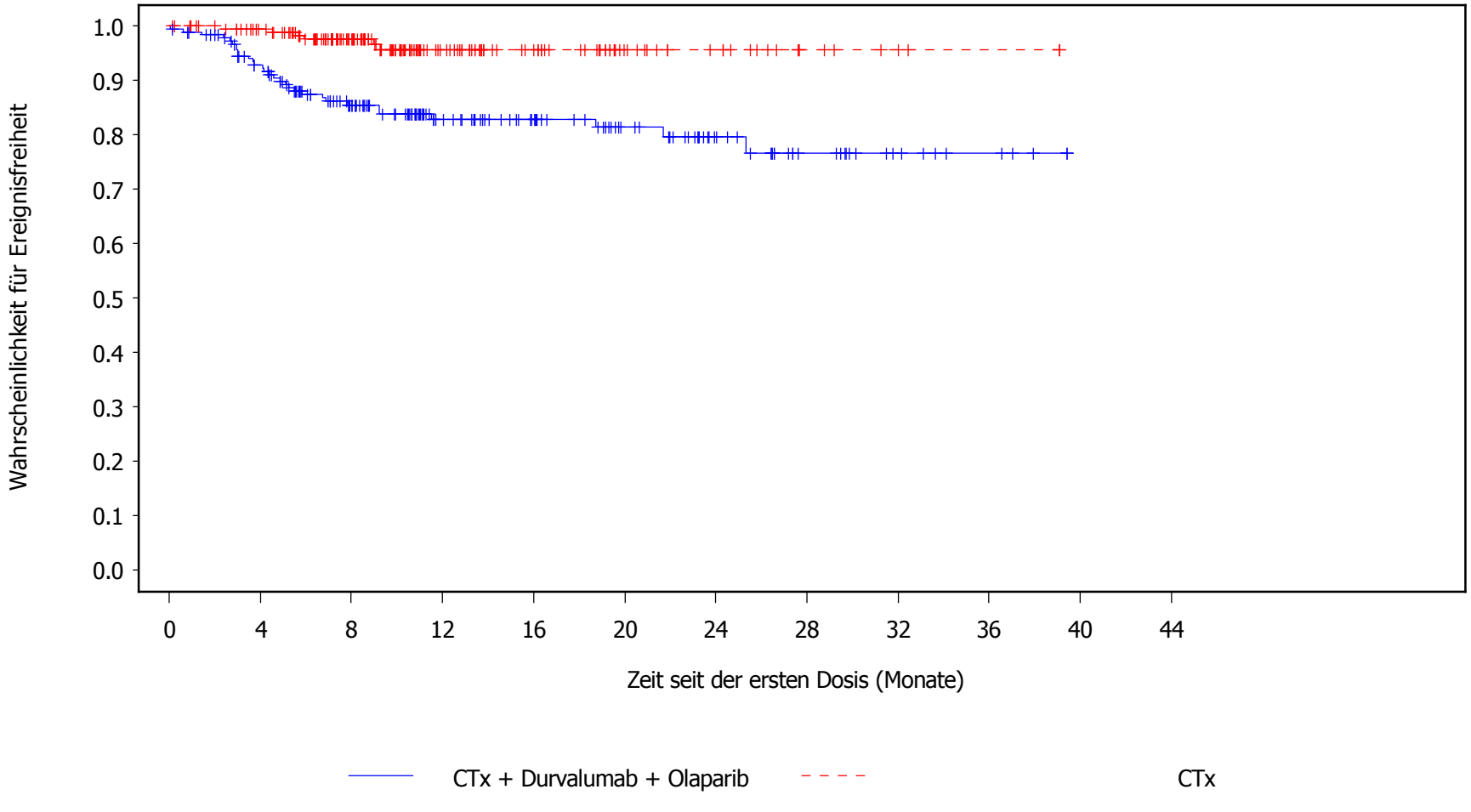
Figure 3.3.2.2D.122 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Hypothyreose Ereignisse
Patients with pMMR tumour status, DCO 18OCT2023

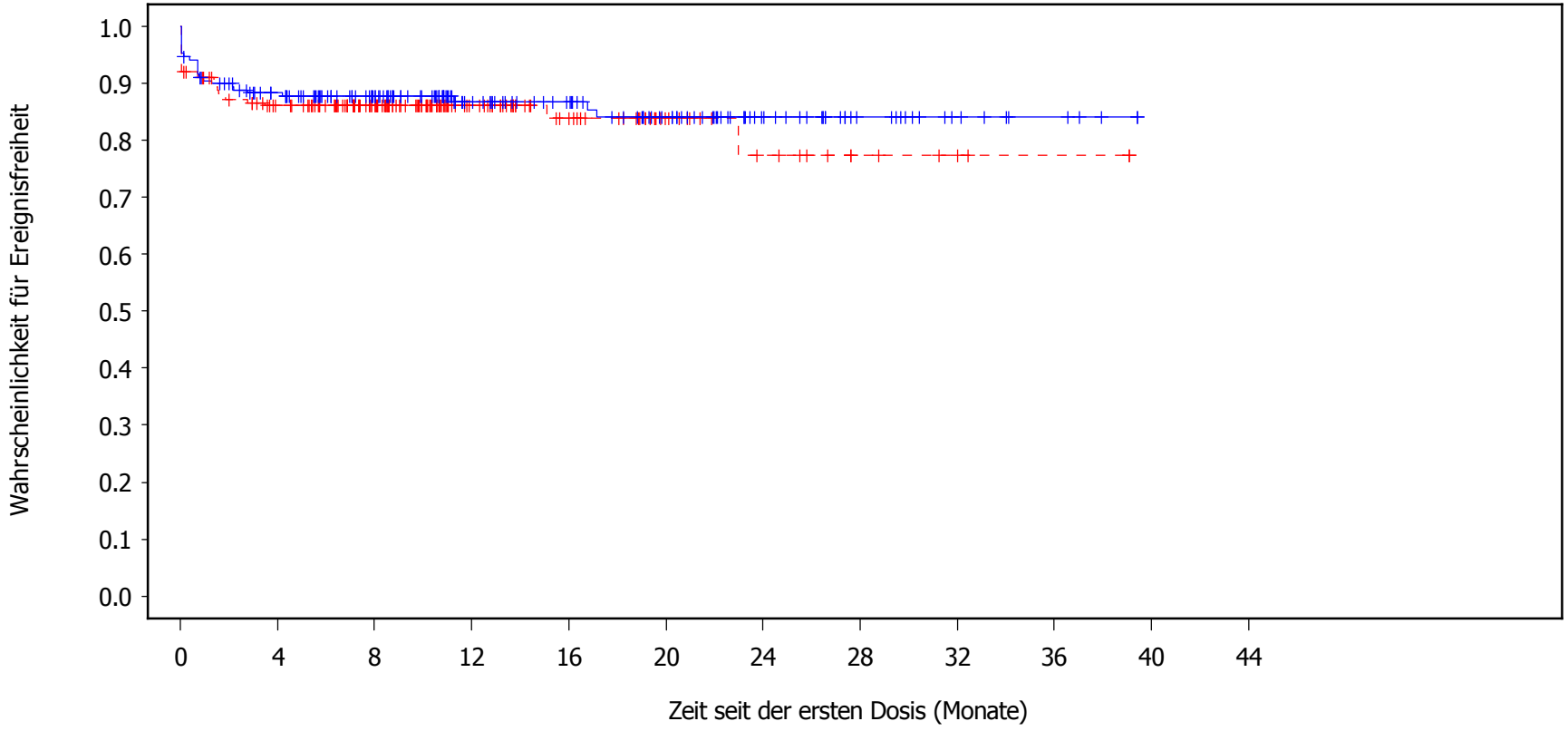


Anzahl an Patienten unter Risiko:

191	163	121	80	63	46	30	16	8	4	0	0	CTx + Durvalumab + Olaparib
190	173	125	67	45	24	16	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaeber 15APR2024:10:33

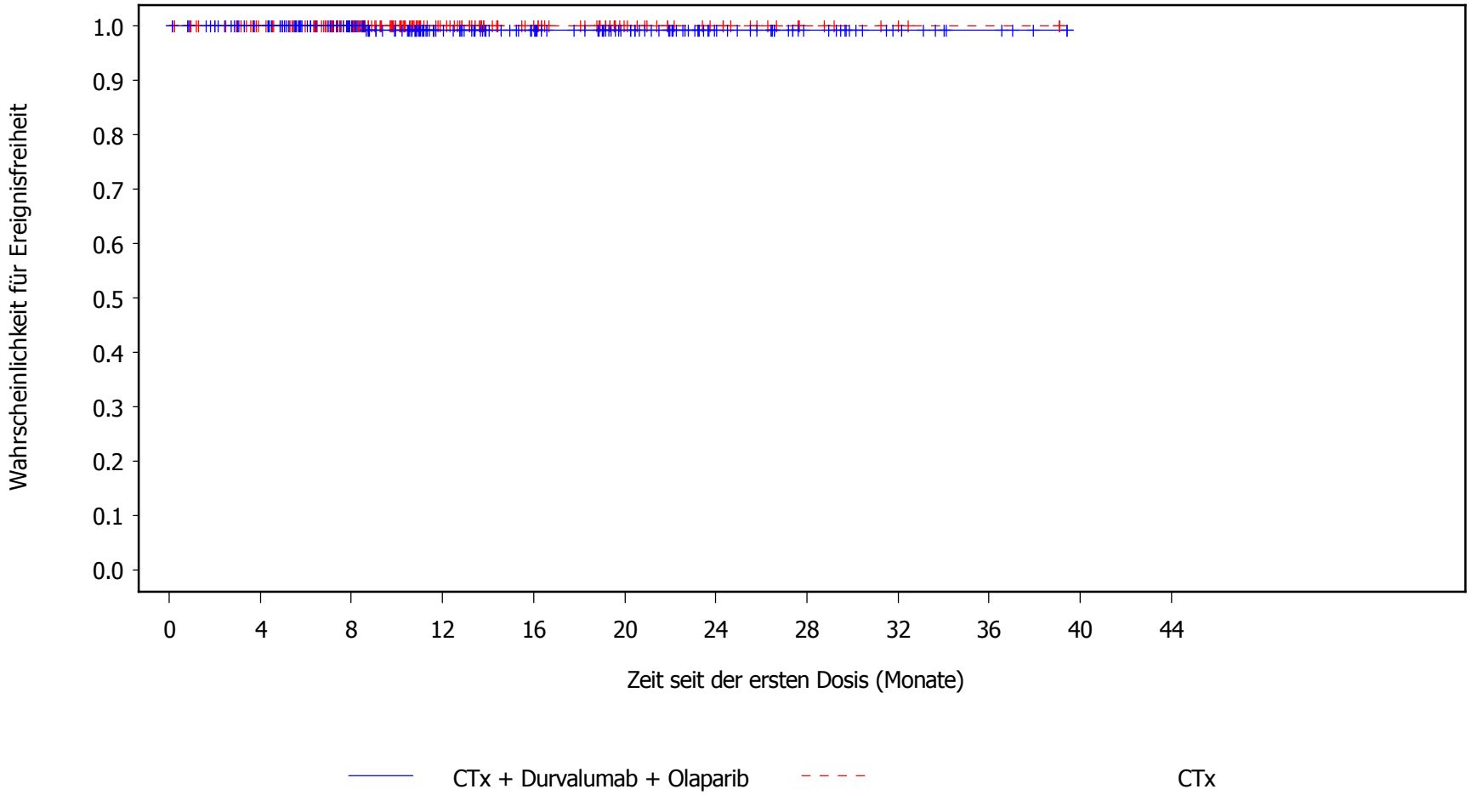
Figure 3.3.2.2D.123 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	154	124	83	69	52	31	16	8	4	0	0	CTx + Durvalumab + Olaparib
190	149	111	59	37	19	11	5	3	1	0	0	CTx

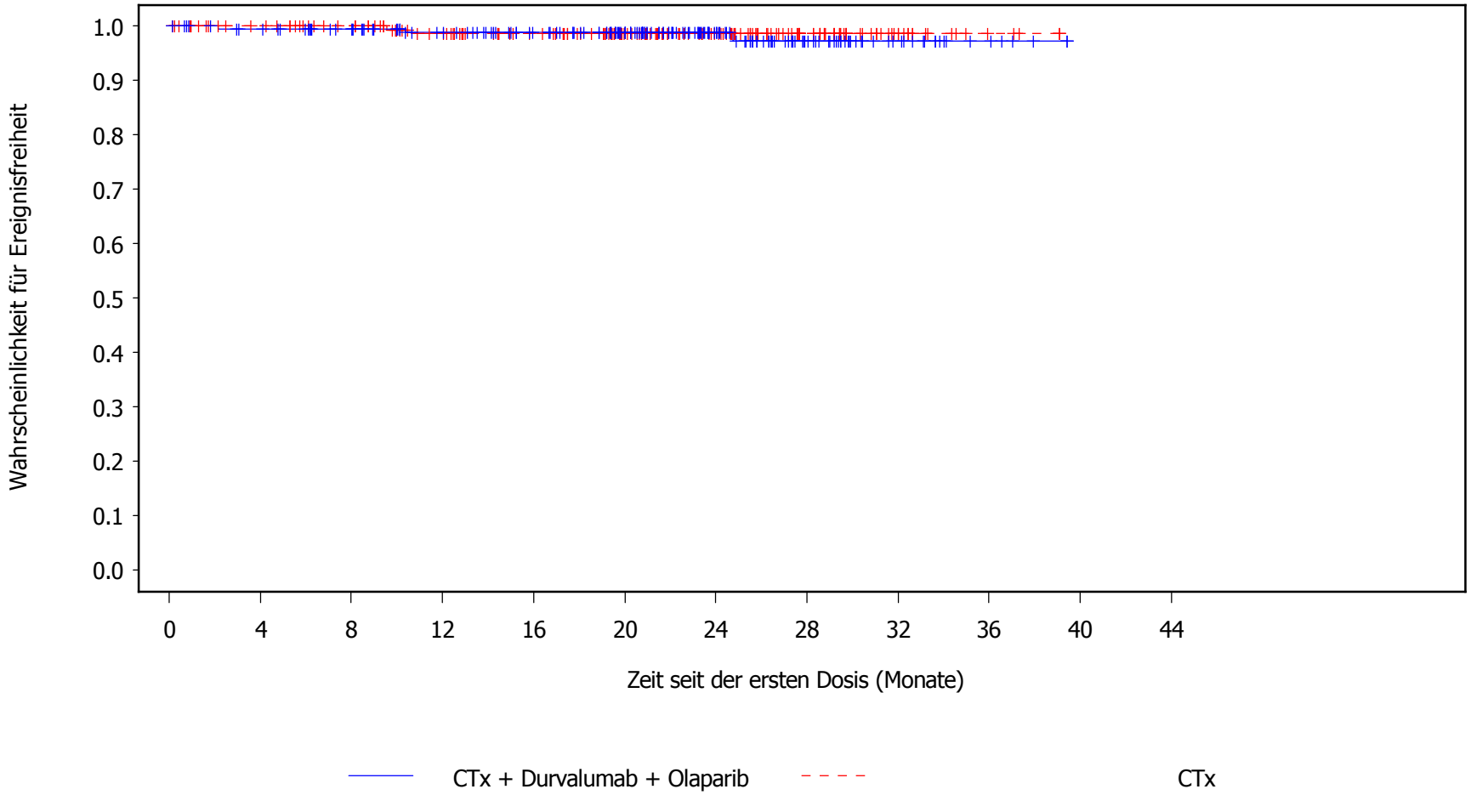
Figure 3.3.2.2D.124 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Myositis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	176	141	97	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	70	47	26	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.125 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Neue primäre Malignität
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	183	173	157	141	118	71	37	16	5	0	0	CTx + Durvalumab + Olaparib
190	178	167	149	133	105	76	43	16	3	0	0	CTx

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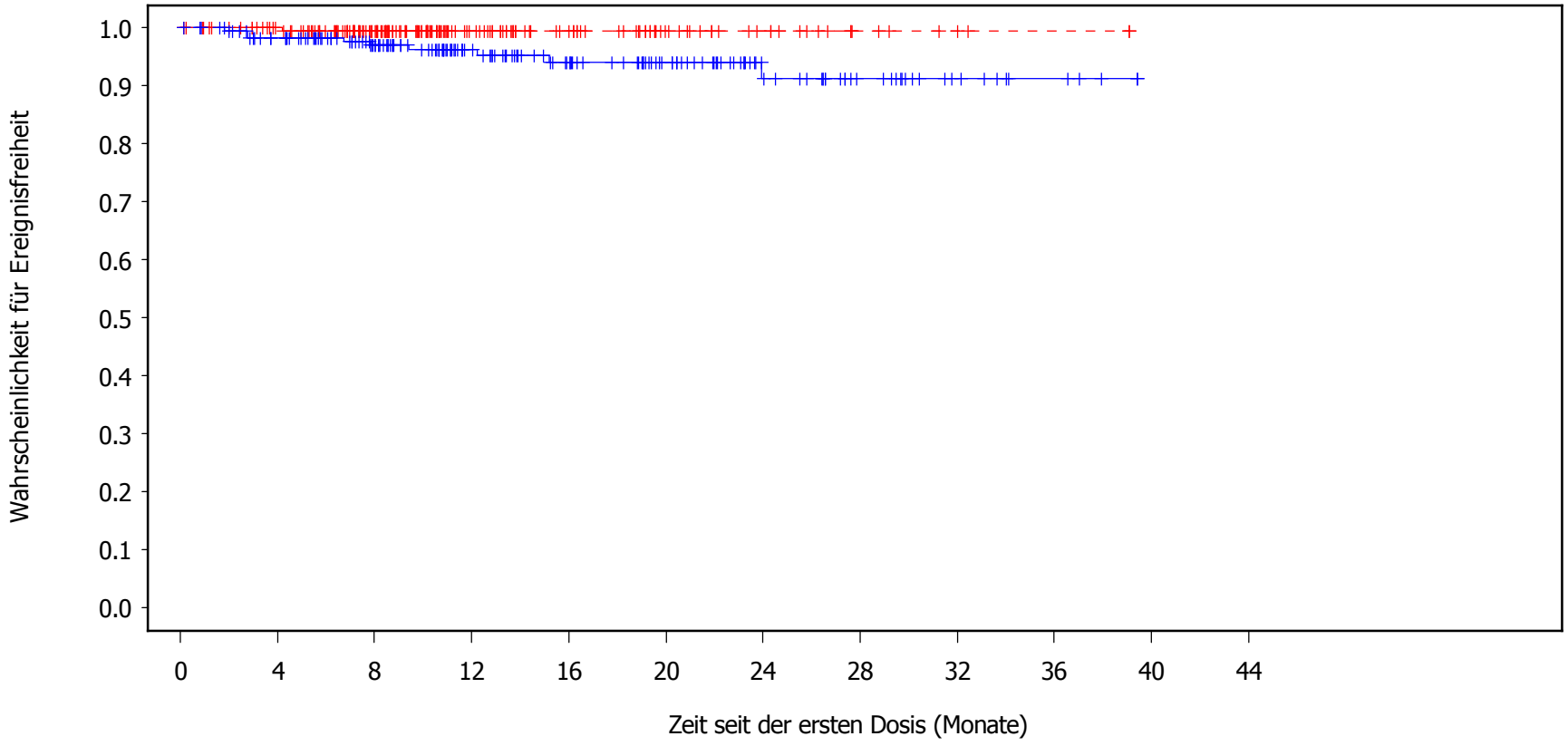
Figure 3.3.2.2D.126 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Pneumonitis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	173	140	98	76	57	33	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	128	70	47	26	16	6	3	1	0	0	CTx

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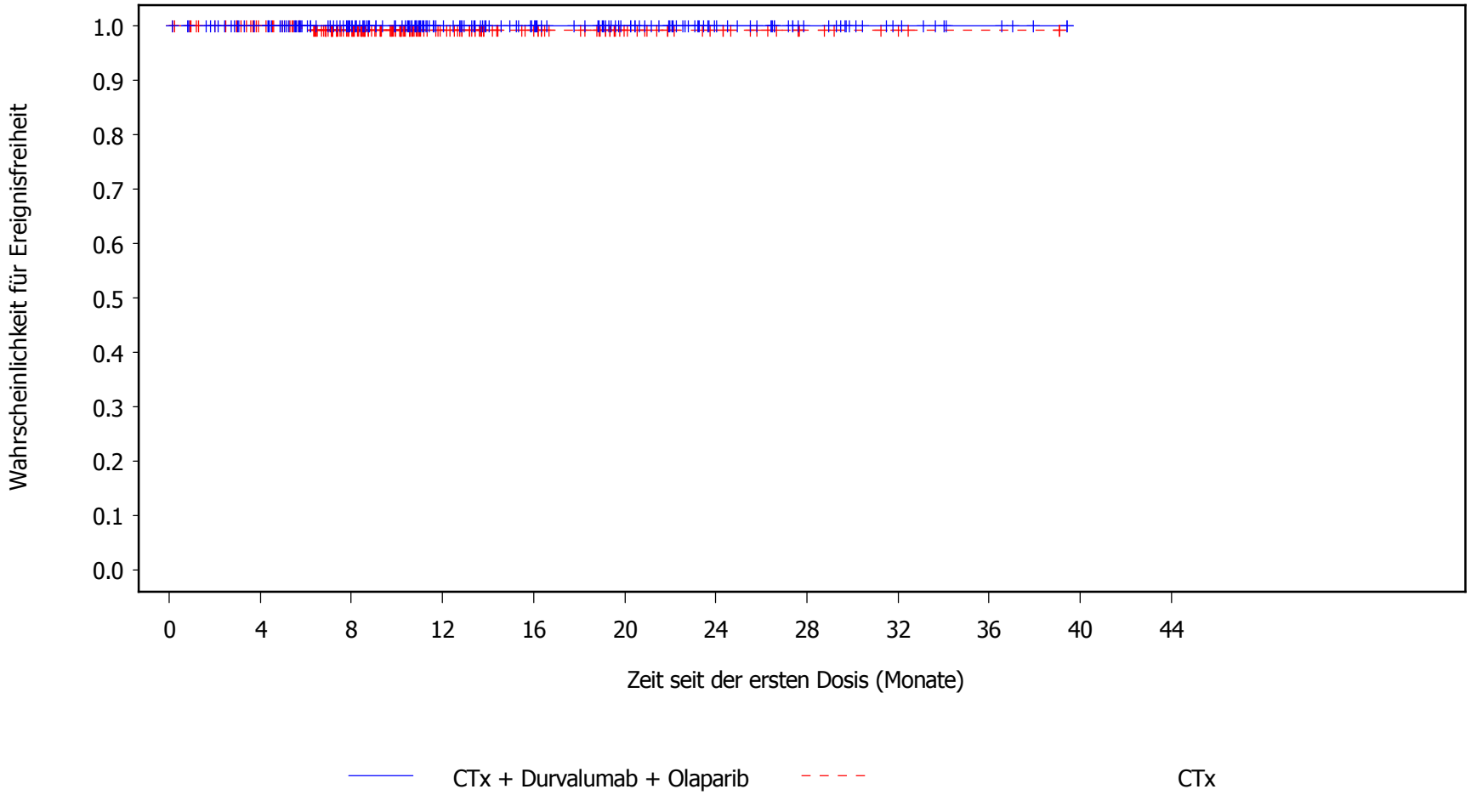
Figure 3.3.2.2D.127 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Renale Ereignisse
Patients with pMMR tumour status, DCO 18OCT2023

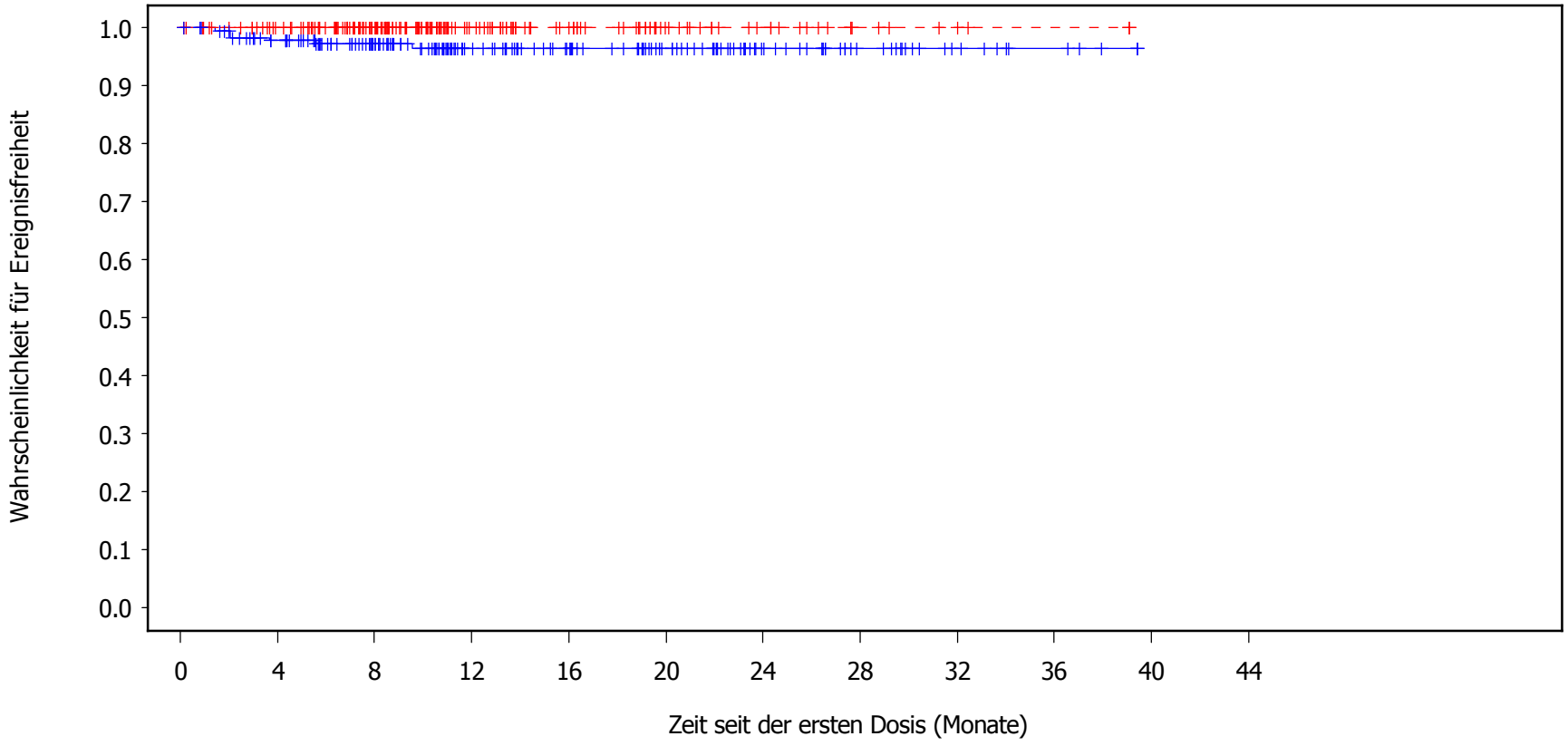


Anzahl an Patienten unter Risiko:

191	176	141	97	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	70	47	26	16	6	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebew 15APR2024:10:33

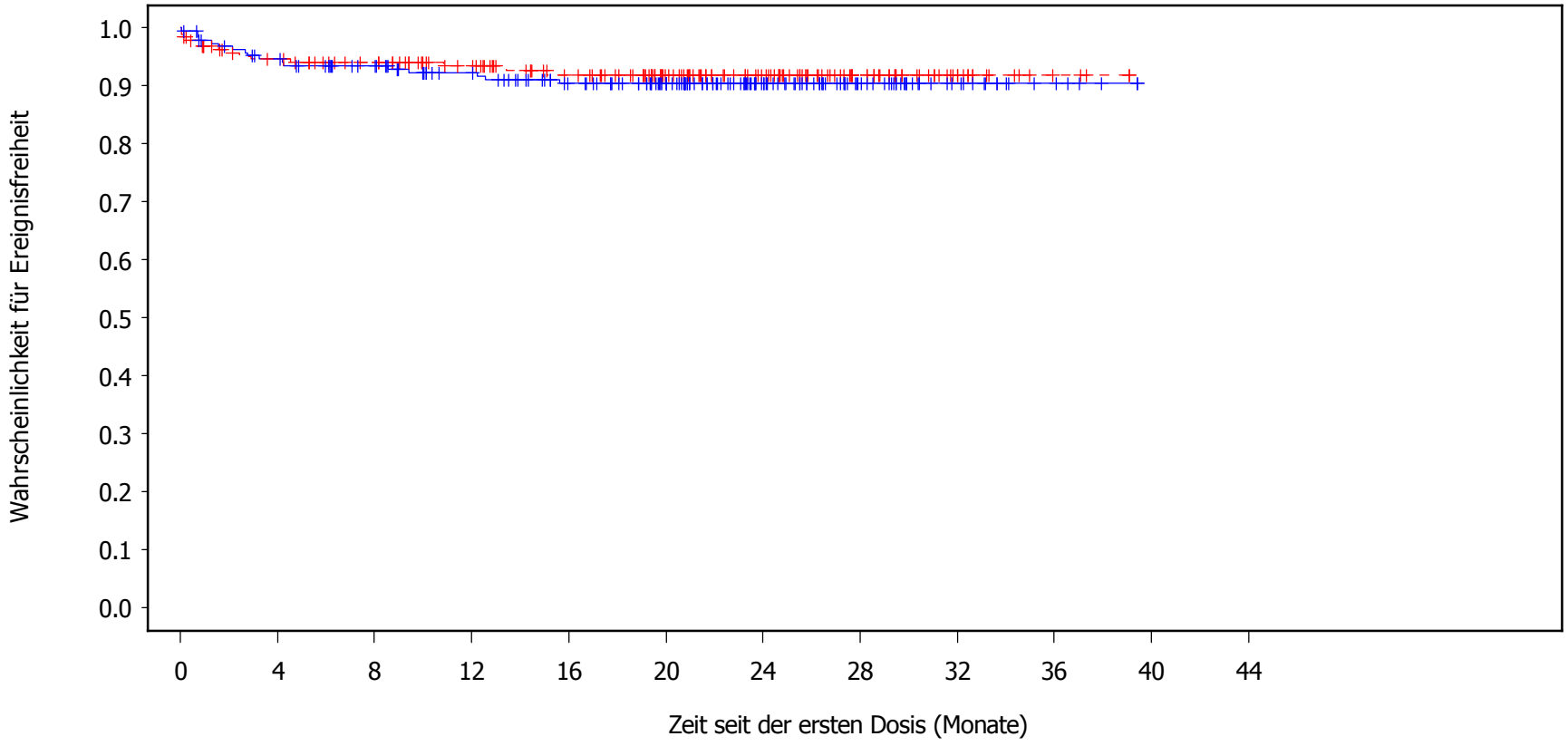
Figure 3.3.2.2D.128 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI GT: Thyreoiditis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	172	138	94	76	57	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	70	47	26	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.129 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	174	162	147	130	109	66	35	15	5	0	0	CTx + Durvalumab + Olaparib
190	169	158	142	124	96	70	39	16	3	0	0	CTx

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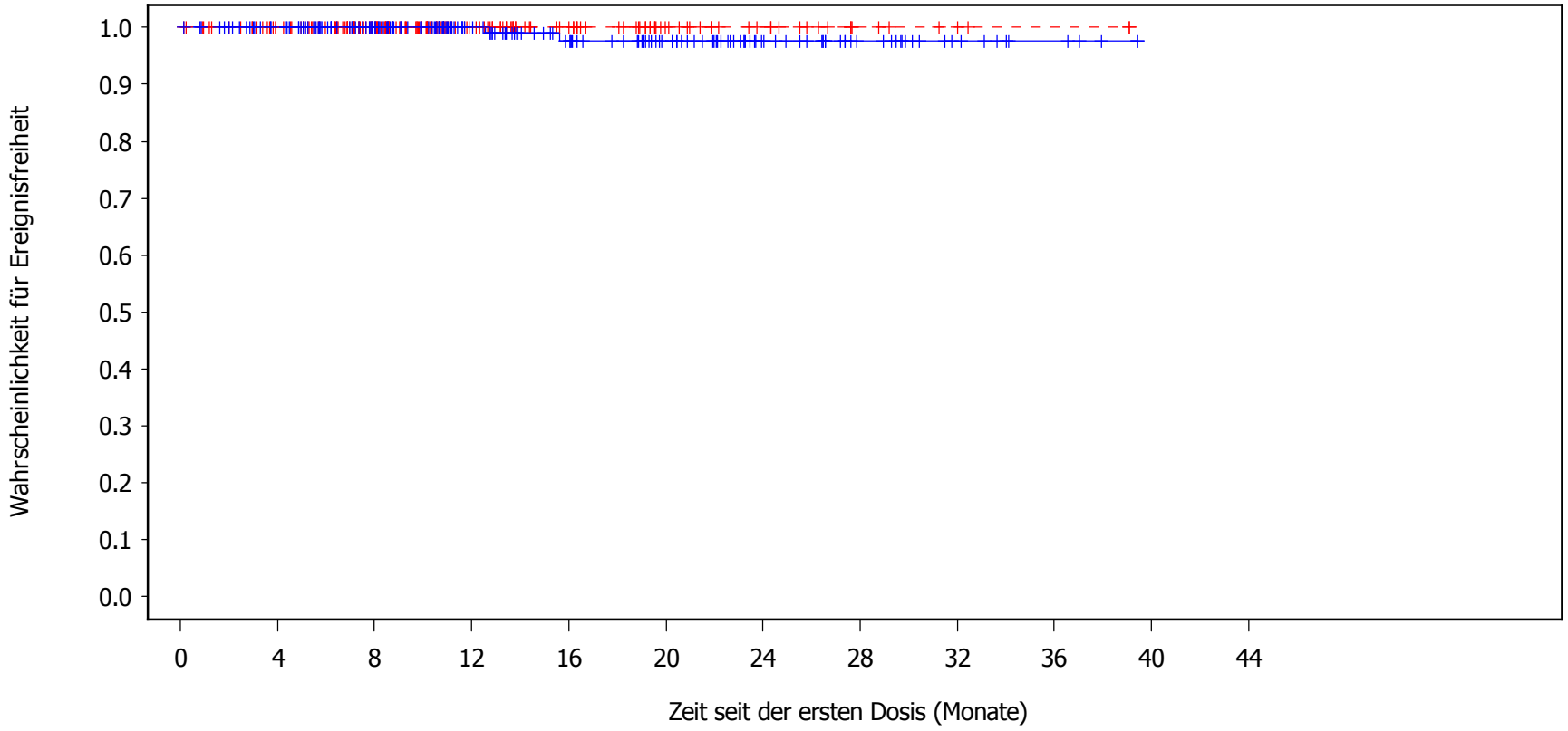
Figure 3.3.2.2D.130 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	176	141	98	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	70	47	26	16	6	3	1	0	0	CTx

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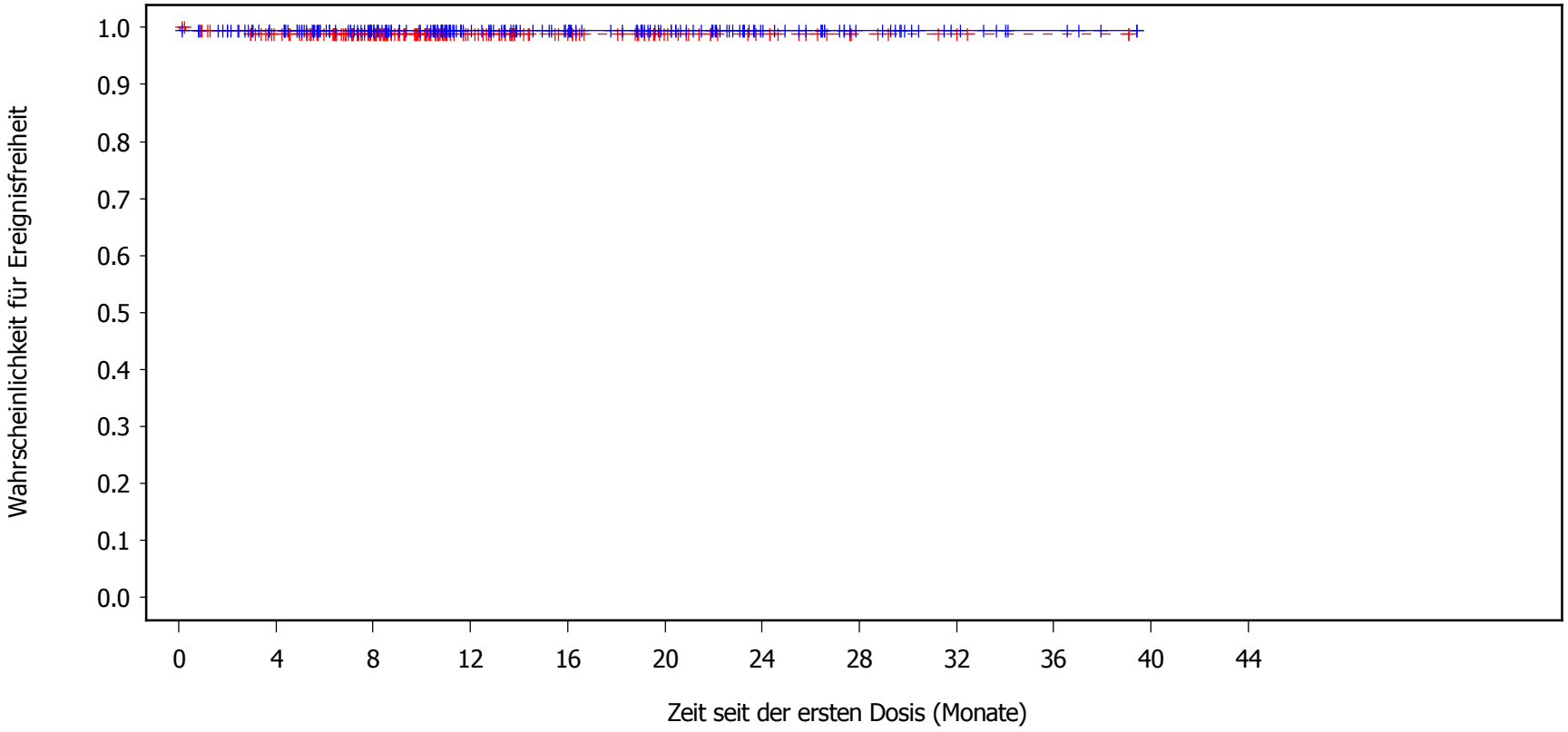
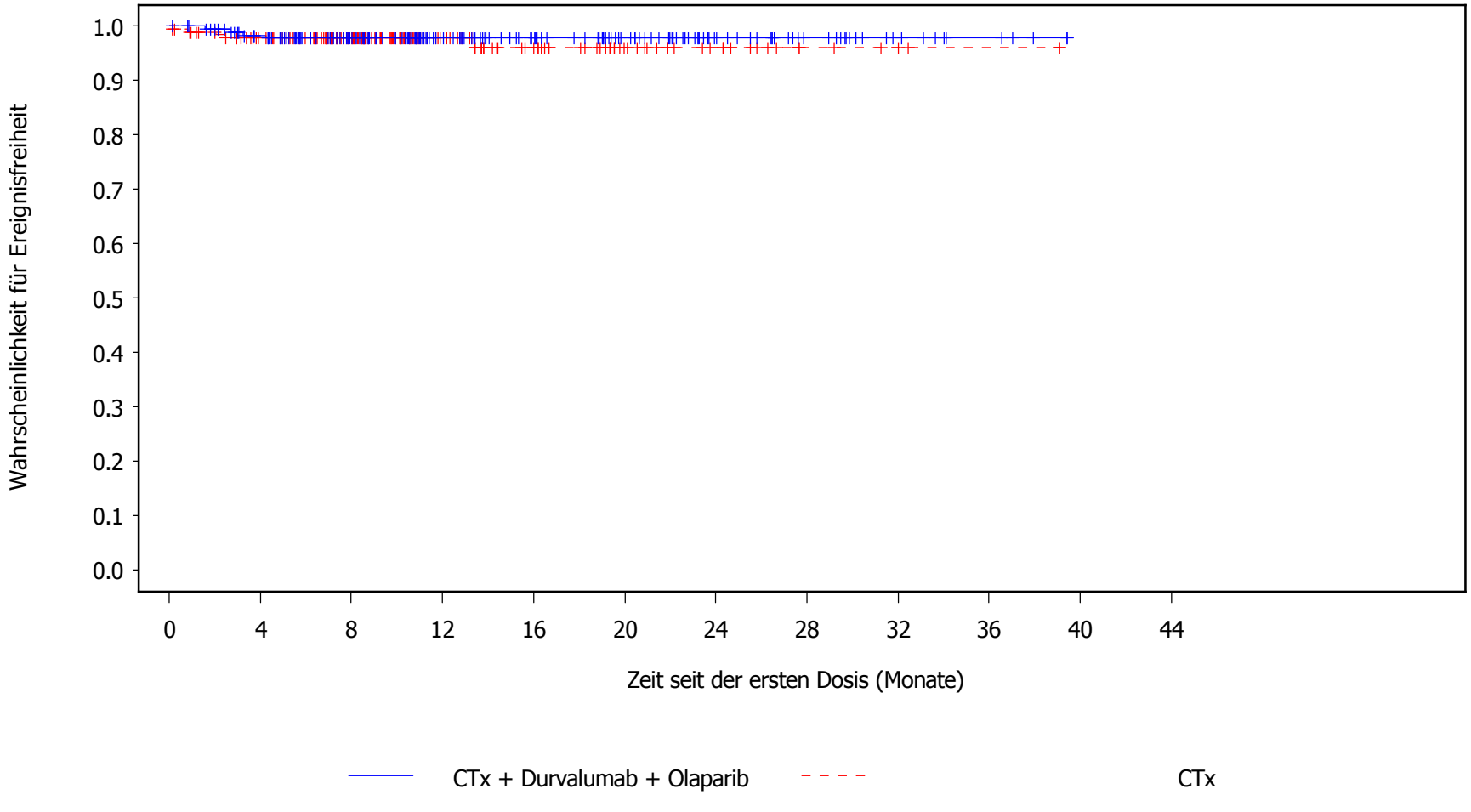
Figure 3.3.2.2D.131 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Dermatitis/Hautausschlag
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	175	140	97	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	172	128	70	47	26	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.132 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Diarrhö/Kolitis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	173	138	95	75	56	33	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	170	125	67	45	25	15	5	3	1	0	0	CTx

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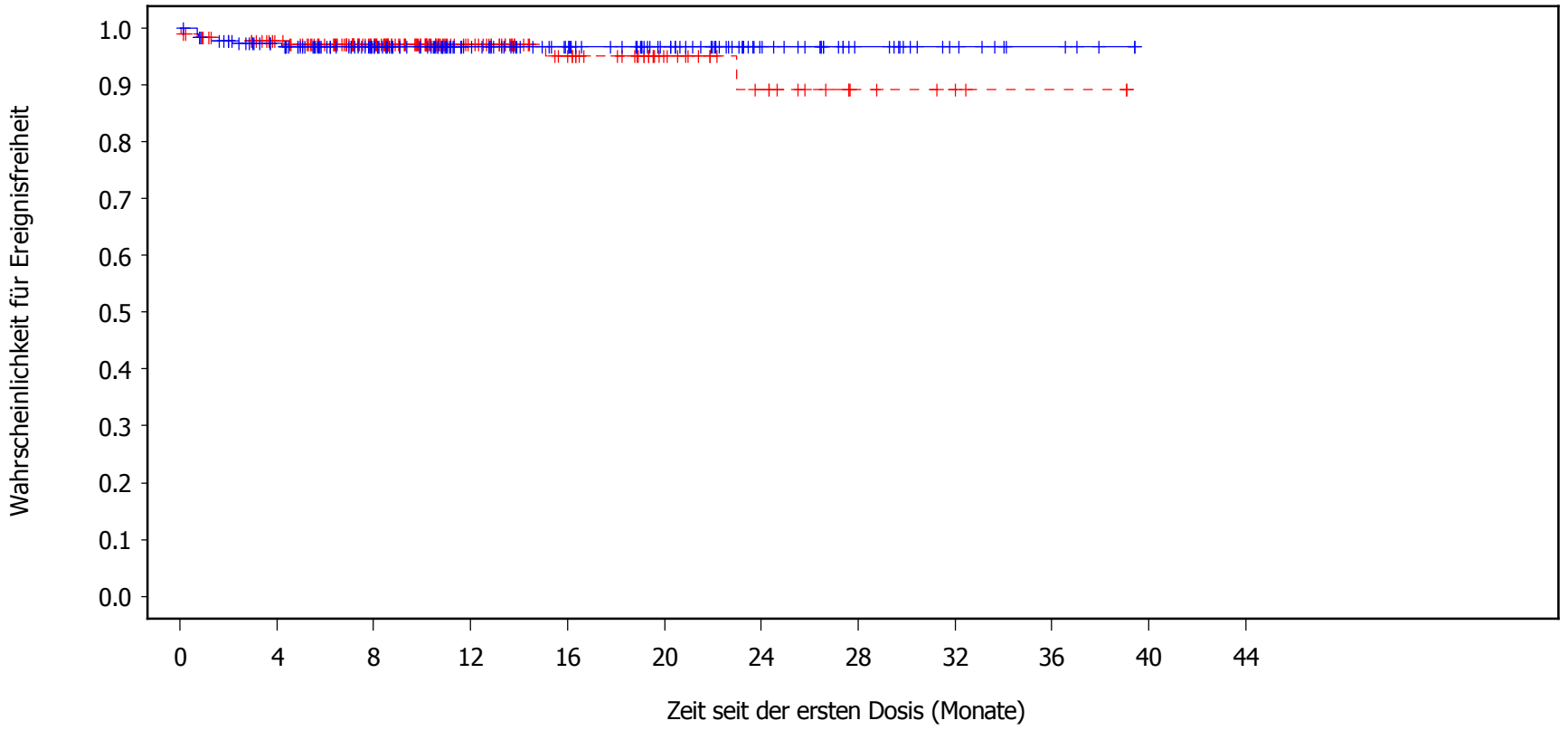
Figure 3.3.2.2D.133 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Infusions- und Überempfindlichkeitsreaktionen
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	171	136	94	75	57	33	18	9	4	0	0	CTx + Durvalumab + Olaparib
190	171	126	69	45	24	14	5	3	1	0	0	CTx

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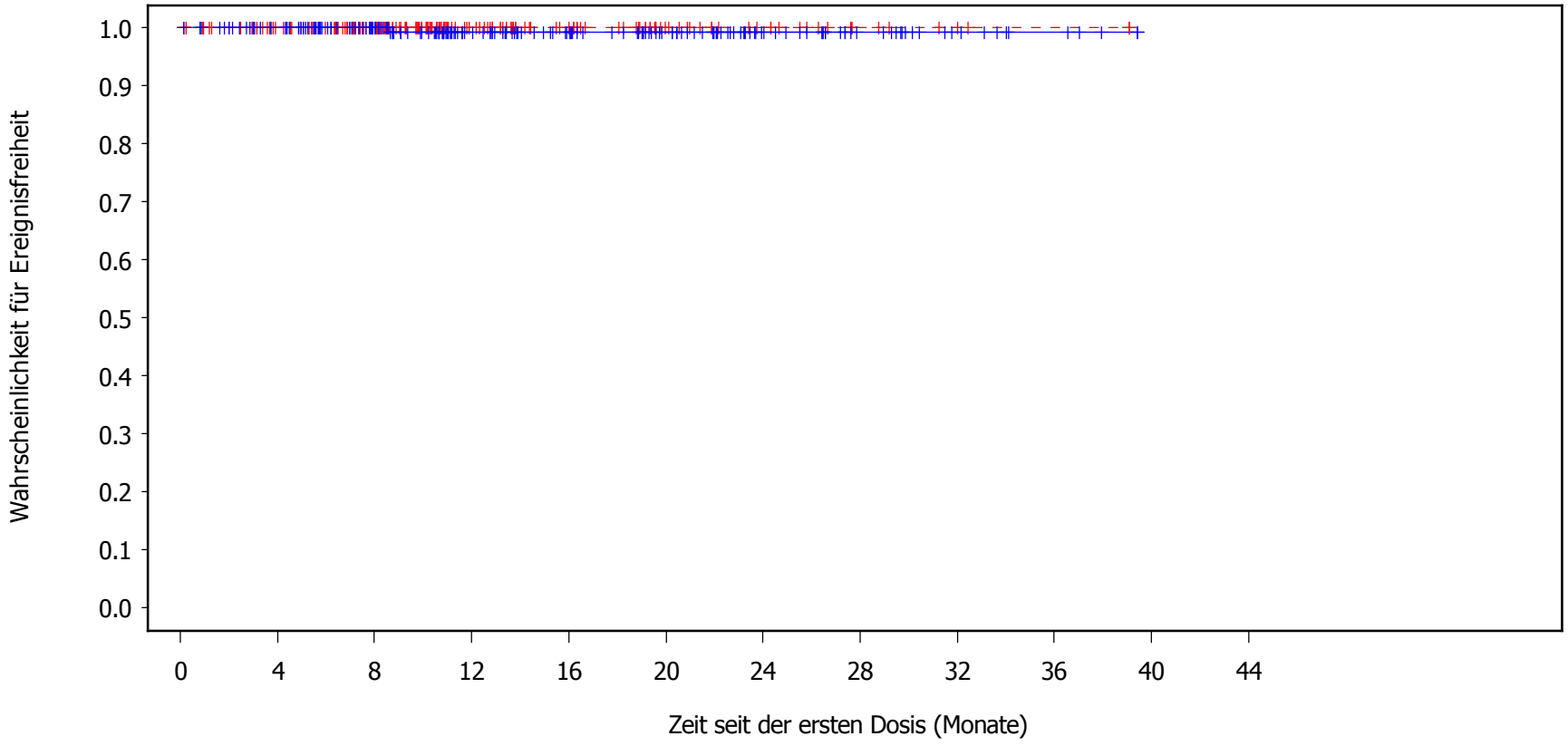
Figure 3.3.2.2D.134 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Myositis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	176	141	97	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	70	47	26	16	6	3	1	0	0	CTx

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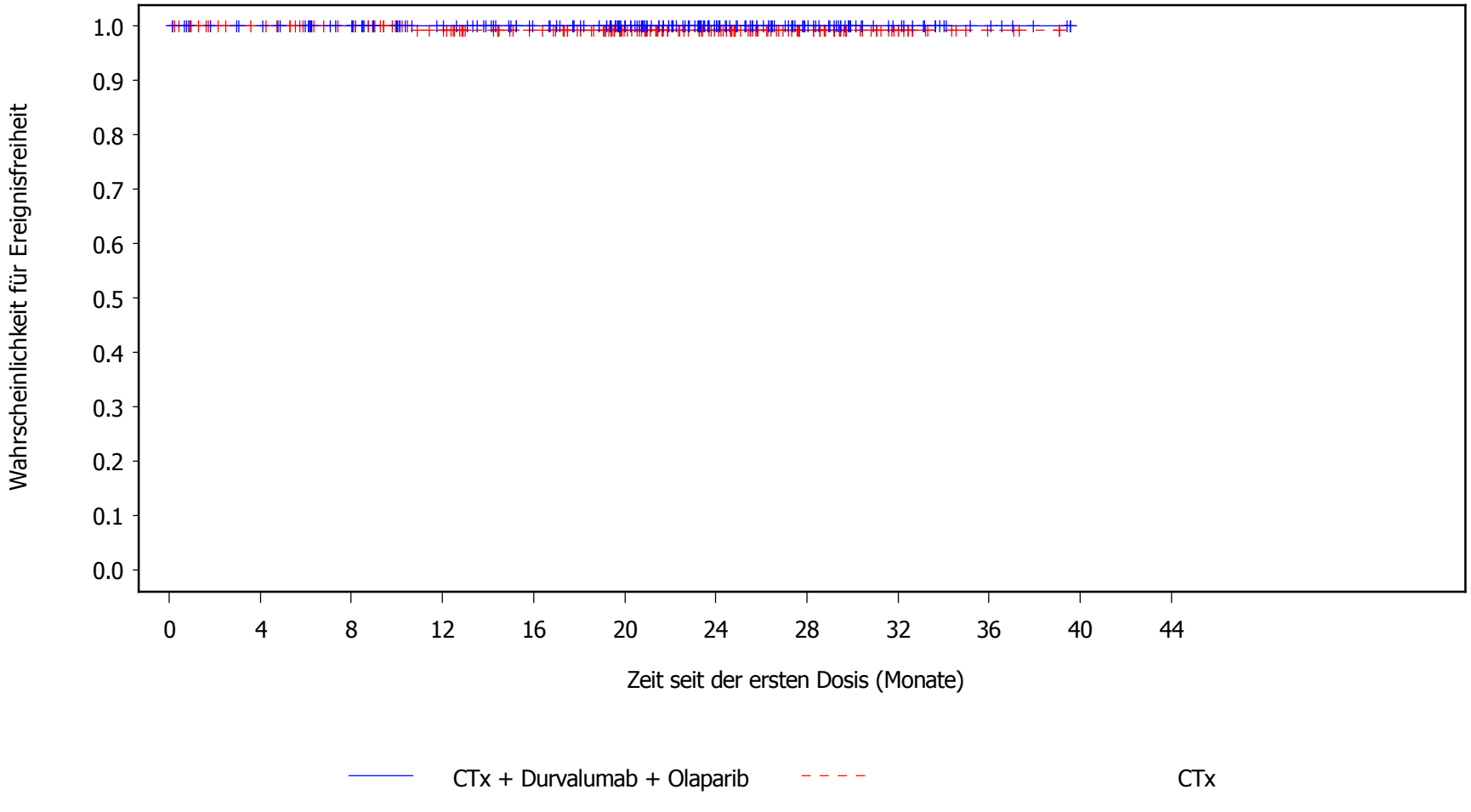
Figure 3.3.2.2D.135 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Neue primäre Malignität
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	184	174	159	143	120	73	39	17	6	0	0	CTx + Durvalumab + Olaparib
190	178	167	150	134	105	76	43	16	3	0	0	CTx

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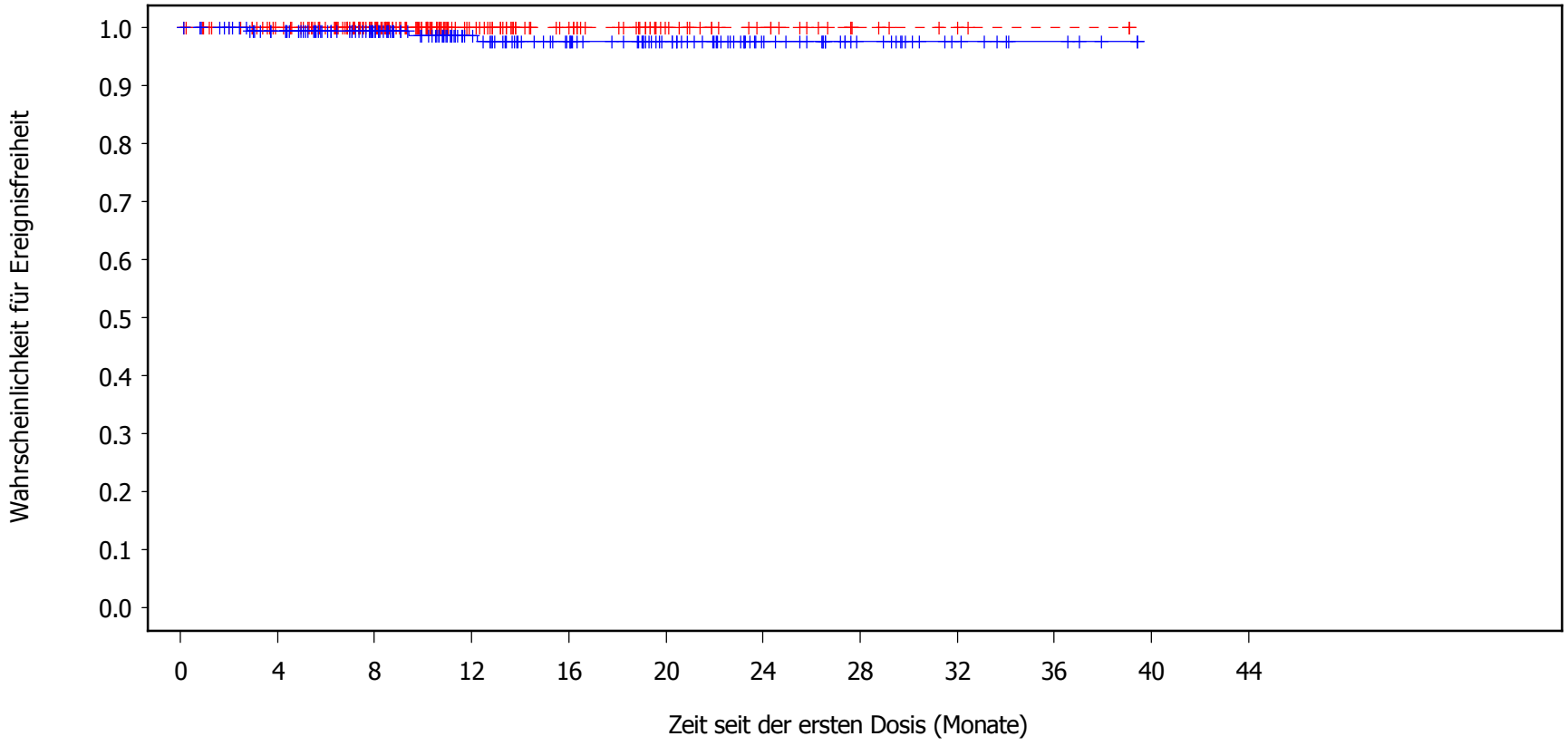
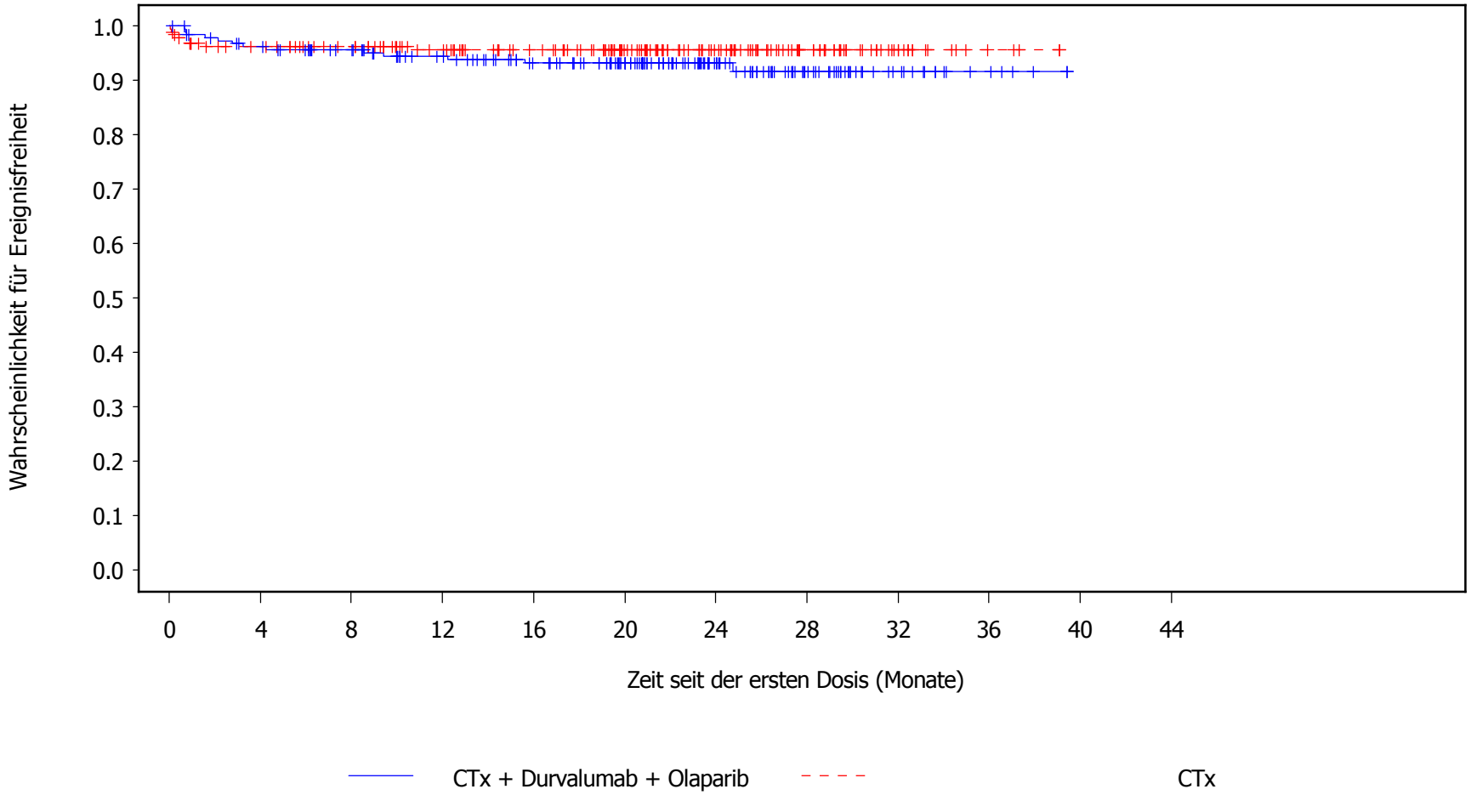
Figure 3.3.2.2D.136 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Pneumonitis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	175	141	98	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	70	47	26	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.137 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	177	166	150	133	112	67	36	15	5	0	0	CTx + Durvalumab + Olaparib
190	172	161	144	128	100	71	41	16	3	0	0	CTx

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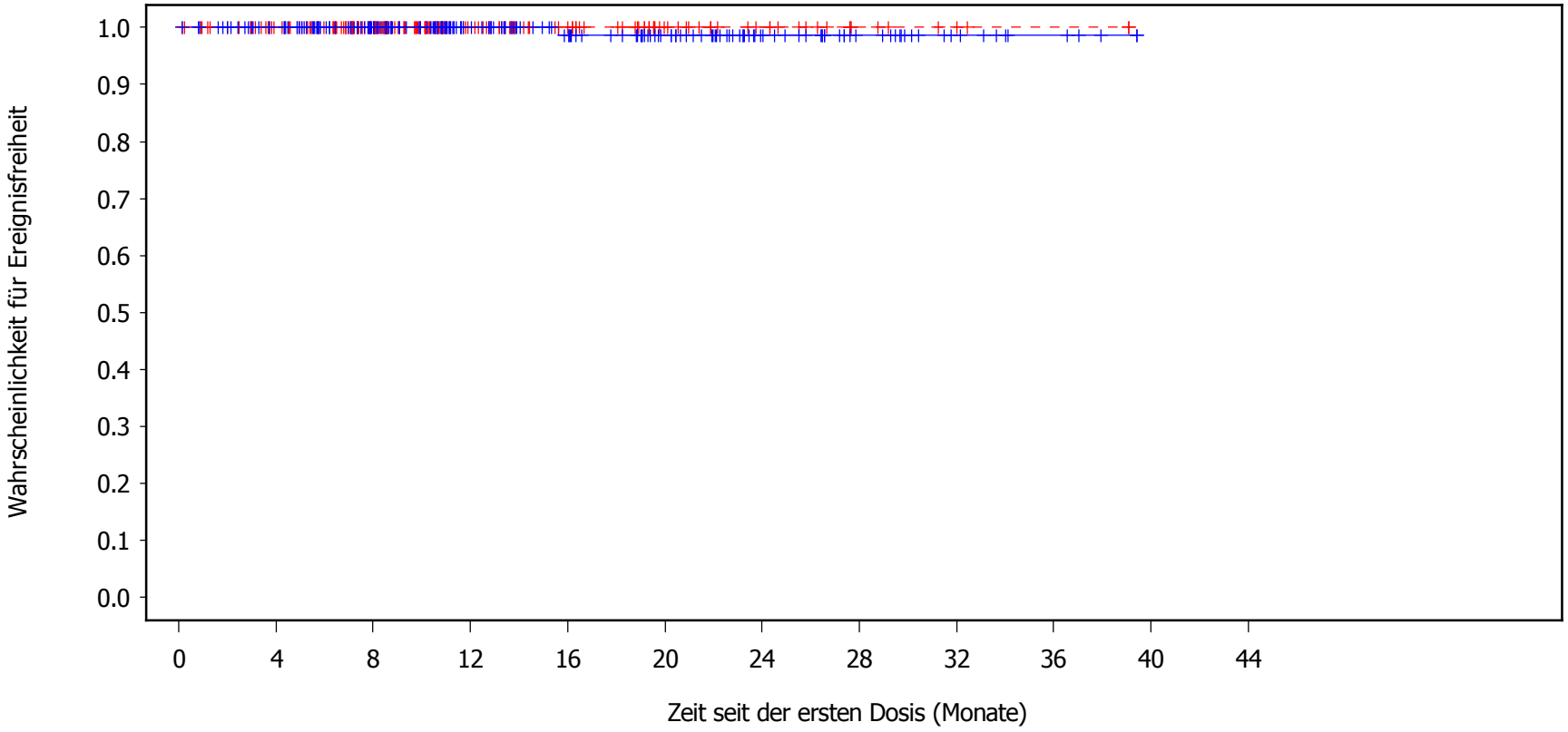
Figure 3.3.2.2D.138 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Andere seltene/sonstige Ereignisse
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	176	141	97	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	70	47	26	16	6	3	1	0	0	CTx

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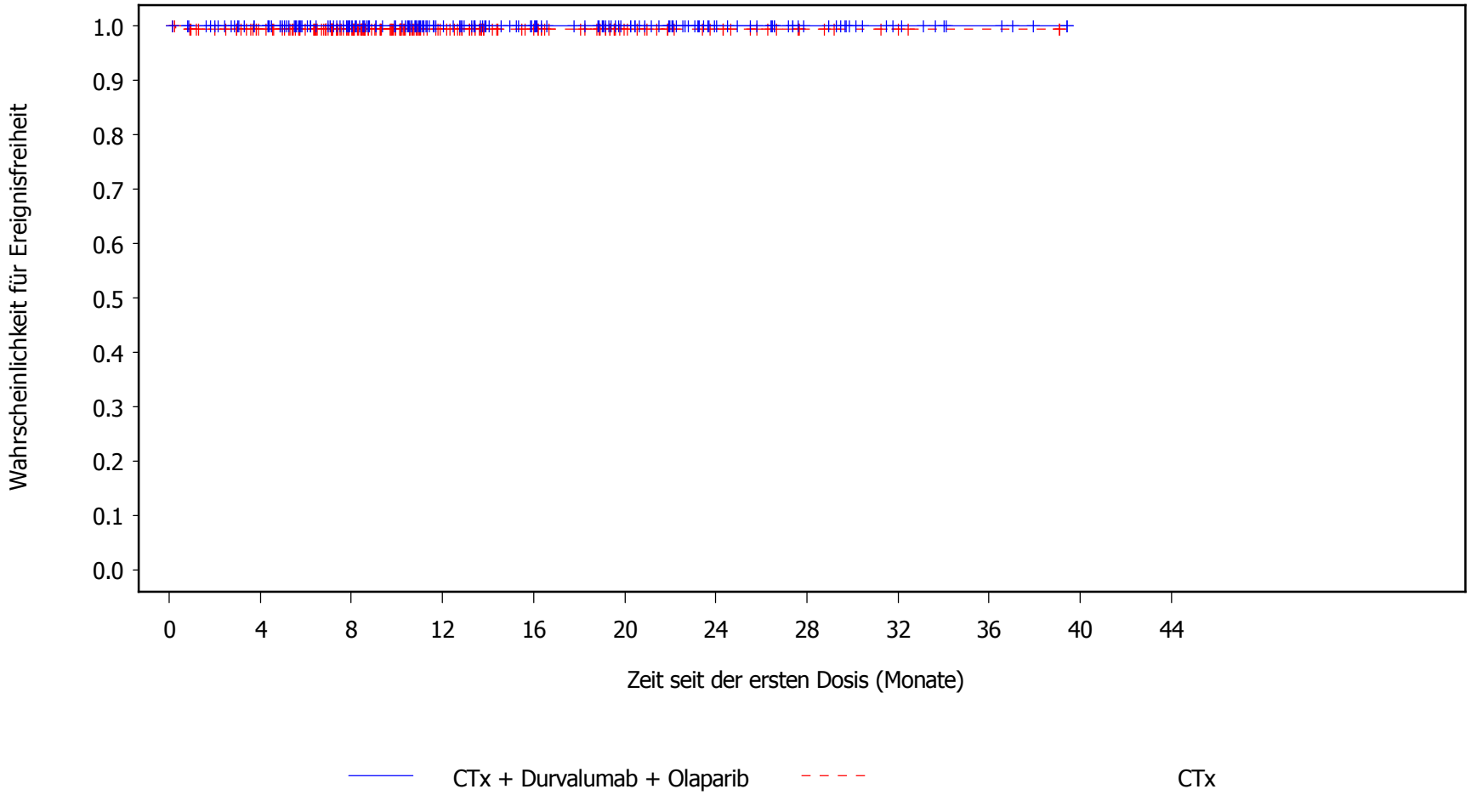
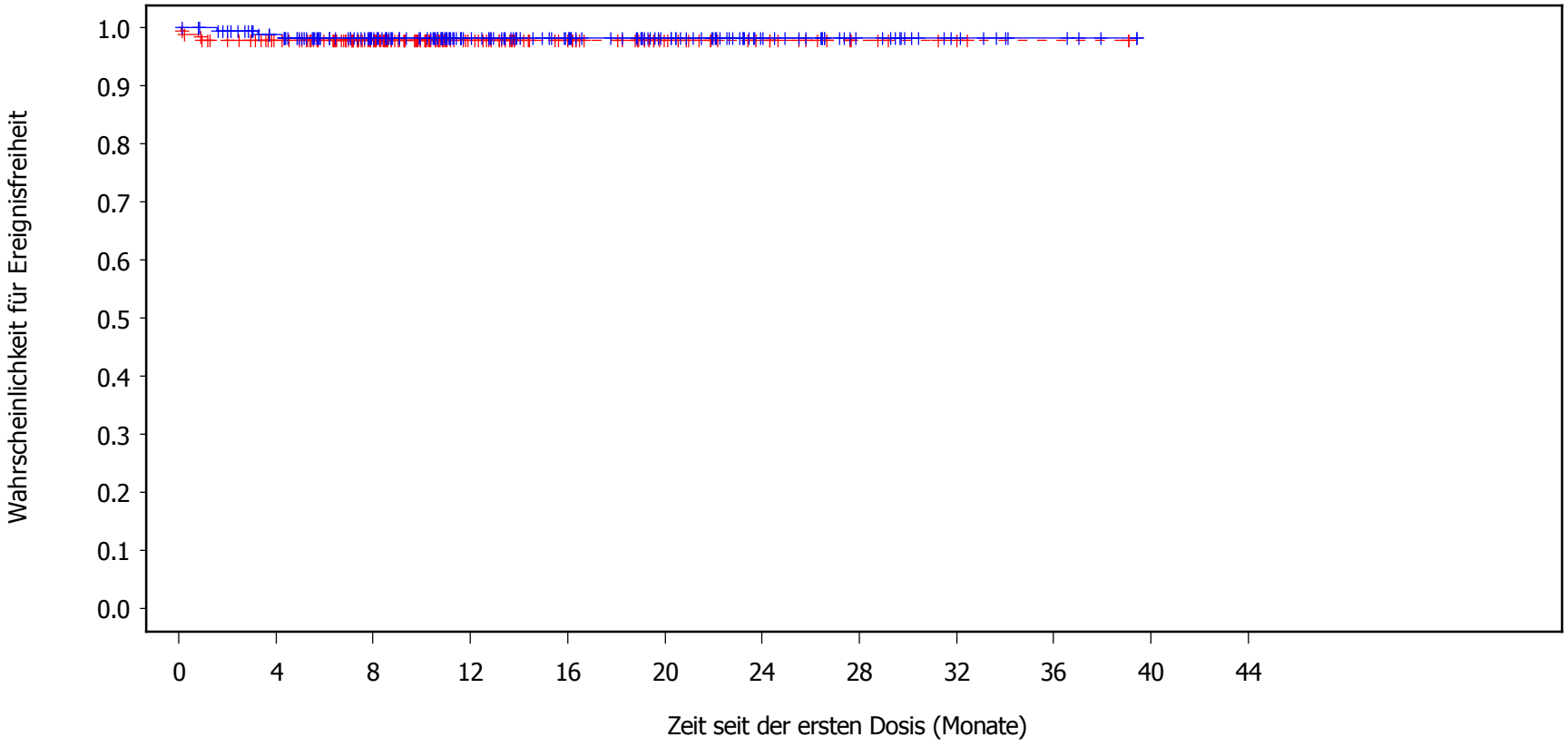
Figure 3.3.2.2D.139 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Dermatitis/Hautausschlag
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	176	141	97	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	173	128	70	47	26	16	6	3	1	0	0	CTx

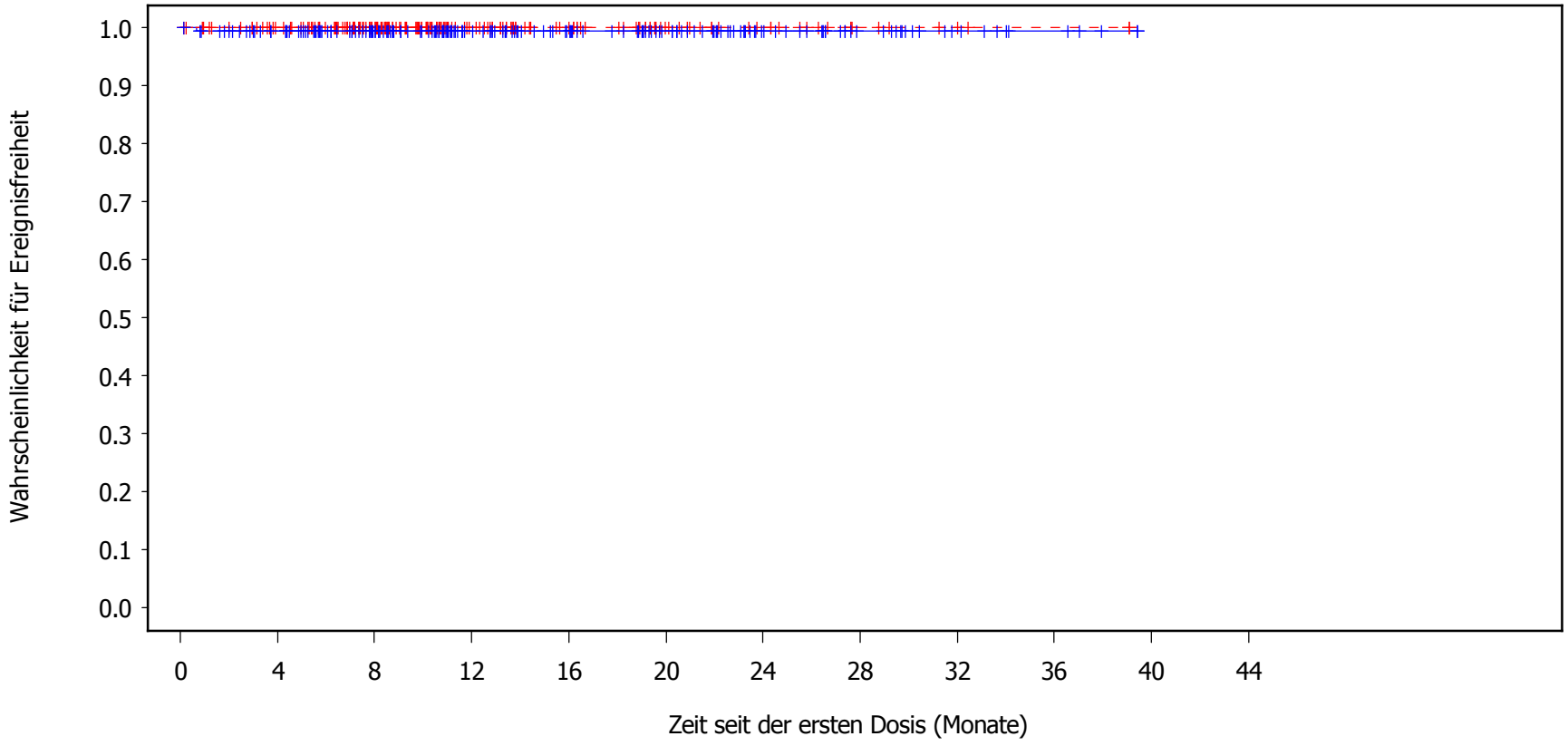
Figure 3.3.2.2D.140 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Diarrhö/Kolitis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	174	139	96	76	57	33	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	171	127	69	46	26	16	6	3	1	0	0	CTx

Figure 3.3.2.2D.141 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Hepatische Ereignisse
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	175	141	97	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	70	47	26	16	6	3	1	0	0	CTx

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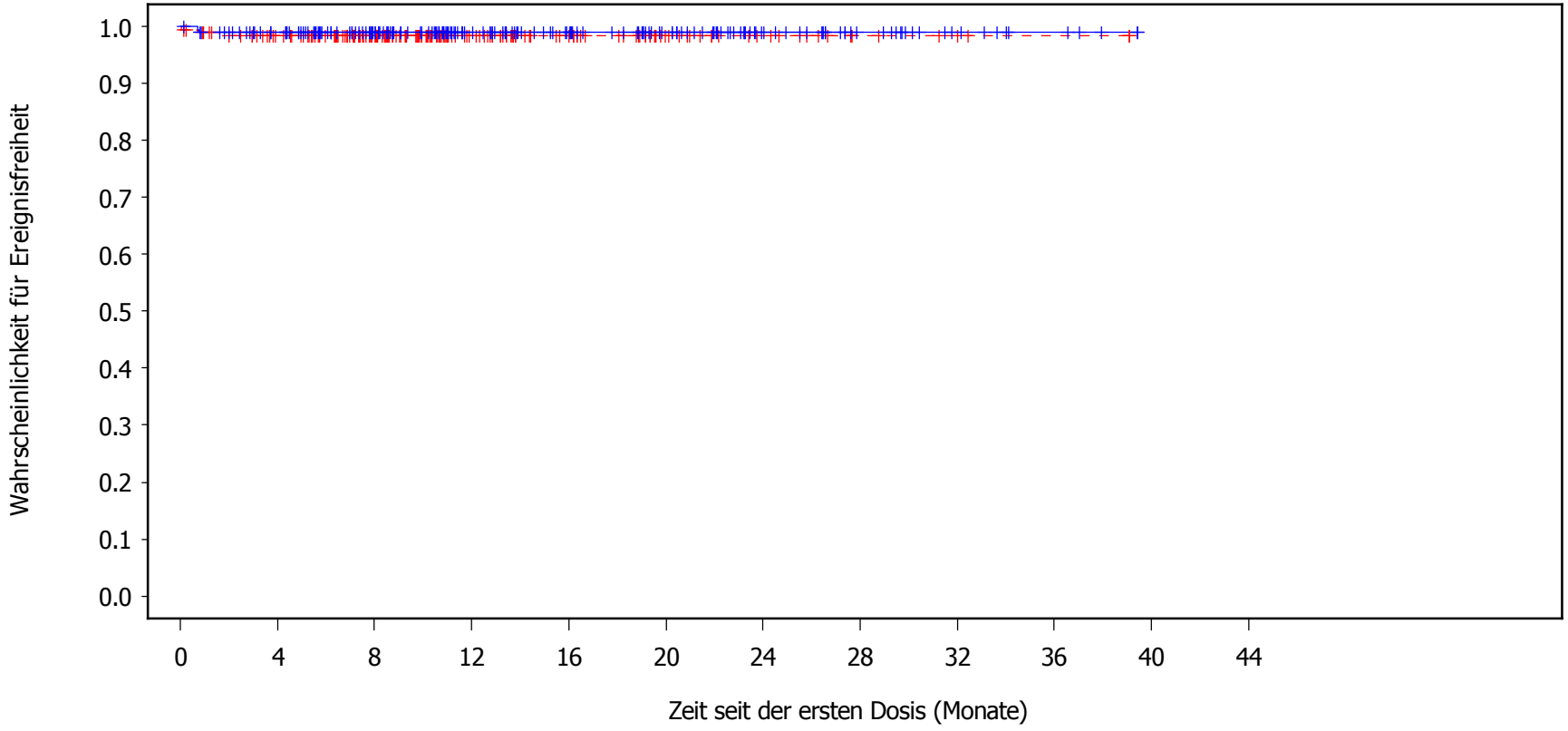
Figure 3.3.2.2D.142 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Infusions- und Überempfindlichkeitsreaktionen
Patients with pMMR tumour status, DCO 18OCT2023

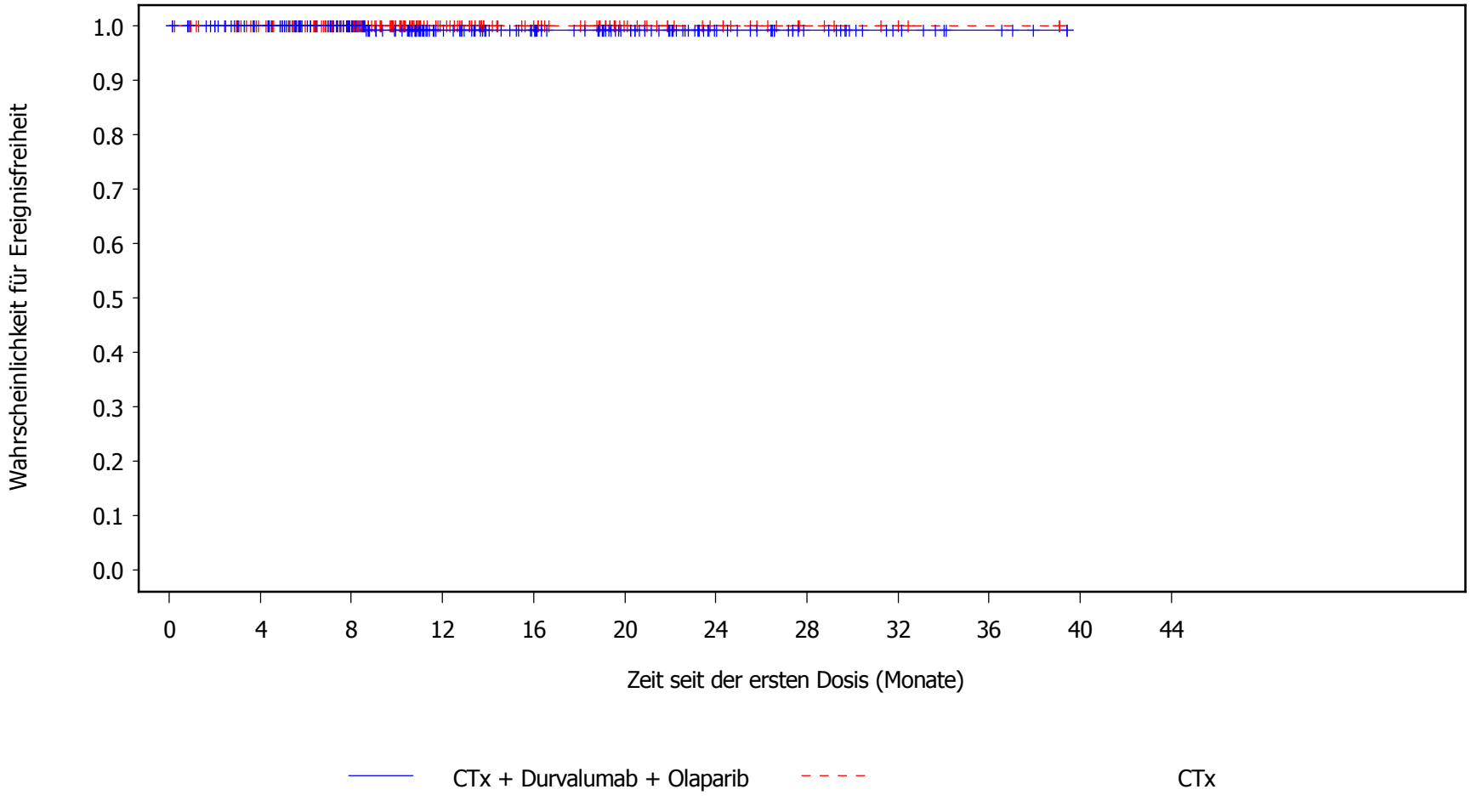


Anzahl an Patienten unter Risiko:

191	174	139	96	76	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	171	126	68	45	24	14	5	3	1	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaebfl 15APR2024:10:33

Figure 3.3.2.2D.143 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Myositis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	176	141	97	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	70	47	26	16	6	3	1	0	0	CTx

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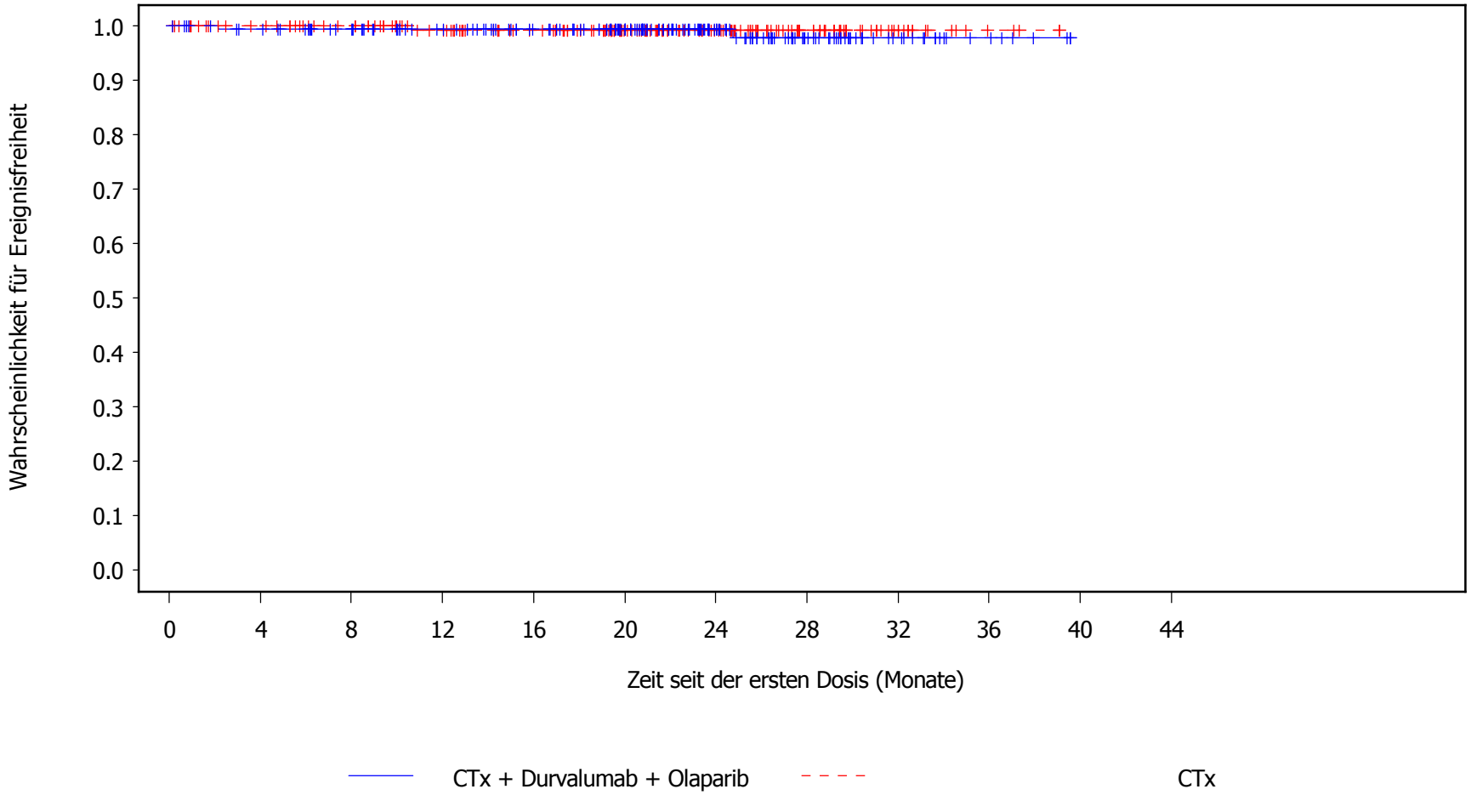
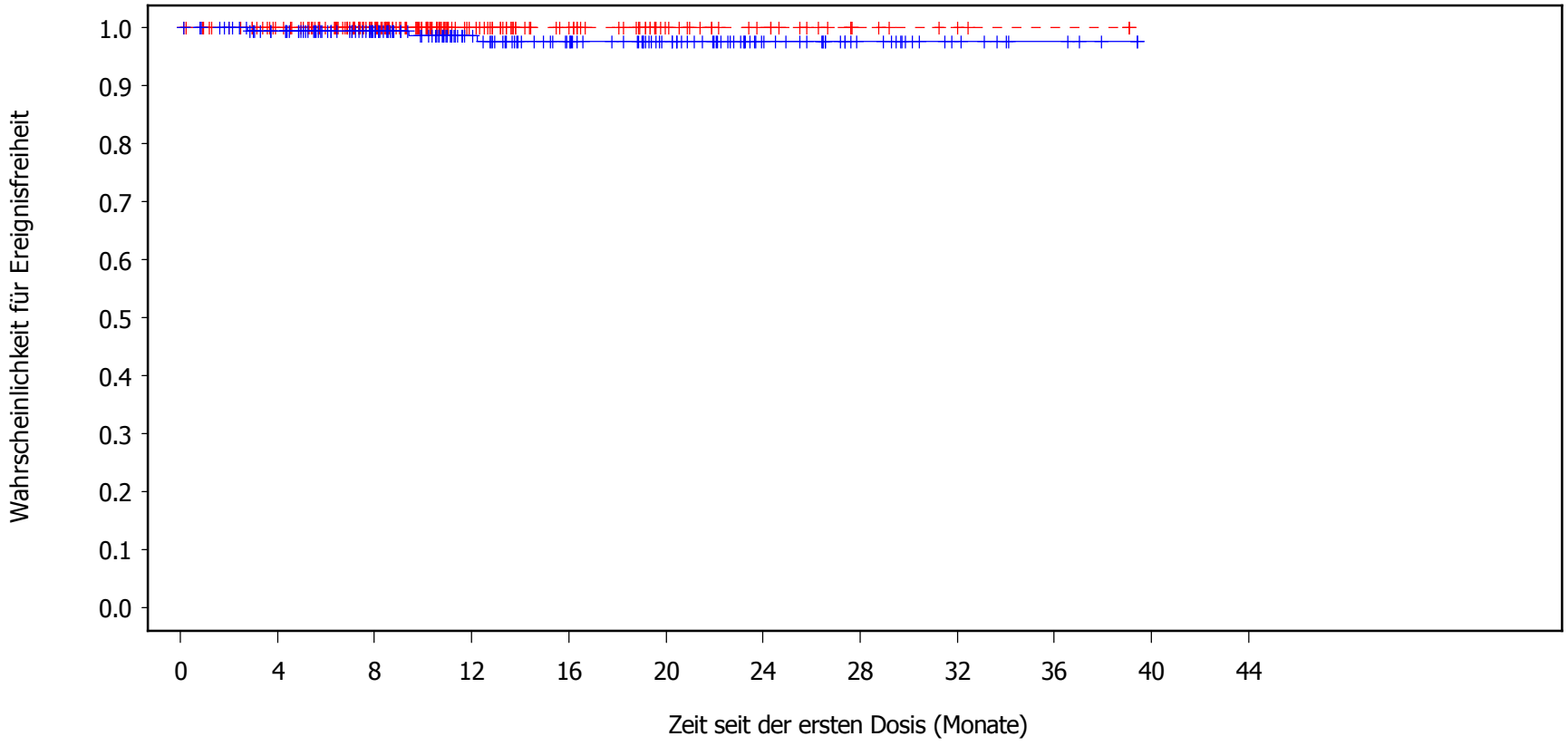
Figure 3.3.2.2D.144 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Neue primäre Malignität
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	183	173	158	142	119	72	38	17	6	0	0	CTx + Durvalumab + Olaparib
190	178	167	150	134	105	76	43	16	3	0	0	CTx

Figure 3.3.2.2D.145 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of time to first occurrence of SUESI GT: Pneumonitis
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

191	175	141	98	77	58	34	19	9	4	0	0	CTx + Durvalumab + Olaparib
190	174	129	70	47	26	16	6	3	1	0	0	CTx

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Table 4.1.1.2.1D DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of overall survival (OS)
Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	25 (25,3)	NE [NE; NE]	101	26 (25,7)	NE [NE; NE]	1,04	[0,60; 1,81]	0,8825
Neu diagnostiziert	92	21 (22,8)	NE [NE; NE]	91	38 (41,8)	25,1 [17,4; NE]	0,45	[0,26; 0,77]	0,0030*
Interaktion p-Wert									0,0330*
Region									
Asien	54	13 (24,1)	NE [NE; NE]	54	13 (24,1)	NE [NE; NE]	1,00	[0,46; 2,17]	0,9912
Rest der Welt	137	33 (24,1)	NE [NE; NE]	138	51 (37,0)	25,5 [23,5; NE]	0,61	[0,39; 0,94]	0,0237*
Interaktion p-Wert									0,2739
Alter									
<65	101	24 (23,8)	NE [NE; NE]	99	31 (31,3)	NE [NE; NE]	0,72	[0,42; 1,22]	0,2239
>=65	90	22 (24,4)	NE [NE; NE]	93	33 (35,5)	25,5 [22,9; NE]	0,66	[0,38; 1,12]	0,1223
Interaktion p-Wert									0,8125
Abstammung									
Weiß	104	24 (23,1)	NE [NE; NE]	113	40 (35,4)	25,8 [23,5; NE]	0,63	[0,38; 1,04]	0,0725
Schwarz/Afroamerikanisch	13	5 (38,5)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	2,82	[0,45; 54,03]	0,2938
Asiatisch	57	13 (22,8)	NE [NE; NE]	58	15 (25,9)	NE [NE; NE]	0,83	[0,39; 1,75]	0,6260
Andere	16	4 (25,0)	NE [NE; NE]	12	7 (58,3)	18,6 [1,3; NE]	0,36	[0,09; 1,18]	0,0924
Interaktion p-Wert									0,3010
HRR Mutationsstatus									
HRRm	21	3 (14,3)	NE [NE; NE]	17	5 (29,4)	25,5 [17,3; NE]	0,43	[0,09; 1,76]	0,2399
Nicht-HRRm	118	30 (25,4)	NE [NE; NE]	111	42 (37,8)	25,1 [23,5; NE]	0,63	[0,39; 0,9999]	0,0500*
Unbekannt	52	13 (25,0)	NE [NE; NE]	64	17 (26,6)	NE [NE; NE]	1,00	[0,47; 2,04]	0,9910
Interaktion p-Wert									0,4612
PD-L1 Expression									
Positiv	112	20 (17,9)	NE [NE; NE]	124	40 (32,3)	25,9 [25,1; NE]	0,51	[0,29; 0,85]	0,0105*

For certain subgroups there are patients with missing status or belong to a subgroup with too few patients who are therefore not included in the analysis. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05.
[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE = Not estimable (i.e. median is not reached).
[b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
CTx = Carboplatin + Paclitaxel.

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Table 4.1.1.2.1D DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of overall survival (OS)
Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Negativ	73	25 (34,2)	NE [NE; NE]	67	23 (34,3)	NE [NE; NE]	1,01	[0,57; 1,78]	0,9845
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	1 (100)	11,4 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0824
Histologie									
Endometrioid	107	22 (20,6)	NE [NE; NE]	98	31 (31,6)	NE [NE; NE]	0,66	[0,38; 1,13]	0,1293
Serös	42	10 (23,8)	NE [NE; NE]	52	15 (28,8)	25,8 [25,5; NE]	0,70	[0,30; 1,55]	0,3812
Andere	42	14 (33,3)	NE [NE; NE]	42	18 (42,9)	20,9 [15,9; NE]	0,71	[0,35; 1,43]	0,3414
Interaktion p-Wert									0,9811
Histologischer Grad									
High grade (G3)	77	21 (27,3)	NE [NE; NE]	84	33 (39,3)	25,8 [17,5; NE]	0,55	[0,31; 0,94]	0,0283*
Low grade (G1+G2)	90	19 (21,1)	NE [NE; NE]	87	22 (25,3)	NE [NE; NE]	0,93	[0,50; 1,71]	0,8082
Interaktion p-Wert									0,2091
ECOG Performance Status zu Baseline									
0	135	30 (22,2)	NE [NE; NE]	127	35 (27,6)	NE [NE; NE]	0,80	[0,49; 1,30]	0,3621
1	56	16 (28,6)	NE [NE; NE]	65	29 (44,6)	22,9 [16,5; NE]	0,56	[0,30; 1,03]	0,0612
Interaktion p-Wert									0,3852
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	3 (30,0)	NE [NE; NE]	0,26	[0,01; 2,04]	0,2063
IV	78	19 (24,4)	NE [NE; NE]	79	34 (43,0)	25,1 [15,9; NE]	0,48	[0,27; 0,83]	0,0088*
Interaktion p-Wert									0,5925

For certain subgroups there are patients with missing status or belong to a subgroup with too few patients who are therefore not included in the analysis. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05.
[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE = Not estimable (i.e. median is not reached).
[b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
CTx = Carboplatin + Paclitaxel.

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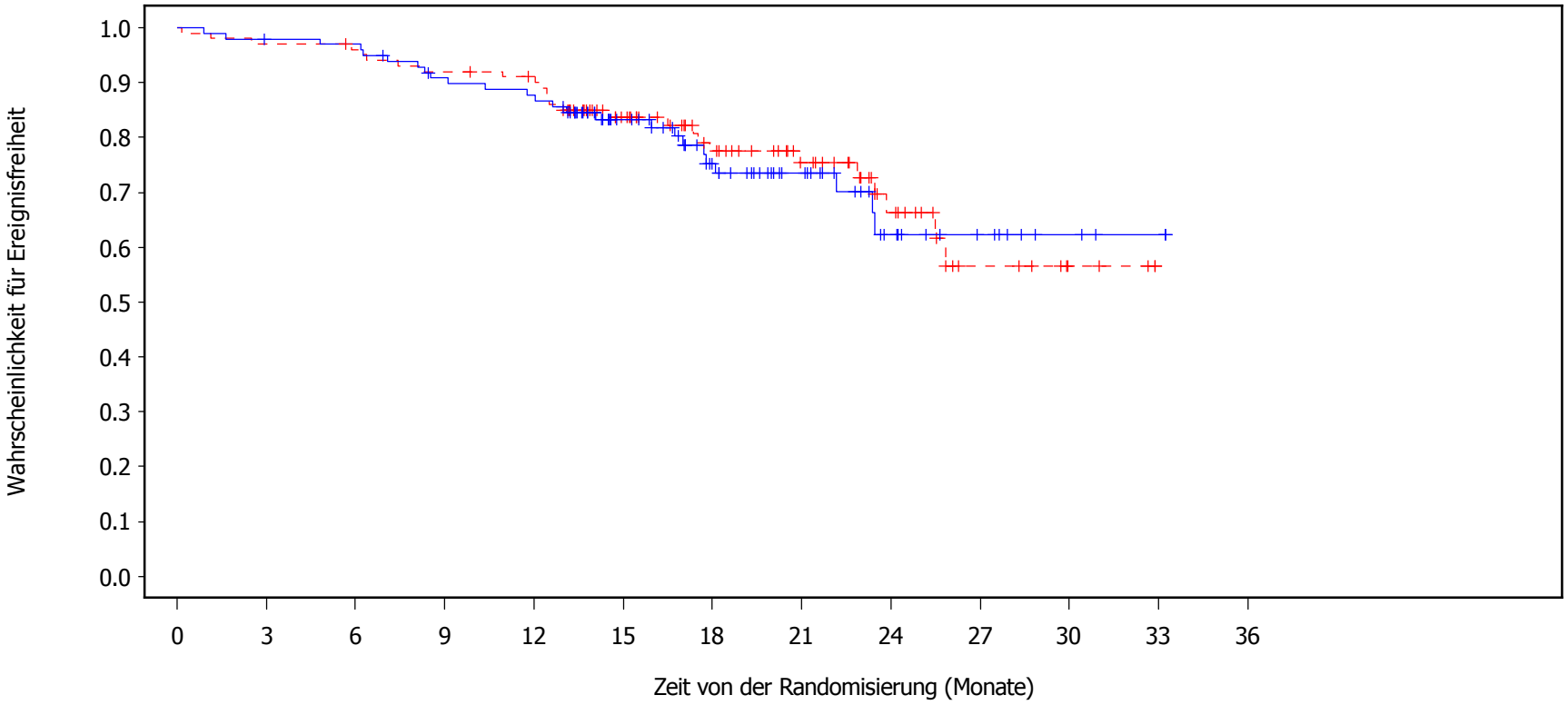
Figure 4.1.1.2.1D.1 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Gesamtüberleben for Krankheitsstatus = Rezidivierend
Patients with pMMR tumour status, DCO 12ARP2023



Anzahl an Patienten unter Risiko:

99	96	95	87	84	60	41	28	14	8	3	1	0	CTx + Durvalumab + Olaparib
101	98	96	92	89	65	48	35	20	8	3	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
CTx = Carboplatin + Paclitaxel.

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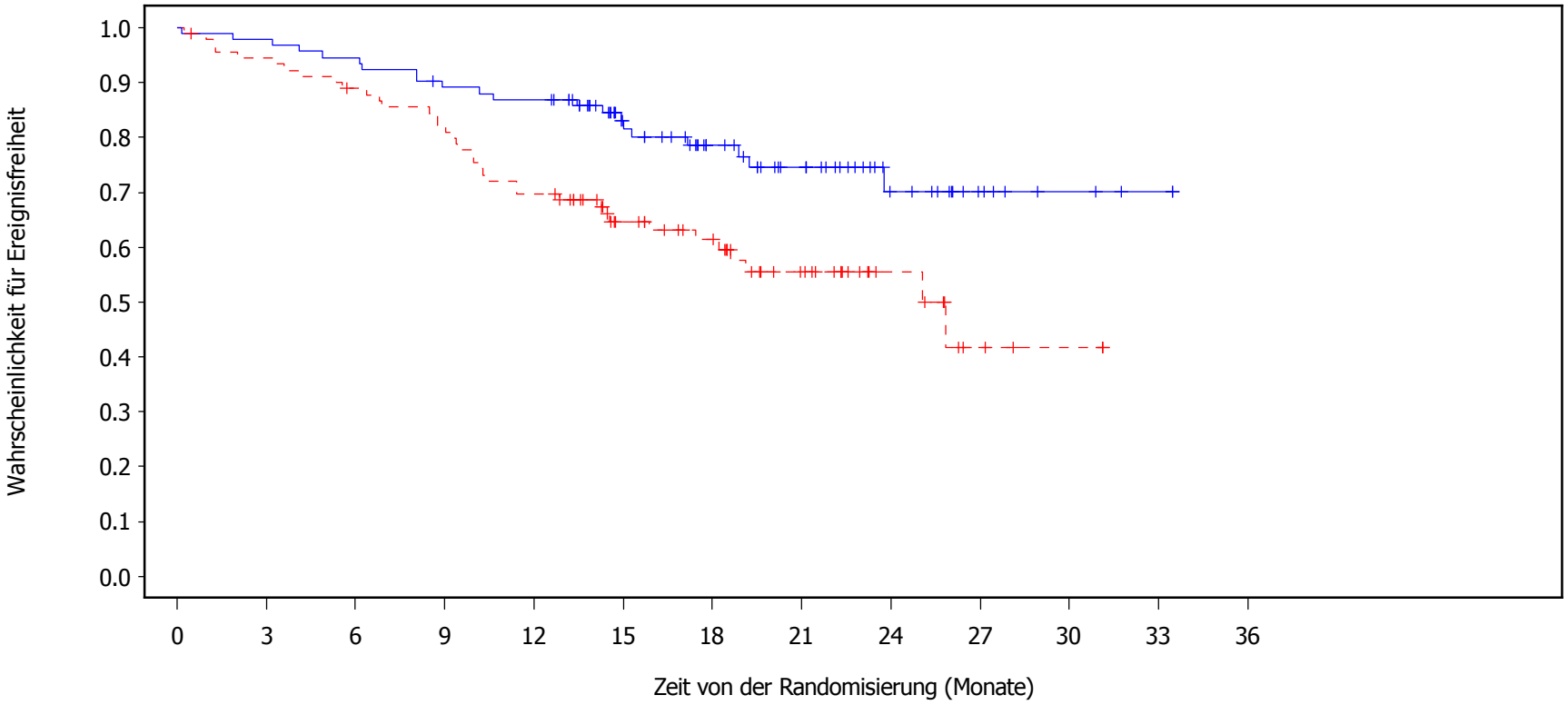
Figure 4.1.1.2.1D.2 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Gesamtüberleben for Krankheitsstatus = Neu diagnostiziert
Patients with pMMR tumour status, DCO 12ARP2023



Anzahl an Patienten unter Risiko:

92	90	87	81	79	57	41	30	15	7	3	1	0	CTx + Durvalumab + Olaparib
91	85	79	73	62	44	36	22	10	3	1	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
CTx = Carboplatin + Paclitaxel.

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Table 4.1.1.2.2D DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of overall survival (OS)
Patients with pMMR tumour status, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	34 (34,3)	36,1 [27,9; NE]	101	32 (31,7)	NE [NE; NE]	1,16	[0,72; 1,89]	0,5422
Neu diagnostiziert	92	30 (32,6)	NE [NE; NE]	91	43 (47,3)	26,7 [17,4; NE]	0,56	[0,35; 0,89]	0,0142*
Interaktion p-Wert									0,0331*
Region									
Asien	54	18 (33,3)	36,1 [29,8; NE]	54	16 (29,6)	NE [NE; NE]	1,14	[0,58; 2,25]	0,7086
Rest der Welt	137	46 (33,6)	NE [NE; NE]	138	59 (42,8)	33,4 [25,1; NE]	0,72	[0,49; 1,06]	0,0956
Interaktion p-Wert									0,2504
Alter									
<65	101	34 (33,7)	36,1 [29,8; NE]	99	36 (36,4)	NE [NE; NE]	0,89	[0,55; 1,42]	0,6139
>=65	90	30 (33,3)	NE [NE; NE]	93	39 (41,9)	33,4 [23,5; NE]	0,74	[0,46; 1,19]	0,2152
Interaktion p-Wert									0,5992
Abstammung									
Weiß	104	34 (32,7)	NE [NE; NE]	113	48 (42,5)	33,4 [23,9; NE]	0,73	[0,47; 1,13]	0,1588
Schwarz/Afroamerikanisch	13	6 (46,2)	26,4 [8,1; NE]	8	1 (12,5)	NE [NE; NE]	3,98	[0,68; 75,20]	0,1382
Asiatisch	57	18 (31,6)	36,1 [29,8; NE]	58	18 (31,0)	NE [NE; NE]	0,98	[0,51; 1,89]	0,9512
Andere	16	6 (37,5)	25,6 [10,2; NE]	12	7 (58,3)	18,6 [1,3; NE]	0,48	[0,15; 1,44]	0,1864
Interaktion p-Wert									0,2161
HRR Mutationsstatus									
HRRm	21	4 (19,0)	NE [NE; NE]	17	7 (41,2)	NE [NE; NE]	0,40	[0,11; 1,34]	0,1378
Nicht-HRRm	118	43 (36,4)	36,1 [27,9; NE]	111	46 (41,4)	33,4 [23,9; NE]	0,81	[0,54; 1,23]	0,3297
Unbekannt	52	17 (32,7)	NE [NE; NE]	64	22 (34,4)	NE [NE; NE]	1,00	[0,52; 1,87]	0,9905
Interaktion p-Wert									0,4284
PD-L1 Expression									
Positiv	112	28 (25,0)	NE [NE; NE]	124	46 (37,1)	33,4 [25,9; NE]	0,60	[0,37; 0,95]	0,0307*
Negativ	73	35 (47,9)	26,4 [22,2; NE]	67	28 (41,8)	NE [NE; NE]	1,21	[0,73; 2,00]	0,4599

For certain subgroups there are patients with missing status or belong to a subgroup with too few patients who are therefore not included in the analysis. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05.
[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE = Not estimable (i.e. median is not reached).
[b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
CTx = Carboplatin + Paclitaxel.

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Table 4.1.1.2.2D DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of overall survival (OS)
Patients with pMMR tumour status, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	1 (100)	11,4 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0443*
Histologie									
Endometrioid	107	27 (25,2)	36,1 [36,1; NE]	98	33 (33,7)	NE [NE; NE]	0,74	[0,44; 1,23]	0,2426
Serös	42	15 (35,7)	NE [NE; NE]	52	19 (36,5)	33,4 [25,8; NE]	0,86	[0,43; 1,68]	0,6508
Andere	42	22 (52,4)	27,0 [17,1; NE]	42	23 (54,8)	19,7 [15,1; NE]	0,88	[0,49; 1,59]	0,6743
Interaktion p-Wert									0,8907
Histologischer Grad									
High grade (G3)	77	31 (40,3)	36,1 [25,6; NE]	84	41 (48,8)	25,8 [16,9; NE]	0,65	[0,40; 1,03]	0,0676
Low grade (G1+G2)	90	22 (24,4)	NE [NE; NE]	87	24 (27,6)	NE [NE; NE]	0,97	[0,54; 1,73]	0,9068
Interaktion p-Wert									0,2942
ECOG Performance Status zu Baseline									
0	135	43 (31,9)	36,1 [29,8; NE]	127	43 (33,9)	NE [NE; NE]	0,93	[0,61; 1,42]	0,7238
1	56	21 (37,5)	NE [NE; NE]	65	32 (49,2)	25,8 [16,7; NE]	0,66	[0,38; 1,14]	0,1415
Interaktion p-Wert									0,3463
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	4 (40,0)	NE [NE; NE]	0,39	[0,05; 2,00]	0,2600
IV	78	27 (34,6)	NE [NE; NE]	79	38 (48,1)	25,9 [16,9; NE]	0,59	[0,36; 0,97]	0,0374*
Interaktion p-Wert									0,6338

For certain subgroups there are patients with missing status or belong to a subgroup with too few patients who are therefore not included in the analysis. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05.
[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE = Not estimable (i.e. median is not reached).
[b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
CTx = Carboplatin + Paclitaxel.
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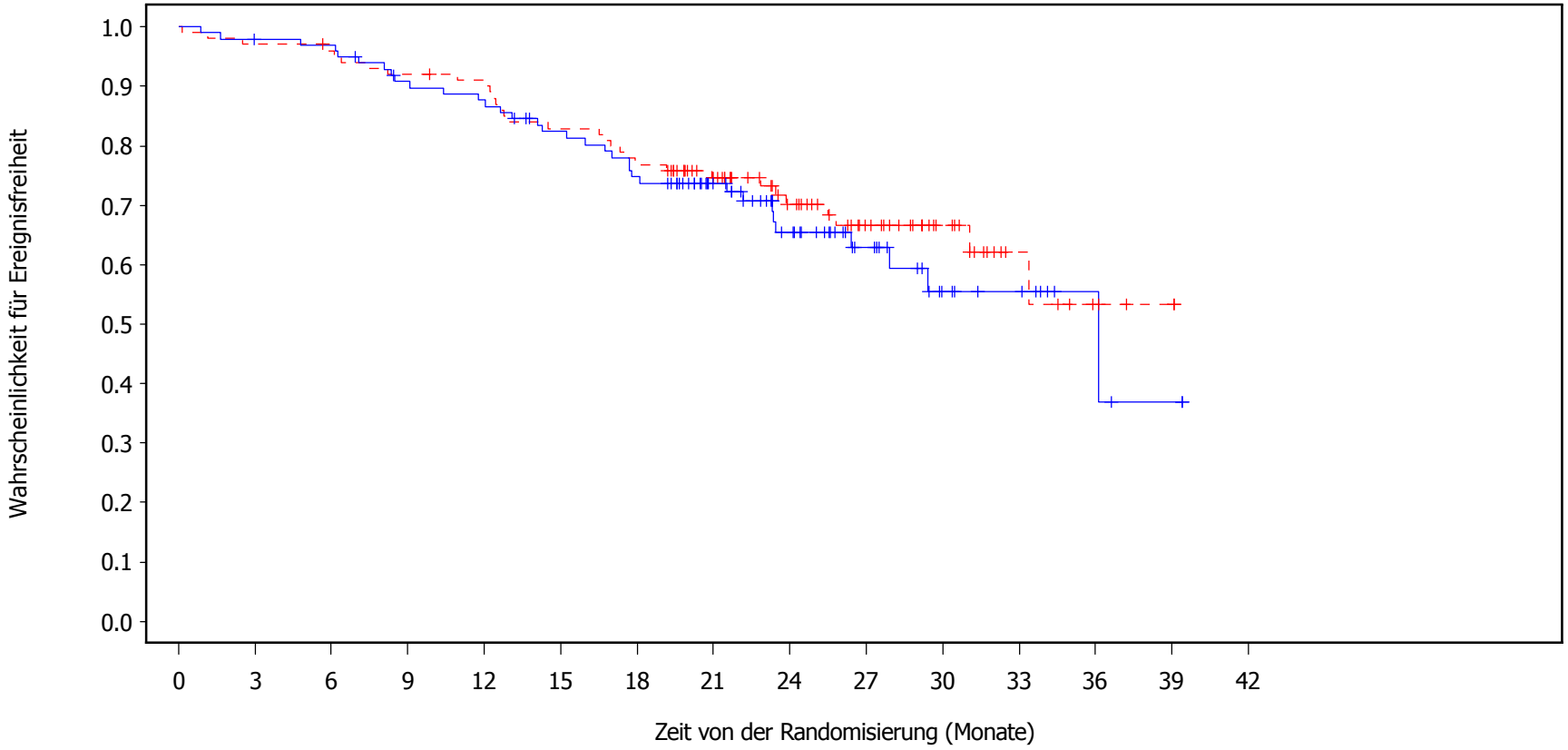
Figure 4.1.1.2.2D.1 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Gesamtüberleben for Krankheitsstatus = Rezidivierend
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

99	96	95	87	84	76	69	53	36	22	11	8	3	1	0	CTx + Durvalumab + Olaparib
101	98	96	92	90	82	76	61	45	31	18	7	3	1	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
CTx = Carboplatin + Paclitaxel.

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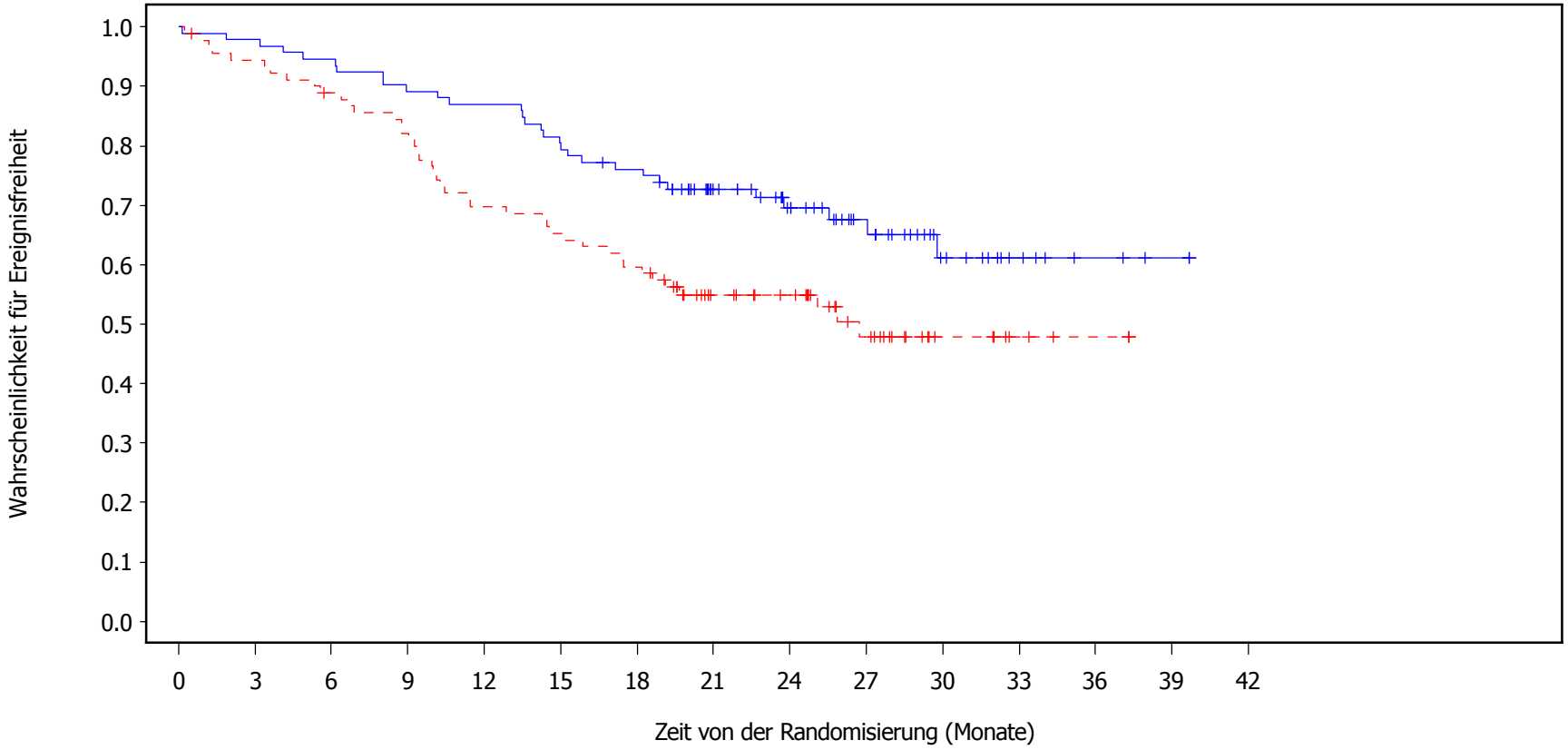
Figure 4.1.1.2.2D.2 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Gesamtüberleben for Krankheitsstatus = Neu diagnostiziert
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

92	90	87	82	80	74	69	52	40	28	14	7	3	1	0	CTx + Durvalumab + Olaparib
91	85	79	73	62	58	53	37	32	19	7	3	1	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
CTx = Carboplatin + Paclitaxel.

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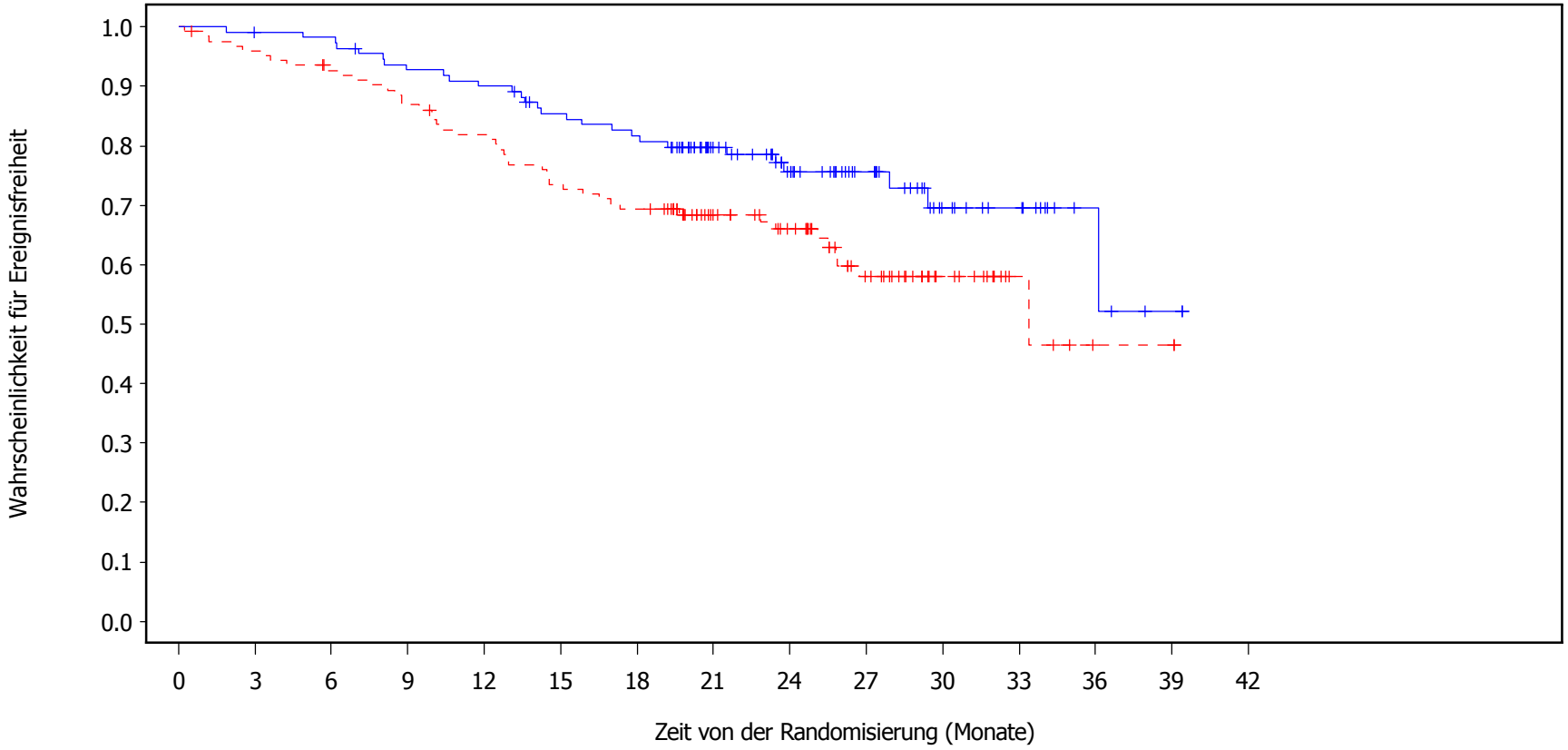
Figure 4.1.1.2.2D.3 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Gesamtüberleben for PD-L1 Expression = Positiv
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

112	110	109	102	99	91	87	65	48	33	17	12	4	1	0	CTx + Durvalumab + Olaparib
124	118	112	105	98	88	83	61	51	32	16	5	1	1	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
CTx = Carboplatin + Paclitaxel.

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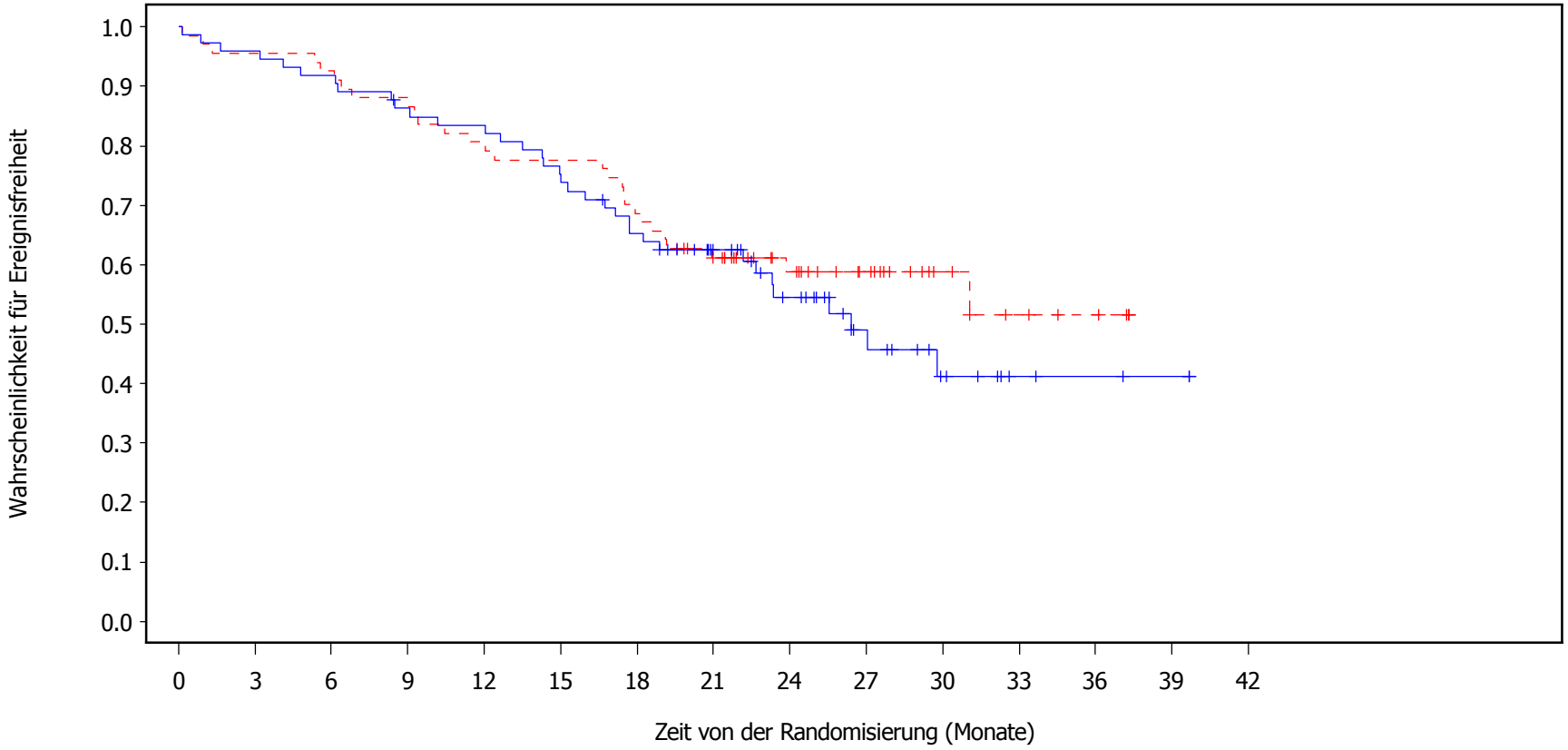
Figure 4.1.1.2.2D.4 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Gesamtüberleben for PD-L1 Expression = Negativ Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

73	70	67	62	60	54	46	36	26	15	8	3	2	1	0	CTx + Durvalumab + Olaparib
67	64	62	59	54	52	46	37	26	18	9	5	3	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
CTx = Carboplatin + Paclitaxel.

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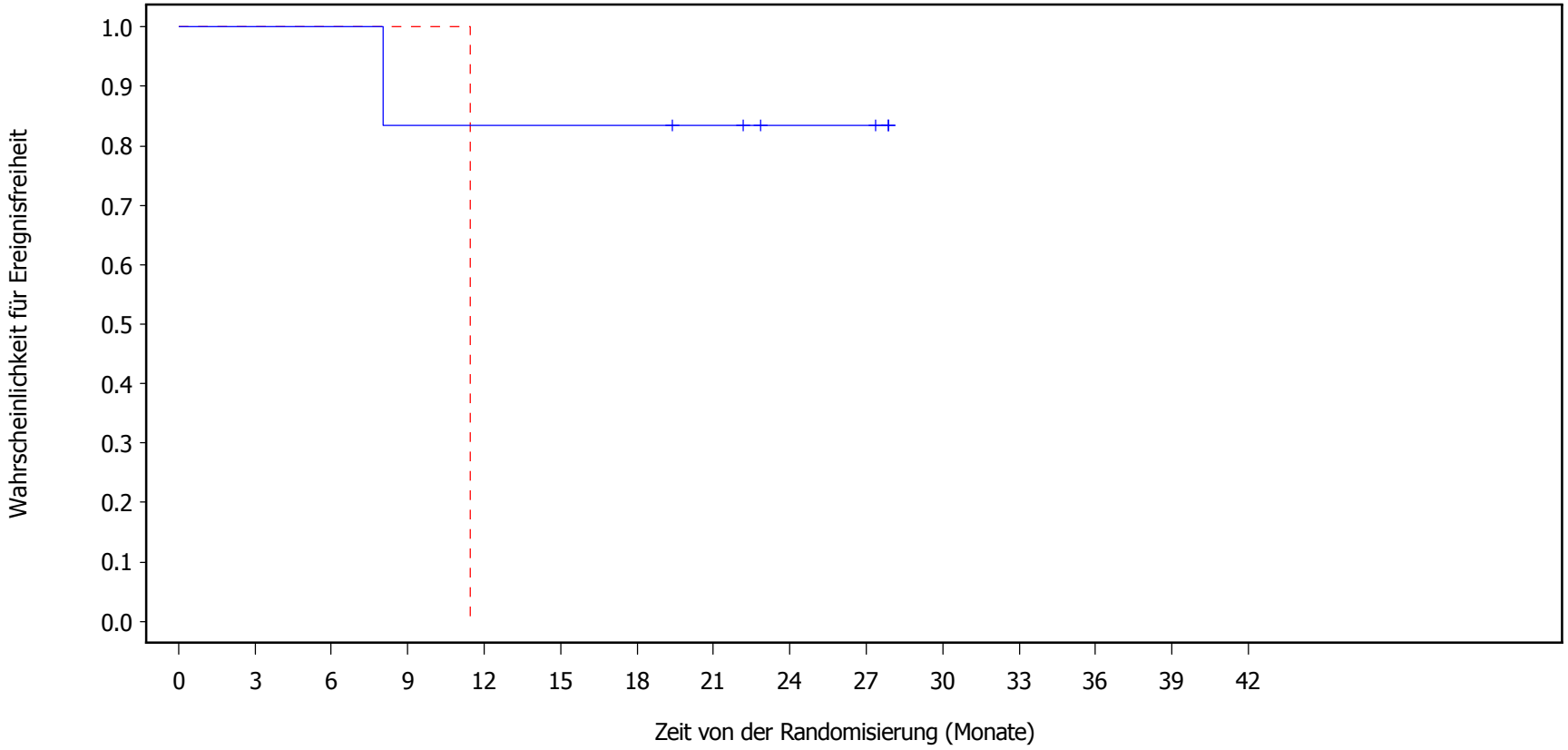
Figure 4.1.1.2.2D.5 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Gesamtüberleben for PD-L1 Expression = Unbekannt
Patients with pMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

6	6	6	5	5	5	5	4	2	2	0	0	0	0	0	CTx + Durvalumab + Olaparib
1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
CTx = Carboplatin + Paclitaxel.

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Table 4.1.2.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of progression-free survival (PFS)
Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	60 (60,6)	12,6 [9,9;18,0]	101	79 (78,2)	9,9 [9,5;12,3]	0,70	[0,50; 0,98]	0,0350*
Neu diagnostiziert	92	48 (52,2)	15,1 [12,4;20,8]	91	69 (75,8)	9,0 [6,9; 9,7]	0,44	[0,30; 0,64]	<0,0001*
Interaktion p-Wert									0,0705
Region									
Asien	54	33 (61,1)	15,0 [9,7;20,8]	54	36 (66,7)	11,4 [9,5;15,3]	0,76	[0,47; 1,22]	0,2591
Rest der Welt	137	75 (54,7)	15,0 [11,8;19,4]	138	112 (81,2)	9,5 [7,3; 9,8]	0,51	[0,38; 0,68]	<0,0001*
Interaktion p-Wert									0,1488
Alter									
<65	101	60 (59,4)	15,0 [9,7;15,2]	99	77 (77,8)	9,7 [8,0;12,2]	0,65	[0,46; 0,90]	0,0108*
>=65	90	48 (53,3)	15,4 [12,2;20,8]	93	71 (76,3)	9,7 [8,3;11,6]	0,49	[0,34; 0,71]	0,0001*
Interaktion p-Wert									0,2835
Abstammung									
Weiß	104	56 (53,8)	12,6 [10,6;20,7]	113	89 (78,8)	9,5 [7,4; 9,9]	0,52	[0,37; 0,73]	0,0001*
Schwarz/Afroamerikanisch	13	7 (53,8)	15,0 [1,9; NE]	8	7 (87,5)	10,7 [2,1;15,4]	0,54	[0,19; 1,59]	0,2588
Asiatisch	57	35 (61,4)	15,0 [9,9;20,8]	58	40 (69,0)	9,9 [9,5;12,5]	0,70	[0,44; 1,11]	0,1284
Andere	16	10 (62,5)	12,6 [5,3; NE]	12	11 (91,7)	6,9 [1,3;12,6]	0,49	[0,20; 1,16]	0,1023
Interaktion p-Wert									0,7478
HRR Mutationsstatus									
HRRm	21	11 (52,4)	15,2 [10,1; NE]	17	15 (88,2)	9,5 [6,8;12,3]	0,34	[0,15; 0,74]	0,0070*
Nicht-HRRm	118	70 (59,3)	15,0 [12,2;19,4]	111	85 (76,6)	9,7 [9,0;12,5]	0,63	[0,46; 0,86]	0,0040*
Unbekannt	52	27 (51,9)	12,3 [7,1; NE]	64	48 (75,0)	9,5 [7,1;11,4]	0,55	[0,34; 0,88]	0,0122*
Interaktion p-Wert									0,3593
PD-L1 Expression									
Positiv	112	54 (48,2)	18,1 [12,7; NE]	124	94 (75,8)	9,5 [8,3; 9,9]	0,44	[0,31; 0,61]	<0,0001*
Negativ	73	52 (71,2)	9,7 [8,4;12,6]	67	53 (79,1)	9,8 [7,6;12,4]	0,86	[0,59; 1,27]	0,4546

For certain subgroups there are patients with missing status or belong to a subgroup with too few patients who are therefore not included in the analysis. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05.
[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE = Not estimable (i.e. median is not reached).
[b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
CTx = Carboplatin + Paclitaxel.

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Table 4.1.2.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of progression-free survival (PFS)
Patients with pMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	1 (100)	6,9 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0081*
Histologie									
Endometrioid	107	56 (52,3)	15,4 [12,5;20,8]	98	71 (72,4)	11,4 [9,5;12,5]	0,60	[0,42; 0,85]	0,0043*
Serös	42	24 (57,1)	15,0 [9,7;20,8]	52	43 (82,7)	9,7 [8,3;12,3]	0,48	[0,29; 0,79]	0,0036*
Andere	42	28 (66,7)	9,7 [6,9;15,0]	42	34 (81,0)	7,1 [6,7; 9,5]	0,58	[0,35; 0,96]	0,0350*
Interaktion p-Wert									0,7647
Histologischer Grad									
High grade (G3)	77	45 (58,4)	15,0 [10,2;20,7]	84	66 (78,6)	8,3 [6,9; 9,6]	0,43	[0,29; 0,63]	<0,0001*
Low grade (G1+G2)	90	48 (53,3)	15,2 [12,3;20,8]	87	64 (73,6)	12,4 [9,7;15,1]	0,68	[0,46; 0,98]	0,0403*
Interaktion p-Wert									0,1008
ECOG Performance Status zu Baseline									
0	135	74 (54,8)	15,0 [12,2;20,3]	127	96 (75,6)	9,8 [9,5;12,4]	0,61	[0,45; 0,82]	0,0012*
1	56	34 (60,7)	13,1 [9,7;19,4]	65	52 (80,0)	8,1 [7,0; 9,7]	0,49	[0,31; 0,75]	0,0011*
Interaktion p-Wert									0,4224
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	4 (36,4)	NE [NE; NE]	10	7 (70,0)	9,5 [6,3; NE]	0,25	[0,07; 0,83]	0,0243*
IV	78	42 (53,8)	15,1 [12,2;20,3]	79	61 (77,2)	9,0 [7,0; 9,7]	0,49	[0,32; 0,72]	0,0003*
Interaktion p-Wert									0,3059

For certain subgroups there are patients with missing status or belong to a subgroup with too few patients who are therefore not included in the analysis. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. Hazard ratio <1 favours CTx + Durvalumab + Olaparib. * p<0.05.
[a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE = Not estimable (i.e. median is not reached).
[b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
CTx = Carboplatin + Paclitaxel.
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Table 4.2.1.2.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Allgemeine Lebensqualität/Gesundheitsszustand
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	55 (55,6)	2,8 [1,4; 3,5]	101	55 (54,5)	2,2 [1,4; 3,5]	1,02	[0,70; 1,49]	0,9038
Neu diagnostiziert	92	41 (44,6)	6,0 [2,8;16,0]	91	42 (46,2)	3,6 [2,1; 7,7]	0,81	[0,52; 1,24]	0,3291
Interaktion p-Wert									0,4149
Region									
Asien	54	32 (59,3)	3,4 [1,4; 8,7]	54	37 (68,5)	3,4 [2,0; 4,2]	0,94	[0,58; 1,51]	0,7874
Rest der Welt	137	64 (46,7)	3,5 [2,7; 6,0]	138	60 (43,5)	3,4 [2,1; 5,2]	0,90	[0,63; 1,29]	0,5692
Interaktion p-Wert									0,9021
Alter									
<65	101	53 (52,5)	2,8 [2,1; 4,4]	99	50 (50,5)	3,6 [2,1; 5,2]	1,01	[0,69; 1,50]	0,9401
>=65	90	43 (47,8)	4,1 [2,8; 9,6]	93	47 (50,5)	2,7 [2,0; 3,5]	0,80	[0,53; 1,21]	0,2865
Interaktion p-Wert									0,4065
Abstammung									
Weiß	104	45 (43,3)	3,4 [2,4; NE]	113	50 (44,2)	3,4 [2,1; 7,7]	0,86	[0,57; 1,29]	0,4709
Schwarz/Afroamerikanisch	13	7 (53,8)	4,1 [0,7; NE]	8	3 (37,5)	3,1 [0,7; NE]	1,37	[0,38; 6,39]	0,6397
Asiatisch	57	34 (59,6)	3,4 [1,4; 8,7]	58	37 (63,8)	3,4 [2,0; 4,2]	0,96	[0,60; 1,54]	0,8729
Andere	16	9 (56,3)	4,4 [2,1;16,1]	12	7 (58,3)	2,1 [0,7; NE]	0,58	[0,22; 1,64]	0,2957
Interaktion p-Wert									0,7492
HRR Mutationsstatus									
HRRm	21	9 (42,9)	3,4 [1,3; NE]	17	11 (64,7)	2,9 [1,4; 9,7]	0,68	[0,27; 1,66]	0,3998
Nicht-HRRm	118	60 (50,8)	4,1 [2,4; 7,8]	111	57 (51,4)	2,2 [1,4; 4,2]	0,80	[0,55; 1,15]	0,2231
Unbekannt	52	27 (51,9)	2,8 [0,8; 6,0]	64	29 (45,3)	3,5 [2,1; 9,6]	1,33	[0,78; 2,26]	0,2884
Interaktion p-Wert									0,2371
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Allgemeine Lebensqualität/Gesundheitsszustand
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	58 (51,8)	3,4 [2,1; 4,4]	124	60 (48,4)	3,5 [2,1; 5,2]	0,98	[0,68; 1,41]	0,9273
Negativ	73	33 (45,2)	5,1 [2,1;10,5]	67	37 (55,2)	2,2 [1,5; 4,2]	0,73	[0,46; 1,17]	0,1942
Unbekannt	6	5 (83,3)	1,8 [0,6; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3306
Histologie									
Endometrioid	107	57 (53,3)	2,8 [2,0; 3,5]	98	55 (56,1)	2,8 [2,1; 4,2]	1,01	[0,70; 1,46]	0,9660
Serös	42	24 (57,1)	4,2 [0,8; 7,8]	52	25 (48,1)	2,2 [1,4; 5,2]	0,93	[0,53; 1,64]	0,8082
Andere	42	15 (35,7)	9,6 [4,1; NE]	42	17 (40,5)	3,6 [1,4; NE]	0,65	[0,32; 1,31]	0,2271
Interaktion p-Wert									0,5540
Histologischer Grad									
High grade (G3)	77	38 (49,4)	5,1 [2,7;10,5]	84	40 (47,6)	3,5 [2,1; 6,0]	0,75	[0,48; 1,17]	0,2070
Low grade (G1+G2)	90	47 (52,2)	2,7 [1,4; 3,5]	87	45 (51,7)	2,8 [1,9; 9,7]	1,14	[0,76; 1,72]	0,5319
Interaktion p-Wert									0,1771
ECOG Performance Status zu Baseline									
0	135	71 (52,6)	3,4 [2,2; 4,1]	127	74 (58,3)	2,2 [1,9; 3,5]	0,84	[0,60; 1,16]	0,2804
1	56	25 (44,6)	5,1 [1,4;17,0]	65	23 (35,4)	7,7 [2,7;14,3]	1,11	[0,63; 1,98]	0,7098
Interaktion p-Wert									0,3904
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	7 (63,6)	1,4 [0,7; 3,5]	10	7 (70,0)	3,2 [0,7; NE]	1,41	[0,48; 4,13]	0,5208
IV	78	33 (42,3)	8,7 [4,1;16,1]	79	35 (44,3)	3,6 [2,1; 7,7]	0,74	[0,46; 1,19]	0,2161
Interaktion p-Wert									0,2747

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Körper
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	58 (58,6)	2,2 [1,4; 3,5]	101	52 (51,5)	2,2 [2,0; 3,6]	1,09	[0,75; 1,59]	0,6554
Neu diagnostiziert	92	45 (48,9)	3,5 [2,2; 9,6]	91	46 (50,5)	3,4 [2,0; 5,2]	0,84	[0,56; 1,27]	0,4175
Interaktion p-Wert									0,3678
Region									
Asien	54	32 (59,3)	3,4 [1,4; 8,8]	54	39 (72,2)	2,2 [1,4; 3,5]	0,74	[0,46; 1,18]	0,2064
Rest der Welt	137	71 (51,8)	2,8 [2,0; 4,1]	138	59 (42,8)	3,4 [2,1; 4,2]	1,11	[0,79; 1,57]	0,5485
Interaktion p-Wert									0,1696
Alter									
<65	101	53 (52,5)	2,8 [1,4; 4,3]	99	49 (49,5)	3,4 [2,2; 4,2]	1,09	[0,74; 1,61]	0,6775
>=65	90	50 (55,6)	2,8 [2,0; 4,1]	93	49 (52,7)	2,1 [1,5; 3,4]	0,84	[0,56; 1,25]	0,3834
Interaktion p-Wert									0,3610
Abstammung									
Weiß	104	53 (51,0)	2,8 [2,0; 4,2]	113	51 (45,1)	2,9 [2,1; 4,2]	1,07	[0,73; 1,57]	0,7320
Schwarz/Afroamerikanisch	13	7 (53,8)	1,4 [0,7; 2,2]	8	2 (25,0)	NE [NE; NE]	3,52	[0,85; 23,69]	0,0862
Asiatisch	57	34 (59,6)	3,4 [1,4; 8,8]	58	39 (67,2)	2,2 [1,4; 3,5]	0,75	[0,47; 1,19]	0,2219
Andere	16	8 (50,0)	5,8 [0,7; NE]	12	6 (50,0)	4,1 [0,7; NE]	0,68	[0,24; 2,09]	0,4907
Interaktion p-Wert									0,1789
HRR Mutationsstatus									
HRRm	21	8 (38,1)	9,6 [1,4; NE]	17	10 (58,8)	2,1 [0,7; 3,4]	0,45	[0,17; 1,15]	0,0958
Nicht-HRRm	118	64 (54,2)	3,4 [2,2; 4,2]	111	60 (54,1)	2,2 [2,0; 3,6]	0,81	[0,57; 1,16]	0,2534
Unbekannt	52	31 (59,6)	2,0 [0,8; 2,8]	64	28 (43,8)	4,2 [2,2; 9,6]	1,79	[1,07; 3,01]	0,0256*
Interaktion p-Wert									0,0113*
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Körper
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	61 (54,5)	2,8 [1,5; 4,2]	124	58 (46,8)	3,5 [2,1; 4,2]	1,06	[0,74; 1,52]	0,7580
Negativ	73	36 (49,3)	3,5 [2,2; 8,8]	67	40 (59,7)	2,1 [1,6; 3,4]	0,71	[0,45; 1,12]	0,1436
Unbekannt	6	6 (100)	0,8 [0,7; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1814
Histologie									
Endometrioid	107	57 (53,3)	2,8 [1,5; 4,3]	98	55 (56,1)	2,9 [2,1; 4,1]	0,96	[0,66; 1,40]	0,8436
Serös	42	24 (57,1)	2,8 [0,9; 8,8]	52	27 (51,9)	2,1 [1,4; 3,4]	0,78	[0,44; 1,35]	0,3660
Andere	42	22 (52,4)	3,4 [2,2; 6,0]	42	16 (38,1)	4,2 [1,5; NE]	1,28	[0,68; 2,48]	0,4495
Interaktion p-Wert									0,5088
Histologischer Grad									
High grade (G3)	77	45 (58,4)	2,7 [1,4; 5,1]	84	41 (48,8)	2,1 [1,6; 3,6]	0,92	[0,60; 1,41]	0,7111
Low grade (G1+G2)	90	48 (53,3)	2,8 [1,4; 4,2]	87	45 (51,7)	3,4 [2,1; 4,2]	1,11	[0,74; 1,67]	0,6216
Interaktion p-Wert									0,5426
ECOG Performance Status zu Baseline									
0	135	72 (53,3)	2,8 [1,5; 4,1]	127	70 (55,1)	2,2 [2,0; 3,4]	0,89	[0,64; 1,24]	0,4871
1	56	31 (55,4)	2,8 [2,0; 4,3]	65	28 (43,1)	3,6 [2,2; 7,8]	1,16	[0,69; 1,94]	0,5789
Interaktion p-Wert									0,3990
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	6 (54,5)	2,1 [0,7; NE]	10	6 (60,0)	2,1 [0,7; NE]	1,14	[0,36; 3,65]	0,8201
IV	78	37 (47,4)	4,1 [2,2;16,1]	79	39 (49,4)	3,5 [2,1; 5,2]	0,80	[0,51; 1,25]	0,3208
Interaktion p-Wert									0,5637

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Nutzenbewertung nach AMNOG

Table 4.2.1.2.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Rolle
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	65 (65,7)	1,4 [1,4; 2,7]	101	60 (59,4)	1,6 [1,4; 2,7]	1,08	[0,76; 1,54]	0,6628
Neu diagnostiziert	92	51 (55,4)	2,2 [2,1; 3,4]	91	55 (60,4)	1,6 [0,8; 2,2]	0,75	[0,51; 1,09]	0,1310
Interaktion p-Wert									0,1596
Region									
Asien	54	37 (68,5)	1,4 [0,8; 2,7]	54	38 (70,4)	2,1 [1,4; 2,8]	1,07	[0,68; 1,69]	0,7681
Rest der Welt	137	79 (57,7)	2,2 [1,4; 2,9]	138	77 (55,8)	1,6 [1,3; 2,2]	0,84	[0,61; 1,15]	0,2763
Interaktion p-Wert									0,3885
Alter									
<65	101	58 (57,4)	2,1 [1,4; 2,8]	99	58 (58,6)	2,1 [1,4; 2,8]	0,95	[0,66; 1,37]	0,7837
>=65	90	58 (64,4)	2,1 [1,4; 2,9]	93	57 (61,3)	1,4 [0,8; 2,1]	0,85	[0,59; 1,23]	0,3992
Interaktion p-Wert									0,6861
Abstammung									
Weiß	104	63 (60,6)	2,1 [1,4; 2,9]	113	64 (56,6)	1,6 [0,9; 2,7]	0,92	[0,65; 1,31]	0,6545
Schwarz/Afroamerikanisch	13	7 (53,8)	0,8 [0,7; NE]	8	3 (37,5)	1,9 [0,7; NE]	1,56	[0,43; 7,27]	0,5067
Asiatisch	57	37 (64,9)	2,1 [1,3; 2,8]	58	38 (65,5)	2,1 [1,4; 2,8]	0,99	[0,63; 1,57]	0,9807
Andere	16	9 (56,3)	2,8 [0,7; NE]	12	10 (83,3)	1,4 [0,7; 2,1]	0,47	[0,19; 1,18]	0,1077
Interaktion p-Wert									0,4277
HRR Mutationsstatus									
HRRm	21	13 (61,9)	1,4 [1,3; 2,8]	17	10 (58,8)	2,1 [0,7; 3,5]	1,03	[0,45; 2,41]	0,9443
Nicht-HRRm	118	73 (61,9)	2,1 [1,4; 2,8]	111	71 (64,0)	1,4 [0,9; 2,1]	0,79	[0,57; 1,09]	0,1506
Unbekannt	52	30 (57,7)	2,2 [0,8; 2,9]	64	34 (53,1)	2,1 [1,4; 3,4]	1,16	[0,70; 1,89]	0,5658
Interaktion p-Wert									0,4195
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Rolle
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	71 (63,4)	2,1 [1,4; 2,7]	124	72 (58,1)	2,0 [1,4; 2,7]	0,94	[0,68; 1,31]	0,7232
Negativ	73	39 (53,4)	2,7 [1,4; 3,5]	67	42 (62,7)	1,4 [0,8; 2,7]	0,78	[0,50; 1,21]	0,2650
Unbekannt	6	6 (100)	0,8 [0,7; NE]	1	1 (100)	1,4 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4978
Histologie									
Endometrioid	107	66 (61,7)	2,1 [1,4; 2,7]	98	64 (65,3)	2,0 [1,4; 2,2]	0,93	[0,66; 1,32]	0,6910
Serös	42	27 (64,3)	2,1 [0,8; 3,0]	52	28 (53,8)	1,4 [0,7; 3,4]	0,88	[0,52; 1,49]	0,6304
Andere	42	23 (54,8)	2,2 [1,4; 4,2]	42	23 (54,8)	2,0 [1,3; 3,5]	0,86	[0,48; 1,55]	0,6187
Interaktion p-Wert									0,9670
Histologischer Grad									
High grade (G3)	77	48 (62,3)	2,2 [1,4; 3,5]	84	49 (58,3)	2,1 [1,3; 2,9]	0,82	[0,55; 1,22]	0,3185
Low grade (G1+G2)	90	58 (64,4)	1,4 [1,3; 2,2]	87	52 (59,8)	1,6 [1,3; 2,1]	1,16	[0,80; 1,69]	0,4377
Interaktion p-Wert									0,2084
ECOG Performance Status zu Baseline									
0	135	83 (61,5)	2,1 [1,4; 2,7]	127	83 (65,4)	1,6 [1,3; 2,1]	0,86	[0,63; 1,16]	0,3155
1	56	33 (58,9)	1,4 [1,3; 4,2]	65	32 (49,2)	2,1 [1,4; 3,4]	1,02	[0,63; 1,67]	0,9359
Interaktion p-Wert									0,5483
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	7 (63,6)	1,1 [0,7; 6,0]	10	7 (70,0)	2,4 [0,7;12,4]	1,38	[0,47; 4,03]	0,5520
IV	78	42 (53,8)	2,7 [2,1; 3,4]	79	47 (59,5)	1,5 [0,8; 2,2]	0,68	[0,45; 1,03]	0,0695
Interaktion p-Wert									0,2242

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Emotionalität
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	40 (40,4)	5,1 [2,8; NE]	101	34 (33,7)	9,6 [4,2; NE]	1,24	[0,79; 1,98]	0,3472
Neu diagnostiziert	92	37 (40,2)	6,0 [3,6; NE]	91	27 (29,7)	15,2 [7,2; NE]	1,23	[0,75; 2,03]	0,4205
Interaktion p-Wert									0,9636
Region									
Asien	54	26 (48,1)	6,0 [2,8; NE]	54	23 (42,6)	10,7 [3,5; NE]	1,16	[0,66; 2,04]	0,6129
Rest der Welt	137	51 (37,2)	5,1 [3,5; NE]	138	38 (27,5)	15,2 [7,1; NE]	1,28	[0,84; 1,95]	0,2540
Interaktion p-Wert									0,7822
Alter									
<65	101	42 (41,6)	5,0 [3,4; NE]	99	34 (34,3)	10,7 [5,2;16,1]	1,28	[0,82; 2,03]	0,2808
>=65	90	35 (38,9)	7,0 [3,6; NE]	93	27 (29,0)	NE [NE; NE]	1,18	[0,71; 1,96]	0,5241
Interaktion p-Wert									0,8040
Abstammung									
Weiß	104	39 (37,5)	6,8 [3,6; NE]	113	32 (28,3)	15,2 [7,1; NE]	1,25	[0,79; 2,02]	0,3405
Schwarz/Afroamerikanisch	13	4 (30,8)	3,5 [0,7; NE]	8	1 (12,5)	NE [NE; NE]	3,09	[0,46; 60,60]	0,2666
Asiatisch	57	27 (47,4)	6,0 [2,8; NE]	58	23 (39,7)	10,7 [3,5; NE]	1,17	[0,67; 2,05]	0,5857
Andere	16	7 (43,8)	2,8 [0,7; NE]	12	5 (41,7)	2,1 [0,7; NE]	0,98	[0,31; 3,32]	0,9751
Interaktion p-Wert									0,8048
HRR Mutationsstatus									
HRRm	21	8 (38,1)	NE [NE; NE]	17	8 (47,1)	3,5 [0,7; NE]	0,72	[0,26; 1,95]	0,5090
Nicht-HRRm	118	52 (44,1)	6,0 [3,6;10,0]	111	38 (34,2)	13,3 [5,1; NE]	1,21	[0,80; 1,85]	0,3732
Unbekannt	52	17 (32,7)	3,5 [2,8; NE]	64	15 (23,4)	NE [NE; NE]	1,51	[0,75; 3,06]	0,2470
Interaktion p-Wert									0,4830
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Emotionalität
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	42 (37,5)	13,4 [3,5; NE]	124	37 (29,8)	NE [NE; NE]	1,08	[0,69; 1,69]	0,7301
Negativ	73	30 (41,1)	5,0 [3,4;10,0]	67	23 (34,3)	13,3 [7,2; NE]	1,36	[0,79; 2,37]	0,2603
Unbekannt	6	5 (83,3)	2,1 [0,6; NE]	1	1 (100)	2,1 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5140
Histologie									
Endometrioid	107	43 (40,2)	5,0 [2,9; NE]	98	39 (39,8)	9,6 [4,1; NE]	1,10	[0,71; 1,70]	0,6685
Serös	42	20 (47,6)	6,0 [2,8;13,4]	52	14 (26,9)	15,2 [3,5; NE]	1,40	[0,71; 2,83]	0,3303
Andere	42	14 (33,3)	10,0 [3,5; NE]	42	8 (19,0)	NE [NE; NE]	1,59	[0,68; 3,97]	0,2898
Interaktion p-Wert									0,6933
Histologischer Grad									
High grade (G3)	77	32 (41,6)	6,0 [3,5; NE]	84	23 (27,4)	16,1 [6,9; NE]	1,28	[0,75; 2,22]	0,3613
Low grade (G1+G2)	90	40 (44,4)	5,0 [2,8;10,0]	87	33 (37,9)	10,7 [4,1; NE]	1,32	[0,83; 2,11]	0,2359
Interaktion p-Wert									0,9332
ECOG Performance Status zu Baseline									
0	135	53 (39,3)	7,0 [4,1; NE]	127	38 (29,9)	NE [NE; NE]	1,35	[0,89; 2,06]	0,1561
1	56	24 (42,9)	3,5 [2,8; NE]	65	23 (35,4)	7,1 [3,5;10,7]	1,04	[0,58; 1,85]	0,9027
Interaktion p-Wert									0,4648
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	NE [NE; NE]	10	5 (50,0)	0,8 [0,7; NE]	0,42	[0,09; 1,70]	0,2216
IV	78	31 (39,7)	6,0 [4,1; NE]	79	22 (27,8)	16,1 [7,2; NE]	1,33	[0,78; 2,33]	0,2997
Interaktion p-Wert									0,1296

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Kognition
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	55 (55,6)	2,8 [2,1; 4,2]	101	48 (47,5)	3,4 [2,1; 5,9]	1,17	[0,80; 1,73]	0,4216
Neu diagnostiziert	92	56 (60,9)	2,3 [1,5; 2,9]	91	46 (50,5)	3,5 [2,1; 6,1]	1,26	[0,85; 1,87]	0,2454
Interaktion p-Wert									0,7967
Region									
Asien	54	38 (70,4)	2,0 [1,4; 2,8]	54	32 (59,3)	4,1 [1,4;11,6]	1,52	[0,95; 2,45]	0,0791
Rest der Welt	137	73 (53,3)	2,8 [2,1; 3,6]	138	62 (44,9)	3,4 [2,1; 5,1]	1,10	[0,78; 1,54]	0,5989
Interaktion p-Wert									0,2646
Alter									
<65	101	64 (63,4)	2,3 [1,5; 2,8]	99	43 (43,4)	5,9 [3,4;11,6]	1,82	[1,24; 2,70]	0,0022*
>=65	90	47 (52,2)	2,9 [2,1; 7,8]	93	51 (54,8)	2,1 [1,4; 3,4]	0,78	[0,52; 1,16]	0,2117
Interaktion p-Wert									0,0026*
Abstammung									
Weiß	104	55 (52,9)	2,7 [2,1; 6,0]	113	53 (46,9)	3,4 [2,1; 5,1]	1,02	[0,70; 1,49]	0,9173
Schwarz/Afroamerikanisch	13	5 (38,5)	3,5 [0,7; NE]	8	1 (12,5)	NE [NE; NE]	5,71	[0,91;109,82]	0,0637
Asiatisch	57	39 (68,4)	2,1 [1,4; 3,4]	58	32 (55,2)	4,1 [1,4;11,6]	1,49	[0,93; 2,39]	0,0961
Andere	16	11 (68,8)	2,8 [0,7; 5,9]	12	8 (66,7)	2,1 [0,8; 3,5]	1,03	[0,41; 2,65]	0,9569
Interaktion p-Wert									0,2334
HRR Mutationsstatus									
HRRm	21	9 (42,9)	2,7 [1,3; NE]	17	13 (76,5)	1,5 [1,4; 3,4]	0,46	[0,19; 1,07]	0,0714
Nicht-HRRm	118	73 (61,9)	2,7 [2,1; 3,6]	111	57 (51,4)	3,4 [2,0; 5,1]	1,10	[0,78; 1,56]	0,5819
Unbekannt	52	29 (55,8)	2,7 [1,4; 2,8]	64	24 (37,5)	5,9 [2,7; NE]	2,10	[1,22; 3,64]	0,0075*
Interaktion p-Wert									0,0099*
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Kognition
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	65 (58,0)	2,7 [2,0; 2,9]	124	60 (48,4)	3,4 [2,1; 5,0]	1,14	[0,80; 1,62]	0,4788
Negativ	73	43 (58,9)	2,7 [1,4; 3,5]	67	33 (49,3)	3,4 [2,1; 6,9]	1,43	[0,91; 2,27]	0,1174
Unbekannt	6	3 (50,0)	2,2 [0,7; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4240
Histologie									
Endometrioid	107	61 (57,0)	2,8 [2,1; 3,4]	98	50 (51,0)	4,3 [2,1; 8,7]	1,17	[0,81; 1,71]	0,4118
Serös	42	27 (64,3)	2,7 [1,4; 6,0]	52	28 (53,8)	2,2 [1,4; 3,4]	1,01	[0,59; 1,71]	0,9808
Andere	42	23 (54,8)	1,5 [1,3; 4,1]	42	16 (38,1)	3,5 [1,5; NE]	1,83	[0,97; 3,53]	0,0616
Interaktion p-Wert									0,3468
Histologischer Grad									
High grade (G3)	77	46 (59,7)	2,7 [1,5; 5,1]	84	42 (50,0)	3,4 [2,1; 5,1]	1,07	[0,70; 1,63]	0,7521
Low grade (G1+G2)	90	52 (57,8)	2,7 [1,5; 2,9]	87	43 (49,4)	3,4 [2,0; 7,0]	1,29	[0,86; 1,95]	0,2122
Interaktion p-Wert									0,5237
ECOG Performance Status zu Baseline									
0	135	81 (60,0)	2,7 [2,0; 2,9]	127	63 (49,6)	3,5 [2,2; 5,9]	1,35	[0,97; 1,88]	0,0735
1	56	30 (53,6)	2,7 [1,4; 9,7]	65	31 (47,7)	2,8 [1,4; 4,1]	0,95	[0,57; 1,57]	0,8361
Interaktion p-Wert									0,2497
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	5 (45,5)	2,8 [1,4; NE]	10	6 (60,0)	3,1 [0,7; NE]	0,85	[0,25; 2,83]	0,7916
IV	78	48 (61,5)	2,2 [1,4; 3,4]	79	39 (49,4)	3,5 [2,1; 7,0]	1,30	[0,85; 1,99]	0,2277
Interaktion p-Wert									0,5129

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Sozial
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	57 (57,6)	2,1 [1,4; 3,5]	101	52 (51,5)	2,6 [1,4; 3,5]	1,09	[0,75; 1,60]	0,6418
Neu diagnostiziert	92	50 (54,3)	2,2 [2,1; 3,4]	91	40 (44,0)	3,5 [2,2; 9,6]	1,27	[0,84; 1,94]	0,2553
Interaktion p-Wert									0,5962
Region									
Asien	54	34 (63,0)	2,1 [1,3; 3,5]	54	30 (55,6)	2,8 [1,4;14,3]	1,35	[0,83; 2,22]	0,2262
Rest der Welt	137	73 (53,3)	2,8 [1,6; 3,5]	138	62 (44,9)	2,8 [2,0; 4,1]	1,10	[0,78; 1,54]	0,5886
Interaktion p-Wert									0,4908
Alter									
<65	101	54 (53,5)	2,2 [1,4; 4,1]	99	43 (43,4)	3,4 [2,7; 9,6]	1,39	[0,94; 2,09]	0,1021
>=65	90	53 (58,9)	2,1 [1,5; 3,4]	93	49 (52,7)	2,0 [1,4; 3,6]	0,97	[0,66; 1,43]	0,8756
Interaktion p-Wert									0,2010
Abstammung									
Weiß	104	58 (55,8)	2,7 [1,6; 3,5]	113	54 (47,8)	2,9 [2,0; 4,1]	1,09	[0,75; 1,59]	0,6360
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	2 (25,0)	2,8 [1,0; NE]	0,76	[0,13; 5,78]	0,7672
Asiatisch	57	35 (61,4)	2,1 [1,3; 4,2]	58	30 (51,7)	2,8 [1,4;14,3]	1,32	[0,81; 2,16]	0,2696
Andere	16	10 (62,5)	1,1 [0,7; 6,9]	12	6 (50,0)	2,1 [0,8; NE]	1,46	[0,54; 4,30]	0,4567
Interaktion p-Wert									0,8613
HRR Mutationsstatus									
HRRm	21	15 (71,4)	1,1 [0,7; 1,4]	17	10 (58,8)	1,4 [0,7; NE]	2,58	[1,17; 5,94]	0,0192*
Nicht-HRRm	118	67 (56,8)	2,8 [2,1; 3,4]	111	55 (49,5)	2,8 [1,5; 4,1]	1,05	[0,73; 1,50]	0,7959
Unbekannt	52	25 (48,1)	2,9 [1,4; 6,9]	64	27 (42,2)	3,5 [2,0; NE]	1,14	[0,66; 1,97]	0,6310
Interaktion p-Wert									0,1248
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Sozial
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	64 (57,1)	2,7 [1,5; 3,5]	124	59 (47,6)	2,8 [2,0; 4,1]	1,11	[0,78; 1,58]	0,5688
Negativ	73	38 (52,1)	2,2 [1,4; 5,1]	67	33 (49,3)	2,9 [1,4; 4,2]	1,16	[0,73; 1,86]	0,5315
Unbekannt	6	5 (83,3)	1,5 [0,7; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8778
Histologie									
Endometrioid	107	61 (57,0)	2,7 [1,4; 3,4]	98	50 (51,0)	2,8 [2,1; 4,1]	1,24	[0,85; 1,80]	0,2676
Serös	42	26 (61,9)	2,7 [1,4; 3,5]	52	27 (51,9)	1,5 [0,8; 3,5]	0,94	[0,55; 1,62]	0,8316
Andere	42	20 (47,6)	2,1 [1,6; 4,2]	42	15 (35,7)	3,5 [1,4; NE]	1,37	[0,70; 2,72]	0,3581
Interaktion p-Wert									0,6368
Histologischer Grad									
High grade (G3)	77	47 (61,0)	2,1 [1,4; 2,8]	84	39 (46,4)	2,8 [1,4; 4,2]	1,21	[0,79; 1,86]	0,3767
Low grade (G1+G2)	90	49 (54,4)	2,8 [1,5; 3,5]	87	42 (48,3)	2,9 [1,5; 4,2]	1,21	[0,80; 1,83]	0,3666
Interaktion p-Wert									0,9957
ECOG Performance Status zu Baseline									
0	135	76 (56,3)	2,2 [1,6; 3,4]	127	62 (48,8)	2,8 [2,0; 4,1]	1,18	[0,84; 1,65]	0,3337
1	56	31 (55,4)	2,7 [0,9; 3,5]	65	30 (46,2)	2,9 [1,4; 4,1]	1,17	[0,71; 1,94]	0,5450
Interaktion p-Wert									0,9740
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	7 (63,6)	1,4 [0,7; 6,9]	10	5 (50,0)	2,7 [0,7; NE]	1,91	[0,61; 6,47]	0,2633
IV	78	40 (51,3)	2,8 [2,1; 4,2]	79	34 (43,0)	4,1 [2,2; NE]	1,17	[0,74; 1,85]	0,5114
Interaktion p-Wert									0,4283

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Fatigue
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	69 (69,7)	0,8 [0,8; 1,4]	101	65 (64,4)	1,4 [0,8; 1,5]	0,97	[0,69; 1,37]	0,8824
Neu diagnostiziert	92	58 (63,0)	1,4 [0,8; 2,7]	91	57 (62,6)	2,1 [1,4; 2,7]	1,01	[0,70; 1,46]	0,9492
Interaktion p-Wert									0,8828
Region									
Asien	54	38 (70,4)	1,4 [0,8; 2,2]	54	43 (79,6)	1,4 [0,8; 2,1]	0,85	[0,54; 1,31]	0,4537
Rest der Welt	137	89 (65,0)	1,0 [0,8; 1,4]	138	79 (57,2)	1,5 [1,0; 2,1]	1,08	[0,80; 1,46]	0,6323
Interaktion p-Wert									0,3740
Alter									
<65	101	69 (68,3)	0,9 [0,8; 1,4]	99	61 (61,6)	1,5 [1,4; 2,2]	1,22	[0,87; 1,73]	0,2554
>=65	90	58 (64,4)	1,4 [0,8; 2,2]	93	61 (65,6)	1,3 [0,8; 2,0]	0,79	[0,55; 1,14]	0,2084
Interaktion p-Wert									0,0897
Abstammung									
Weiß	104	69 (66,3)	1,0 [0,8; 1,5]	113	67 (59,3)	1,6 [0,9; 2,2]	1,08	[0,77; 1,52]	0,6377
Schwarz/Afroamerikanisch	13	7 (53,8)	1,4 [0,7; NE]	8	3 (37,5)	1,5 [1,0; NE]	1,44	[0,40; 6,67]	0,5927
Asiatisch	57	39 (68,4)	1,4 [0,8; 2,7]	58	43 (74,1)	1,4 [0,8; 2,1]	0,82	[0,53; 1,26]	0,3592
Andere	16	11 (68,8)	0,8 [0,7; 5,5]	12	9 (75,0)	1,4 [0,7; 2,1]	0,89	[0,37; 2,23]	0,8041
Interaktion p-Wert									0,7084
HRR Mutationsstatus									
HRRm	21	12 (57,1)	1,4 [0,7; NE]	17	12 (70,6)	0,7 [0,7; 2,1]	0,60	[0,27; 1,36]	0,2173
Nicht-HRRm	118	80 (67,8)	0,9 [0,8; 1,4]	111	73 (65,8)	1,4 [1,3; 2,1]	0,98	[0,71; 1,35]	0,8975
Unbekannt	52	35 (67,3)	1,3 [0,8; 2,2]	64	37 (57,8)	1,9 [1,3; 2,7]	1,20	[0,75; 1,91]	0,4368
Interaktion p-Wert									0,3428
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Fatigue
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	74 (66,1)	1,3 [0,8; 1,5]	124	77 (62,1)	1,4 [0,9; 2,0]	0,91	[0,66; 1,25]	0,5584
Negativ	73	47 (64,4)	1,4 [0,8; 2,2]	67	45 (67,2)	1,5 [1,3; 2,2]	1,05	[0,70; 1,59]	0,8023
Unbekannt	6	6 (100)	0,8 [0,7; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5765
Histologie									
Endometrioid	107	72 (67,3)	1,4 [0,8; 2,0]	98	70 (71,4)	1,4 [1,3; 2,0]	0,92	[0,66; 1,28]	0,6207
Serös	42	27 (64,3)	0,9 [0,8; 2,8]	52	32 (61,5)	1,4 [0,7; 2,2]	0,76	[0,45; 1,26]	0,2859
Andere	42	28 (66,7)	1,0 [0,7; 2,7]	42	20 (47,6)	2,1 [0,9; 4,2]	1,72	[0,97; 3,09]	0,0632
Interaktion p-Wert									0,0898
Histologischer Grad									
High grade (G3)	77	54 (70,1)	1,3 [0,8; 2,2]	84	52 (61,9)	1,4 [0,8; 2,1]	0,91	[0,62; 1,34]	0,6271
Low grade (G1+G2)	90	59 (65,6)	1,3 [0,8; 2,0]	87	55 (63,2)	1,5 [1,3; 2,1]	1,08	[0,75; 1,57]	0,6746
Interaktion p-Wert									0,5205
ECOG Performance Status zu Baseline									
0	135	91 (67,4)	1,3 [0,8; 1,4]	127	86 (67,7)	1,4 [0,9; 1,9]	0,99	[0,74; 1,34]	0,9663
1	56	36 (64,3)	1,3 [0,8; 2,7]	65	36 (55,4)	2,1 [1,3; 2,9]	0,99	[0,62; 1,58]	0,9782
Interaktion p-Wert									0,9997
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	6 (54,5)	0,7 [0,7; NE]	10	7 (70,0)	2,8 [0,7; 7,0]	1,31	[0,42; 3,96]	0,6272
IV	78	50 (64,1)	1,5 [0,8; 2,8]	79	49 (62,0)	2,0 [1,4; 2,7]	0,92	[0,62; 1,37]	0,6771
Interaktion p-Wert									0,5493

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Übelkeit und Erbrechen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	63 (63,6)	2,8 [1,4; 4,1]	101	39 (38,6)	7,0 [3,6; NE]	2,16	[1,45; 3,25]	0,0001*
Neu diagnostiziert	92	47 (51,1)	3,4 [2,7; 5,1]	91	42 (46,2)	5,2 [2,1; 9,6]	1,17	[0,77; 1,78]	0,4727
Interaktion p-Wert									0,0362*
Region									
Asien	54	33 (61,1)	2,8 [1,4; 6,0]	54	31 (57,4)	4,1 [2,0;16,1]	1,21	[0,74; 1,99]	0,4393
Rest der Welt	137	77 (56,2)	2,9 [2,2; 3,5]	138	50 (36,2)	7,0 [4,1;12,4]	1,87	[1,31; 2,69]	0,0005*
Interaktion p-Wert									0,1643
Alter									
<65	101	61 (60,4)	2,8 [2,1; 4,1]	99	47 (47,5)	4,1 [3,4; 6,8]	1,53	[1,05; 2,26]	0,0271*
>=65	90	49 (54,4)	3,1 [2,1; 5,9]	93	34 (36,6)	9,6 [4,8;18,9]	1,73	[1,12; 2,70]	0,0133*
Interaktion p-Wert									0,6843
Abstammung									
Weiß	104	60 (57,7)	3,1 [2,1; 4,1]	113	41 (36,3)	8,7 [5,1; NE]	2,04	[1,37; 3,06]	0,0004*
Schwarz/Afroamerikanisch	13	4 (30,8)	2,9 [0,7; NE]	8	3 (37,5)	1,0 [0,8; NE]	0,53	[0,12; 2,72]	0,4226
Asiatisch	57	35 (61,4)	2,8 [1,4; 6,0]	58	31 (53,4)	4,1 [2,0;16,1]	1,24	[0,76; 2,03]	0,3816
Andere	16	10 (62,5)	2,5 [0,7; 5,1]	12	6 (50,0)	3,4 [0,7; NE]	1,20	[0,44; 3,52]	0,7261
Interaktion p-Wert									0,2009
HRR Mutationsstatus									
HRRm	21	8 (38,1)	5,1 [2,1; NE]	17	6 (35,3)	NE [NE; NE]	1,18	[0,41; 3,58]	0,7598
Nicht-HRRm	118	72 (61,0)	3,1 [2,3; 4,1]	111	54 (48,6)	5,1 [2,7; 8,7]	1,40	[0,98; 2,00]	0,0636
Unbekannt	52	30 (57,7)	2,2 [1,4; 3,5]	64	21 (32,8)	9,6 [3,4; NE]	2,52	[1,45; 4,46]	0,0011*
Interaktion p-Wert									0,1796
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Übelkeit und Erbrechen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	65 (58,0)	3,4 [2,2; 5,1]	124	49 (39,5)	6,1 [3,5;17,9]	1,63	[1,13; 2,38]	0,0096*
Negativ	73	40 (54,8)	2,8 [1,5; 4,1]	67	32 (47,8)	5,2 [2,8; 9,8]	1,48	[0,93; 2,37]	0,0989
Unbekannt	6	5 (83,3)	3,4 [0,7; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7475
Histologie									
Endometrioid	107	66 (61,7)	2,8 [2,1; 3,5]	98	49 (50,0)	5,1 [3,5; 8,8]	1,67	[1,16; 2,44]	0,0063*
Serös	42	26 (61,9)	2,8 [1,4; 6,0]	52	21 (40,4)	4,1 [1,4;17,9]	1,39	[0,78; 2,50]	0,2609
Andere	42	18 (42,9)	5,1 [1,4; NE]	42	11 (26,2)	9,8 [3,4; NE]	1,84	[0,88; 4,02]	0,1066
Interaktion p-Wert									0,8152
Histologischer Grad									
High grade (G3)	77	45 (58,4)	3,0 [2,1; 5,1]	84	36 (42,9)	5,1 [2,8; 9,6]	1,31	[0,84; 2,04]	0,2302
Low grade (G1+G2)	90	54 (60,0)	2,8 [1,5; 3,5]	87	35 (40,2)	8,7 [3,6; NE]	2,10	[1,37; 3,25]	0,0006*
Interaktion p-Wert									0,1287
ECOG Performance Status zu Baseline									
0	135	76 (56,3)	2,8 [2,2; 4,1]	127	59 (46,5)	5,2 [3,5; 9,6]	1,57	[1,12; 2,22]	0,0095*
1	56	34 (60,7)	3,0 [1,4; 4,3]	65	22 (33,8)	8,8 [2,7; NE]	1,72	[1,01; 2,99]	0,0448*
Interaktion p-Wert									0,7771
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	5 (45,5)	2,8 [0,7; NE]	10	5 (50,0)	2,4 [0,7; NE]	1,24	[0,34; 4,47]	0,7376
IV	78	40 (51,3)	3,4 [2,7; 5,2]	79	36 (45,6)	5,2 [3,4; 9,6]	1,15	[0,73; 1,82]	0,5455
Interaktion p-Wert									0,9139

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	49 (49,5)	3,5 [1,4; 7,0]	101	55 (54,5)	2,2 [1,4; 3,5]	0,72	[0,49; 1,06]	0,0993
Neu diagnostiziert	92	49 (53,3)	3,5 [2,1; 6,9]	91	45 (49,5)	4,1 [2,2; 6,8]	0,92	[0,61; 1,38]	0,6798
Interaktion p-Wert									0,4010
Region									
Asien	54	29 (53,7)	3,5 [1,9; 9,7]	54	34 (63,0)	2,1 [1,4; 4,1]	0,68	[0,41; 1,11]	0,1226
Rest der Welt	137	69 (50,4)	3,5 [2,1; 5,9]	138	66 (47,8)	2,9 [2,2; 5,0]	0,88	[0,63; 1,24]	0,4721
Interaktion p-Wert									0,3852
Alter									
<65	101	48 (47,5)	4,1 [1,5; 9,7]	99	50 (50,5)	3,4 [2,2; 6,0]	0,82	[0,55; 1,22]	0,3162
>=65	90	50 (55,6)	3,4 [2,1; 6,0]	93	50 (53,8)	2,7 [1,4; 4,1]	0,80	[0,54; 1,19]	0,2699
Interaktion p-Wert									0,9508
Abstammung									
Weiß	104	56 (53,8)	2,9 [1,5; 5,9]	113	56 (49,6)	3,5 [2,2; 6,0]	0,99	[0,68; 1,44]	0,9634
Schwarz/Afroamerikanisch	13	5 (38,5)	2,8 [0,7; NE]	8	3 (37,5)	2,8 [1,0; NE]	1,20	[0,29; 5,84]	0,8043
Asiatisch	57	30 (52,6)	3,5 [1,9; 9,7]	58	34 (58,6)	2,1 [1,4; 4,1]	0,67	[0,41; 1,09]	0,1095
Andere	16	6 (37,5)	9,7 [1,4; NE]	12	7 (58,3)	1,4 [0,7; NE]	0,30	[0,10; 0,91]	0,0335*
Interaktion p-Wert									0,1630
HRR Mutationsstatus									
HRRm	21	11 (52,4)	4,5 [1,4; 9,7]	17	12 (70,6)	1,1 [0,7; 2,9]	0,43	[0,19; 0,995]	0,0487*
Nicht-HRRm	118	65 (55,1)	3,5 [2,8; 6,0]	111	56 (50,5)	4,1 [2,8; 6,0]	0,89	[0,62; 1,28]	0,5374
Unbekannt	52	22 (42,3)	2,1 [1,4; NE]	64	32 (50,0)	2,1 [1,5; 4,2]	0,81	[0,46; 1,38]	0,4375
Interaktion p-Wert									0,2890
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	60 (53,6)	3,5 [1,5; 9,6]	124	64 (51,6)	2,8 [1,5; 3,5]	0,75	[0,53; 1,08]	0,1188
Negativ	73	34 (46,6)	3,5 [2,1; 6,9]	67	36 (53,7)	4,1 [1,9; 6,8]	0,87	[0,54; 1,39]	0,5507
Unbekannt	6	4 (66,7)	2,1 [0,6; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6422
Histologie									
Endometrioid	107	51 (47,7)	4,1 [1,5; 9,7]	98	59 (60,2)	2,1 [1,4; 4,1]	0,67	[0,46; 0,98]	0,0389*
Serös	42	26 (61,9)	2,8 [1,3; 7,0]	52	23 (44,2)	3,4 [1,4; 6,8]	1,06	[0,61; 1,88]	0,8316
Andere	42	21 (50,0)	3,5 [2,2; 6,9]	42	18 (42,9)	3,5 [2,1; 6,0]	0,99	[0,52; 1,87]	0,9650
Interaktion p-Wert									0,3297
Histologischer Grad									
High grade (G3)	77	42 (54,5)	2,8 [2,1; 7,3]	84	41 (48,8)	3,5 [2,1; 6,0]	0,89	[0,58; 1,38]	0,6054
Low grade (G1+G2)	90	43 (47,8)	4,1 [1,5; 7,0]	87	51 (58,6)	2,1 [1,4; 2,9]	0,63	[0,42; 0,95]	0,0261*
Interaktion p-Wert									0,2467
ECOG Performance Status zu Baseline									
0	135	71 (52,6)	2,8 [1,4; 4,2]	127	72 (56,7)	2,8 [1,5; 4,1]	0,88	[0,63; 1,22]	0,4334
1	56	27 (48,2)	7,0 [2,9;16,1]	65	28 (43,1)	4,1 [2,1; 7,8]	0,69	[0,40; 1,17]	0,1658
Interaktion p-Wert									0,4392
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	5 (45,5)	4,2 [0,7; NE]	10	8 (80,0)	3,8 [0,7; 8,8]	0,69	[0,21; 2,08]	0,5160
IV	78	42 (53,8)	3,5 [2,2; 6,9]	79	35 (44,3)	4,1 [2,2; 7,8]	0,96	[0,61; 1,52]	0,8580
Interaktion p-Wert									0,5948

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Dyspnoe
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	58 (58,6)	2,1 [1,4; 3,4]	101	46 (45,5)	3,6 [2,2; 6,9]	1,46	[0,99; 2,16]	0,0564
Neu diagnostiziert	92	45 (48,9)	4,2 [2,2;10,5]	91	35 (38,5)	5,9 [3,4; NE]	1,15	[0,74; 1,80]	0,5274
Interaktion p-Wert									0,4364
Region									
Asien	54	32 (59,3)	2,2 [1,4; 6,0]	54	32 (59,3)	3,4 [2,1; 6,9]	1,08	[0,66; 1,77]	0,7526
Rest der Welt	137	71 (51,8)	3,1 [2,1; 5,0]	138	49 (35,5)	5,1 [3,5; NE]	1,43	[0,996; 2,07]	0,0526
Interaktion p-Wert									0,3715
Alter									
<65	101	51 (50,5)	3,4 [2,1; 6,0]	99	41 (41,4)	5,2 [3,5;10,0]	1,28	[0,85; 1,93]	0,2456
>=65	90	52 (57,8)	2,8 [1,5; 3,7]	93	40 (43,0)	3,5 [2,1; 8,7]	1,30	[0,86; 1,98]	0,2068
Interaktion p-Wert									0,9420
Abstammung									
Weiß	104	56 (53,8)	2,8 [2,0; 3,7]	113	43 (38,1)	5,1 [3,5; NE]	1,48	[0,997; 2,21]	0,0519
Schwarz/Afroamerikanisch	13	8 (61,5)	1,4 [0,7; NE]	8	1 (12,5)	NE [NE; NE]	7,06	[1,29;131,02]	0,0209*
Asiatisch	57	32 (56,1)	2,8 [1,4; 6,0]	58	32 (55,2)	3,4 [2,1; 6,9]	1,02	[0,62; 1,66]	0,9471
Andere	16	6 (37,5)	17,0 [1,4; NE]	12	5 (41,7)	6,8 [0,9; NE]	0,71	[0,21; 2,45]	0,5687
Interaktion p-Wert									0,1048
HRR Mutationsstatus									
HRRm	21	11 (52,4)	2,9 [0,8; 9,6]	17	8 (47,1)	3,5 [2,1; NE]	1,22	[0,49; 3,16]	0,6652
Nicht-HRRm	118	64 (54,2)	3,4 [2,2; 6,0]	111	44 (39,6)	5,9 [2,9;11,5]	1,25	[0,86; 1,85]	0,2466
Unbekannt	52	28 (53,8)	2,0 [1,4; 2,8]	64	29 (45,3)	4,2 [2,1; 9,6]	1,50	[0,89; 2,53]	0,1272
Interaktion p-Wert									0,8462
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Dyspnoe
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	68 (60,7)	2,8 [1,6; 3,7]	124	49 (39,5)	5,1 [3,4; 9,6]	1,56	[1,08; 2,27]	0,0168*
Negativ	73	32 (43,8)	4,2 [2,0;10,7]	67	31 (46,3)	4,1 [2,2; 9,6]	0,99	[0,60; 1,63]	0,9752
Unbekannt	6	3 (50,0)	NE [NE; NE]	1	1 (100)	1,4 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1498
Histologie									
Endometrioid	107	61 (57,0)	2,8 [2,1; 5,1]	98	50 (51,0)	3,5 [2,1; 6,9]	1,16	[0,80; 1,69]	0,4439
Serös	42	22 (52,4)	2,8 [1,4;10,5]	52	18 (34,6)	4,1 [2,9; NE]	1,42	[0,76; 2,68]	0,2655
Andere	42	20 (47,6)	2,9 [1,4; 8,7]	42	13 (31,0)	8,7 [4,2; NE]	1,60	[0,81; 3,31]	0,1792
Interaktion p-Wert									0,6706
Histologischer Grad									
High grade (G3)	77	42 (54,5)	3,4 [2,0; 8,7]	84	35 (41,7)	4,1 [2,7; 9,6]	1,17	[0,75; 1,84]	0,4927
Low grade (G1+G2)	90	48 (53,3)	3,1 [2,1; 5,2]	87	39 (44,8)	4,2 [2,2; 9,6]	1,23	[0,80; 1,88]	0,3432
Interaktion p-Wert									0,8809
ECOG Performance Status zu Baseline									
0	135	77 (57,0)	2,8 [2,0; 4,2]	127	60 (47,2)	3,6 [2,9; 6,4]	1,30	[0,93; 1,83]	0,1229
1	56	26 (46,4)	3,7 [1,5;17,0]	65	21 (32,3)	8,7 [2,9; NE]	1,25	[0,71; 2,25]	0,4411
Interaktion p-Wert									0,9077
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	4 (36,4)	10,7 [0,7; NE]	10	5 (50,0)	1,1 [0,7; NE]	0,64	[0,16; 2,41]	0,5009
IV	78	38 (48,7)	5,0 [2,8;10,6]	79	29 (36,7)	5,9 [3,4; NE]	1,22	[0,75; 1,99]	0,4209
Interaktion p-Wert									0,3633

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.11 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schlaflosigkeit
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	41 (41,4)	5,1 [2,1; NE]	101	36 (35,6)	12,4 [3,9;15,2]	1,27	[0,81; 1,99]	0,2977
Neu diagnostiziert	92	37 (40,2)	5,1 [2,7; NE]	91	35 (38,5)	6,9 [1,5; NE]	0,81	[0,51; 1,29]	0,3693
Interaktion p-Wert									0,1711
Region									
Asien	54	27 (50,0)	8,8 [2,0; NE]	54	27 (50,0)	10,5 [2,7;15,2]	1,08	[0,63; 1,85]	0,7686
Rest der Welt	137	51 (37,2)	5,1 [3,5; NE]	138	44 (31,9)	8,7 [3,5; NE]	1,01	[0,68; 1,52]	0,9500
Interaktion p-Wert									0,8439
Alter									
<65	101	42 (41,6)	8,8 [2,8;17,0]	99	41 (41,4)	6,9 [2,8;13,4]	0,93	[0,60; 1,44]	0,7436
>=65	90	36 (40,0)	5,1 [2,1; NE]	93	30 (32,3)	10,5 [3,5; NE]	1,16	[0,72; 1,90]	0,5376
Interaktion p-Wert									0,4977
Abstammung									
Weiß	104	41 (39,4)	5,1 [2,1; NE]	113	39 (34,5)	8,7 [3,5; NE]	1,06	[0,68; 1,65]	0,7994
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	2 (25,0)	9,0 [0,8; NE]	0,68	[0,11; 5,19]	0,6809
Asiatisch	57	27 (47,4)	8,8 [2,1; NE]	58	27 (46,6)	10,5 [2,7;15,2]	1,03	[0,60; 1,76]	0,9151
Andere	16	7 (43,8)	3,8 [1,4; NE]	12	3 (25,0)	NE [NE; NE]	1,32	[0,37; 6,15]	0,6799
Interaktion p-Wert									0,9531
HRR Mutationsstatus									
HRRm	21	9 (42,9)	4,2 [1,4; NE]	17	10 (58,8)	3,5 [0,7;10,5]	0,66	[0,26; 1,64]	0,3671
Nicht-HRRm	118	51 (43,2)	6,0 [2,8;17,0]	111	39 (35,1)	9,0 [3,4; NE]	1,07	[0,71; 1,63]	0,7524
Unbekannt	52	18 (34,6)	5,1 [2,1; NE]	64	22 (34,4)	12,4 [2,8; NE]	1,11	[0,59; 2,07]	0,7403
Interaktion p-Wert									0,6020
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.11 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schlaflosigkeit
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	45 (40,2)	6,0 [2,1; NE]	124	42 (33,9)	10,5 [2,8; NE]	1,03	[0,67; 1,57]	0,9035
Negativ	73	28 (38,4)	8,8 [2,2;17,0]	67	28 (41,8)	7,9 [3,5;15,1]	0,99	[0,58; 1,68]	0,9712
Unbekannt	6	5 (83,3)	4,1 [2,1; NE]	1	1 (100)	1,4 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9171
Histologie									
Endometrioid	107	46 (43,0)	5,1 [2,8;17,0]	98	42 (42,9)	9,0 [3,5;15,1]	1,09	[0,72; 1,66]	0,6885
Serös	42	15 (35,7)	NE [NE; NE]	52	16 (30,8)	6,9 [1,5; NE]	0,82	[0,40; 1,67]	0,5842
Andere	42	17 (40,5)	4,2 [1,5; NE]	42	13 (31,0)	NE [NE; NE]	1,10	[0,54; 2,32]	0,7873
Interaktion p-Wert									0,7783
Histologischer Grad									
High grade (G3)	77	32 (41,6)	4,2 [2,0; NE]	84	30 (35,7)	6,0 [2,7; NE]	0,84	[0,51; 1,39]	0,5010
Low grade (G1+G2)	90	38 (42,2)	4,2 [2,7;16,0]	87	36 (41,4)	9,0 [3,5;15,2]	1,11	[0,70; 1,75]	0,6659
Interaktion p-Wert									0,4307
ECOG Performance Status zu Baseline									
0	135	54 (40,0)	8,8 [2,8; NE]	127	44 (34,6)	13,4 [3,9; NE]	1,19	[0,80; 1,78]	0,3926
1	56	24 (42,9)	4,1 [2,0; NE]	65	27 (41,5)	3,5 [1,5;10,5]	0,77	[0,44; 1,33]	0,3466
Interaktion p-Wert									0,2062
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	5,1 [4,1; NE]	10	4 (40,0)	7,0 [0,7; NE]	0,59	[0,12; 2,67]	0,4845
IV	78	33 (42,3)	4,2 [2,1; NE]	79	31 (39,2)	3,5 [1,4; NE]	0,83	[0,51; 1,37]	0,4744
Interaktion p-Wert									0,6623

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.12 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Appetitverlust
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	61 (61,6)	3,5 [1,5; 5,1]	101	43 (42,6)	4,2 [2,2;11,4]	1,55	[1,05; 2,30]	0,0270*
Neu diagnostiziert	92	49 (53,3)	2,9 [2,2; 4,1]	91	30 (33,0)	9,7 [6,0; NE]	2,01	[1,28; 3,20]	0,0023*
Interaktion p-Wert									0,3940
Region									
Asien	54	35 (64,8)	2,7 [1,4; 5,1]	54	30 (55,6)	4,1 [2,1; 9,6]	1,46	[0,90; 2,39]	0,1277
Rest der Welt	137	75 (54,7)	3,5 [2,8; 5,0]	138	43 (31,2)	9,7 [6,1; NE]	1,97	[1,36; 2,89]	0,0003*
Interaktion p-Wert									0,3445
Alter									
<65	101	62 (61,4)	2,7 [1,4; 3,4]	99	41 (41,4)	6,1 [3,5;11,4]	1,99	[1,35; 2,98]	0,0005*
>=65	90	48 (53,3)	4,2 [3,4; 6,0]	93	32 (34,4)	9,7 [2,8; NE]	1,55	[0,99; 2,44]	0,0546
Interaktion p-Wert									0,4062
Abstammung									
Weiß	104	59 (56,7)	3,5 [2,2; 4,3]	113	36 (31,9)	11,4 [6,9; NE]	2,09	[1,38; 3,19]	0,0004*
Schwarz/Afroamerikanisch	13	4 (30,8)	6,1 [0,7; NE]	8	3 (37,5)	6,1 [1,0; NE]	0,70	[0,15; 3,54]	0,6409
Asiatisch	57	36 (63,2)	2,7 [1,4; 5,1]	58	30 (51,7)	4,1 [2,1; 9,6]	1,42	[0,87; 2,32]	0,1566
Andere	16	10 (62,5)	3,5 [0,8; 8,7]	12	4 (33,3)	NE [NE; NE]	2,00	[0,67; 7,29]	0,2226
Interaktion p-Wert									0,4211
HRR Mutationsstatus									
HRRm	21	13 (61,9)	2,7 [1,4; 5,9]	17	8 (47,1)	9,7 [0,7; NE]	1,83	[0,77; 4,64]	0,1703
Nicht-HRRm	118	67 (56,8)	3,6 [2,8; 5,1]	111	42 (37,8)	8,7 [2,9; NE]	1,60	[1,09; 2,37]	0,0158*
Unbekannt	52	30 (57,7)	2,7 [1,4; 4,2]	64	23 (35,9)	5,4 [3,5; NE]	2,17	[1,26; 3,78]	0,0050*
Interaktion p-Wert									0,6652
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.12 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Appetitverlust
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	63 (56,3)	3,5 [2,1; 5,1]	124	43 (34,7)	9,6 [4,1; NE]	1,83	[1,24; 2,71]	0,0021*
Negativ	73	43 (58,9)	2,8 [1,6; 4,1]	67	30 (44,8)	5,4 [2,1;14,4]	1,62	[1,02; 2,60]	0,0419*
Unbekannt	6	4 (66,7)	4,1 [0,8; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6931
Histologie									
Endometrioid	107	65 (60,7)	3,0 [2,1; 4,1]	98	46 (46,9)	5,4 [2,8;11,4]	1,68	[1,15; 2,46]	0,0071*
Serös	42	25 (59,5)	3,6 [1,4; 7,8]	52	16 (30,8)	9,7 [4,2; NE]	1,89	[1,02; 3,62]	0,0429*
Andere	42	20 (47,6)	3,4 [2,1; 8,7]	42	11 (26,2)	NE [NE; NE]	1,88	[0,92; 4,07]	0,0842
Interaktion p-Wert									0,9283
Histologischer Grad									
High grade (G3)	77	47 (61,0)	3,4 [2,1; 5,9]	84	30 (35,7)	6,9 [4,1; NE]	1,75	[1,12; 2,80]	0,0147*
Low grade (G1+G2)	90	53 (58,9)	2,9 [2,0; 4,1]	87	38 (43,7)	4,2 [2,7;14,4]	1,73	[1,14; 2,65]	0,0098*
Interaktion p-Wert									0,9629
ECOG Performance Status zu Baseline									
0	135	78 (57,8)	3,0 [2,1; 4,2]	127	48 (37,8)	9,6 [4,2; NE]	2,02	[1,41; 2,92]	0,0001*
1	56	32 (57,1)	3,5 [2,2; 5,1]	65	25 (38,5)	4,2 [2,1;14,4]	1,26	[0,75; 2,14]	0,3911
Interaktion p-Wert									0,1442
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	7 (63,6)	0,8 [0,7; 3,5]	10	6 (60,0)	3,1 [0,7; NE]	2,29	[0,76; 7,14]	0,1381
IV	78	40 (51,3)	3,5 [2,7; 7,8]	79	23 (29,1)	14,4 [6,1; NE]	2,10	[1,27; 3,58]	0,0039*
Interaktion p-Wert									0,8887

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.13 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Verstopfung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	51 (51,5)	4,4 [2,0; 6,9]	101	37 (36,6)	9,7 [3,3; NE]	1,57	[1,03; 2,42]	0,0355*
Neu diagnostiziert	92	46 (50,0)	2,8 [1,6; 7,8]	91	31 (34,1)	8,8 [2,7; NE]	1,39	[0,89; 2,22]	0,1513
Interaktion p-Wert									0,7046
Region									
Asien	54	25 (46,3)	6,0 [2,1; NE]	54	24 (44,4)	4,1 [2,1; NE]	1,00	[0,57; 1,75]	0,9877
Rest der Welt	137	72 (52,6)	3,5 [1,6; 5,1]	138	44 (31,9)	9,7 [3,4; NE]	1,78	[1,23; 2,61]	0,0022*
Interaktion p-Wert									0,0917
Alter									
<65	101	51 (50,5)	3,5 [1,4; 9,7]	99	42 (42,4)	3,5 [2,1; NE]	1,23	[0,82; 1,87]	0,3106
>=65	90	46 (51,1)	4,1 [2,1; 6,0]	93	26 (28,0)	18,8 [7,0; NE]	1,88	[1,17; 3,09]	0,0084*
Interaktion p-Wert									0,1880
Abstammung									
Weiß	104	59 (56,7)	2,8 [1,5; 4,2]	113	38 (33,6)	9,7 [3,5; NE]	1,93	[1,29; 2,93]	0,0014*
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	2 (25,0)	2,3 [0,8; NE]	1,04	[0,17; 7,92]	0,9680
Asiatisch	57	26 (45,6)	6,0 [2,0; NE]	58	24 (41,4)	4,1 [2,1; NE]	0,99	[0,57; 1,74]	0,9854
Andere	16	8 (50,0)	9,7 [0,8; NE]	12	4 (33,3)	3,4 [0,7; NE]	1,20	[0,38; 4,50]	0,7675
Interaktion p-Wert									0,2789
HRR Mutationsstatus									
HRRm	21	11 (52,4)	3,8 [0,7; NE]	17	8 (47,1)	5,9 [1,4; NE]	1,33	[0,54; 3,45]	0,5327
Nicht-HRRm	118	64 (54,2)	2,8 [1,4; 5,0]	111	41 (36,9)	8,8 [2,7; NE]	1,53	[1,03; 2,28]	0,0328*
Unbekannt	52	22 (42,3)	5,9 [2,1; 9,7]	64	19 (29,7)	NE [NE; NE]	1,39	[0,75; 2,60]	0,2902
Interaktion p-Wert									0,9475
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.13 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Verstopfung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	61 (54,5)	3,5 [2,0; 6,0]	124	37 (29,8)	18,8 [6,8; NE]	1,96	[1,31; 2,97]	0,0011*
Negativ	73	32 (43,8)	4,1 [2,0;16,1]	67	31 (46,3)	2,9 [1,4; NE]	0,90	[0,55; 1,48]	0,6757
Unbekannt	6	4 (66,7)	1,4 [0,7; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0177*
Histologie									
Endometrioid	107	52 (48,6)	5,1 [2,1; 9,7]	98	41 (41,8)	7,0 [3,3; NE]	1,27	[0,84; 1,92]	0,2508
Serös	42	23 (54,8)	3,5 [2,1; 7,8]	52	16 (30,8)	NE [NE; NE]	1,49	[0,79; 2,87]	0,2158
Andere	42	22 (52,4)	1,4 [0,8; 4,2]	42	11 (26,2)	NE [NE; NE]	2,37	[1,17; 5,08]	0,0159*
Interaktion p-Wert									0,3305
Histologischer Grad									
High grade (G3)	77	40 (51,9)	4,2 [2,0;10,5]	84	28 (33,3)	6,8 [2,7; NE]	1,28	[0,79; 2,10]	0,3087
Low grade (G1+G2)	90	45 (50,0)	3,5 [1,4; 6,9]	87	31 (35,6)	18,8 [3,4; NE]	1,77	[1,12; 2,82]	0,0139*
Interaktion p-Wert									0,3481
ECOG Performance Status zu Baseline									
0	135	65 (48,1)	3,5 [2,1; 5,9]	127	49 (38,6)	9,7 [3,3; NE]	1,38	[0,96; 2,01]	0,0858
1	56	32 (57,1)	2,8 [1,4; 7,9]	65	19 (29,2)	8,8 [2,7; NE]	1,75	[1,001; 3,14]	0,0497*
Interaktion p-Wert									0,4947
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	5 (45,5)	1,1 [0,7; NE]	10	4 (40,0)	NE [NE; NE]	2,04	[0,54; 8,26]	0,2877
IV	78	40 (51,3)	2,8 [2,0; 7,8]	79	27 (34,2)	8,8 [2,1; NE]	1,35	[0,83; 2,22]	0,2309
Interaktion p-Wert									0,5605

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.14 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Diarrhö
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	45 (45,5)	6,9 [2,2;12,5]	101	47 (46,5)	4,1 [2,8; 6,8]	0,92	[0,61; 1,39]	0,6935
Neu diagnostiziert	92	35 (38,0)	6,1 [4,1; NE]	91	32 (35,2)	8,7 [3,5; NE]	0,95	[0,59; 1,55]	0,8456
Interaktion p-Wert									0,9144
Region									
Asien	54	26 (48,1)	5,2 [3,5; NE]	54	26 (48,1)	4,3 [2,2; NE]	0,90	[0,52; 1,55]	0,6987
Rest der Welt	137	54 (39,4)	6,9 [3,5;17,0]	138	53 (38,4)	5,2 [3,5; 9,7]	0,94	[0,65; 1,38]	0,7654
Interaktion p-Wert									0,8831
Alter									
<65	101	39 (38,6)	7,8 [4,1; NE]	99	39 (39,4)	5,9 [3,5; NE]	0,96	[0,61; 1,50]	0,8532
>=65	90	41 (45,6)	5,0 [3,5; 9,8]	93	40 (43,0)	4,3 [2,7; 9,7]	0,89	[0,58; 1,38]	0,6125
Interaktion p-Wert									0,8236
Abstammung									
Weiß	104	41 (39,4)	7,8 [3,6; NE]	113	44 (38,9)	6,0 [3,4;12,5]	0,93	[0,60; 1,42]	0,7320
Schwarz/Afroamerikanisch	13	4 (30,8)	2,2 [1,4; NE]	8	2 (25,0)	8,8 [1,6; NE]	1,84	[0,36; 13,37]	0,4695
Asiatisch	57	26 (45,6)	6,9 [4,1; NE]	58	26 (44,8)	4,3 [2,2; NE]	0,85	[0,49; 1,48]	0,5694
Andere	16	8 (50,0)	2,1 [0,8; NE]	12	7 (58,3)	3,5 [0,9; NE]	0,70	[0,25; 1,99]	0,4892
Interaktion p-Wert									0,7977
HRR Mutationsstatus									
HRRm	21	8 (38,1)	7,8 [2,1; NE]	17	9 (52,9)	4,1 [1,4; NE]	0,67	[0,25; 1,75]	0,4096
Nicht-HRRm	118	51 (43,2)	5,1 [3,5;17,0]	111	48 (43,2)	5,0 [3,4; 9,7]	0,91	[0,61; 1,35]	0,6279
Unbekannt	52	21 (40,4)	6,1 [3,5; NE]	64	22 (34,4)	5,9 [3,4; NE]	1,08	[0,59; 1,98]	0,7925
Interaktion p-Wert									0,6981
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.14 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Diarrhö
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	51 (45,5)	5,2 [2,8;12,5]	124	51 (41,1)	5,0 [3,5; 8,7]	1,00	[0,67; 1,47]	0,9829
Negativ	73	25 (34,2)	9,6 [4,1; NE]	67	28 (41,8)	5,1 [2,8; NE]	0,78	[0,45; 1,33]	0,3594
Unbekannt	6	4 (66,7)	4,1 [1,4; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4648
Histologie									
Endometrioid	107	45 (42,1)	7,3 [4,1; NE]	98	48 (49,0)	4,1 [2,8; 6,8]	0,78	[0,52; 1,17]	0,2332
Serös	42	16 (38,1)	9,8 [2,8; NE]	52	18 (34,6)	8,8 [3,5; NE]	0,99	[0,50; 1,95]	0,9812
Andere	42	19 (45,2)	4,2 [1,8; 9,6]	42	13 (31,0)	11,4 [2,2; NE]	1,40	[0,69; 2,89]	0,3513
Interaktion p-Wert									0,3619
Histologischer Grad									
High grade (G3)	77	32 (41,6)	7,8 [2,8; NE]	84	31 (36,9)	7,9 [2,2; NE]	0,95	[0,58; 1,56]	0,8274
Low grade (G1+G2)	90	38 (42,2)	6,9 [3,5;17,0]	87	38 (43,7)	4,3 [3,4; 9,7]	0,89	[0,57; 1,40]	0,6122
Interaktion p-Wert									0,8569
ECOG Performance Status zu Baseline									
0	135	59 (43,7)	6,1 [3,6; 9,8]	127	54 (42,5)	6,0 [3,5;11,4]	1,01	[0,70; 1,47]	0,9475
1	56	21 (37,5)	12,5 [2,8; NE]	65	25 (38,5)	4,3 [2,2; 8,7]	0,75	[0,41; 1,34]	0,3294
Interaktion p-Wert									0,3911
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	4 (36,4)	4,2 [0,8; NE]	10	7 (70,0)	2,7 [0,7; NE]	0,48	[0,13; 1,60]	0,2362
IV	78	30 (38,5)	6,1 [4,1; NE]	79	25 (31,6)	12,5 [3,5; NE]	1,07	[0,63; 1,83]	0,8085
Interaktion p-Wert									0,2374

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.15 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Finanzielle Schwierigkeiten
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	40 (40,4)	8,8 [4,3; NE]	101	25 (24,8)	22,6 [10,0; NE]	1,77	[1,08; 2,95]	0,0233*
Neu diagnostiziert	92	34 (37,0)	15,1 [2,8; NE]	91	33 (36,3)	11,5 [2,2; NE]	0,90	[0,56; 1,46]	0,6741
Interaktion p-Wert									0,0562
Region									
Asien	54	30 (55,6)	4,1 [2,2;16,0]	54	21 (38,9)	NE [NE; NE]	1,63	[0,94; 2,88]	0,0837
Rest der Welt	137	44 (32,1)	15,1 [5,9; NE]	138	37 (26,8)	17,9 [9,8; NE]	1,11	[0,72; 1,73]	0,6398
Interaktion p-Wert									0,2878
Alter									
<65	101	41 (40,6)	10,5 [2,8; NE]	99	39 (39,4)	9,8 [2,8; NE]	1,07	[0,69; 1,67]	0,7514
>=65	90	33 (36,7)	10,5 [5,1; NE]	93	19 (20,4)	22,6 [22,6; NE]	1,69	[0,97; 3,02]	0,0644
Interaktion p-Wert									0,2119
Abstammung									
Weiß	104	36 (34,6)	15,1 [4,3; NE]	113	29 (25,7)	17,9 [8,7; NE]	1,30	[0,80; 2,13]	0,2916
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	2 (25,0)	12,6 [10,0; NE]	0,30	[0,01; 3,12]	0,3055
Asiatisch	57	30 (52,6)	4,2 [2,2;16,0]	58	21 (36,2)	NE [NE; NE]	1,55	[0,89; 2,75]	0,1191
Andere	16	7 (43,8)	6,0 [0,8; NE]	12	6 (50,0)	4,1 [0,7; NE]	0,76	[0,25; 2,36]	0,6201
Interaktion p-Wert									0,4139
HRR Mutationsstatus									
HRRm	21	8 (38,1)	20,7 [1,4; NE]	17	5 (29,4)	NE [NE; NE]	1,48	[0,50; 4,92]	0,4831
Nicht-HRRm	118	44 (37,3)	11,5 [5,9; NE]	111	32 (28,8)	17,9 [10,0; NE]	1,26	[0,80; 2,01]	0,3122
Unbekannt	52	22 (42,3)	4,2 [2,8; NE]	64	21 (32,8)	11,5 [4,1; NE]	1,29	[0,71; 2,35]	0,4092
Interaktion p-Wert									0,9658
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.1.2.15 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Finanzielle Schwierigkeiten
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	45 (40,2)	6,9 [3,5; NE]	124	32 (25,8)	NE [NE; NE]	1,51	[0,96; 2,39]	0,0727
Negativ	73	27 (37,0)	11,5 [2,6; NE]	67	26 (38,8)	11,5 [5,0;22,6]	1,00	[0,58; 1,73]	0,9916
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2549
Histologie									
Endometrioid	107	46 (43,0)	10,5 [2,8;20,7]	98	35 (35,7)	17,9 [8,7; NE]	1,34	[0,87; 2,10]	0,1887
Serös	42	13 (31,0)	NE [NE; NE]	52	14 (26,9)	12,6 [4,2; NE]	0,94	[0,43; 2,00]	0,8641
Andere	42	15 (35,7)	5,9 [2,2; NE]	42	9 (21,4)	NE [NE; NE]	1,51	[0,67; 3,60]	0,3225
Interaktion p-Wert									0,6521
Histologischer Grad									
High grade (G3)	77	29 (37,7)	15,1 [3,4; NE]	84	25 (29,8)	12,6 [5,0; NE]	1,07	[0,62; 1,84]	0,8090
Low grade (G1+G2)	90	37 (41,1)	10,5 [2,8;20,7]	87	26 (29,9)	22,6 [9,8; NE]	1,60	[0,97; 2,67]	0,0642
Interaktion p-Wert									0,2819
ECOG Performance Status zu Baseline									
0	135	48 (35,6)	15,1 [6,9; NE]	127	36 (28,3)	22,6 [12,6; NE]	1,29	[0,84; 2,01]	0,2394
1	56	26 (46,4)	4,2 [2,2;10,5]	65	22 (33,8)	9,8 [3,5; NE]	1,26	[0,71; 2,24]	0,4260
Interaktion p-Wert									0,9388
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	NE [NE; NE]	10	5 (50,0)	2,0 [0,7; NE]	0,47	[0,10; 1,90]	0,2869
IV	78	29 (37,2)	15,1 [2,8; NE]	79	27 (34,2)	11,5 [3,5; NE]	0,96	[0,57; 1,63]	0,8867
Interaktion p-Wert									0,3439

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelles Interesse
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	13 (13,1)	NE [NE; NE]	101	19 (18,8)	NE [NE; NE]	0,68	[0,33; 1,37]	0,2843
Neu diagnostiziert	92	23 (25,0)	NE [NE; NE]	91	15 (16,5)	NE [NE; NE]	1,48	[0,78; 2,91]	0,2302
Interaktion p-Wert									0,1094
Region									
Asien	54	11 (20,4)	NE [NE; NE]	54	8 (14,8)	NE [NE; NE]	1,43	[0,58; 3,69]	0,4400
Rest der Welt	137	25 (18,2)	NE [NE; NE]	138	26 (18,8)	NE [NE; NE]	0,92	[0,53; 1,59]	0,7525
Interaktion p-Wert									0,4100
Alter									
<65	101	22 (21,8)	NE [NE; NE]	99	23 (23,2)	NE [NE; NE]	0,99	[0,55; 1,79]	0,9814
>=65	90	14 (15,6)	NE [NE; NE]	93	11 (11,8)	NE [NE; NE]	1,18	[0,54; 2,67]	0,6775
Interaktion p-Wert									0,7280
Abstammung									
Weiß	104	20 (19,2)	NE [NE; NE]	113	22 (19,5)	NE [NE; NE]	0,96	[0,52; 1,77]	0,9045
Schwarz/Afroamerikanisch	13	2 (15,4)	21,8 [0,7; NE]	8	1 (12,5)	NE [NE; NE]	1,17	[0,11; 25,28]	0,8952
Asiatisch	57	11 (19,3)	NE [NE; NE]	58	8 (13,8)	NE [NE; NE]	1,37	[0,56; 3,55]	0,4912
Andere	16	3 (18,8)	NE [NE; NE]	12	3 (25,0)	NE [NE; NE]	0,61	[0,11; 3,28]	0,5425
Interaktion p-Wert									0,8341
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	17	3 (17,6)	NE [NE; NE]	0,53	[0,07; 3,21]	0,4838
Nicht-HRRm	118	24 (20,3)	NE [NE; NE]	111	20 (18,0)	NE [NE; NE]	1,13	[0,63; 2,07]	0,6793
Unbekannt	52	10 (19,2)	21,8 [15,1; NE]	64	11 (17,2)	NE [NE; NE]	1,05	[0,44; 2,48]	0,9177
Interaktion p-Wert									0,7287
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelles Interesse
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	23 (20,5)	NE [NE; NE]	124	23 (18,5)	NE [NE; NE]	1,01	[0,56; 1,80]	0,9808
Negativ	73	12 (16,4)	NE [NE; NE]	67	11 (16,4)	NE [NE; NE]	1,12	[0,49; 2,59]	0,7796
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8301
Histologie									
Endometrioid	107	20 (18,7)	NE [NE; NE]	98	20 (20,4)	NE [NE; NE]	1,03	[0,55; 1,93]	0,9224
Serös	42	8 (19,0)	NE [NE; NE]	52	8 (15,4)	NE [NE; NE]	0,90	[0,33; 2,47]	0,8424
Andere	42	8 (19,0)	18,0 [9,8; NE]	42	6 (14,3)	NE [NE; NE]	1,25	[0,44; 3,81]	0,6738
Interaktion p-Wert									0,9054
Histologischer Grad									
High grade (G3)	77	17 (22,1)	NE [NE; NE]	84	12 (14,3)	NE [NE; NE]	1,33	[0,64; 2,87]	0,4444
Low grade (G1+G2)	90	15 (16,7)	NE [NE; NE]	87	17 (19,5)	NE [NE; NE]	0,92	[0,46; 1,85]	0,8236
Interaktion p-Wert									0,4786
ECOG Performance Status zu Baseline									
0	135	22 (16,3)	NE [NE; NE]	127	28 (22,0)	NE [NE; NE]	0,73	[0,42; 1,28]	0,2784
1	56	14 (25,0)	18,0 [15,1; NE]	65	6 (9,2)	NE [NE; NE]	2,60	[1,04; 7,35]	0,0401*
Interaktion p-Wert									0,0206*
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	NE [NE; NE]	10	2 (20,0)	NE [NE; NE]	2,25	[0,37; 17,13]	0,3684
IV	78	19 (24,4)	NE [NE; NE]	79	13 (16,5)	NE [NE; NE]	1,37	[0,68; 2,85]	0,3742
Interaktion p-Wert									0,6127

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Nutzenbewertung nach AMNOG

Table 4.2.2.2.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelle Aktivität
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	9 (9,1)	NE [NE; NE]	101	15 (14,9)	NE [NE; NE]	0,59	[0,25; 1,34]	0,2095
Neu diagnostiziert	92	16 (17,4)	NE [NE; NE]	91	18 (19,8)	NE [NE; NE]	0,77	[0,39; 1,51]	0,4420
Interaktion p-Wert									0,6379
Region									
Asien	54	6 (11,1)	NE [NE; NE]	54	8 (14,8)	NE [NE; NE]	0,76	[0,25; 2,18]	0,6035
Rest der Welt	137	19 (13,9)	NE [NE; NE]	138	25 (18,1)	NE [NE; NE]	0,67	[0,37; 1,22]	0,1930
Interaktion p-Wert									0,8532
Alter									
<65	101	14 (13,9)	NE [NE; NE]	99	24 (24,2)	NE [NE; NE]	0,54	[0,27; 1,03]	0,0596
>=65	90	11 (12,2)	NE [NE; NE]	93	9 (9,7)	NE [NE; NE]	1,15	[0,47; 2,84]	0,7628
Interaktion p-Wert									0,1754
Abstammung									
Weiß	104	16 (15,4)	NE [NE; NE]	113	20 (17,7)	NE [NE; NE]	0,81	[0,41; 1,56]	0,5268
Schwarz/Afroamerikanisch	13	3 (23,1)	23,6 [1,4; NE]	8	1 (12,5)	NE [NE; NE]	1,47	[0,19; 29,80]	0,7328
Asiatisch	57	6 (10,5)	NE [NE; NE]	58	8 (13,8)	NE [NE; NE]	0,72	[0,24; 2,08]	0,5462
Andere	16	0	NE [NE; NE]	12	4 (33,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8474
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	17	1 (5,9)	NE [NE; NE]	1,69	[0,16; 36,29]	0,6618
Nicht-HRRm	118	15 (12,7)	NE [NE; NE]	111	21 (18,9)	NE [NE; NE]	0,60	[0,31; 1,16]	0,1312
Unbekannt	52	8 (15,4)	23,6 [23,6; NE]	64	11 (17,2)	NE [NE; NE]	0,85	[0,33; 2,10]	0,7210
Interaktion p-Wert									0,6336
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelle Aktivität
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	15 (13,4)	NE [NE; NE]	124	21 (16,9)	NE [NE; NE]	0,70	[0,35; 1,36]	0,2928
Negativ	73	9 (12,3)	NE [NE; NE]	67	12 (17,9)	NE [NE; NE]	0,69	[0,28; 1,63]	0,3933
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9706
Histologie									
Endometrioid	107	11 (10,3)	NE [NE; NE]	98	18 (18,4)	NE [NE; NE]	0,59	[0,27; 1,23]	0,1588
Serös	42	6 (14,3)	NE [NE; NE]	52	8 (15,4)	NE [NE; NE]	0,64	[0,21; 1,85]	0,4109
Andere	42	8 (19,0)	23,6 [9,8; NE]	42	7 (16,7)	NE [NE; NE]	1,05	[0,38; 3,00]	0,9233
Interaktion p-Wert									0,6530
Histologischer Grad									
High grade (G3)	77	13 (16,9)	NE [NE; NE]	84	12 (14,3)	NE [NE; NE]	0,98	[0,45; 2,19]	0,9694
Low grade (G1+G2)	90	10 (11,1)	NE [NE; NE]	87	16 (18,4)	NE [NE; NE]	0,61	[0,27; 1,32]	0,2102
Interaktion p-Wert									0,3939
ECOG Performance Status zu Baseline									
0	135	16 (11,9)	NE [NE; NE]	127	26 (20,5)	NE [NE; NE]	0,55	[0,29; 1,01]	0,0533
1	56	9 (16,1)	NE [NE; NE]	65	7 (10,8)	NE [NE; NE]	1,34	[0,50; 3,74]	0,5632
Interaktion p-Wert									0,1310
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	5 (45,5)	1,4 [0,7; NE]	10	4 (40,0)	10,5 [0,7; NE]	1,85	[0,49; 7,51]	0,3598
IV	78	11 (14,1)	NE [NE; NE]	79	14 (17,7)	NE [NE; NE]	0,68	[0,30; 1,50]	0,3408
Interaktion p-Wert									0,2030

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelles Vergnügen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	91	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	3 (2,2)	NE [NE; NE]	138	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	99	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	2 (2,2)	NE [NE; NE]	93	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	113	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	1 (6,3)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	2 (1,7)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening
Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are
censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable
baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients
at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median
time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the
main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction.
Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelles Vergnügen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	2 (1,8)	NE [NE; NE]	124	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	3 (2,8)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	42	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	2 (2,6)	NE [NE; NE]	84	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	127	0	NE [NE; NE]	NC	[NC]	NC
1	56	1 (1,8)	NE [NE; NE]	65	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	1,4 [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	79	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Lymphödem
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	58 (58,6)	1,5 [1,4; 2,8]	101	51 (50,5)	3,5 [1,4; 5,2]	1,43	[0,98; 2,09]	0,0640
Neu diagnostiziert	92	57 (62,0)	2,1 [1,3; 2,2]	91	50 (54,9)	2,1 [1,4; 2,7]	1,21	[0,83; 1,78]	0,3165
Interaktion p-Wert									0,5522
Region									
Asien	54	40 (74,1)	1,4 [0,7; 3,4]	54	40 (74,1)	1,4 [1,3; 2,9]	1,15	[0,74; 1,78]	0,5450
Rest der Welt	137	75 (54,7)	2,1 [1,4; 2,2]	138	61 (44,2)	2,7 [2,0; 4,2]	1,44	[1,02; 2,02]	0,0362*
Interaktion p-Wert									0,4249
Alter									
<65	101	62 (61,4)	1,5 [0,9; 2,2]	99	52 (52,5)	2,7 [2,0; 4,1]	1,45	[1,01; 2,11]	0,0460*
>=65	90	53 (58,9)	2,1 [1,4; 2,8]	93	49 (52,7)	1,4 [1,4; 2,7]	1,18	[0,80; 1,75]	0,4030
Interaktion p-Wert									0,4460
Abstammung									
Weiß	104	62 (59,6)	1,5 [1,3; 2,2]	113	51 (45,1)	2,7 [2,1; 5,2]	1,65	[1,14; 2,41]	0,0080*
Schwarz/Afroamerikanisch	13	4 (30,8)	2,9 [0,7; NE]	8	1 (12,5)	NE [NE; NE]	3,25	[0,48; 63,71]	0,2441
Asiatisch	57	41 (71,9)	1,4 [0,8; 3,4]	58	40 (69,0)	1,4 [1,3; 2,9]	1,13	[0,73; 1,74]	0,5962
Andere	16	8 (50,0)	2,8 [1,4; 8,8]	12	9 (75,0)	1,4 [0,8; 2,1]	0,50	[0,19; 1,32]	0,1596
Interaktion p-Wert									0,0903
HRR Mutationsstatus									
HRRm	21	14 (66,7)	1,4 [0,7; 2,2]	17	13 (76,5)	1,4 [0,7; 2,1]	0,99	[0,46; 2,14]	0,9864
Nicht-HRRm	118	72 (61,0)	1,5 [1,4; 2,1]	111	58 (52,3)	2,1 [1,4; 2,7]	1,28	[0,91; 1,82]	0,1600
Unbekannt	52	29 (55,8)	2,8 [0,8; 4,1]	64	30 (46,9)	5,0 [2,1; 6,9]	1,47	[0,88; 2,45]	0,1434
Interaktion p-Wert									0,7040
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Lymphödem
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	70 (62,5)	1,4 [1,4; 2,1]	124	69 (55,6)	2,1 [1,4; 2,7]	1,34	[0,96; 1,88]	0,0863
Negativ	73	40 (54,8)	2,2 [1,4; 3,5]	67	31 (46,3)	3,5 [1,5; 6,9]	1,35	[0,85; 2,18]	0,2068
Unbekannt	6	5 (83,3)	1,3 [0,7; NE]	1	1 (100)	1,4 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9801
Histologie									
Endometrioid	107	70 (65,4)	2,1 [1,4; 2,2]	98	59 (60,2)	2,1 [1,4; 2,9]	1,33	[0,94; 1,88]	0,1086
Serös	42	22 (52,4)	2,1 [1,3; 8,8]	52	26 (50,0)	2,1 [1,4; 2,7]	0,91	[0,51; 1,60]	0,7400
Andere	42	23 (54,8)	1,5 [0,7; 4,1]	42	16 (38,1)	5,2 [2,1; NE]	2,00	[1,06; 3,86]	0,0318*
Interaktion p-Wert									0,1906
Histologischer Grad									
High grade (G3)	77	49 (63,6)	1,5 [1,3; 2,2]	84	39 (46,4)	2,1 [1,4; 5,2]	1,43	[0,94; 2,20]	0,0917
Low grade (G1+G2)	90	56 (62,2)	1,5 [1,3; 2,2]	87	51 (58,6)	2,1 [1,4; 3,5]	1,39	[0,95; 2,04]	0,0912
Interaktion p-Wert									0,9097
ECOG Performance Status zu Baseline									
0	135	77 (57,0)	2,1 [1,4; 2,2]	127	73 (57,5)	2,1 [1,4; 2,9]	1,15	[0,83; 1,58]	0,3971
1	56	38 (67,9)	1,5 [1,3; 2,2]	65	28 (43,1)	2,9 [1,4; 7,9]	1,82	[1,12; 3,00]	0,0161*
Interaktion p-Wert									0,1228
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	4 (36,4)	2,8 [0,7; NE]	10	6 (60,0)	2,1 [0,7; NE]	0,83	[0,21; 2,90]	0,7689
IV	78	50 (64,1)	2,1 [1,3; 2,2]	79	43 (54,4)	2,1 [1,4; 2,7]	1,23	[0,82; 1,86]	0,3103
Interaktion p-Wert									0,5526

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Urologische Symptome
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	37 (37,4)	7,0 [3,4;19,7]	101	30 (29,7)	NE [NE; NE]	1,45	[0,90; 2,37]	0,1286
Neu diagnostiziert	92	36 (39,1)	6,9 [3,5; NE]	91	36 (39,6)	7,8 [3,4;12,5]	0,90	[0,56; 1,43]	0,6442
Interaktion p-Wert									0,1578
Region									
Asien	54	24 (44,4)	7,0 [3,4; NE]	54	19 (35,2)	15,2 [6,8; NE]	1,51	[0,83; 2,78]	0,1802
Rest der Welt	137	49 (35,8)	6,0 [3,4;19,7]	138	47 (34,1)	6,8 [3,4; NE]	0,99	[0,66; 1,48]	0,9665
Interaktion p-Wert									0,2557
Alter									
<65	101	38 (37,6)	5,0 [3,4;14,2]	99	30 (30,3)	14,4 [6,8; NE]	1,54	[0,95; 2,50]	0,0773
>=65	90	35 (38,9)	7,9 [3,4; NE]	93	36 (38,7)	3,5 [2,2; NE]	0,82	[0,51; 1,31]	0,4101
Interaktion p-Wert									0,0662
Abstammung									
Weiß	104	42 (40,4)	4,2 [2,8;19,7]	113	40 (35,4)	6,8 [3,4; NE]	1,14	[0,74; 1,76]	0,5655
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	24 (42,1)	7,0 [3,5; NE]	58	19 (32,8)	15,2 [6,8; NE]	1,44	[0,79; 2,66]	0,2331
Andere	16	6 (37,5)	4,2 [2,1; NE]	12	7 (58,3)	1,4 [0,7; NE]	0,43	[0,14; 1,29]	0,1291
Interaktion p-Wert									0,1637
HRR Mutationsstatus									
HRRm	21	9 (42,9)	4,2 [0,8; NE]	17	6 (35,3)	6,9 [1,4; NE]	1,46	[0,53; 4,37]	0,4660
Nicht-HRRm	118	46 (39,0)	6,9 [3,4;19,7]	111	44 (39,6)	7,8 [3,5;14,4]	0,97	[0,64; 1,47]	0,8739
Unbekannt	52	18 (34,6)	9,8 [3,5; NE]	64	16 (25,0)	NE [NE; NE]	1,47	[0,75; 2,92]	0,2603
Interaktion p-Wert									0,5026
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Urologische Symptome
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	42 (37,5)	9,6 [3,4; NE]	124	39 (31,5)	14,4 [5,0; NE]	1,20	[0,78; 1,87]	0,4047
Negativ	73	27 (37,0)	6,9 [3,4; NE]	67	26 (38,8)	6,9 [3,4; NE]	1,04	[0,61; 1,79]	0,8831
Unbekannt	6	4 (66,7)	4,1 [2,1; NE]	1	1 (100)	3,5 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6822
Histologie									
Endometrioid	107	45 (42,1)	4,2 [3,4; 9,8]	98	37 (37,8)	12,5 [5,0; NE]	1,37	[0,89; 2,13]	0,1568
Serös	42	14 (33,3)	19,7 [3,4; NE]	52	14 (26,9)	9,6 [3,4; NE]	0,91	[0,43; 1,93]	0,8071
Andere	42	14 (33,3)	9,6 [2,7; NE]	42	15 (35,7)	5,2 [1,5; NE]	0,87	[0,42; 1,82]	0,7130
Interaktion p-Wert									0,4628
Histologischer Grad									
High grade (G3)	77	26 (33,8)	14,2 [4,1; NE]	84	28 (33,3)	6,9 [3,5; NE]	0,79	[0,46; 1,35]	0,3868
Low grade (G1+G2)	90	39 (43,3)	4,2 [2,8; 8,8]	87	32 (36,8)	14,4 [3,4; NE]	1,38	[0,87; 2,22]	0,1756
Interaktion p-Wert									0,1244
ECOG Performance Status zu Baseline									
0	135	47 (34,8)	8,8 [4,2; NE]	127	43 (33,9)	14,4 [6,9; NE]	1,14	[0,76; 1,74]	0,5243
1	56	26 (46,4)	3,4 [2,7;14,2]	65	23 (35,4)	3,5 [2,9; NE]	1,13	[0,64; 1,99]	0,6789
Interaktion p-Wert									0,9643
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	14,2 [1,4; NE]	10	5 (50,0)	6,4 [0,7; NE]	0,60	[0,12; 2,43]	0,4722
IV	78	30 (38,5)	6,9 [3,4; NE]	79	31 (39,2)	7,8 [3,4;12,5]	0,86	[0,52; 1,43]	0,5708
Interaktion p-Wert									0,6279

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Gastrointestinale Symptome
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	38 (38,4)	5,9 [2,2;17,0]	101	34 (33,7)	10,5 [6,8; NE]	1,25	[0,79; 1,99]	0,3473
Neu diagnostiziert	92	40 (43,5)	3,5 [2,8;12,4]	91	32 (35,2)	8,7 [3,5; NE]	1,30	[0,82; 2,09]	0,2634
Interaktion p-Wert									0,8981
Region									
Asien	54	25 (46,3)	5,9 [2,8; NE]	54	26 (48,1)	9,6 [3,5;18,2]	1,10	[0,63; 1,90]	0,7411
Rest der Welt	137	53 (38,7)	3,5 [2,1;17,0]	138	40 (29,0)	8,7 [5,0; NE]	1,39	[0,93; 2,11]	0,1126
Interaktion p-Wert									0,4950
Alter									
<65	101	45 (44,6)	3,5 [2,2;13,3]	99	33 (33,3)	9,6 [5,0; NE]	1,61	[1,03; 2,54]	0,0370*
>=65	90	33 (36,7)	6,0 [2,7; NE]	93	33 (35,5)	8,7 [2,8;18,2]	0,98	[0,60; 1,59]	0,9359
Interaktion p-Wert									0,1409
Abstammung									
Weiß	104	43 (41,3)	3,5 [2,1;17,0]	113	34 (30,1)	10,5 [5,0; NE]	1,47	[0,94; 2,32]	0,0931
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	2,50	[0,32; 50,60]	0,3973
Asiatisch	57	25 (43,9)	5,9 [2,8; NE]	58	26 (44,8)	9,6 [3,5;18,2]	1,04	[0,60; 1,81]	0,8755
Andere	16	7 (43,8)	2,8 [1,4; NE]	12	5 (41,7)	3,4 [0,9; NE]	0,93	[0,30; 3,14]	0,8990
Interaktion p-Wert									0,6716
HRR Mutationsstatus									
HRRm	21	9 (42,9)	5,0 [0,8; NE]	17	7 (41,2)	12,4 [1,4; NE]	1,01	[0,37; 2,82]	0,9907
Nicht-HRRm	118	52 (44,1)	3,5 [2,1;12,4]	111	37 (33,3)	8,7 [6,9; NE]	1,48	[0,97; 2,27]	0,0660
Unbekannt	52	17 (32,7)	NE [NE; NE]	64	22 (34,4)	9,6 [3,4; NE]	0,99	[0,52; 1,85]	0,9693
Interaktion p-Wert									0,5124
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Gastrointestinale Symptome
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	42 (37,5)	12,4 [2,8; NE]	124	39 (31,5)	13,4 [6,8; NE]	1,19	[0,77; 1,84]	0,4398
Negativ	73	33 (45,2)	3,5 [2,1; 5,9]	67	27 (40,3)	7,8 [2,8; NE]	1,40	[0,84; 2,35]	0,1928
Unbekannt	6	3 (50,0)	4,1 [0,8; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6281
Histologie									
Endometrioid	107	46 (43,0)	4,2 [2,8;13,3]	98	43 (43,9)	7,8 [3,5;16,1]	1,11	[0,73; 1,68]	0,6321
Serös	42	18 (42,9)	5,9 [2,1; NE]	52	12 (23,1)	NE [NE; NE]	1,77	[0,86; 3,78]	0,1198
Andere	42	14 (33,3)	NE [NE; NE]	42	11 (26,2)	NE [NE; NE]	1,40	[0,64; 3,17]	0,3977
Interaktion p-Wert									0,5226
Histologischer Grad									
High grade (G3)	77	33 (42,9)	3,4 [2,2; NE]	84	29 (34,5)	8,7 [3,5;12,4]	1,18	[0,72; 1,96]	0,5089
Low grade (G1+G2)	90	38 (42,2)	4,1 [2,1;17,0]	87	34 (39,1)	7,8 [2,9;18,2]	1,23	[0,77; 1,96]	0,3849
Interaktion p-Wert									0,9152
ECOG Performance Status zu Baseline									
0	135	60 (44,4)	3,5 [2,8; 6,0]	127	42 (33,1)	12,4 [6,9; NE]	1,64	[1,11; 2,46]	0,0128*
1	56	18 (32,1)	NE [NE; NE]	65	24 (36,9)	7,2 [2,8;13,4]	0,69	[0,37; 1,27]	0,2382
Interaktion p-Wert									0,0194*
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	6 (54,5)	2,8 [0,8; NE]	10	5 (50,0)	3,5 [0,7; NE]	2,21	[0,66; 7,78]	0,1963
IV	78	32 (41,0)	4,2 [2,8; NE]	79	27 (34,2)	8,7 [3,5; NE]	1,19	[0,71; 2,01]	0,4995
Interaktion p-Wert									0,3537

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Eingeschränkte Körperwahrnehmung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	60 (60,6)	1,3 [0,8; 1,4]	101	51 (50,5)	1,4 [1,4; 2,1]	1,47	[1,01; 2,15]	0,0426*
Neu diagnostiziert	92	57 (62,0)	1,4 [1,3; 2,2]	91	49 (53,8)	1,4 [0,9; 2,1]	1,06	[0,73; 1,56]	0,7556
Interaktion p-Wert									0,2321
Region									
Asien	54	40 (74,1)	1,3 [0,8; 2,0]	54	39 (72,2)	1,4 [0,7; 1,5]	1,02	[0,66; 1,59]	0,9254
Rest der Welt	137	77 (56,2)	1,4 [1,0; 1,5]	138	61 (44,2)	1,5 [1,4; 3,5]	1,39	[0,99; 1,95]	0,0570
Interaktion p-Wert									0,2825
Alter									
<65	101	60 (59,4)	1,4 [1,0; 2,1]	99	55 (55,6)	1,4 [0,9; 2,1]	1,07	[0,74; 1,54]	0,7313
>=65	90	57 (63,3)	1,3 [0,8; 1,4]	93	45 (48,4)	1,4 [1,4; 2,7]	1,50	[1,01; 2,23]	0,0420*
Interaktion p-Wert									0,2123
Abstammung									
Weiß	104	60 (57,7)	1,3 [0,8; 1,5]	113	51 (45,1)	1,5 [1,4; 4,1]	1,45	[1,001; 2,12]	0,0496*
Schwarz/Afroamerikanisch	13	6 (46,2)	1,5 [0,7; NE]	8	2 (25,0)	20,0 [0,8; NE]	2,34	[0,53; 16,18]	0,2731
Asiatisch	57	41 (71,9)	1,4 [0,8; 2,0]	58	39 (67,2)	1,4 [0,7; 1,5]	0,98	[0,63; 1,53]	0,9403
Andere	16	10 (62,5)	1,5 [0,7; 4,2]	12	8 (66,7)	1,4 [0,7; 2,1]	0,94	[0,37; 2,47]	0,9024
Interaktion p-Wert									0,4374
HRR Mutationsstatus									
HRRm	21	14 (66,7)	1,4 [0,7; 2,0]	17	9 (52,9)	1,4 [0,7; NE]	1,56	[0,68; 3,74]	0,2954
Nicht-HRRm	118	74 (62,7)	1,4 [0,9; 1,5]	111	57 (51,4)	1,4 [1,4; 2,1]	1,24	[0,88; 1,76]	0,2169
Unbekannt	52	29 (55,8)	1,4 [0,8; 2,7]	64	34 (53,1)	1,5 [1,2; 2,7]	1,13	[0,68; 1,86]	0,6281
Interaktion p-Wert									0,8109
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Eingeschränkte Körperwahrnehmung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	69 (61,6)	1,4 [0,8; 1,5]	124	64 (51,6)	1,4 [1,4; 2,1]	1,22	[0,87; 1,72]	0,2559
Negativ	73	43 (58,9)	1,4 [1,0; 2,1]	67	35 (52,2)	1,5 [1,4; 3,5]	1,28	[0,82; 2,01]	0,2745
Unbekannt	6	5 (83,3)	1,0 [0,7; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8602
Histologie									
Endometrioid	107	66 (61,7)	1,4 [0,8; 1,5]	98	61 (62,2)	1,4 [1,2; 1,5]	1,08	[0,76; 1,53]	0,6640
Serös	42	32 (76,2)	0,8 [0,8; 1,5]	52	21 (40,4)	2,0 [0,9; 4,2]	2,07	[1,20; 3,65]	0,0085*
Andere	42	19 (45,2)	1,5 [1,3; NE]	42	18 (42,9)	2,1 [0,9; 8,7]	1,05	[0,55; 2,01]	0,8850
Interaktion p-Wert									0,1176
Histologischer Grad									
High grade (G3)	77	46 (59,7)	1,4 [1,0; 2,0]	84	42 (50,0)	1,4 [1,3; 3,5]	1,13	[0,75; 1,73]	0,5556
Low grade (G1+G2)	90	58 (64,4)	1,3 [0,8; 1,4]	87	48 (55,2)	1,4 [1,2; 2,1]	1,34	[0,92; 1,98]	0,1323
Interaktion p-Wert									0,5620
ECOG Performance Status zu Baseline									
0	135	84 (62,2)	1,4 [0,8; 1,5]	127	69 (54,3)	1,4 [1,3; 2,1]	1,26	[0,92; 1,74]	0,1551
1	56	33 (58,9)	1,4 [0,9; 2,7]	65	31 (47,7)	1,5 [1,4; 2,7]	1,21	[0,74; 1,98]	0,4470
Interaktion p-Wert									0,8920
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	6 (54,5)	2,8 [0,7; NE]	10	4 (40,0)	4,1 [0,8; NE]	1,97	[0,56; 7,73]	0,2875
IV	78	48 (61,5)	1,4 [1,0; 2,2]	79	44 (55,7)	1,4 [0,8; 2,1]	0,98	[0,65; 1,47]	0,9072
Interaktion p-Wert									0,2951

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Sexuelle/vaginale Probleme
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	5 (5,1)	2,8 [0,6; NE]	101	5 (5,0)	0,8 [0,7; NE]	0,52	[0,12; 2,03]	0,3422
Neu diagnostiziert	92	6 (6,5)	1,5 [0,7; NE]	91	2 (2,2)	1,4 [NE; NE]	0,57	[0,12; 4,03]	0,5247
Interaktion p-Wert									0,9346
Region									
Asien	54	2 (3,7)	2,1 [1,3; NE]	54	1 (1,9)	0,8 [NE; NE]	0,31	[0,03; 6,93]	0,3865
Rest der Welt	137	9 (6,6)	2,8 [0,8; 9,0]	138	6 (4,3)	1,4 [0,7; NE]	0,64	[0,21; 1,99]	0,4239
Interaktion p-Wert									0,6065
Alter									
<65	101	6 (5,9)	2,8 [0,6; NE]	99	4 (4,0)	1,4 [0,8; NE]	1,23	[0,34; 5,08]	0,7516
>=65	90	5 (5,6)	8,8 [0,7; NE]	93	3 (3,2)	0,8 [0,7; NE]	0,21	[0,04; 1,23]	0,0817
Interaktion p-Wert									0,1164
Abstammung									
Weiß	104	6 (5,8)	1,5 [0,6; NE]	113	6 (5,3)	1,4 [0,7; NE]	0,92	[0,26; 3,07]	0,8845
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	2 (3,5)	2,1 [1,3; NE]	58	1 (1,7)	0,8 [NE; NE]	0,24	[0,02; 5,54]	0,3084
Andere	16	2 (12,5)	8,8 [0,8; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3694
HRR Mutationsstatus									
HRRm	21	1 (4,8)	0,8 [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	6 (5,1)	2,8 [0,6; NE]	111	5 (4,5)	1,4 [0,7; NE]	0,77	[0,22; 2,76]	0,6758
Unbekannt	52	4 (7,7)	1,5 [0,8; NE]	64	2 (3,1)	1,1 [0,8; NE]	0,27	[0,05; 2,11]	0,1885
Interaktion p-Wert									0,3543
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Sexuelle/vaginale Probleme
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	7 (6,3)	1,1 [0,6; 9,0]	124	5 (4,0)	0,8 [0,7; NE]	0,44	[0,11; 1,70]	0,2276
Negativ	73	4 (5,5)	2,8 [1,5; NE]	67	2 (3,0)	5,1 [1,4; NE]	1,18	[0,22; 8,68]	0,8512
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3737
Histologie									
Endometrioid	107	8 (7,5)	2,8 [0,8; NE]	98	4 (4,1)	1,4 [0,7; NE]	0,31	[0,07; 1,35]	0,1137
Serös	42	3 (7,1)	2,2 [0,7; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	42	3 (7,1)	2,9 [0,8; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	5 (6,5)	8,8 [0,7; NE]	84	3 (3,6)	1,1 [0,8; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	6 (6,7)	1,5 [0,6; NE]	87	3 (3,4)	0,8 [0,7; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	9 (6,7)	1,5 [0,8; 8,8]	127	3 (2,4)	0,8 [0,7; NE]	0,14	[0,03; 0,79]	0,0279*
1	56	2 (3,6)	9,0 [0,8; NE]	65	4 (6,2)	3,3 [0,8; NE]	0,69	[0,09; 3,78]	0,6768
Interaktion p-Wert									0,2047
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	8,8 [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	4 (5,1)	1,5 [0,7; NE]	79	2 (2,5)	1,4 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Rücken- und Beckenschmerzen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	30 (30,3)	16,1 [5,0; NE]	101	31 (30,7)	16,1 [6,9; NE]	0,98	[0,59; 1,62]	0,9280
Neu diagnostiziert	92	33 (35,9)	10,6 [5,0; NE]	91	32 (35,2)	7,0 [6,8; NE]	1,00	[0,62; 1,64]	0,9848
Interaktion p-Wert									0,9376
Region									
Asien	54	22 (40,7)	15,2 [4,2; NE]	54	20 (37,0)	17,9 [5,1; NE]	1,23	[0,67; 2,27]	0,5055
Rest der Welt	137	41 (29,9)	15,1 [6,9; NE]	138	43 (31,2)	7,8 [6,8;16,1]	0,89	[0,58; 1,37]	0,5925
Interaktion p-Wert									0,3941
Alter									
<65	101	36 (35,6)	15,1 [4,2; NE]	99	29 (29,3)	16,1 [7,0; NE]	1,39	[0,85; 2,28]	0,1892
>=65	90	27 (30,0)	22,7 [5,9; NE]	93	34 (36,6)	6,9 [5,0;17,9]	0,69	[0,41; 1,15]	0,1529
Interaktion p-Wert									0,0519
Abstammung									
Weiß	104	32 (30,8)	22,7 [5,9; NE]	113	36 (31,9)	7,9 [6,8; NE]	0,90	[0,55; 1,45]	0,6584
Schwarz/Afroamerikanisch	13	3 (23,1)	12,6 [0,7; NE]	8	2 (25,0)	7,9 [1,6; NE]	0,87	[0,14; 6,63]	0,8825
Asiatisch	57	22 (38,6)	15,2 [4,2; NE]	58	20 (34,5)	17,9 [5,1; NE]	1,17	[0,64; 2,17]	0,6070
Andere	16	6 (37,5)	7,9 [0,7; NE]	12	5 (41,7)	6,8 [0,8; NE]	0,90	[0,27; 3,14]	0,8678
Interaktion p-Wert									0,9194
HRR Mutationsstatus									
HRRm	21	6 (28,6)	NE [NE; NE]	17	7 (41,2)	10,7 [1,4; NE]	0,70	[0,22; 2,12]	0,5234
Nicht-HRRm	118	43 (36,4)	15,1 [4,6; NE]	111	45 (40,5)	6,8 [3,4; 7,9]	0,83	[0,54; 1,26]	0,3817
Unbekannt	52	14 (26,9)	NE [NE; NE]	64	11 (17,2)	NE [NE; NE]	1,72	[0,78; 3,88]	0,1763
Interaktion p-Wert									0,2361
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Rücken- und Beckenschmerzen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	31 (27,7)	16,1 [7,8; NE]	124	38 (30,6)	10,5 [6,8; NE]	0,80	[0,49; 1,28]	0,3522
Negativ	73	28 (38,4)	7,9 [1,8; NE]	67	24 (35,8)	10,6 [6,0;17,9]	1,27	[0,74; 2,22]	0,3853
Unbekannt	6	4 (66,7)	1,4 [0,7; NE]	1	1 (100)	6,8 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2045
Histologie									
Endometrioid	107	33 (30,8)	15,2 [7,8; NE]	98	36 (36,7)	10,7 [6,8; NE]	0,94	[0,58; 1,51]	0,8056
Serös	42	17 (40,5)	10,6 [1,5; NE]	52	16 (30,8)	7,9 [3,4; NE]	0,99	[0,49; 1,98]	0,9660
Andere	42	13 (31,0)	12,6 [4,1; NE]	42	11 (26,2)	7,8 [5,1; NE]	1,15	[0,51; 2,62]	0,7318
Interaktion p-Wert									0,9152
Histologischer Grad									
High grade (G3)	77	27 (35,1)	12,6 [5,0; NE]	84	29 (34,5)	6,9 [6,0;12,5]	0,81	[0,47; 1,37]	0,4254
Low grade (G1+G2)	90	29 (32,2)	15,1 [4,7; NE]	87	28 (32,2)	16,1 [6,8; NE]	1,14	[0,67; 1,92]	0,6249
Interaktion p-Wert									0,3618
ECOG Performance Status zu Baseline									
0	135	46 (34,1)	15,1 [5,9; NE]	127	44 (34,6)	12,5 [6,9; NE]	1,04	[0,69; 1,58]	0,8530
1	56	17 (30,4)	10,6 [4,7; NE]	65	19 (29,2)	7,0 [6,0; NE]	0,88	[0,45; 1,71]	0,7154
Interaktion p-Wert									0,6830
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	4 (36,4)	7,9 [0,7; NE]	10	5 (50,0)	3,4 [0,7; NE]	0,97	[0,24; 3,67]	0,9649
IV	78	29 (37,2)	15,2 [4,1; NE]	79	26 (32,9)	7,9 [6,8; NE]	1,08	[0,63; 1,85]	0,7823
Interaktion p-Wert									0,8845

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening
Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are
censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable
baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients
at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median
time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the
main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction.
Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	57 (57,6)	1,4 [0,8; 2,0]	101	58 (57,4)	1,4 [1,4; 2,1]	1,04	[0,72; 1,49]	0,8516
Neu diagnostiziert	92	63 (68,5)	1,4 [0,8; 2,0]	91	59 (64,8)	0,9 [0,8; 1,4]	0,84	[0,59; 1,20]	0,3439
Interaktion p-Wert									0,4267
Region									
Asien	54	41 (75,9)	0,8 [0,7; 1,4]	54	39 (72,2)	1,4 [0,8; 1,5]	1,22	[0,79; 1,90]	0,3742
Rest der Welt	137	79 (57,7)	1,4 [1,3; 2,1]	138	78 (56,5)	1,4 [0,8; 1,5]	0,85	[0,62; 1,16]	0,3043
Interaktion p-Wert									0,1870
Alter									
<65	101	61 (60,4)	1,4 [0,8; 2,1]	99	64 (64,6)	1,4 [0,9; 2,1]	0,91	[0,64; 1,29]	0,5945
>=65	90	59 (65,6)	0,9 [0,8; 1,4]	93	53 (57,0)	1,4 [0,8; 1,4]	0,98	[0,68; 1,43]	0,9349
Interaktion p-Wert									0,7591
Abstammung									
Weiß	104	64 (61,5)	1,4 [0,8; 2,0]	113	67 (59,3)	1,4 [0,8; 1,5]	0,92	[0,65; 1,29]	0,6187
Schwarz/Afroamerikanisch	13	5 (38,5)	2,2 [1,4; NE]	8	3 (37,5)	1,0 [0,8; NE]	0,56	[0,14; 2,72]	0,4385
Asiatisch	57	42 (73,7)	0,8 [0,7; 1,4]	58	39 (67,2)	1,4 [0,8; 1,5]	1,18	[0,76; 1,84]	0,4473
Andere	16	9 (56,3)	2,1 [0,7; 4,2]	12	8 (66,7)	0,9 [0,7; 2,8]	0,64	[0,24; 1,71]	0,3672
Interaktion p-Wert									0,5410
HRR Mutationsstatus									
HRRm	21	13 (61,9)	1,4 [0,7; 3,6]	17	13 (76,5)	0,7 [0,7; 0,9]	0,46	[0,21; 1,001]	0,0503
Nicht-HRRm	118	75 (63,6)	1,4 [0,8; 2,0]	111	71 (64,0)	1,4 [0,8; 1,4]	0,84	[0,60; 1,16]	0,2851
Unbekannt	52	32 (61,5)	0,8 [0,8; 1,4]	64	33 (51,6)	1,4 [1,4; 2,7]	1,48	[0,91; 2,42]	0,1158
Interaktion p-Wert									0,0306*
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	75 (67,0)	0,8 [0,8; 1,4]	124	71 (57,3)	1,4 [0,8; 1,4]	1,05	[0,76; 1,46]	0,7656
Negativ	73	40 (54,8)	1,4 [1,3; 2,2]	67	45 (67,2)	1,4 [0,8; 2,6]	0,80	[0,52; 1,23]	0,3141
Unbekannt	6	5 (83,3)	1,4 [0,7; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3262
Histologie									
Endometrioid	107	68 (63,6)	0,8 [0,8; 1,4]	98	72 (73,5)	1,4 [0,8; 1,4]	0,86	[0,61; 1,20]	0,3741
Serös	42	29 (69,0)	1,4 [0,8; 2,2]	52	26 (50,0)	1,4 [0,8; 2,1]	1,14	[0,67; 1,94]	0,6368
Andere	42	23 (54,8)	2,2 [1,4; 3,4]	42	19 (45,2)	2,7 [0,8; 8,7]	1,05	[0,57; 1,94]	0,8859
Interaktion p-Wert									0,6451
Histologischer Grad									
High grade (G3)	77	50 (64,9)	1,4 [0,8; 2,2]	84	43 (51,2)	1,4 [0,8; 2,1]	1,12	[0,75; 1,69]	0,5780
Low grade (G1+G2)	90	56 (62,2)	1,3 [0,8; 1,4]	87	61 (70,1)	1,4 [0,8; 1,4]	0,79	[0,55; 1,14]	0,2124
Interaktion p-Wert									0,2131
ECOG Performance Status zu Baseline									
0	135	87 (64,4)	0,8 [0,8; 1,4]	127	83 (65,4)	1,4 [0,8; 1,4]	0,97	[0,71; 1,31]	0,8193
1	56	33 (58,9)	2,0 [1,4; 3,4]	65	34 (52,3)	1,4 [0,8; 2,8]	0,90	[0,56; 1,46]	0,6712
Interaktion p-Wert									0,8126
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	7 (63,6)	0,8 [0,7; NE]	10	8 (80,0)	0,8 [0,7; 1,4]	0,89	[0,31; 2,49]	0,8268
IV	78	54 (69,2)	1,4 [0,8; 2,1]	79	51 (64,6)	0,9 [0,8; 1,5]	0,80	[0,54; 1,18]	0,2534
Interaktion p-Wert									0,8397

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.11 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Muskulärer Schmerz
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	51 (51,5)	2,1 [1,4; 4,6]	101	54 (53,5)	2,1 [1,4; 2,9]	0,84	[0,57; 1,23]	0,3676
Neu diagnostiziert	92	59 (64,1)	2,2 [1,5; 2,8]	91	55 (60,4)	1,4 [1,4; 2,9]	0,91	[0,63; 1,32]	0,6266
Interaktion p-Wert									0,7541
Region									
Asien	54	36 (66,7)	2,1 [0,8; 4,6]	54	37 (68,5)	2,1 [1,4; 3,6]	1,00	[0,63; 1,59]	0,9947
Rest der Welt	137	74 (54,0)	2,2 [1,4; 2,8]	138	72 (52,2)	1,5 [1,4; 2,1]	0,82	[0,59; 1,13]	0,2265
Interaktion p-Wert									0,4806
Alter									
<65	101	60 (59,4)	2,0 [1,4; 2,7]	99	60 (60,6)	2,1 [1,4; 2,9]	1,02	[0,72; 1,47]	0,8950
>=65	90	50 (55,6)	2,8 [1,5; 4,7]	93	49 (52,7)	1,4 [1,3; 2,8]	0,74	[0,50; 1,10]	0,1388
Interaktion p-Wert									0,2347
Abstammung									
Weiß	104	57 (54,8)	2,2 [1,4; 2,9]	113	62 (54,9)	1,5 [1,4; 2,1]	0,84	[0,58; 1,20]	0,3370
Schwarz/Afroamerikanisch	13	6 (46,2)	1,9 [0,7; NE]	8	3 (37,5)	1,0 [0,8; NE]	0,73	[0,19; 3,48]	0,6670
Asiatisch	57	38 (66,7)	2,1 [0,8; 3,5]	58	37 (63,8)	2,1 [1,4; 3,6]	1,04	[0,66; 1,64]	0,8773
Andere	16	9 (56,3)	2,8 [1,4; 8,8]	12	7 (58,3)	1,4 [0,7; NE]	0,51	[0,19; 1,45]	0,1995
Interaktion p-Wert									0,6334
HRR Mutationsstatus									
HRRm	21	8 (38,1)	6,9 [0,7; NE]	17	10 (58,8)	2,1 [0,7; 4,1]	0,45	[0,17; 1,15]	0,0949
Nicht-HRRm	118	73 (61,9)	2,1 [1,4; 2,8]	111	69 (62,2)	1,4 [1,4; 2,1]	0,82	[0,59; 1,15]	0,2479
Unbekannt	52	29 (55,8)	2,2 [1,4; 3,5]	64	30 (46,9)	2,7 [1,5; 5,9]	1,17	[0,70; 1,96]	0,5390
Interaktion p-Wert									0,1901
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.11 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Muskulärer Schmerz
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	62 (55,4)	2,8 [1,5; 3,0]	124	70 (56,5)	1,4 [1,4; 2,1]	0,72	[0,51; 1,01]	0,0558
Negativ	73	43 (58,9)	1,5 [1,4; 2,8]	67	38 (56,7)	2,7 [1,4; 4,2]	1,16	[0,75; 1,80]	0,5164
Unbekannt	6	5 (83,3)	1,4 [0,7; NE]	1	1 (100)	1,4 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0902
Histologie									
Endometrioid	107	61 (57,0)	2,0 [1,4; 2,8]	98	63 (64,3)	2,0 [1,4; 2,9]	0,86	[0,60; 1,22]	0,3903
Serös	42	28 (66,7)	1,5 [0,8; 4,1]	52	27 (51,9)	1,4 [0,7; 2,1]	0,78	[0,46; 1,33]	0,3557
Andere	42	21 (50,0)	2,2 [2,1; 4,6]	42	19 (45,2)	3,5 [1,3; 6,0]	1,08	[0,58; 2,02]	0,8184
Interaktion p-Wert									0,7326
Histologischer Grad									
High grade (G3)	77	43 (55,8)	2,2 [1,5; 4,1]	84	48 (57,1)	1,5 [1,4; 2,1]	0,65	[0,43; 0,98]	0,0414*
Low grade (G1+G2)	90	54 (60,0)	2,0 [1,4; 2,8]	87	49 (56,3)	1,9 [1,4; 2,9]	1,08	[0,73; 1,59]	0,7097
Interaktion p-Wert									0,0807
ECOG Performance Status zu Baseline									
0	135	81 (60,0)	1,5 [1,4; 2,2]	127	75 (59,1)	2,1 [1,4; 2,9]	1,02	[0,74; 1,40]	0,9032
1	56	29 (51,8)	2,8 [2,2; 4,7]	65	34 (52,3)	1,4 [1,4; 2,9]	0,62	[0,38; 1,02]	0,0616
Interaktion p-Wert									0,1000
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	5 (45,5)	2,2 [0,7; NE]	10	7 (70,0)	3,5 [0,8; 6,8]	0,93	[0,28; 2,93]	0,9050
IV	78	52 (66,7)	2,1 [1,4; 2,8]	79	48 (60,8)	1,4 [1,4; 2,1]	0,86	[0,58; 1,29]	0,4675
Interaktion p-Wert									0,9015

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.12 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Haarausfall
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	76 (76,8)	0,7 [0,7; 0,8]	101	72 (71,3)	0,7 [NE; NE]	1,02	[0,74; 1,41]	0,9207
Neu diagnostiziert	92	72 (78,3)	0,7 [NE; NE]	91	69 (75,8)	0,7 [0,7; 0,8]	1,02	[0,73; 1,42]	0,9033
Interaktion p-Wert									0,9864
Region									
Asien	54	46 (85,2)	0,7 [0,7; 0,7]	54	49 (90,7)	0,7 [0,7; 0,7]	0,98	[0,65; 1,46]	0,9141
Rest der Welt	137	102 (74,5)	0,7 [0,7; 0,8]	138	92 (66,7)	0,7 [0,7; 0,8]	1,05	[0,79; 1,40]	0,7229
Interaktion p-Wert									0,7705
Alter									
<65	101	79 (78,2)	0,7 [NE; NE]	99	74 (74,7)	0,7 [0,7; 0,8]	1,24	[0,90; 1,71]	0,1821
>=65	90	69 (76,7)	0,7 [0,7; 0,8]	93	67 (72,0)	0,7 [NE; NE]	0,82	[0,59; 1,15]	0,2507
Interaktion p-Wert									0,0801
Abstammung									
Weiß	104	81 (77,9)	0,7 [0,7; 0,8]	113	78 (69,0)	0,7 [0,7; 0,8]	1,09	[0,80; 1,49]	0,5838
Schwarz/Afroamerikanisch	13	7 (53,8)	0,8 [0,7; NE]	8	3 (37,5)	0,8 [0,8; NE]	1,10	[0,31; 5,11]	0,8896
Asiatisch	57	48 (84,2)	0,7 [NE; NE]	58	49 (84,5)	0,7 [0,7; 0,7]	0,94	[0,63; 1,41]	0,7755
Andere	16	12 (75,0)	0,7 [0,7; 1,4]	12	11 (91,7)	0,8 [0,7; 1,4]	1,20	[0,52; 2,76]	0,6668
Interaktion p-Wert									0,9327
HRR Mutationsstatus									
HRRm	21	15 (71,4)	0,7 [0,7; 0,7]	17	13 (76,5)	0,7 [NE; NE]	0,98	[0,47; 2,10]	0,9646
Nicht-HRRm	118	95 (80,5)	0,7 [NE; NE]	111	83 (74,8)	0,7 [0,7; 0,8]	1,08	[0,80; 1,45]	0,6094
Unbekannt	52	38 (73,1)	0,8 [0,7; 0,8]	64	45 (70,3)	0,7 [0,7; 0,8]	0,88	[0,57; 1,36]	0,5745
Interaktion p-Wert									0,7516
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.12 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Haarausfall
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	87 (77,7)	0,7 [0,7; 0,8]	124	88 (71,0)	0,7 [NE; NE]	0,85	[0,63; 1,15]	0,2994
Negativ	73	55 (75,3)	0,7 [NE; NE]	67	52 (77,6)	0,7 [0,7; 0,8]	1,29	[0,88; 1,89]	0,1881
Unbekannt	6	6 (100)	0,7 [0,7; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0940
Histologie									
Endometrioid	107	86 (80,4)	0,7 [NE; NE]	98	79 (80,6)	0,7 [NE; NE]	1,06	[0,78; 1,44]	0,7143
Serös	42	33 (78,6)	0,7 [0,7; 0,8]	52	33 (63,5)	0,7 [0,7; 0,8]	1,07	[0,65; 1,73]	0,7979
Andere	42	29 (69,0)	0,7 [0,7; 0,8]	42	29 (69,0)	0,7 [0,7; 0,8]	0,87	[0,52; 1,47]	0,6115
Interaktion p-Wert									0,8087
Histologischer Grad									
High grade (G3)	77	61 (79,2)	0,7 [0,7; 0,8]	84	58 (69,0)	0,7 [0,7; 0,8]	0,87	[0,60; 1,24]	0,4317
Low grade (G1+G2)	90	71 (78,9)	0,7 [0,7; 0,8]	87	67 (77,0)	0,7 [0,7; 0,8]	1,23	[0,88; 1,72]	0,2295
Interaktion p-Wert									0,1642
ECOG Performance Status zu Baseline									
0	135	102 (75,6)	0,7 [NE; NE]	127	99 (78,0)	0,7 [NE; NE]	0,94	[0,71; 1,24]	0,6558
1	56	46 (82,1)	0,7 [0,7; 0,8]	65	42 (64,6)	0,8 [0,7; 0,8]	1,20	[0,79; 1,84]	0,3837
Interaktion p-Wert									0,3310
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	8 (72,7)	0,7 [0,7; 0,8]	10	8 (80,0)	0,8 [0,7; 1,4]	1,47	[0,54; 4,01]	0,4431
IV	78	61 (78,2)	0,7 [NE; NE]	79	59 (74,7)	0,7 [0,7; 0,8]	0,96	[0,67; 1,38]	0,8271
Interaktion p-Wert									0,4267

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.13 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Geschmacksveränderung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	65 (65,7)	1,4 [0,8; 1,4]	101	47 (46,5)	2,0 [1,4;11,4]	1,93	[1,32; 2,84]	0,0006*
Neu diagnostiziert	92	53 (57,6)	2,2 [2,0; 2,9]	91	40 (44,0)	2,7 [1,4; 9,6]	1,28	[0,85; 1,94]	0,2342
Interaktion p-Wert									0,1505
Region									
Asien	54	35 (64,8)	1,4 [0,8; 2,7]	54	25 (46,3)	9,6 [1,4; NE]	2,08	[1,25; 3,52]	0,0051*
Rest der Welt	137	83 (60,6)	2,1 [1,4; 2,7]	138	62 (44,9)	1,5 [1,4; 3,4]	1,37	[0,98; 1,91]	0,0628
Interaktion p-Wert									0,1771
Alter									
<65	101	66 (65,3)	1,4 [0,8; 2,1]	99	46 (46,5)	3,4 [1,4; 9,6]	1,82	[1,25; 2,68]	0,0017*
>=65	90	52 (57,8)	2,2 [1,4; 2,8]	93	41 (44,1)	2,1 [1,3;16,1]	1,32	[0,88; 2,00]	0,1842
Interaktion p-Wert									0,2550
Abstammung									
Weiß	104	63 (60,6)	2,1 [1,4; 2,7]	113	52 (46,0)	2,1 [1,4; 3,6]	1,44	[1,0001; 2,10]	0,0500*
Schwarz/Afroamerikanisch	13	6 (46,2)	2,9 [0,7; NE]	8	2 (25,0)	1,0 [0,8; NE]	1,23	[0,28; 8,39]	0,7982
Asiatisch	57	37 (64,9)	1,4 [0,8; 2,1]	58	25 (43,1)	9,6 [1,4; NE]	2,13	[1,29; 3,59]	0,0033*
Andere	16	12 (75,0)	2,8 [0,7; 4,2]	12	8 (66,7)	1,4 [0,7; 1,4]	0,83	[0,34; 2,13]	0,6879
Interaktion p-Wert									0,3224
HRR Mutationsstatus									
HRRm	21	13 (61,9)	1,4 [0,7; 5,1]	17	7 (41,2)	3,6 [0,7; NE]	1,90	[0,78; 5,08]	0,1601
Nicht-HRRm	118	71 (60,2)	2,1 [1,4; 2,8]	111	51 (45,9)	1,4 [1,4;11,4]	1,35	[0,94; 1,95]	0,1003
Unbekannt	52	34 (65,4)	1,3 [0,8; 2,0]	64	29 (45,3)	3,4 [1,4;11,4]	2,02	[1,23; 3,34]	0,0056*
Interaktion p-Wert									0,4011

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.2.2.13 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Geschmacksveränderung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	70 (62,5)	1,4 [1,4; 2,1]	124	52 (41,9)	3,4 [1,4;11,4]	1,71	[1,19; 2,46]	0,0035*
Negativ	73	43 (58,9)	2,2 [1,4; 2,9]	67	34 (50,7)	1,4 [1,4; 5,0]	1,36	[0,87; 2,14]	0,1815
Unbekannt	6	5 (83,3)	1,4 [0,8; NE]	1	1 (100)	1,4 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4363
Histologie									
Endometrioid	107	69 (64,5)	1,4 [1,4; 2,2]	98	50 (51,0)	2,2 [1,4;11,4]	1,65	[1,14; 2,39]	0,0072*
Serös	42	28 (66,7)	2,1 [0,8; 2,8]	52	22 (42,3)	1,4 [0,7; 9,6]	1,33	[0,76; 2,35]	0,3202
Andere	42	21 (50,0)	1,4 [0,8; 9,6]	42	15 (35,7)	3,5 [1,4; NE]	1,61	[0,84; 3,19]	0,1542
Interaktion p-Wert									0,8132
Histologischer Grad									
High grade (G3)	77	52 (67,5)	1,4 [0,8; 2,1]	84	38 (45,2)	1,4 [1,3; 3,5]	1,56	[1,03; 2,39]	0,0365*
Low grade (G1+G2)	90	57 (63,3)	2,0 [1,4; 2,8]	87	39 (44,8)	2,2 [1,4;16,1]	1,74	[1,16; 2,64]	0,0076*
Interaktion p-Wert									0,7161
ECOG Performance Status zu Baseline									
0	135	84 (62,2)	1,4 [1,4; 2,1]	127	56 (44,1)	3,4 [1,4;16,2]	1,82	[1,30; 2,57]	0,0005*
1	56	34 (60,7)	2,1 [1,4; 2,8]	65	31 (47,7)	1,4 [1,4; 3,4]	1,12	[0,69; 1,84]	0,6395
Interaktion p-Wert									0,1124
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	6 (54,5)	0,8 [0,7; 3,5]	10	7 (70,0)	1,5 [0,7; 3,5]	1,12	[0,36; 3,37]	0,8402
IV	78	46 (59,0)	2,7 [2,1; 3,0]	79	31 (39,2)	3,4 [1,4; NE]	1,44	[0,92; 2,30]	0,1139
Interaktion p-Wert									0,6749

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Nutzenbewertung nach AMNOG

Table 4.2.3.2.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EQ-5D-5L Visuelle Analogskala
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	44 (44,4)	3,5 [2,7; 6,0]	101	36 (35,6)	6,0 [3,5;17,1]	1,31	[0,84; 2,05]	0,2295
Neu diagnostiziert	92	36 (39,1)	7,9 [3,4; NE]	91	33 (36,3)	9,6 [4,2;17,0]	1,08	[0,67; 1,73]	0,7629
Interaktion p-Wert									0,5503
Region									
Asien	54	28 (51,9)	3,5 [2,2; 9,7]	54	27 (50,0)	5,0 [2,9;15,3]	1,12	[0,66; 1,92]	0,6643
Rest der Welt	137	52 (38,0)	5,1 [2,9;16,1]	138	42 (30,4)	10,7 [4,2; NE]	1,24	[0,82; 1,87]	0,3053
Interaktion p-Wert									0,7796
Alter									
<65	101	40 (39,6)	6,8 [2,8;20,8]	99	37 (37,4)	5,2 [3,6; NE]	1,10	[0,70; 1,72]	0,6846
>=65	90	40 (44,4)	3,5 [2,8; 6,0]	93	32 (34,4)	14,3 [3,5;17,1]	1,30	[0,82; 2,08]	0,2723
Interaktion p-Wert									0,6113
Abstammung									
Weiß	104	43 (41,3)	3,5 [2,8;15,2]	113	36 (31,9)	10,7 [4,2; NE]	1,39	[0,89; 2,17]	0,1477
Schwarz/Afroamerikanisch	13	3 (23,1)	7,9 [0,8; NE]	8	1 (12,5)	NE [NE; NE]	1,80	[0,23; 36,49]	0,5933
Asiatisch	57	29 (50,9)	3,5 [2,2; 9,7]	58	27 (46,6)	5,0 [2,9;15,3]	1,12	[0,66; 1,90]	0,6800
Andere	16	5 (31,3)	16,1 [2,1; NE]	12	5 (41,7)	2,8 [0,7; NE]	0,48	[0,13; 1,73]	0,2507
Interaktion p-Wert									0,4507
HRR Mutationsstatus									
HRRm	21	8 (38,1)	3,5 [0,7; NE]	17	8 (47,1)	6,0 [2,1; NE]	0,93	[0,34; 2,53]	0,8833
Nicht-HRRm	118	48 (40,7)	5,6 [3,4;16,1]	111	43 (38,7)	5,0 [3,5;17,0]	0,99	[0,65; 1,50]	0,9552
Unbekannt	52	24 (46,2)	3,5 [2,8; 6,0]	64	18 (28,1)	15,3 [4,2; NE]	1,90	[1,03; 3,55]	0,0387*
Interaktion p-Wert									0,1924
PD-L1 Expression									

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.3.2.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EQ-5D-5L Visuelle Analogskala
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	52 (46,4)	3,5 [2,8; 6,0]	124	42 (33,9)	9,6 [4,1;17,0]	1,47	[0,98; 2,22]	0,0612
Negativ	73	25 (34,2)	7,9 [3,5; NE]	67	27 (40,3)	5,2 [2,9; NE]	0,80	[0,46; 1,39]	0,4314
Unbekannt	6	3 (50,0)	2,8 [0,7; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0806
Histologie									
Endometrioid	107	42 (39,3)	3,5 [2,8; NE]	98	39 (39,8)	10,7 [4,1;17,0]	1,15	[0,74; 1,78]	0,5307
Serös	42	24 (57,1)	3,4 [2,1; 9,7]	52	14 (26,9)	9,6 [3,5; NE]	1,75	[0,91; 3,46]	0,0918
Andere	42	14 (33,3)	6,0 [2,1; NE]	42	16 (38,1)	5,2 [2,8; NE]	0,81	[0,39; 1,66]	0,5544
Interaktion p-Wert									0,2877
Histologischer Grad									
High grade (G3)	77	35 (45,5)	3,6 [2,8;15,1]	84	30 (35,7)	7,8 [3,5; NE]	1,10	[0,67; 1,80]	0,7062
Low grade (G1+G2)	90	35 (38,9)	5,1 [2,8; NE]	87	30 (34,5)	14,3 [4,1; NE]	1,31	[0,81; 2,15]	0,2749
Interaktion p-Wert									0,6142
ECOG Performance Status zu Baseline									
0	135	55 (40,7)	5,1 [2,8;15,1]	127	48 (37,8)	9,6 [4,1;17,0]	1,17	[0,79; 1,73]	0,4268
1	56	25 (44,6)	4,1 [2,8;16,1]	65	21 (32,3)	5,2 [3,4; NE]	1,23	[0,69; 2,23]	0,4796
Interaktion p-Wert									0,8823
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	5 (45,5)	5,0 [0,7; NE]	10	3 (30,0)	17,0 [4,1; NE]	2,67	[0,65; 13,06]	0,1697
IV	78	30 (38,5)	15,1 [3,4; NE]	79	29 (36,7)	8,7 [4,1; NE]	0,97	[0,58; 1,62]	0,9023
Interaktion p-Wert									0,1832

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.4.2.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - PGIS
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	46 (46,5)	2,2 [1,3; 5,6]	101	48 (47,5)	2,1 [1,4; 4,2]	0,90	[0,60; 1,34]	0,5947
Neu diagnostiziert	92	55 (59,8)	1,5 [1,0; 2,7]	91	41 (45,1)	3,4 [1,5; 7,7]	1,37	[0,92; 2,06]	0,1259
Interaktion p-Wert									0,1454
Region									
Asien	54	32 (59,3)	1,3 [0,7; 8,7]	54	33 (61,1)	2,7 [1,4; 3,5]	1,01	[0,62; 1,65]	0,9623
Rest der Welt	137	69 (50,4)	2,1 [1,5; 2,8]	138	56 (40,6)	2,8 [1,5; 8,7]	1,17	[0,82; 1,66]	0,3924
Interaktion p-Wert									0,6451
Alter									
<65	101	55 (54,5)	1,4 [0,8; 2,7]	99	47 (47,5)	2,7 [1,6; 8,7]	1,25	[0,84; 1,85]	0,2665
>=65	90	46 (51,1)	2,2 [1,5; 3,5]	93	42 (45,2)	2,8 [1,4; 5,0]	0,97	[0,64; 1,48]	0,9016
Interaktion p-Wert									0,3975
Abstammung									
Weiß	104	56 (53,8)	2,0 [1,4; 2,7]	113	48 (42,5)	3,4 [1,4; 8,7]	1,21	[0,83; 1,79]	0,3260
Schwarz/Afroamerikanisch	13	6 (46,2)	2,2 [0,7; NE]	8	2 (25,0)	2,2 [1,0; NE]	1,90	[0,44; 12,97]	0,4114
Asiatisch	57	34 (59,6)	0,8 [0,8; 6,0]	58	33 (56,9)	2,7 [1,4; 3,5]	1,05	[0,65; 1,71]	0,8386
Andere	16	5 (31,3)	8,7 [0,7; NE]	12	6 (50,0)	2,1 [0,8; NE]	0,55	[0,16; 1,84]	0,3303
Interaktion p-Wert									0,5687
HRR Mutationsstatus									
HRRm	21	12 (57,1)	1,4 [0,7; 2,7]	17	10 (58,8)	0,9 [0,7;10,7]	0,92	[0,39; 2,21]	0,8582
Nicht-HRRm	118	64 (54,2)	2,1 [1,4; 3,5]	111	50 (45,0)	2,8 [1,4; 5,0]	1,10	[0,76; 1,61]	0,5982
Unbekannt	52	25 (48,1)	2,2 [0,8; 6,0]	64	29 (45,3)	3,4 [2,1; 9,6]	1,16	[0,67; 1,98]	0,5947
Interaktion p-Wert									0,9080
PD-L1 Expression									
Positiv	112	56 (50,0)	1,5 [0,8; 2,7]	124	60 (48,4)	2,7 [1,4; 3,5]	0,96	[0,67; 1,38]	0,8266

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening
Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are
censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable
baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients
at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median
time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the
main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction.
Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.4.2.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - PGIS
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Negativ	73	41 (56,2)	2,1 [1,4; 3,5]	67	29 (43,3)	4,2 [1,4;17,1]	1,39	[0,87; 2,26]	0,1681
Unbekannt	6	4 (66,7)	2,0 [0,8; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2214
Histologie									
Endometrioid	107	57 (53,3)	2,0 [1,4; 3,5]	98	48 (49,0)	3,5 [1,9; 9,8]	1,22	[0,83; 1,80]	0,3066
Serös	42	24 (57,1)	1,5 [0,8; 3,4]	52	23 (44,2)	1,5 [0,7; 4,1]	0,95	[0,53; 1,69]	0,8595
Andere	42	20 (47,6)	2,2 [1,0; 8,7]	42	18 (42,9)	2,1 [1,4; 5,0]	0,99	[0,52; 1,90]	0,9836
Interaktion p-Wert									0,7272
Histologischer Grad									
High grade (G3)	77	44 (57,1)	1,5 [0,9; 2,8]	84	40 (47,6)	2,7 [1,4; 4,1]	1,05	[0,68; 1,61]	0,8368
Low grade (G1+G2)	90	46 (51,1)	2,0 [1,4; 6,0]	87	40 (46,0)	3,4 [1,5;10,7]	1,12	[0,74; 1,72]	0,5884
Interaktion p-Wert									0,8158
ECOG Performance Status zu Baseline									
0	135	75 (55,6)	1,4 [0,8; 2,2]	127	64 (50,4)	2,2 [1,4; 3,5]	1,16	[0,83; 1,62]	0,3850
1	56	26 (46,4)	2,7 [1,5;17,0]	65	25 (38,5)	3,5 [1,4; 8,7]	0,99	[0,57; 1,73]	0,9788
Interaktion p-Wert									0,6366
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	6 (54,5)	2,4 [0,7; NE]	10	4 (40,0)	2,2 [0,7; NE]	1,50	[0,43; 5,88]	0,5238
IV	78	46 (59,0)	2,0 [1,4; 2,8]	79	35 (44,3)	3,5 [2,1; 8,7]	1,37	[0,88; 2,14]	0,1601
Interaktion p-Wert									0,8910

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.5.2.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - PGIC
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	20 (20,2)	NE [NE; NE]	101	17 (16,8)	NE [NE; NE]	1,23	[0,64; 2,37]	0,5329
Neu diagnostiziert	92	14 (15,2)	NE [NE; NE]	91	12 (13,2)	NE [NE; NE]	1,13	[0,52; 2,49]	0,7505
Interaktion p-Wert									0,8756
Region									
Asien	54	7 (13,0)	NE [NE; NE]	54	6 (11,1)	NE [NE; NE]	1,20	[0,40; 3,74]	0,7384
Rest der Welt	137	27 (19,7)	NE [NE; NE]	138	23 (16,7)	NE [NE; NE]	1,17	[0,67; 2,06]	0,5794
Interaktion p-Wert									0,9637
Alter									
<65	101	14 (13,9)	NE [NE; NE]	99	13 (13,1)	NE [NE; NE]	1,10	[0,52; 2,37]	0,8005
>=65	90	20 (22,2)	NE [NE; NE]	93	16 (17,2)	NE [NE; NE]	1,24	[0,64; 2,42]	0,5240
Interaktion p-Wert									0,8206
Abstammung									
Weiß	104	23 (22,1)	NE [NE; NE]	113	19 (16,8)	NE [NE; NE]	1,40	[0,76; 2,60]	0,2771
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	7 (12,3)	NE [NE; NE]	58	7 (12,1)	NE [NE; NE]	0,98	[0,34; 2,87]	0,9744
Andere	16	1 (6,3)	NE [NE; NE]	12	3 (25,0)	11,5 [4,1; NE]	0,17	[0,01; 1,29]	0,0869
Interaktion p-Wert									0,1426
HRR Mutationsstatus									
HRRm	21	3 (14,3)	NE [NE; NE]	17	4 (23,5)	NE [NE; NE]	0,47	[0,09; 2,15]	0,3254
Nicht-HRRm	118	24 (20,3)	NE [NE; NE]	111	17 (15,3)	NE [NE; NE]	1,43	[0,77; 2,70]	0,2581
Unbekannt	52	7 (13,5)	NE [NE; NE]	64	8 (12,5)	NE [NE; NE]	1,02	[0,36; 2,85]	0,9642
Interaktion p-Wert									0,3916
PD-L1 Expression									
Positiv	112	18 (16,1)	NE [NE; NE]	124	17 (13,7)	NE [NE; NE]	1,12	[0,58; 2,20]	0,7306

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction. Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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Table 4.2.5.2.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - PGIC
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=192)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Negativ	73	13 (17,8)	NE [NE; NE]	67	11 (16,4)	NE [NE; NE]	1,18	[0,53; 2,68]	0,6875
Unbekannt	6	3 (50,0)	4,1 [2,8; NE]	1	1 (100)	1,4 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9279
Histologie									
Endometrioid	107	20 (18,7)	NE [NE; NE]	98	15 (15,3)	NE [NE; NE]	1,30	[0,67; 2,59]	0,4385
Serös	42	9 (21,4)	NE [NE; NE]	52	7 (13,5)	NE [NE; NE]	1,31	[0,49; 3,66]	0,5914
Andere	42	5 (11,9)	NE [NE; NE]	42	7 (16,7)	NE [NE; NE]	0,78	[0,23; 2,43]	0,6631
Interaktion p-Wert									0,7241
Histologischer Grad									
High grade (G3)	77	17 (22,1)	NE [NE; NE]	84	13 (15,5)	NE [NE; NE]	1,41	[0,69; 2,96]	0,3491
Low grade (G1+G2)	90	15 (16,7)	NE [NE; NE]	87	14 (16,1)	NE [NE; NE]	1,07	[0,51; 2,24]	0,8543
Interaktion p-Wert									0,5992
ECOG Performance Status zu Baseline									
0	135	23 (17,0)	NE [NE; NE]	127	15 (11,8)	NE [NE; NE]	1,54	[0,81; 3,02]	0,1854
1	56	11 (19,6)	NE [NE; NE]	65	14 (21,5)	NE [NE; NE]	0,79	[0,35; 1,74]	0,5630
Interaktion p-Wert									0,1990
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	1 (10,0)	NE [NE; NE]	0,98	[0,04; 24,80]	0,9892
IV	78	12 (15,4)	NE [NE; NE]	79	11 (13,9)	NE [NE; NE]	1,10	[0,48; 2,54]	0,8139
Interaktion p-Wert									0,9365

Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening
Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are
censored at the date of their last evaluable assessment prior to the second disease progression. Patients with no evaluable
baseline or post-baseline data will be censored at Day 1. Analysis is performed if there are >= 10 patients
at each subgroup level and >= 10 events in at least one subgroup level combined for both arms. [a] Median
time to event (95% CL) based on the Kaplan Meier estimate. NE=Not estimable (e.g. median is not reached). [b] Estimated from the
main effects of an unstratified Cox proportional hazard model including treatment, subgroup and subgroup-by-treatment interaction.
Ties are handled using Efron method and 95% CI derived from profile likelihood estimation.
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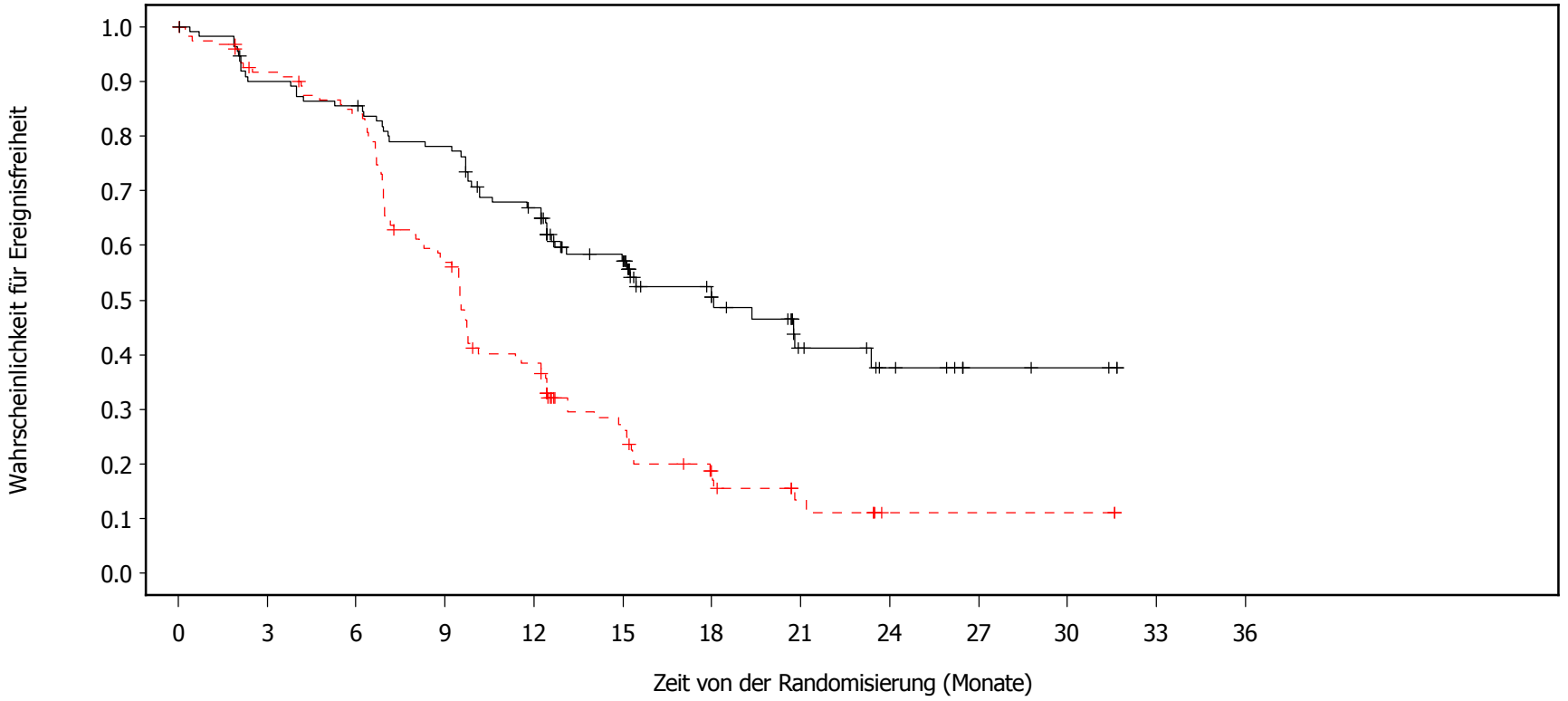
Figure 4.2.2.3 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Progressionsfreies Überleben for PD-L1 Expression = Positiv
Patients with pMMR tumour status, DCO 12ARP2023



Anzahl an Patienten unter Risiko:

112	99	94	85	70	45	25	14	9	3	2	0	0	CTx + Durvalumab + Olaparib
124	109	99	67	43	22	12	6	1	1	1	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
CTx = Carboplatin + Paclitaxel.

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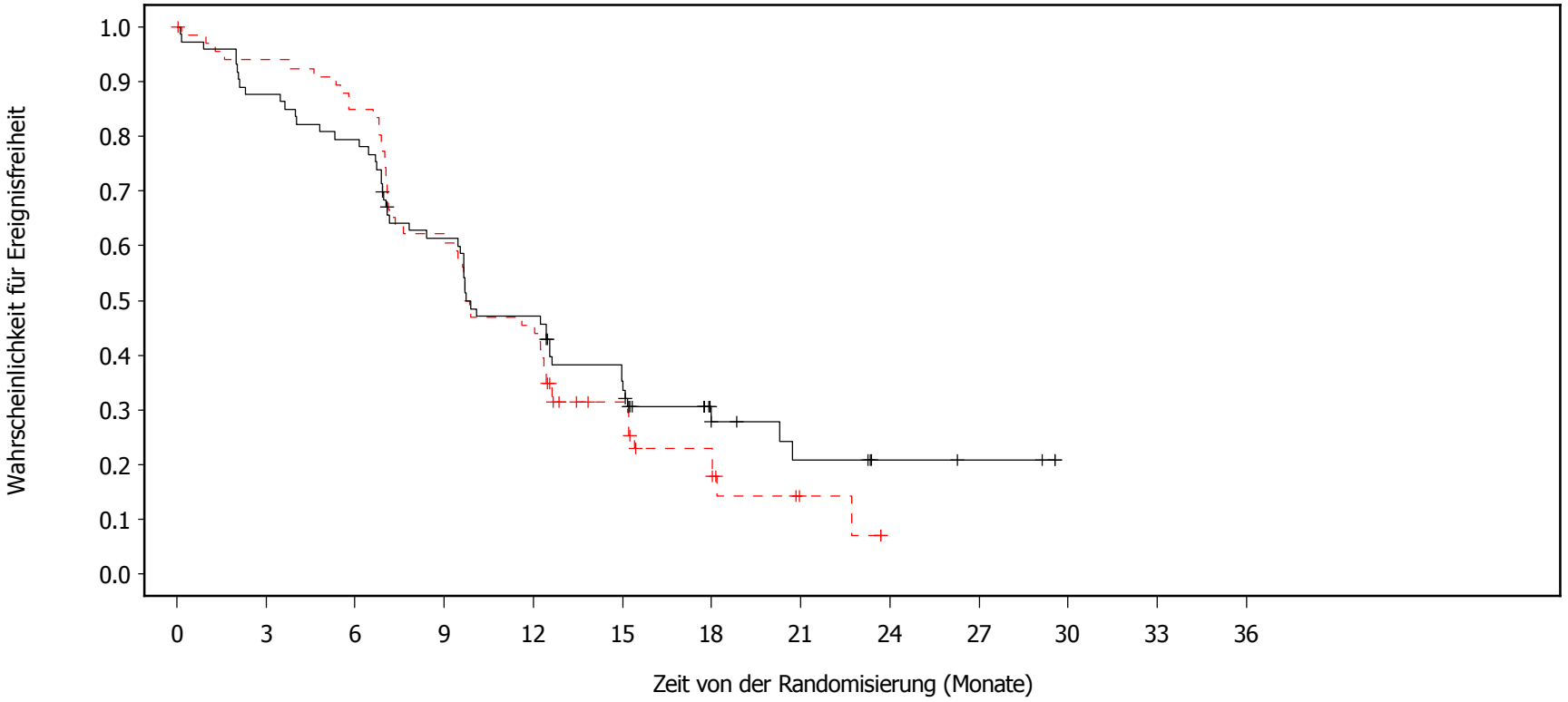
Figure 4.2.2.4 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Progressionsfreies Überleben for PD-L1 Expression = Negativ
Patients with pMMR tumour status, DCO 12ARP2023



Anzahl an Patienten unter Risiko:

73	64	58	43	33	23	9	6	3	2	0	0	0	CTx + Durvalumab + Olaparib
67	62	56	41	30	15	9	2	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
CTx = Carboplatin + Paclitaxel.

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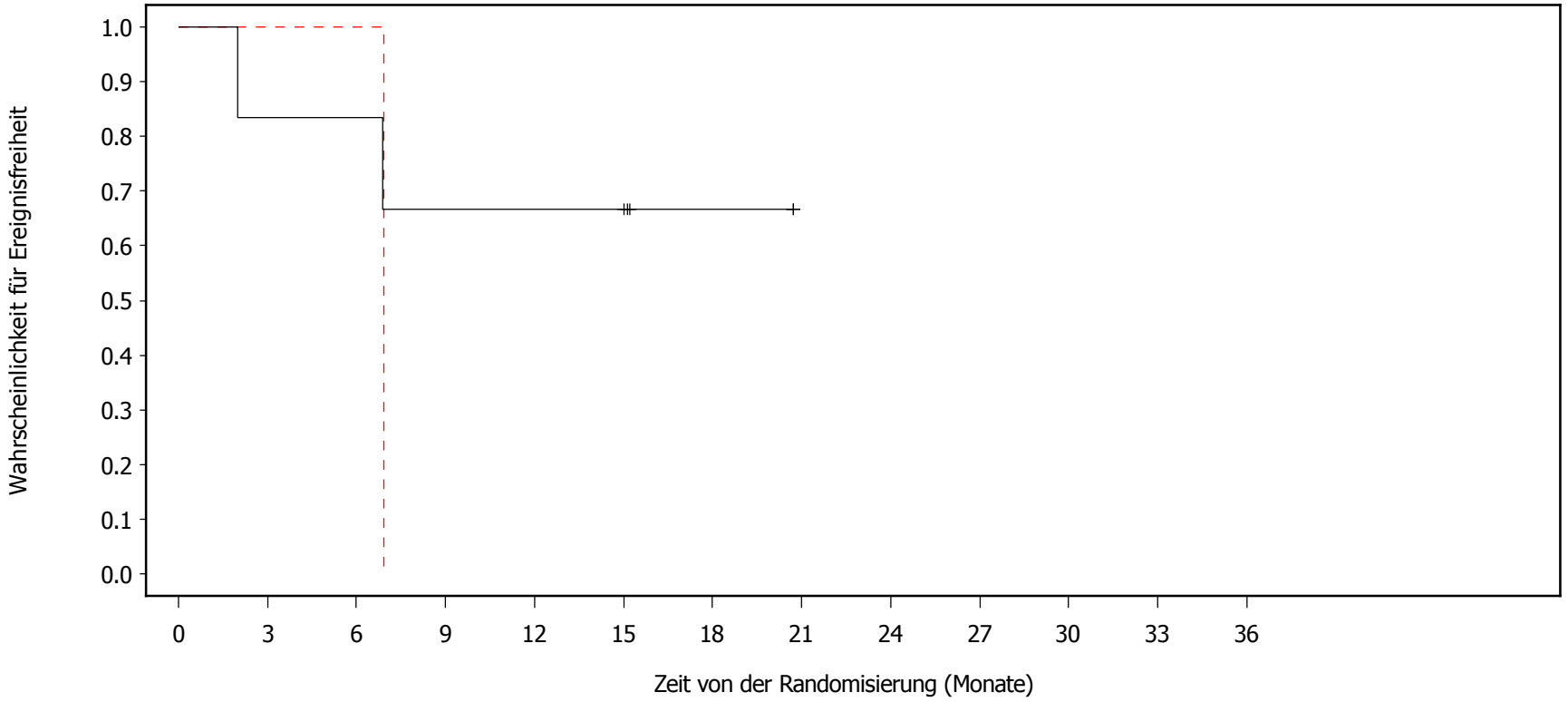
Figure 4.2.2.5 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Progressionsfreies Überleben for PD-L1 Expression = Unbekannt
Patients with pMMR tumour status, DCO 12ARP2023



Anzahl an Patienten unter Risiko:

6	5	5	4	4	4	1	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
1	1	1	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
CTx = Carboplatin + Paclitaxel.

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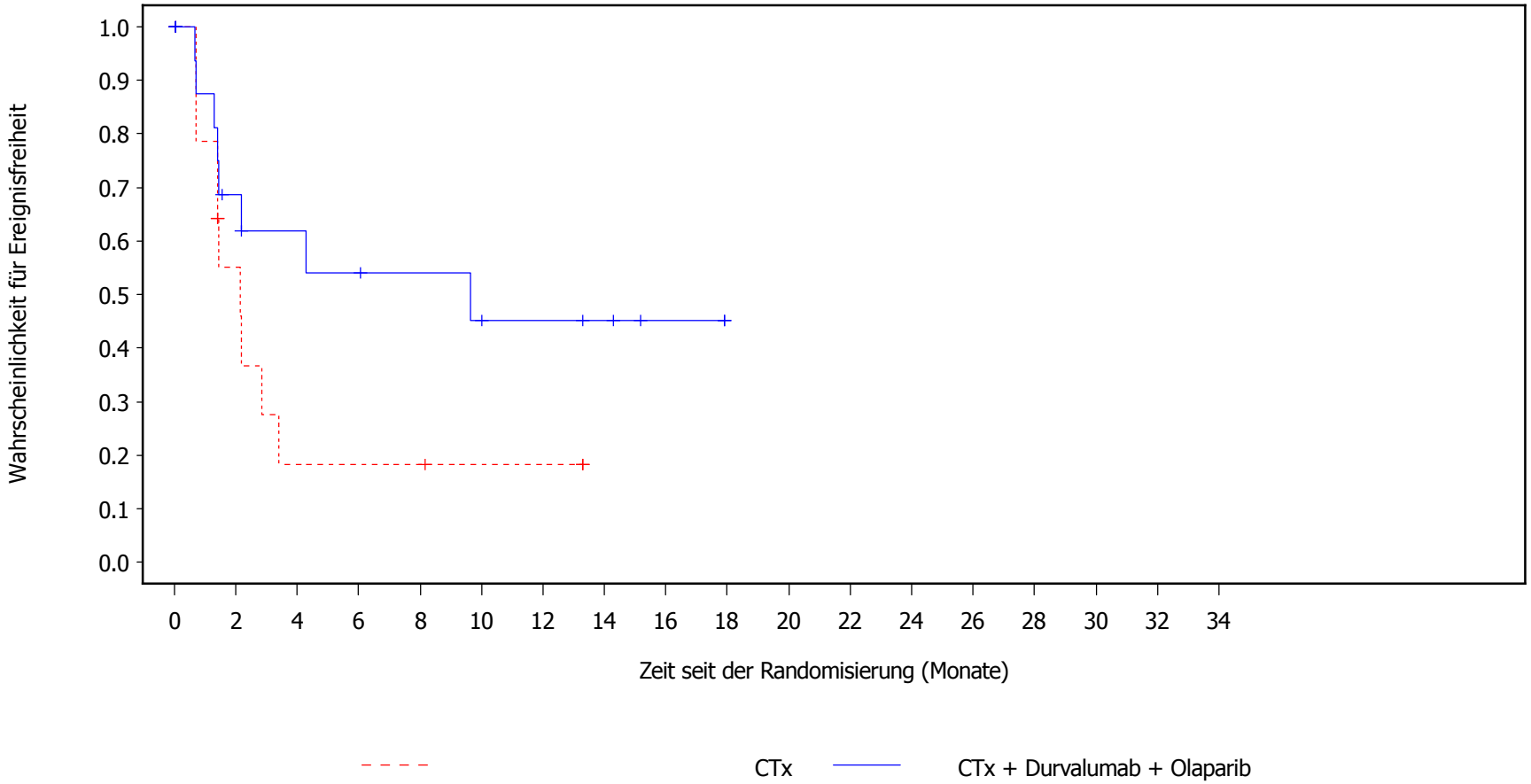
Figure 4.2.7.2.1 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Funktionsskala: Körper for HRR Mutationsstatus=HRRm
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

21	10	8	7	6	5	4	3	1	0	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
17	6	2	2	2	1	1	0	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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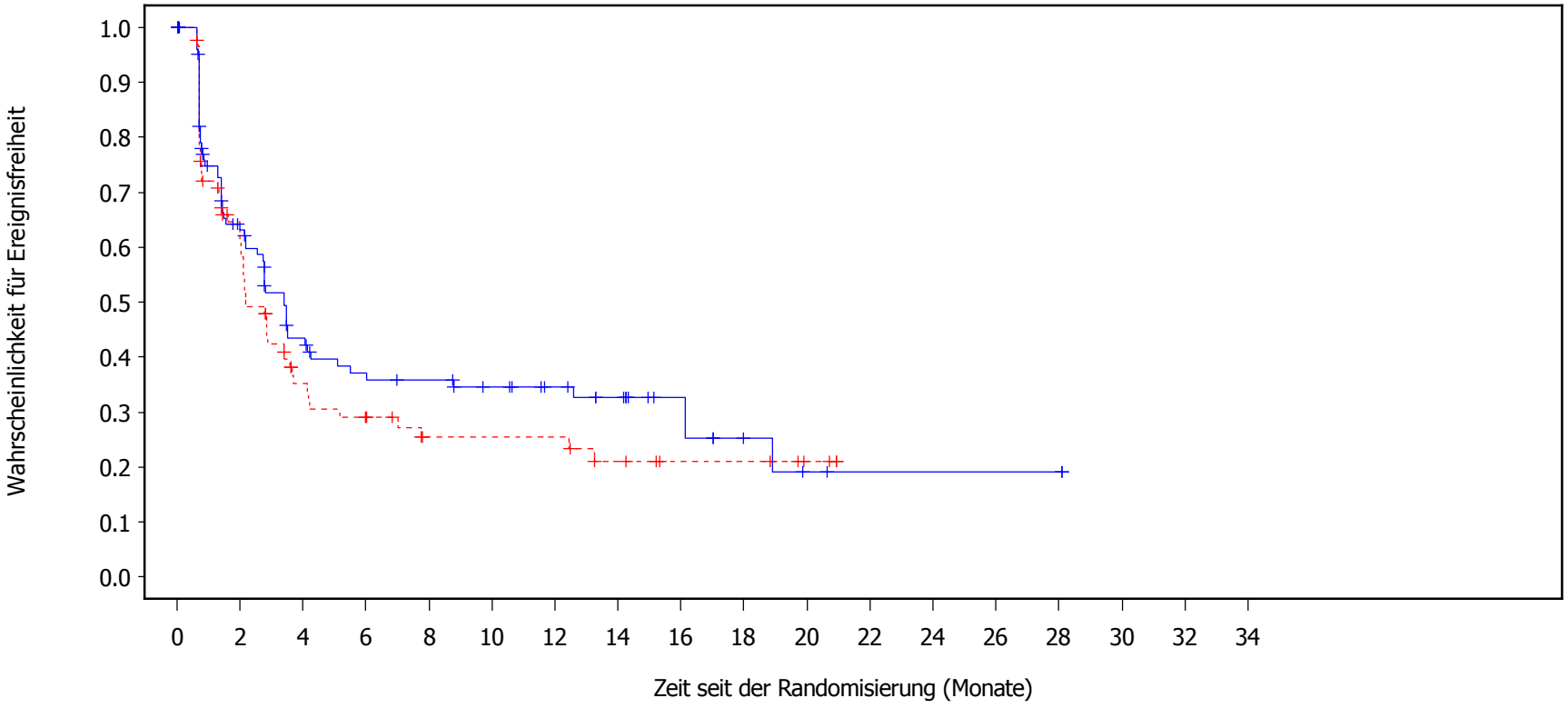
Figure 4.2.7.2.2 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Funktionsskala: Körper for HRR Mutationsstatus=Nicht-HRRm
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

118	58	36	29	27	23	19	15	9	4	2	1	1	1	1	0	0	0	CTx + Durvalumab + Olaparib
111	50	23	18	12	12	12	8	5	5	2	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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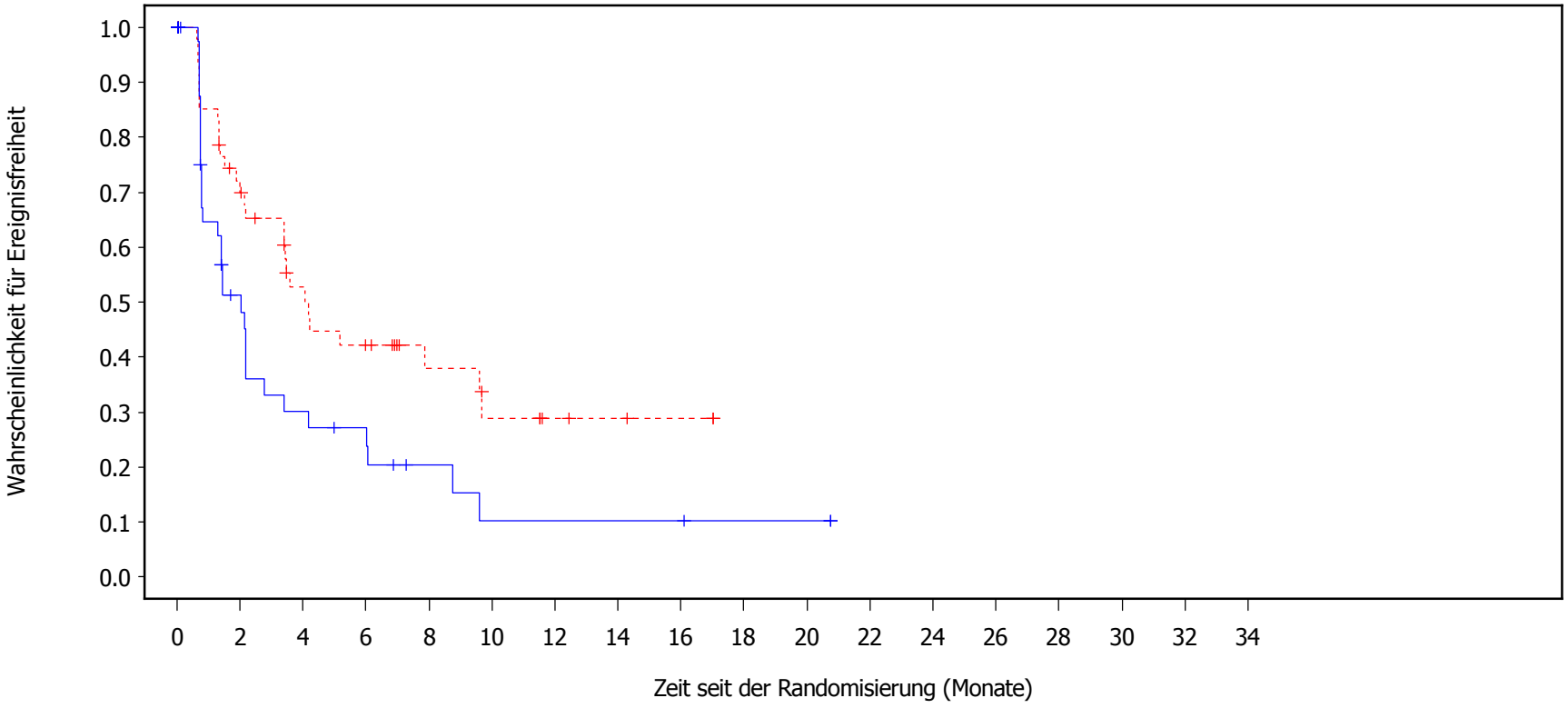
Figure 4.2.7.2.3 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Funktionsskala: Körper for HRR Mutationsstatus=Unbekannt
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

52	17	10	8	4	2	2	2	2	1	1	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
64	32	20	15	9	6	3	2	1	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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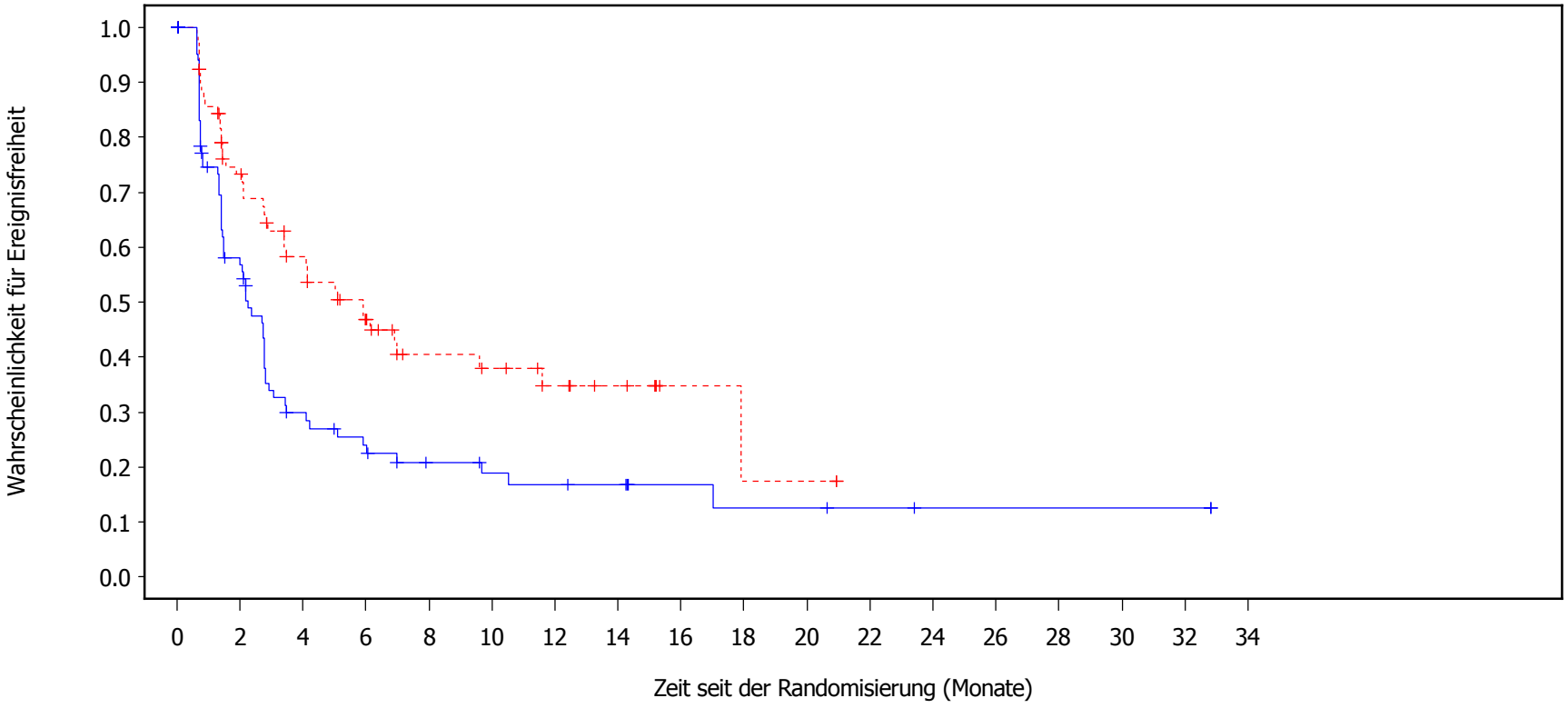
Figure 4.2.7.2.4 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Funktionsskala: Kognition for Alter=<65
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

101	45	21	16	11	9	8	7	4	3	3	2	1	1	1	1	1	0	CTx + Durvalumab + Olaparib
99	51	37	25	16	14	10	7	2	1	1	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
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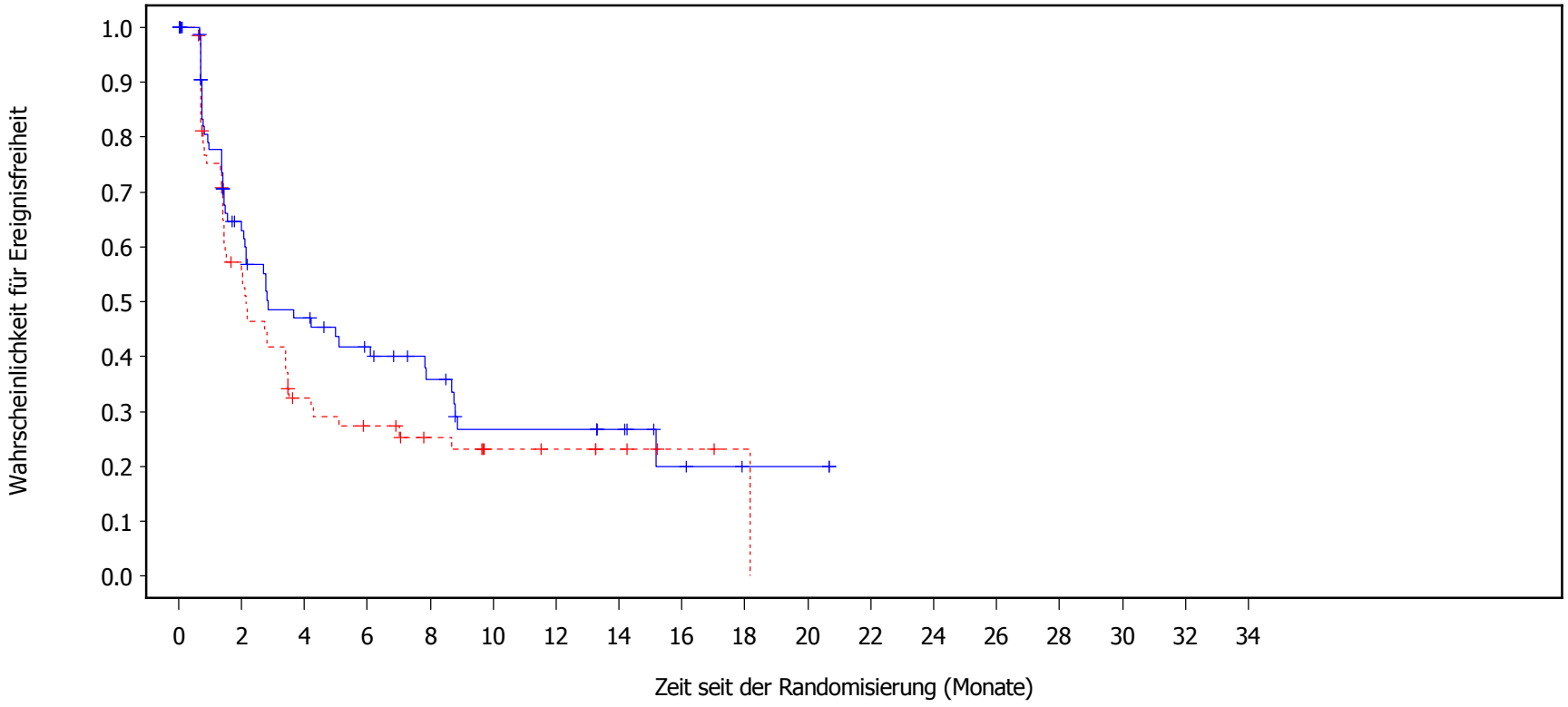
Figure 4.2.7.2.5 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Funktionsskala: Kognition for Alter=>=65
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

90	41	29	23	17	11	11	7	3	1	1	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
93	37	19	15	11	7	6	4	2	1	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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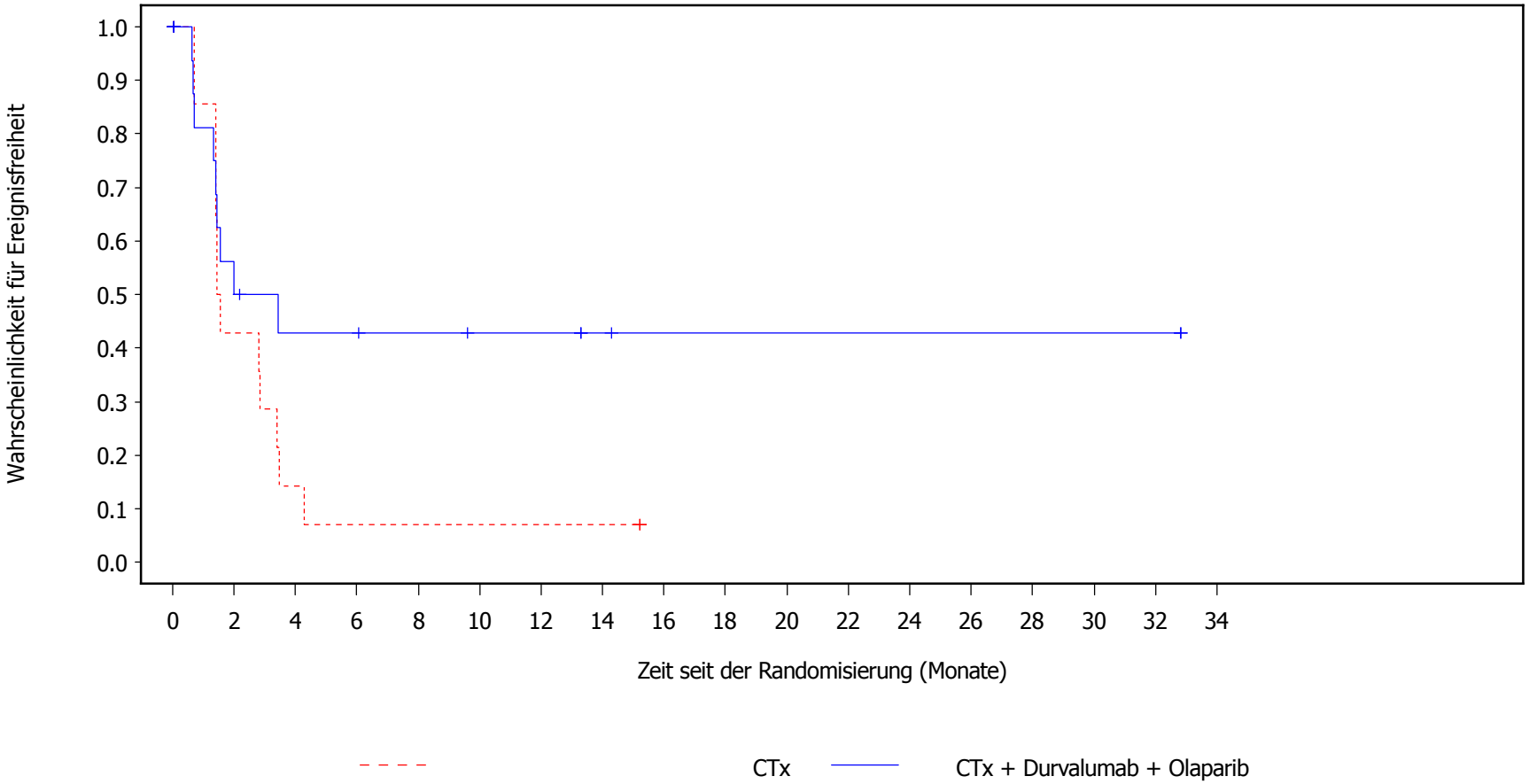
Figure 4.2.7.2.6 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Funktionsskala: Kognition for HRR Mutationsstatus=HRRm
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

21	9	6	6	5	4	4	2	1	1	1	1	1	1	1	1	1	0	CTx + Durvalumab + Olaparib
17	6	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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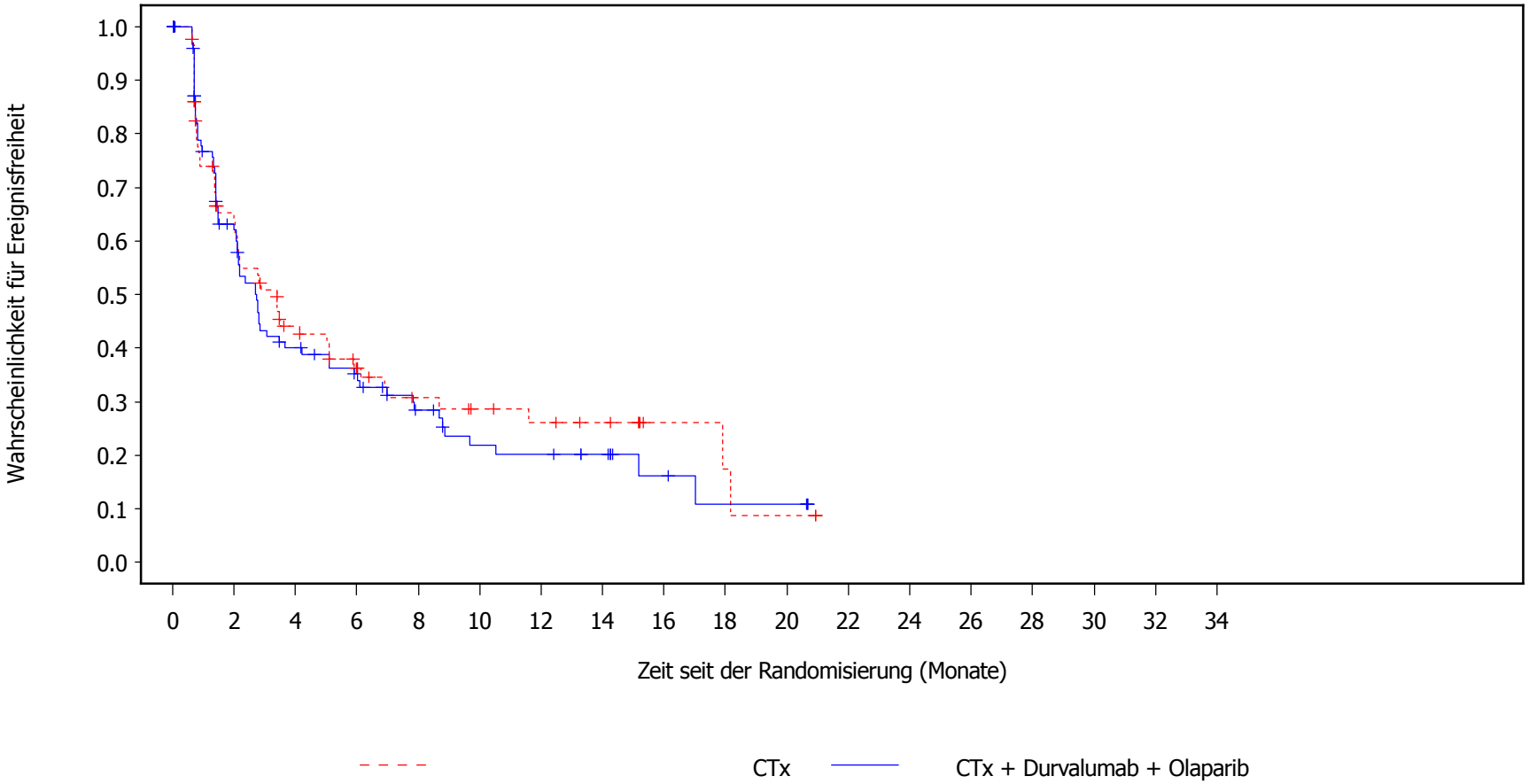
Figure 4.2.7.2.7 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Funktionsskala: Kognition for HRR Mutationsstatus=Nicht-HRRm
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

118	58	35	28	19	13	12	9	4	2	2	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
111	50	30	21	15	12	10	8	3	2	1	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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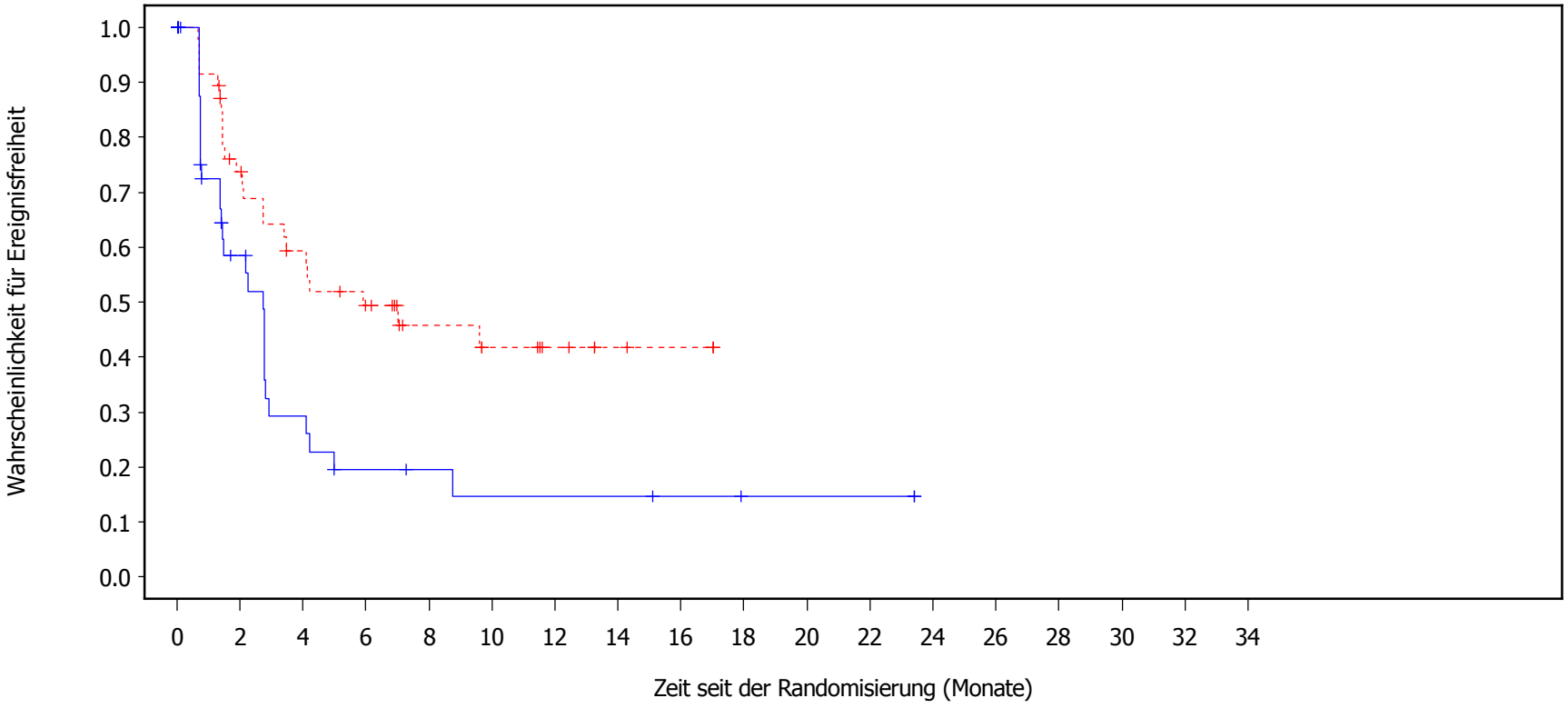
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.7.2.8 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Funktionsskala: Kognition for HRR Mutationsstatus=Unbekannt
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

52	19	9	5	4	3	3	3	2	1	1	1	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
64	32	24	18	11	8	5	2	1	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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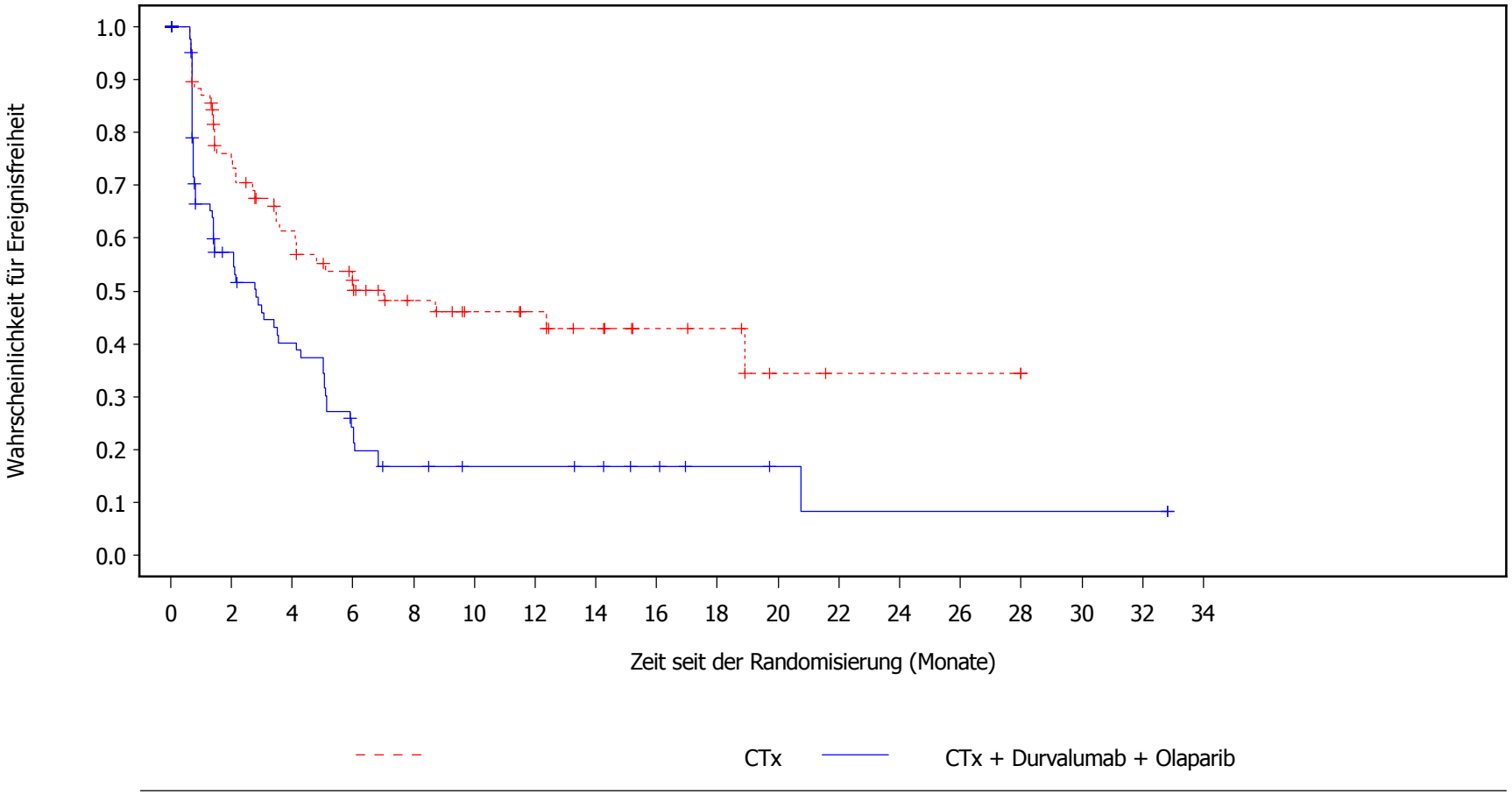
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.7.2.9 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Übelkeit und Erbrechen for Krankheitsstatus=Rezidivierend
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

99	41	28	16	10	8	8	7	5	3	2	1	1	1	1	1	1	0	CTx + Durvalumab + Olaparib
101	54	40	30	22	17	15	11	7	6	2	1	1	1	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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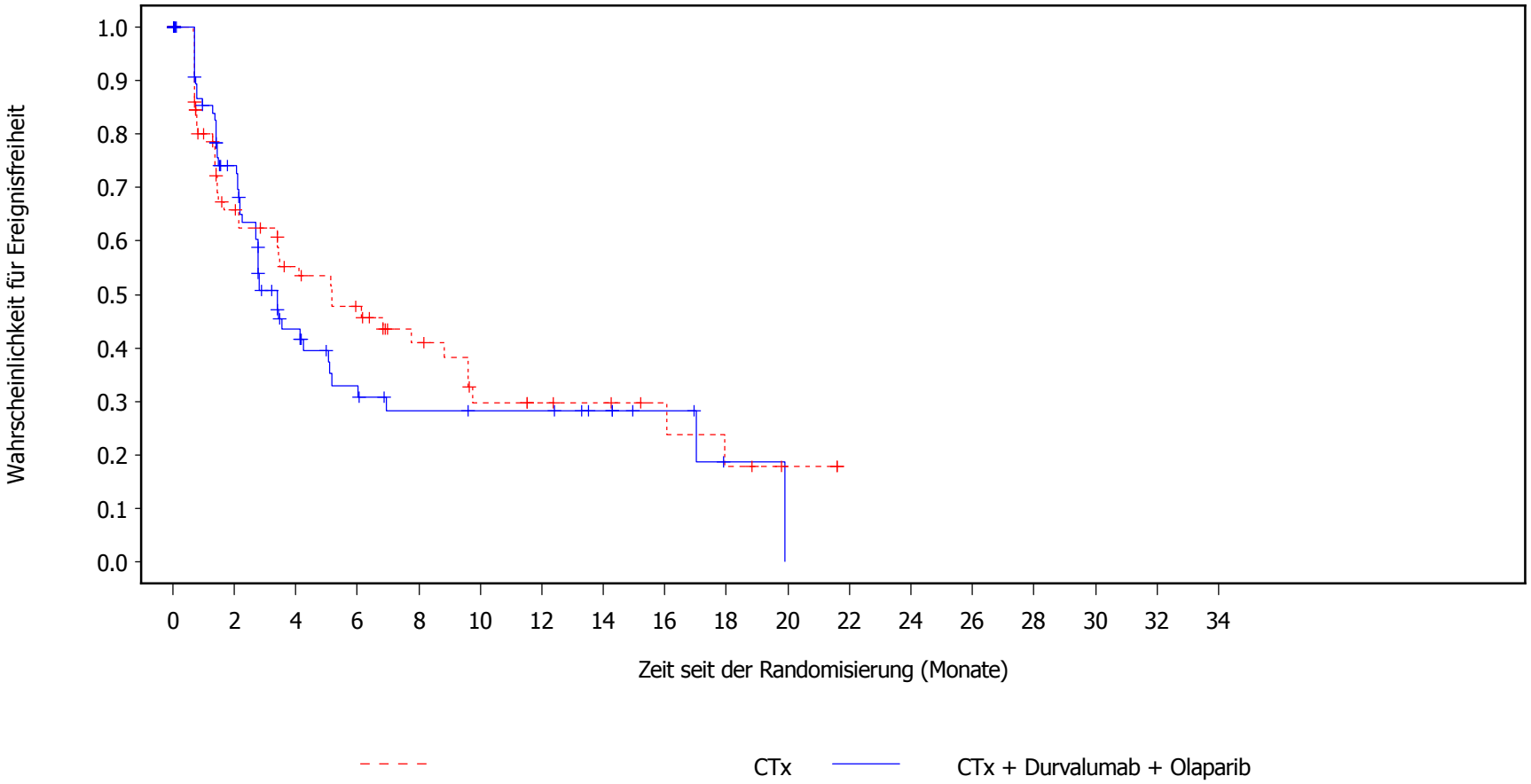
Figure 4.2.7.2.10 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Übelkeit und Erbrechen for Krankheitsstatus=Neu diagnostiziert
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

92	49	23	15	11	10	10	7	4	1	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
91	40	30	24	16	10	8	7	5	3	1	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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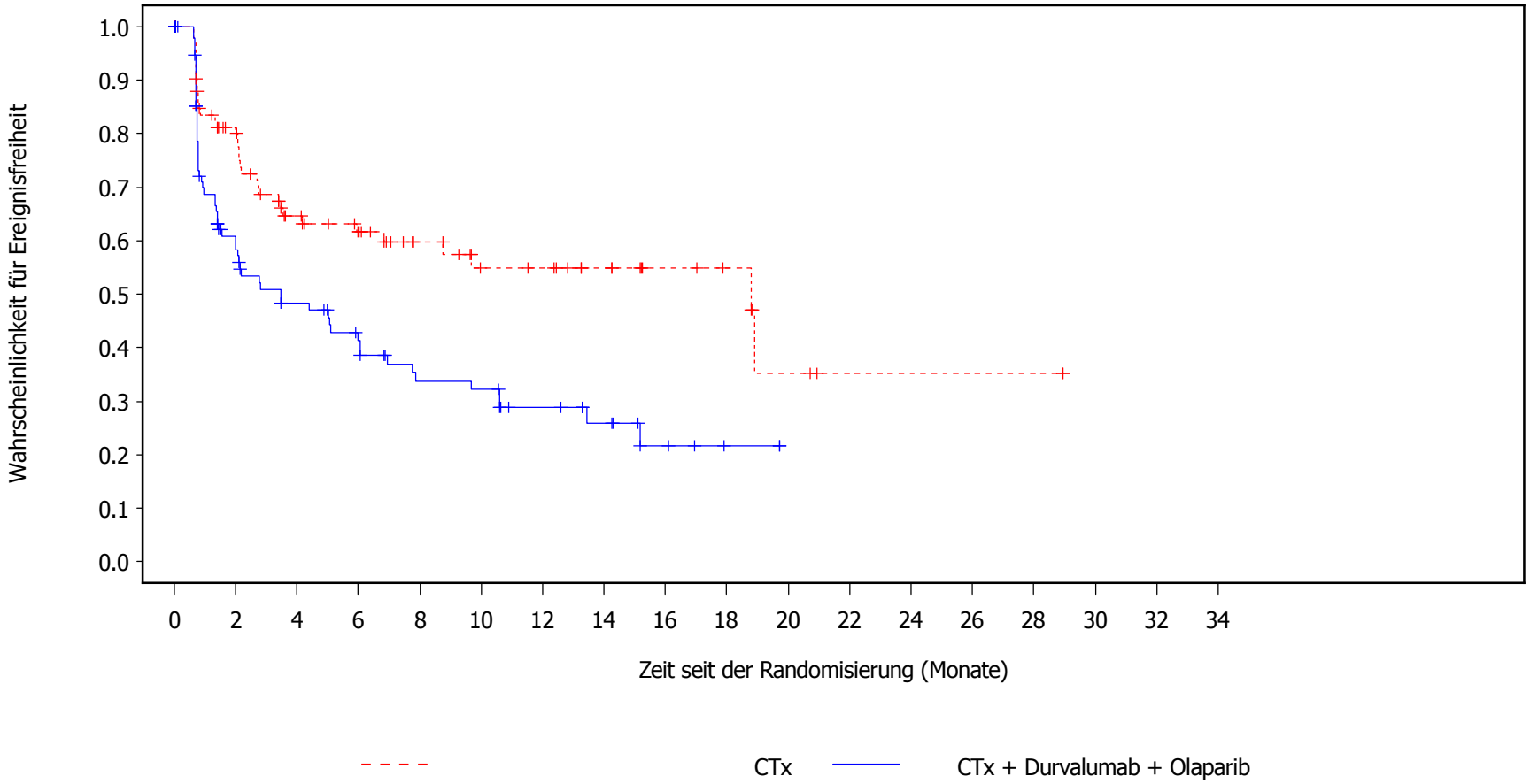
Figure 4.2.7.2.11 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Verstopfung
for PD-L1 Expression=Positiv
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

112	50	37	29	21	20	14	9	4	1	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
124	66	45	37	27	20	19	14	9	7	3	1	1	1	1	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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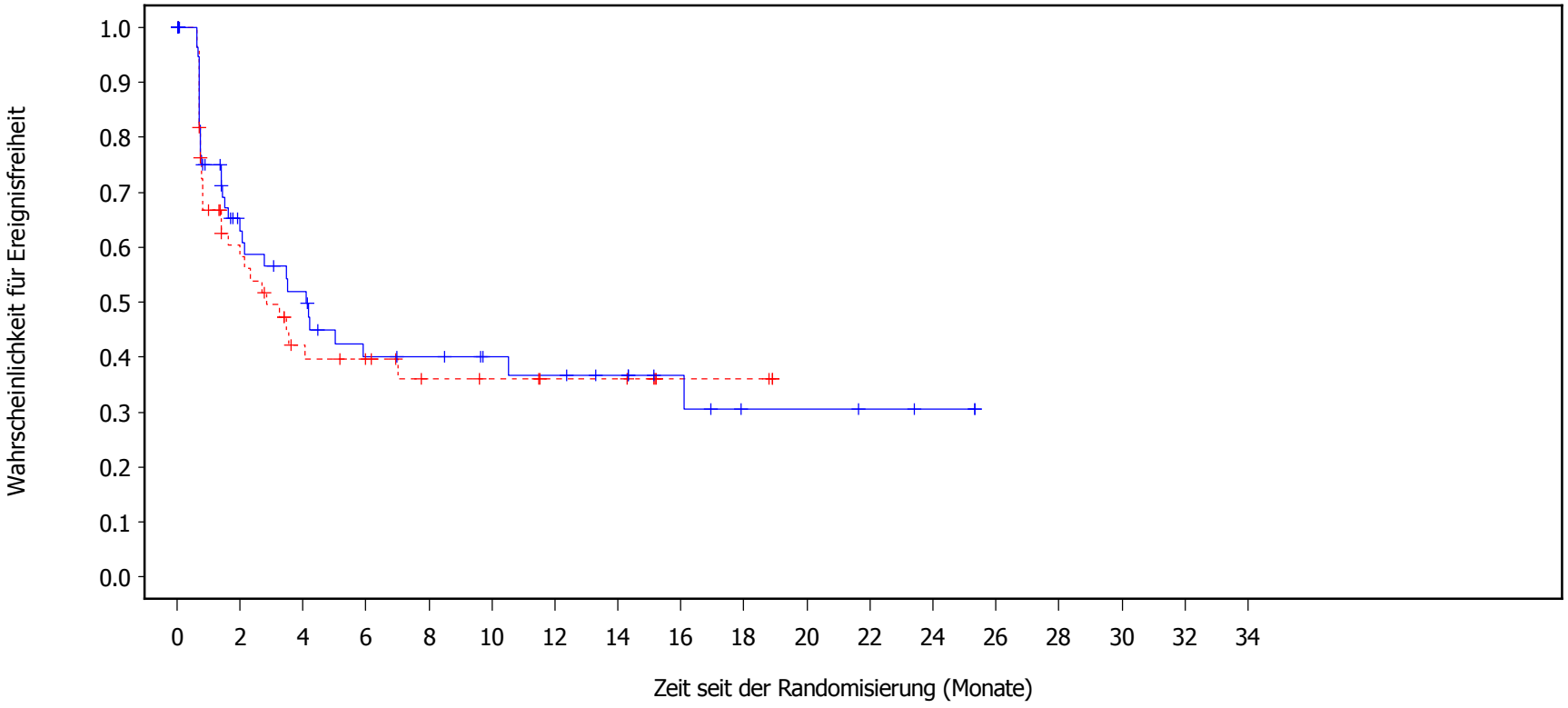
Figure 4.2.7.2.12 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Verstopfung
for PD-L1 Expression=Negativ
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

73	30	23	16	15	12	11	9	6	3	3	2	1	0	0	0	0	0	CTx + Durvalumab + Olaparib
67	28	16	13	9	8	6	6	2	2	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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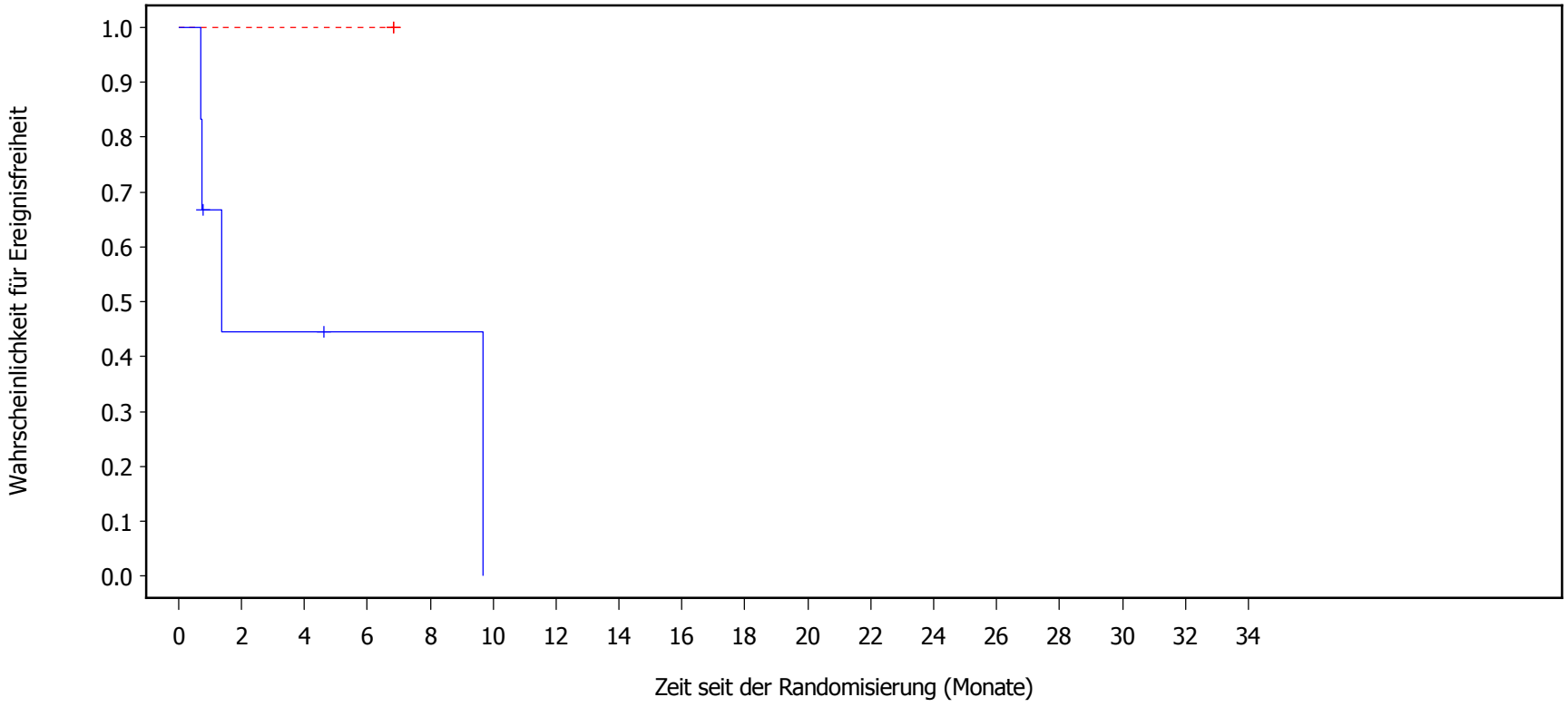
Figure 4.2.7.2.13 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Verstopfung
for PD-L1 Expression=Unbekannt
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

6	2	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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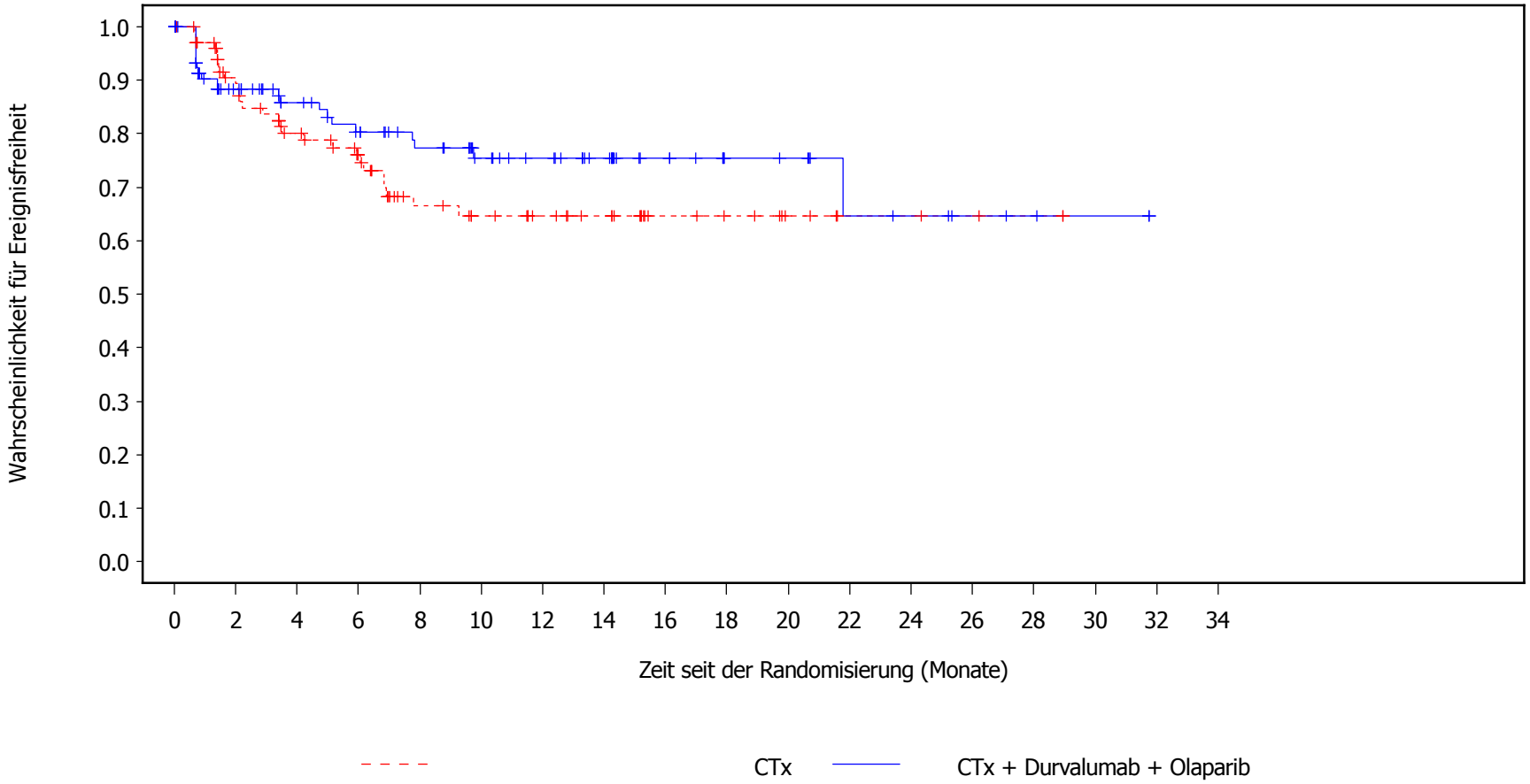
Figure 4.2.8.2.1 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Sexuelles Interesse for ECOG Performance Status zu Baseline=0
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

135	79	66	58	50	41	36	28	18	11	10	6	5	3	2	1	0	0	CTx + Durvalumab + Olaparib
127	80	63	52	36	31	26	22	12	10	6	3	3	2	1	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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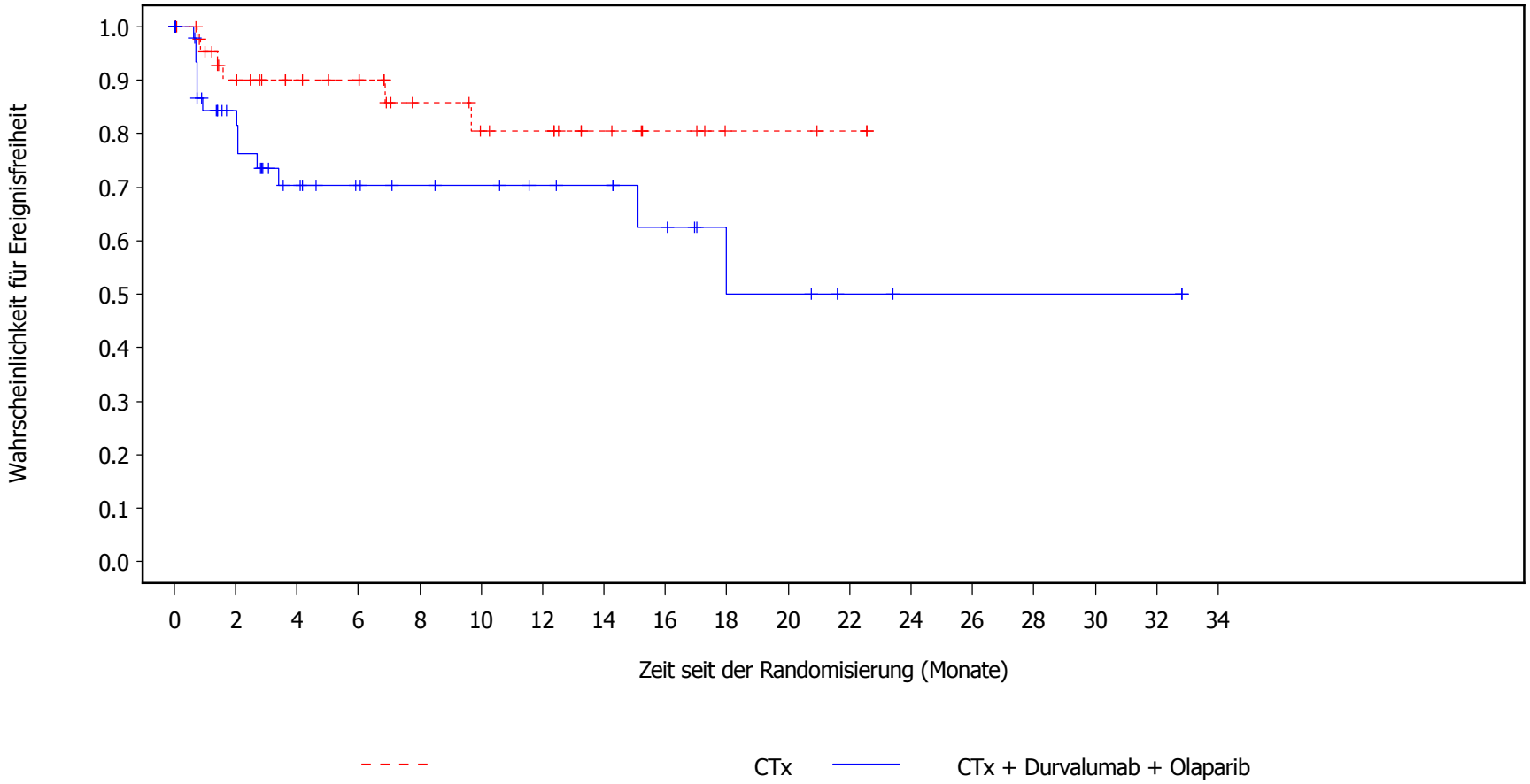
Figure 4.2.8.2.2 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Sexuelles Interesse for ECOG Performance Status zu Baseline=1
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

56	31	21	17	15	14	12	11	8	4	4	2	1	1	1	1	1	0	CTx + Durvalumab + Olaparib
65	34	27	25	17	14	13	8	5	2	2	1	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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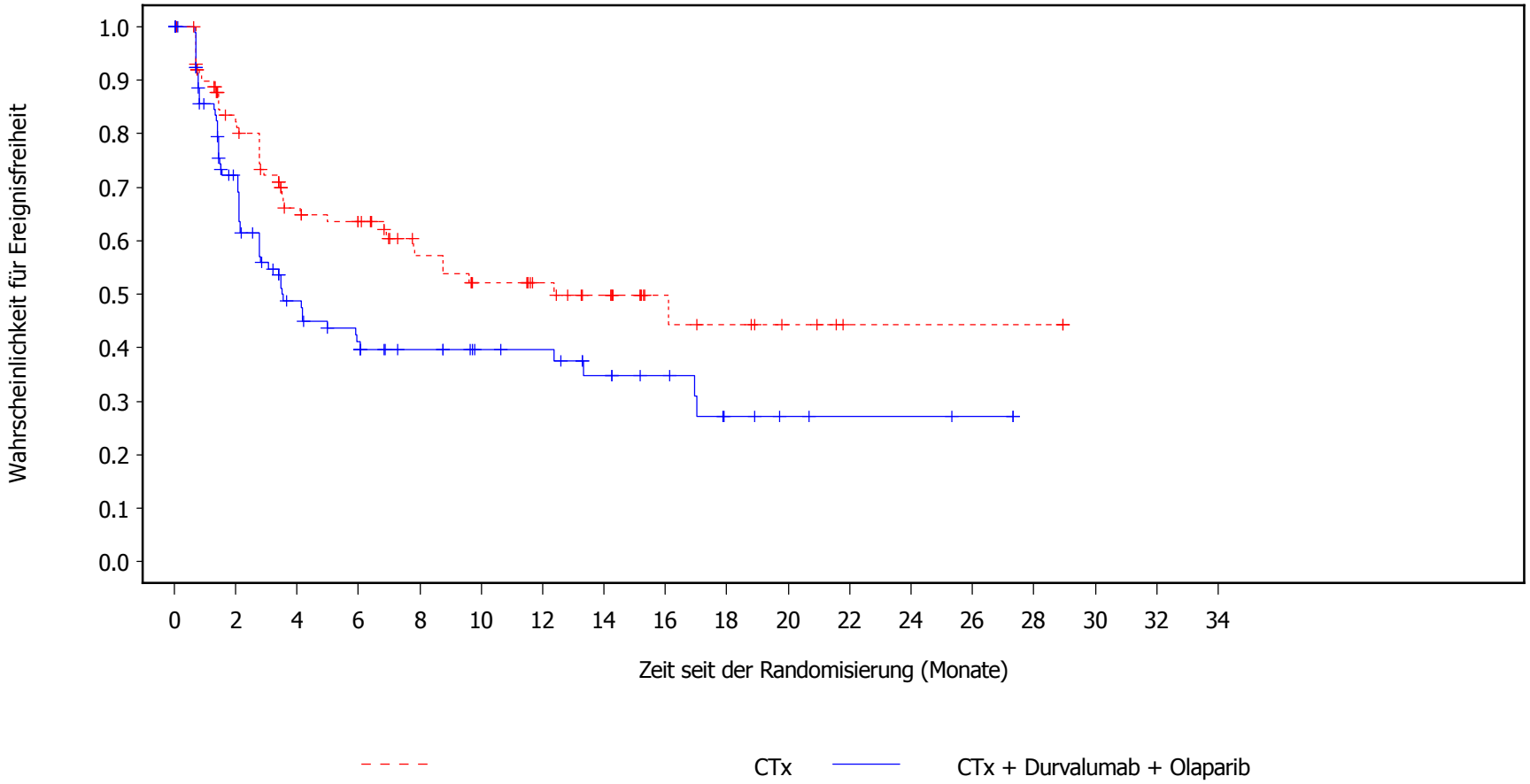
Figure 4.2.8.2.3 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Gastrointestinale Symptome for ECOG Performance Status zu Baseline=0
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

135	67	39	31	24	19	18	13	10	5	3	2	2	1	0	0	0	0	CTx + Durvalumab + Olaparib
127	75	52	46	34	28	23	18	9	7	4	1	1	1	1	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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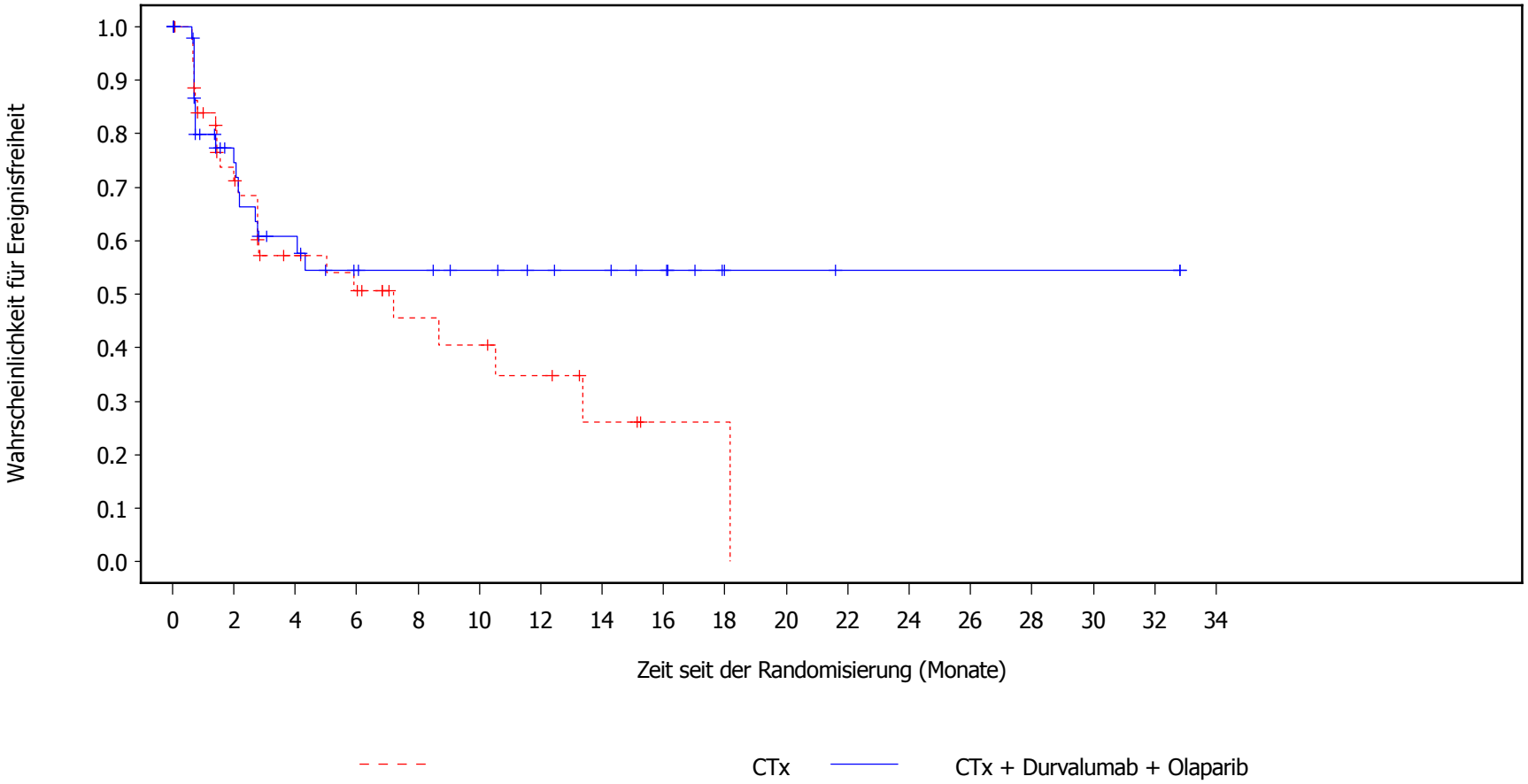
Figure 4.2.8.2.4 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Gastrointestinale Symptome for ECOG Performance Status zu Baseline=1
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

56	28	20	15	14	12	10	9	7	2	2	1	1	1	1	1	1	0	CTx + Durvalumab + Olaparib
65	28	18	15	9	8	6	3	1	1	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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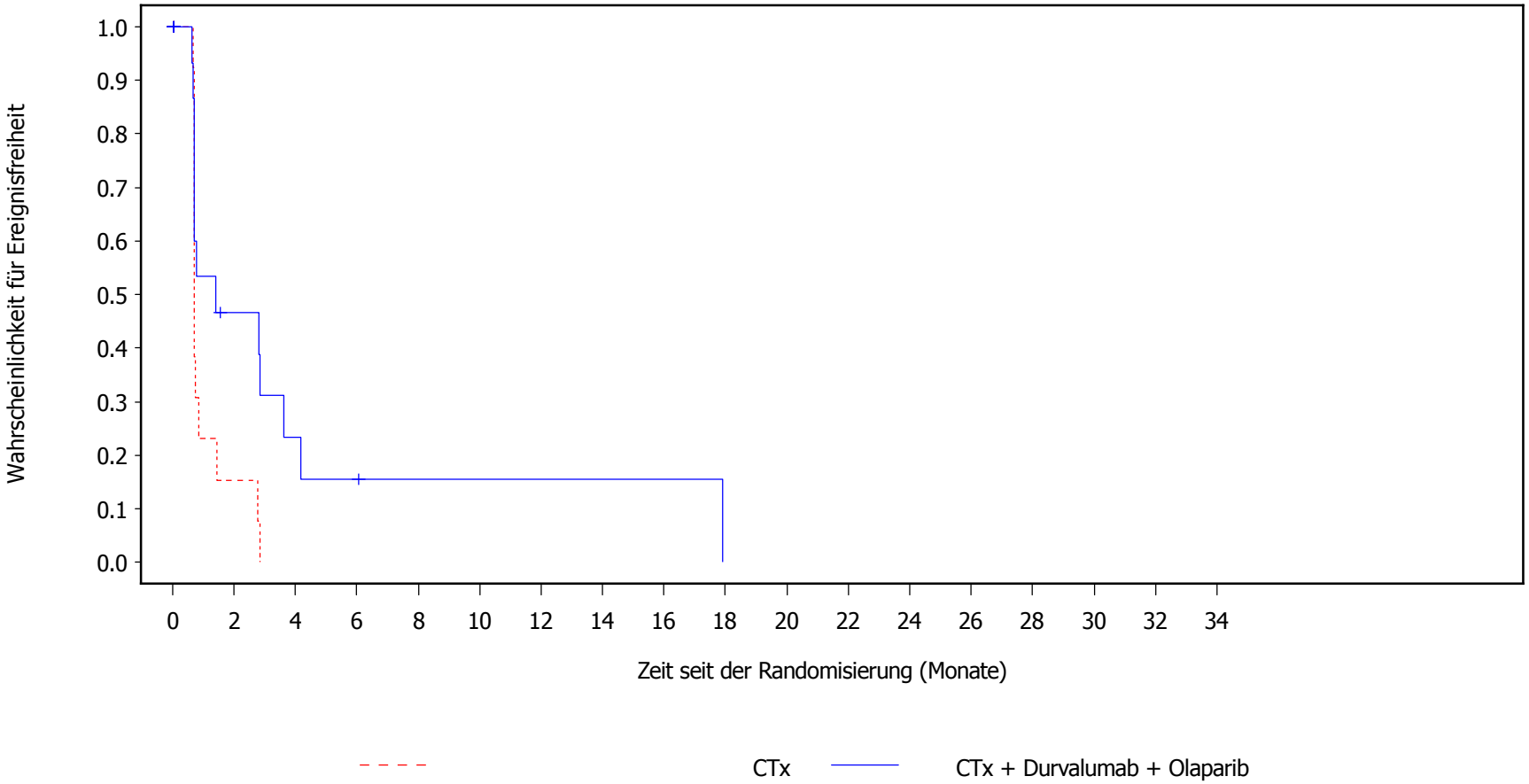
Figure 4.2.8.2.5 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl for HRR Mutationsstatus=HRRm
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

21	6	3	2	1	1	1	1	1	0	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
17	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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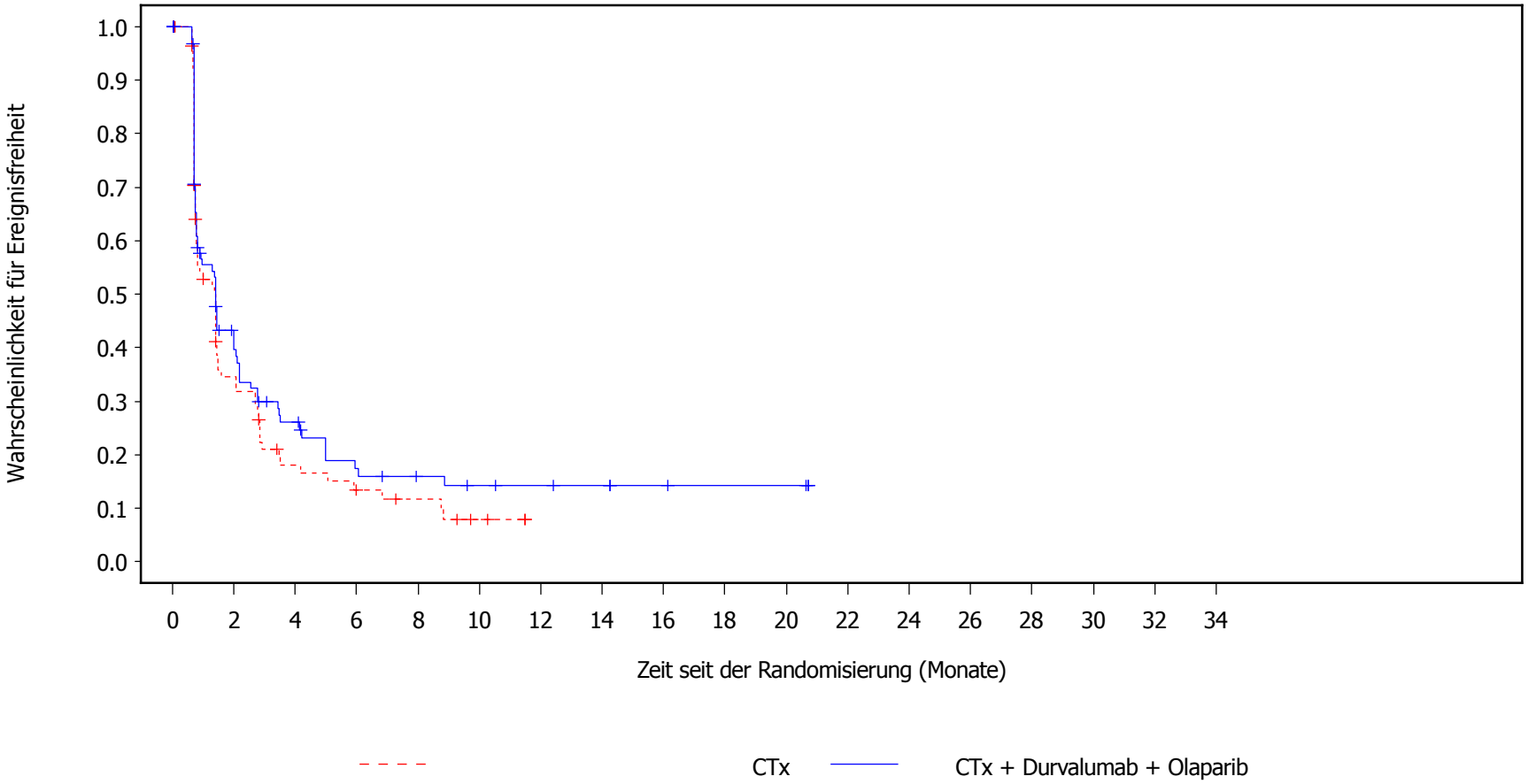
Figure 4.2.8.2.6 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl for HRR Mutationsstatus=Nicht-HRRm
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

118	36	20	12	9	7	6	5	3	2	2	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
111	26	12	8	6	2	0	0	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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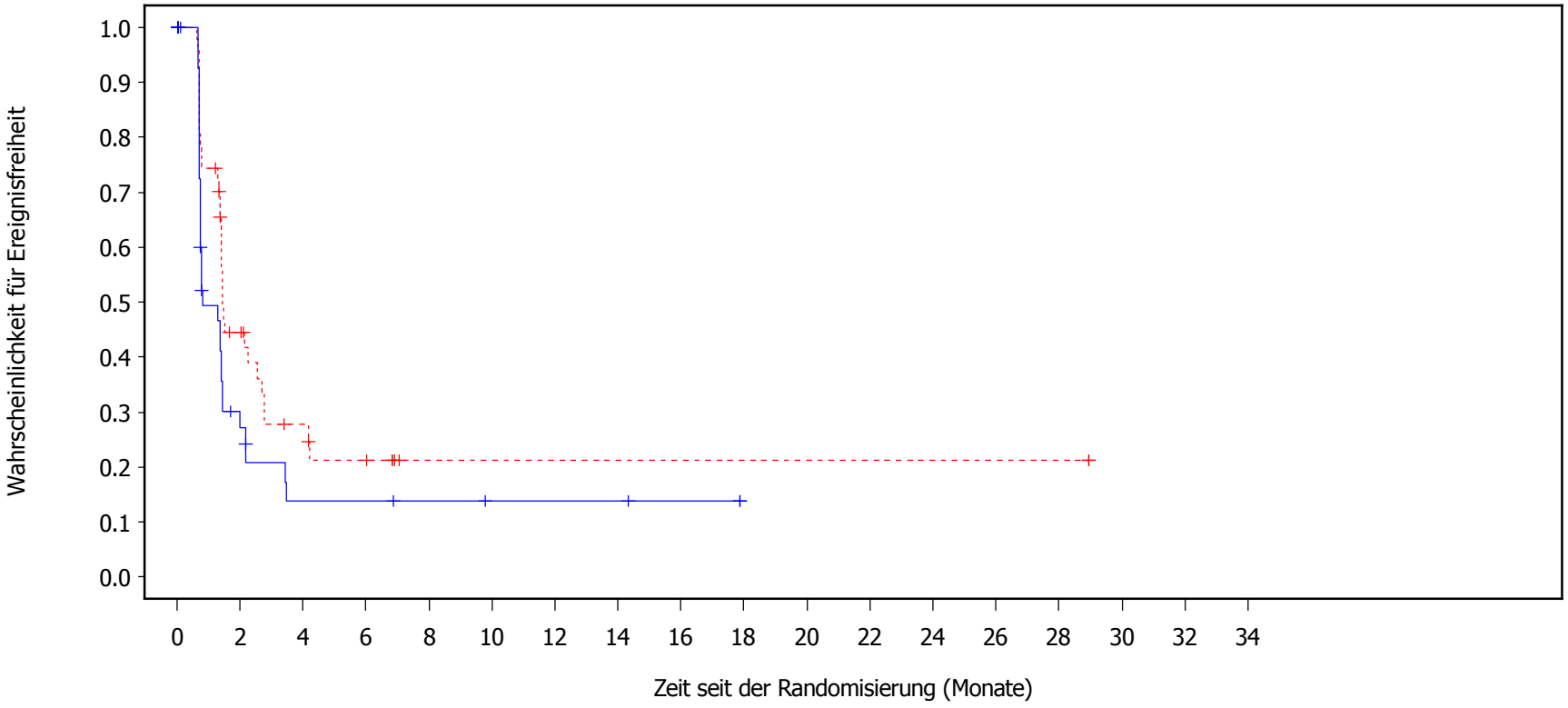
Figure 4.2.8.2.7 DUO-E (pMMR Durva/Ola): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl for HRR Mutationsstatus=Unbekannt
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

52	10	4	4	3	2	2	2	1	0	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
64	18	9	6	1	1	1	1	1	1	1	1	1	1	1	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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Table 4.3.1.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	98 (99,0)	0,1 [0,1; 0,1]	101	101 (100)	0,1 [0,1; 0,1]	0,98	[0,74; 1,29]	0,8691
Neu diagnostiziert	92	92 (100)	0,1 [0,1; 0,2]	89	89 (100)	0,1 [0,1; 0,1]	0,93	[0,69; 1,25]	0,6382
Interaktion p-Wert									0,8213
Region									
Asien	54	54 (100)	0,1 [0,1; 0,1]	54	54 (100)	0,1 [0,1; 0,1]	1,03	[0,71; 1,51]	0,8728
Rest der Welt	137	136 (99,3)	0,1 [0,1; 0,1]	136	136 (100)	0,1 [0,1; 0,1]	0,93	[0,73; 1,18]	0,5676
Interaktion p-Wert									0,6596
Alter									
<65	101	100 (99,0)	0,1 [0,1; 0,1]	98	98 (100)	0,1 [0,1; 0,1]	0,89	[0,68; 1,18]	0,4302
>=65	90	90 (100)	0,1 [0,1; 0,1]	92	92 (100)	0,1 [0,1; 0,2]	1,02	[0,76; 1,36]	0,9101
Interaktion p-Wert									0,5298
Abstammung									
Weiß	104	103 (99,0)	0,1 [0,1; 0,2]	112	112 (100)	0,1 [0,1; 0,1]	0,89	[0,68; 1,16]	0,3867
Schwarz/Afroamerikanisch	13	13 (100)	0,1 [0,0; 0,1]	8	8 (100)	0,1 [0,0; 0,1]	1,02	[0,43; 2,57]	0,9722
Asiatisch	57	57 (100)	0,1 [0,1; 0,1]	58	58 (100)	0,1 [0,1; 0,1]	1,03	[0,72; 1,49]	0,8553
Andere	16	16 (100)	0,1 [0,1; 0,2]	12	12 (100)	0,1 [0,0; 0,6]	1,16	[0,55; 2,51]	0,6993
Interaktion p-Wert									0,8638
HRR Mutationsstatus									
HRRm	21	21 (100)	0,1 [0,1; 0,1]	16	16 (100)	0,1 [0,1; 0,7]	1,46	[0,77; 2,85]	0,2485
Nicht-HRRm	118	117 (99,2)	0,1 [0,1; 0,1]	111	111 (100)	0,1 [0,1; 0,1]	0,80	[0,62; 1,04]	0,0961
Unbekannt	52	52 (100)	0,1 [0,1; 0,1]	63	63 (100)	0,1 [0,1; 0,2]	1,15	[0,80; 1,66]	0,4482
Interaktion p-Wert									0,1101
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	112 (100)	0,1 [0,1; 0,1]	122	122 (100)	0,1 [0,1; 0,1]	0,95	[0,73; 1,23]	0,6849
Negativ	73	72 (98,6)	0,1 [0,1; 0,2]	67	67 (100)	0,1 [0,1; 0,1]	0,95	[0,68; 1,33]	0,7738
Unbekannt	6	6 (100)	0,1 [0,0; NE]	1	1 (100)	0,0 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9843
Histologie									
Endometrioid	107	107 (100)	0,1 [0,1; 0,1]	97	97 (100)	0,1 [0,1; 0,1]	0,95	[0,72; 1,25]	0,7184
Serös	42	42 (100)	0,1 [0,1; 0,2]	52	52 (100)	0,1 [0,1; 0,1]	0,86	[0,57; 1,29]	0,4703
Andere	42	41 (97,6)	0,1 [0,1; 0,1]	41	41 (100)	0,1 [0,1; 0,3]	1,08	[0,70; 1,66]	0,7414
Interaktion p-Wert									0,7643
Histologischer Grad									
High grade (G3)	77	77 (100)	0,1 [0,1; 0,1]	82	82 (100)	0,1 [0,1; 0,1]	0,97	[0,71; 1,32]	0,8356
Low grade (G1+G2)	90	90 (100)	0,1 [0,1; 0,1]	87	87 (100)	0,1 [0,1; 0,1]	1,00	[0,75; 1,35]	0,9786
Interaktion p-Wert									0,8661
ECOG Performance Status zu Baseline									
0	135	134 (99,3)	0,1 [0,1; 0,1]	126	126 (100)	0,1 [0,1; 0,1]	0,88	[0,69; 1,12]	0,3050
1	56	56 (100)	0,1 [0,1; 0,1]	64	64 (100)	0,1 [0,1; 0,1]	1,13	[0,79; 1,62]	0,5105
Interaktion p-Wert									0,2632
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	11 (100)	0,1 [0,0; 0,2]	10	10 (100)	0,7 [0,0; 1,0]	2,75	[1,14; 6,70]	0,0243*
IV	78	78 (100)	0,1 [0,1; 0,2]	77	77 (100)	0,1 [0,0; 0,1]	0,80	[0,58; 1,11]	0,1836
Interaktion p-Wert									0,0101*

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Asthenie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	21 (21,2)	NE [NE; NE]	101	10 (9,9)	NE [NE; NE]	2,23	[1,08; 4,94]	0,0307*
Neu diagnostiziert	92	16 (17,4)	NE [NE; NE]	89	8 (9,0)	NE [NE; NE]	1,90	[0,84; 4,70]	0,1270
Interaktion p-Wert									0,7849
Region									
Asien	54	7 (13,0)	NE [NE; NE]	54	3 (5,6)	NE [NE; NE]	2,39	[0,66; 11,10]	0,1865
Rest der Welt	137	30 (21,9)	NE [NE; NE]	136	15 (11,0)	NE [NE; NE]	2,00	[1,09; 3,82]	0,0240*
Interaktion p-Wert									0,8127
Alter									
<65	101	18 (17,8)	NE [NE; NE]	98	6 (6,1)	NE [NE; NE]	3,07	[1,29; 8,48]	0,0104*
>=65	90	19 (21,1)	NE [NE; NE]	92	12 (13,0)	NE [NE; NE]	1,57	[0,77; 3,32]	0,2182
Interaktion p-Wert									0,2530
Abstammung									
Weiß	104	22 (21,2)	NE [NE; NE]	112	12 (10,7)	NE [NE; NE]	1,97	[0,99; 4,11]	0,0536
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	7 (12,3)	NE [NE; NE]	58	3 (5,2)	NE [NE; NE]	2,42	[0,67; 11,21]	0,1813
Andere	16	5 (31,3)	NE [NE; NE]	12	3 (25,0)	NE [NE; NE]	1,12	[0,27; 5,45]	0,8792
Interaktion p-Wert									0,7283
HRR Mutationsstatus									
HRRm	21	3 (14,3)	NE [NE; NE]	16	4 (25,0)	NE [NE; NE]	0,48	[0,09; 2,17]	0,3316
Nicht-HRRm	118	24 (20,3)	NE [NE; NE]	111	8 (7,2)	NE [NE; NE]	2,96	[1,39; 7,03]	0,0044*
Unbekannt	52	10 (19,2)	NE [NE; NE]	63	6 (9,5)	NE [NE; NE]	2,05	[0,76; 6,03]	0,1561
Interaktion p-Wert									0,1096
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Asthenie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	25 (22,3)	NE [NE; NE]	122	12 (9,8)	NE [NE; NE]	2,25	[1,16; 4,65]	0,0167*
Negativ	73	11 (15,1)	NE [NE; NE]	67	6 (9,0)	NE [NE; NE]	1,76	[0,67; 5,12]	0,2538
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6923
Histologie									
Endometrioid	107	21 (19,6)	NE [NE; NE]	97	9 (9,3)	NE [NE; NE]	2,14	[1,01; 4,91]	0,0474*
Serös	42	9 (21,4)	NE [NE; NE]	52	5 (9,6)	NE [NE; NE]	2,29	[0,79; 7,45]	0,1284
Andere	42	7 (16,7)	NE [NE; NE]	41	4 (9,8)	NE [NE; NE]	1,74	[0,52; 6,63]	0,3704
Interaktion p-Wert									0,9438
Histologischer Grad									
High grade (G3)	77	17 (22,1)	NE [NE; NE]	82	8 (9,8)	NE [NE; NE]	2,20	[0,98; 5,39]	0,0576
Low grade (G1+G2)	90	15 (16,7)	NE [NE; NE]	87	8 (9,2)	NE [NE; NE]	1,88	[0,81; 4,66]	0,1412
Interaktion p-Wert									0,7968
ECOG Performance Status zu Baseline									
0	135	23 (17,0)	NE [NE; NE]	126	7 (5,6)	NE [NE; NE]	3,17	[1,43; 7,99]	0,0037*
1	56	14 (25,0)	NE [NE; NE]	64	11 (17,2)	NE [NE; NE]	1,43	[0,65; 3,23]	0,3710
Interaktion p-Wert									0,1740
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	13 (16,7)	NE [NE; NE]	77	8 (10,4)	NE [NE; NE]	1,62	[0,68; 4,09]	0,2769
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SOC: Endokrine Erkrankungen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	22 (22,2)	NE [NE; NE]	101	6 (5,9)	NE [NE; NE]	4,15	[1,79; 11,28]	0,0006*
Neu diagnostiziert	92	16 (17,4)	NE [NE; NE]	89	3 (3,4)	NE [NE; NE]	5,17	[1,72; 22,23]	0,0022*
Interaktion p-Wert									0,7774
Region									
Asien	54	12 (22,2)	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	7,00	[1,91; 45,06]	0,0020*
Rest der Welt	137	26 (19,0)	NE [NE; NE]	136	7 (5,1)	NE [NE; NE]	3,76	[1,72; 9,41]	0,0006*
Interaktion p-Wert									0,4609
Alter									
<65	101	25 (24,8)	NE [NE; NE]	98	4 (4,1)	NE [NE; NE]	6,90	[2,68; 23,43]	<0,0001*
>=65	90	13 (14,4)	NE [NE; NE]	92	5 (5,4)	NE [NE; NE]	2,61	[0,98; 8,13]	0,0544
Interaktion p-Wert									0,1948
Abstammung									
Weiß	104	18 (17,3)	NE [NE; NE]	112	7 (6,3)	NE [NE; NE]	2,75	[1,20; 7,09]	0,0162*
Schwarz/Afroamerikanisch	13	2 (15,4)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	13 (22,8)	NE [NE; NE]	58	2 (3,4)	NE [NE; NE]	7,66	[2,12; 49,01]	0,0010*
Andere	16	4 (25,0)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2200
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	23 (19,5)	NE [NE; NE]	111	7 (6,3)	NE [NE; NE]	3,27	[1,48; 8,25]	0,0028*
Unbekannt	52	13 (25,0)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	8,76	[2,42; 56,04]	0,0004*
Interaktion p-Wert									0,2343
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SOC: Endokrine Erkrankungen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	23 (20,5)	NE [NE; NE]	122	5 (4,1)	NE [NE; NE]	5,12	[2,11; 15,25]	0,0001*
Negativ	73	14 (19,2)	NE [NE; NE]	67	4 (6,0)	NE [NE; NE]	3,64	[1,31; 12,85]	0,0122*
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6521
Histologie									
Endometrioid	107	19 (17,8)	NE [NE; NE]	97	6 (6,2)	NE [NE; NE]	2,91	[1,23; 7,99]	0,0139*
Serös	42	11 (26,2)	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	7,51	[2,01; 48,54]	0,0016*
Andere	42	8 (19,0)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	9,04	[1,66;167,75]	0,0078*
Interaktion p-Wert									0,4040
Histologischer Grad									
High grade (G3)	77	22 (28,6)	NE [NE; NE]	82	5 (6,1)	NE [NE; NE]	4,74	[1,94; 14,16]	0,0003*
Low grade (G1+G2)	90	13 (14,4)	NE [NE; NE]	87	3 (3,4)	NE [NE; NE]	4,56	[1,47; 19,88]	0,0071*
Interaktion p-Wert									0,9614
ECOG Performance Status zu Baseline									
0	135	29 (21,5)	NE [NE; NE]	126	6 (4,8)	NE [NE; NE]	5,02	[2,23; 13,40]	<0,0001*
1	56	9 (16,1)	NE [NE; NE]	64	3 (4,7)	NE [NE; NE]	3,27	[0,97; 14,76]	0,0553
Interaktion p-Wert									0,5994
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	12 (15,4)	NE [NE; NE]	77	3 (3,9)	NE [NE; NE]	4,03	[1,28; 17,70]	0,0157*
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hypothyreose
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	16 (16,2)	NE [NE; NE]	101	3 (3,0)	NE [NE; NE]	5,96	[1,98; 25,62]	0,0008*
Neu diagnostiziert	92	13 (14,1)	NE [NE; NE]	89	3 (3,4)	NE [NE; NE]	4,05	[1,31; 17,70]	0,0137*
Interaktion p-Wert									0,6685
Region									
Asien	54	6 (11,1)	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	3,21	[0,74; 21,92]	0,1234
Rest der Welt	137	23 (16,8)	NE [NE; NE]	136	4 (2,9)	NE [NE; NE]	5,83	[2,24; 19,90]	0,0001*
Interaktion p-Wert									0,5510
Alter									
<65	101	18 (17,8)	NE [NE; NE]	98	3 (3,1)	NE [NE; NE]	6,40	[2,17; 27,34]	0,0003*
>=65	90	11 (12,2)	NE [NE; NE]	92	3 (3,3)	NE [NE; NE]	3,63	[1,13; 16,07]	0,0288*
Interaktion p-Wert									0,5312
Abstammung									
Weiß	104	15 (14,4)	NE [NE; NE]	112	4 (3,6)	NE [NE; NE]	3,99	[1,45; 14,00]	0,0063*
Schwarz/Afroamerikanisch	13	2 (15,4)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	7 (12,3)	NE [NE; NE]	58	2 (3,4)	NE [NE; NE]	3,79	[0,92; 25,45]	0,0671
Andere	16	4 (25,0)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9587
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	18 (15,3)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	3,55	[1,41; 10,74]	0,0059*
Unbekannt	52	11 (21,2)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	14,54	[2,83;265,77]	0,0004*
Interaktion p-Wert									0,1770
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hypothyreose
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	17 (15,2)	NE [NE; NE]	122	4 (3,3)	NE [NE; NE]	4,51	[1,67; 15,69]	0,0022*
Negativ	73	11 (15,1)	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	5,80	[1,56; 37,52]	0,0067*
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7884
Histologie									
Endometrioid	107	12 (11,2)	NE [NE; NE]	97	5 (5,2)	NE [NE; NE]	2,12	[0,79; 6,68]	0,1401
Serös	42	9 (21,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	8 (19,0)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	9,31	[1,71;172,76]	0,0069*
Interaktion p-Wert									0,1699
Histologischer Grad									
High grade (G3)	77	21 (27,3)	NE [NE; NE]	82	4 (4,9)	NE [NE; NE]	5,57	[2,12; 19,11]	0,0002*
Low grade (G1+G2)	90	7 (7,8)	NE [NE; NE]	87	2 (2,3)	NE [NE; NE]	3,60	[0,87; 24,18]	0,0789
Interaktion p-Wert									0,6585
ECOG Performance Status zu Baseline									
0	135	21 (15,6)	NE [NE; NE]	126	4 (3,2)	NE [NE; NE]	5,29	[2,01; 18,13]	0,0003*
1	56	8 (14,3)	NE [NE; NE]	64	2 (3,1)	NE [NE; NE]	4,34	[1,09; 28,82]	0,0370*
Interaktion p-Wert									0,8389
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	11 (14,1)	NE [NE; NE]	77	3 (3,9)	NE [NE; NE]	3,66	[1,14; 16,19]	0,0278*
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Vaginaler Ausfluss
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	5 (5,1)	NE [NE; NE]	101	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	7 (7,6)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	2 (3,7)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	10 (7,3)	NE [NE; NE]	136	2 (1,5)	NE [NE; NE]	4,83	[1,27; 31,43]	0,0187*
Interaktion p-Wert									NC
Alter									
<65	101	5 (5,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	7 (7,8)	NE [NE; NE]	92	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	7 (6,7)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	2 (3,5)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	3 (18,8)	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	9 (7,6)	NE [NE; NE]	111	2 (1,8)	NE [NE; NE]	4,26	[1,10; 27,98]	0,0351*
Unbekannt	52	2 (3,8)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Vaginaler Ausfluss
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	6 (5,4)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	6 (8,2)	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	5 (4,7)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	6 (14,3)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	6 (7,8)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	5 (5,6)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	7 (5,2)	NE [NE; NE]	126	2 (1,6)	NE [NE; NE]	NC	[NC]	NC
1	56	5 (8,9)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	6 (7,7)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	23 (23,2)	NE [NE; NE]	101	28 (27,7)	NE [NE; NE]	0,79	[0,45; 1,37]	0,4067
Neu diagnostiziert	92	17 (18,5)	NE [NE; NE]	89	20 (22,5)	NE [NE; NE]	0,71	[0,36; 1,35]	0,2908
Interaktion p-Wert									0,7892
Region									
Asien	54	5 (9,3)	NE [NE; NE]	54	10 (18,5)	NE [NE; NE]	0,47	[0,15; 1,32]	0,1543
Rest der Welt	137	35 (25,5)	NE [NE; NE]	136	38 (27,9)	NE [NE; NE]	0,80	[0,51; 1,28]	0,3549
Interaktion p-Wert									0,3567
Alter									
<65	101	21 (20,8)	NE [NE; NE]	98	20 (20,4)	NE [NE; NE]	0,98	[0,53; 1,83]	0,9610
>=65	90	19 (21,1)	NE [NE; NE]	92	28 (30,4)	NE [NE; NE]	0,58	[0,32; 1,03]	0,0624
Interaktion p-Wert									0,2144
Abstammung									
Weiß	104	24 (23,1)	NE [NE; NE]	112	35 (31,3)	NE [NE; NE]	0,62	[0,37; 1,04]	0,0728
Schwarz/Afroamerikanisch	13	4 (30,8)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	2,82	[0,42; 55,06]	0,3108
Asiatisch	57	7 (12,3)	NE [NE; NE]	58	10 (17,2)	NE [NE; NE]	0,67	[0,24; 1,75]	0,4170
Andere	16	5 (31,3)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	1,78	[0,38; 12,40]	0,4775
Interaktion p-Wert									0,3283
HRR Mutationsstatus									
HRRm	21	3 (14,3)	NE [NE; NE]	16	4 (25,0)	NE [NE; NE]	0,43	[0,08; 1,94]	0,2640
Nicht-HRRm	118	28 (23,7)	NE [NE; NE]	111	27 (24,3)	NE [NE; NE]	0,91	[0,54; 1,56]	0,7397
Unbekannt	52	9 (17,3)	NE [NE; NE]	63	17 (27,0)	NE [NE; NE]	0,57	[0,24; 1,25]	0,1645
Interaktion p-Wert									0,4641
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	23 (20,5)	NE [NE; NE]	122	32 (26,2)	NE [NE; NE]	0,66	[0,38; 1,13]	0,1283
Negativ	73	16 (21,9)	NE [NE; NE]	67	16 (23,9)	NE [NE; NE]	0,93	[0,46; 1,87]	0,8394
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4438
Histologie									
Endometrioid	107	18 (16,8)	NE [NE; NE]	97	23 (23,7)	NE [NE; NE]	0,63	[0,33; 1,16]	0,1346
Serös	42	14 (33,3)	NE [NE; NE]	52	14 (26,9)	NE [NE; NE]	1,17	[0,55; 2,47]	0,6866
Andere	42	8 (19,0)	NE [NE; NE]	41	11 (26,8)	NE [NE; NE]	0,66	[0,26; 1,64]	0,3767
Interaktion p-Wert									0,4211
Histologischer Grad									
High grade (G3)	77	19 (24,7)	NE [NE; NE]	82	26 (31,7)	NE [NE; NE]	0,63	[0,35; 1,14]	0,1306
Low grade (G1+G2)	90	18 (20,0)	NE [NE; NE]	87	20 (23,0)	NE [NE; NE]	0,83	[0,43; 1,56]	0,5558
Interaktion p-Wert									0,5534
ECOG Performance Status zu Baseline									
0	135	24 (17,8)	NE [NE; NE]	126	30 (23,8)	NE [NE; NE]	0,70	[0,41; 1,20]	0,1994
1	56	16 (28,6)	NE [NE; NE]	64	18 (28,1)	NE [NE; NE]	0,83	[0,42; 1,64]	0,5938
Interaktion p-Wert									0,7041
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	3 (30,0)	NE [NE; NE]	0,20	[0,01; 1,55]	0,1244
IV	78	16 (20,5)	NE [NE; NE]	77	17 (22,1)	NE [NE; NE]	0,84	[0,42; 1,68]	0,6235
Interaktion p-Wert									0,1941

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.1.2.1D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Thrombozytopenie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	15 (15,2)	NE [NE; NE]	101	7 (6,9)	NE [NE; NE]	2,27	[0,96; 5,95]	0,0628
Neu diagnostiziert	92	16 (17,4)	NE [NE; NE]	89	7 (7,9)	NE [NE; NE]	2,24	[0,96; 5,84]	0,0632
Interaktion p-Wert									0,9847
Region									
Asien	54	4 (7,4)	NE [NE; NE]	54	4 (7,4)	NE [NE; NE]	1,03	[0,24; 4,35]	0,9683
Rest der Welt	137	27 (19,7)	NE [NE; NE]	136	10 (7,4)	NE [NE; NE]	2,76	[1,38; 5,98]	0,0036*
Interaktion p-Wert									0,2200
Alter									
<65	101	20 (19,8)	NE [NE; NE]	98	11 (11,2)	NE [NE; NE]	1,87	[0,91; 4,05]	0,0870
>=65	90	11 (12,2)	NE [NE; NE]	92	3 (3,3)	NE [NE; NE]	3,72	[1,16; 16,45]	0,0257*
Interaktion p-Wert									0,3473
Abstammung									
Weiß	104	19 (18,3)	NE [NE; NE]	112	7 (6,3)	NE [NE; NE]	3,01	[1,32; 7,70]	0,0079*
Schwarz/Afroamerikanisch	13	4 (30,8)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	3,10	[0,46; 60,63]	0,2648
Asiatisch	57	5 (8,8)	NE [NE; NE]	58	4 (6,9)	NE [NE; NE]	1,31	[0,35; 5,27]	0,6902
Andere	16	3 (18,8)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	0,91	[0,15; 6,95]	0,9224
Interaktion p-Wert									0,5598
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	18 (15,3)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	3,53	[1,41; 10,71]	0,0060*
Unbekannt	52	11 (21,2)	NE [NE; NE]	63	9 (14,3)	NE [NE; NE]	1,47	[0,61; 3,65]	0,3878
Interaktion p-Wert									0,1876
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Thrombozytopenie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	19 (17,0)	NE [NE; NE]	122	8 (6,6)	NE [NE; NE]	2,62	[1,19; 6,35]	0,0165*
Negativ	73	10 (13,7)	NE [NE; NE]	67	6 (9,0)	NE [NE; NE]	1,60	[0,59; 4,70]	0,3572
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4605
Histologie									
Endometrioid	107	17 (15,9)	NE [NE; NE]	97	9 (9,3)	NE [NE; NE]	1,66	[0,76; 3,90]	0,2088
Serös	42	6 (14,3)	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	3,90	[0,90; 26,63]	0,0700
Andere	42	8 (19,0)	NE [NE; NE]	41	3 (7,3)	NE [NE; NE]	3,03	[0,88; 13,83]	0,0813
Interaktion p-Wert									0,5436
Histologischer Grad									
High grade (G3)	77	16 (20,8)	NE [NE; NE]	82	6 (7,3)	NE [NE; NE]	2,81	[1,16; 7,84]	0,0218*
Low grade (G1+G2)	90	12 (13,3)	NE [NE; NE]	87	4 (4,6)	NE [NE; NE]	3,03	[1,06; 10,86]	0,0386*
Interaktion p-Wert									0,9195
ECOG Performance Status zu Baseline									
0	135	17 (12,6)	NE [NE; NE]	126	7 (5,6)	NE [NE; NE]	2,39	[1,03; 6,18]	0,0421*
1	56	14 (25,0)	NE [NE; NE]	64	7 (10,9)	NE [NE; NE]	2,24	[0,93; 5,92]	0,0715
Interaktion p-Wert									0,9222
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	12 (15,4)	NE [NE; NE]	77	7 (9,1)	NE [NE; NE]	1,71	[0,69; 4,59]	0,2536
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hypotonie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	5 (5,1)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	5 (5,4)	NE [NE; NE]	89	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	2 (3,7)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	8 (5,8)	NE [NE; NE]	136	2 (1,5)	NE [NE; NE]	3,66	[0,91; 24,32]	0,0686
Interaktion p-Wert									NC
Alter									
<65	101	5 (5,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	5 (5,6)	NE [NE; NE]	92	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	6 (5,8)	NE [NE; NE]	112	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	2 (3,5)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	1 (6,3)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	7 (5,9)	NE [NE; NE]	111	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	2 (3,8)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hypotonie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	6 (5,4)	NE [NE; NE]	122	2 (1,6)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	4 (5,5)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	3 (2,8)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	3 (7,1)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	4 (9,5)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	7 (9,1)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	2 (2,2)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	8 (5,9)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	2 (3,6)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	5 (6,4)	NE [NE; NE]	77	2 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SOC: Leber- und Gallenerkrankungen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	3 (3,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	7 (7,6)	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	4 (7,4)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	6 (4,4)	NE [NE; NE]	136	2 (1,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	4 (4,0)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	6 (6,7)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	5 (4,8)	NE [NE; NE]	112	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	4 (7,0)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	1 (6,3)	NE [NE; NE]	0,71	[0,03; 17,97]	0,8097
Nicht-HRRm	118	9 (7,6)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	8,50	[1,60;156,68]	0,0086*
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1642
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SOC: Leber- und Gallenerkrankungen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	8 (7,1)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	2 (2,7)	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	7 (6,5)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	2 (4,8)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	4 (5,2)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	6 (6,7)	NE [NE; NE]	87	2 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	10 (7,4)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	9,72	[1,86;178,40]	0,0040*
1	56	0	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	4 (5,1)	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Lipase erhoeht
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	6 (5,9)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	4 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	0,47	[0,02; 4,96]	0,5302
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	8 (5,9)	NE [NE; NE]	0,22	[0,03; 0,86]	0,0291*
Interaktion p-Wert									0,5960
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	7 (7,1)	NE [NE; NE]	NC	[NC]	NC
>=65	90	2 (2,2)	NE [NE; NE]	92	3 (3,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	6 (5,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	3 (5,2)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	1 (6,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	2 (1,7)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	4 (6,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.1D.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Lipase erhoeht
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	3 (2,7)	NE [NE; NE]	122	7 (5,7)	NE [NE; NE]	0,44	[0,10; 1,60]	0,2191
Negativ	73	0	NE [NE; NE]	67	3 (4,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	7 (7,2)	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	2 (2,6)	NE [NE; NE]	82	5 (6,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	4 (4,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	7 (5,6)	NE [NE; NE]	NC	[NC]	NC
1	56	1 (1,8)	NE [NE; NE]	64	3 (4,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	1 (1,3)	NE [NE; NE]	77	4 (5,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	98 (99,0)	0,1 [0,1; 0,1]	101	101 (100)	0,1 [0,1; 0,1]	0,98	[0,74; 1,29]	0,8691
Neu diagnostiziert	92	92 (100)	0,1 [0,1; 0,2]	89	89 (100)	0,1 [0,1; 0,1]	0,93	[0,69; 1,25]	0,6382
Interaktion p-Wert									0,8213
Region									
Asien	54	54 (100)	0,1 [0,1; 0,1]	54	54 (100)	0,1 [0,1; 0,1]	1,03	[0,71; 1,51]	0,8728
Rest der Welt	137	136 (99,3)	0,1 [0,1; 0,1]	136	136 (100)	0,1 [0,1; 0,1]	0,93	[0,73; 1,18]	0,5676
Interaktion p-Wert									0,6596
Alter									
<65	101	100 (99,0)	0,1 [0,1; 0,1]	98	98 (100)	0,1 [0,1; 0,1]	0,89	[0,68; 1,18]	0,4302
>=65	90	90 (100)	0,1 [0,1; 0,1]	92	92 (100)	0,1 [0,1; 0,2]	1,02	[0,76; 1,36]	0,9101
Interaktion p-Wert									0,5298
Abstammung									
Weiß	104	103 (99,0)	0,1 [0,1; 0,2]	112	112 (100)	0,1 [0,1; 0,1]	0,89	[0,68; 1,16]	0,3867
Schwarz/Afroamerikanisch	13	13 (100)	0,1 [0,0; 0,1]	8	8 (100)	0,1 [0,0; 0,1]	1,02	[0,43; 2,57]	0,9722
Asiatisch	57	57 (100)	0,1 [0,1; 0,1]	58	58 (100)	0,1 [0,1; 0,1]	1,03	[0,72; 1,49]	0,8553
Andere	16	16 (100)	0,1 [0,1; 0,2]	12	12 (100)	0,1 [0,0; 0,6]	1,16	[0,55; 2,51]	0,6993
Interaktion p-Wert									0,8638
HRR Mutationsstatus									
HRRm	21	21 (100)	0,1 [0,1; 0,1]	16	16 (100)	0,1 [0,1; 0,7]	1,46	[0,77; 2,85]	0,2485
Nicht-HRRm	118	117 (99,2)	0,1 [0,1; 0,1]	111	111 (100)	0,1 [0,1; 0,1]	0,80	[0,62; 1,04]	0,0961
Unbekannt	52	52 (100)	0,1 [0,1; 0,1]	63	63 (100)	0,1 [0,1; 0,2]	1,15	[0,80; 1,66]	0,4482
Interaktion p-Wert									0,1101
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	112 (100)	0,1 [0,1; 0,1]	122	122 (100)	0,1 [0,1; 0,1]	0,95	[0,73; 1,23]	0,6849
Negativ	73	72 (98,6)	0,1 [0,1; 0,2]	67	67 (100)	0,1 [0,1; 0,1]	0,95	[0,68; 1,33]	0,7738
Unbekannt	6	6 (100)	0,1 [0,0; NE]	1	1 (100)	0,0 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9843
Histologie									
Endometrioid	107	107 (100)	0,1 [0,1; 0,1]	97	97 (100)	0,1 [0,1; 0,1]	0,95	[0,72; 1,25]	0,7184
Serös	42	42 (100)	0,1 [0,1; 0,2]	52	52 (100)	0,1 [0,1; 0,1]	0,86	[0,57; 1,29]	0,4703
Andere	42	41 (97,6)	0,1 [0,1; 0,1]	41	41 (100)	0,1 [0,1; 0,3]	1,08	[0,70; 1,66]	0,7414
Interaktion p-Wert									0,7643
Histologischer Grad									
High grade (G3)	77	77 (100)	0,1 [0,1; 0,1]	82	82 (100)	0,1 [0,1; 0,1]	0,97	[0,71; 1,32]	0,8356
Low grade (G1+G2)	90	90 (100)	0,1 [0,1; 0,1]	87	87 (100)	0,1 [0,1; 0,1]	1,00	[0,75; 1,35]	0,9786
Interaktion p-Wert									0,8661
ECOG Performance Status zu Baseline									
0	135	134 (99,3)	0,1 [0,1; 0,1]	126	126 (100)	0,1 [0,1; 0,1]	0,88	[0,69; 1,12]	0,3050
1	56	56 (100)	0,1 [0,1; 0,1]	64	64 (100)	0,1 [0,1; 0,1]	1,13	[0,79; 1,62]	0,5105
Interaktion p-Wert									0,2632
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	11 (100)	0,1 [0,0; 0,2]	10	10 (100)	0,7 [0,0; 1,0]	2,75	[1,14; 6,70]	0,0243*
IV	78	78 (100)	0,1 [0,1; 0,2]	77	77 (100)	0,1 [0,0; 0,1]	0,80	[0,58; 1,11]	0,1836
Interaktion p-Wert									0,0101*

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Asthenie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	22 (22,2)	NE [NE; NE]	101	10 (9,9)	NE [NE; NE]	2,32	[1,13; 5,11]	0,0220*
Neu diagnostiziert	92	16 (17,4)	NE [NE; NE]	89	8 (9,0)	NE [NE; NE]	1,86	[0,82; 4,60]	0,1413
Interaktion p-Wert									0,7063
Region									
Asien	54	8 (14,8)	NE [NE; NE]	54	3 (5,6)	NE [NE; NE]	2,71	[0,79; 12,40]	0,1175
Rest der Welt	137	30 (21,9)	NE [NE; NE]	136	15 (11,0)	NE [NE; NE]	1,97	[1,07; 3,76]	0,0283*
Interaktion p-Wert									0,6601
Alter									
<65	101	19 (18,8)	NE [NE; NE]	98	6 (6,1)	NE [NE; NE]	3,20	[1,35; 8,79]	0,0072*
>=65	90	19 (21,1)	NE [NE; NE]	92	12 (13,0)	NE [NE; NE]	1,54	[0,76; 3,27]	0,2364
Interaktion p-Wert									0,2125
Abstammung									
Weiß	104	22 (21,2)	NE [NE; NE]	112	12 (10,7)	NE [NE; NE]	1,93	[0,97; 4,03]	0,0616
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	8 (14,0)	NE [NE; NE]	58	3 (5,2)	NE [NE; NE]	2,73	[0,79; 12,47]	0,1158
Andere	16	5 (31,3)	NE [NE; NE]	12	3 (25,0)	NE [NE; NE]	1,12	[0,27; 5,45]	0,8787
Interaktion p-Wert									0,6695
HRR Mutationsstatus									
HRRm	21	3 (14,3)	NE [NE; NE]	16	4 (25,0)	NE [NE; NE]	0,47	[0,09; 2,12]	0,3155
Nicht-HRRm	118	25 (21,2)	NE [NE; NE]	111	8 (7,2)	NE [NE; NE]	3,05	[1,44; 7,23]	0,0031*
Unbekannt	52	10 (19,2)	NE [NE; NE]	63	6 (9,5)	NE [NE; NE]	2,01	[0,74; 5,90]	0,1695
Interaktion p-Wert									0,0951
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Asthenie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	26 (23,2)	NE [NE; NE]	122	12 (9,8)	NE [NE; NE]	2,29	[1,18; 4,72]	0,0139*
Negativ	73	11 (15,1)	NE [NE; NE]	67	6 (9,0)	NE [NE; NE]	1,76	[0,67; 5,12]	0,2531
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6722
Histologie									
Endometrioid	107	21 (19,6)	NE [NE; NE]	97	9 (9,3)	NE [NE; NE]	2,11	[0,99; 4,85]	0,0517
Serös	42	10 (23,8)	NE [NE; NE]	52	5 (9,6)	NE [NE; NE]	2,51	[0,89; 8,06]	0,0825
Andere	42	7 (16,7)	NE [NE; NE]	41	4 (9,8)	NE [NE; NE]	1,71	[0,51; 6,52]	0,3861
Interaktion p-Wert									0,8984
Histologischer Grad									
High grade (G3)	77	17 (22,1)	NE [NE; NE]	82	8 (9,8)	NE [NE; NE]	2,16	[0,96; 5,31]	0,0631
Low grade (G1+G2)	90	16 (17,8)	NE [NE; NE]	87	8 (9,2)	NE [NE; NE]	1,97	[0,86; 4,85]	0,1081
Interaktion p-Wert									0,8766
ECOG Performance Status zu Baseline									
0	135	24 (17,8)	NE [NE; NE]	126	7 (5,6)	NE [NE; NE]	3,26	[1,48; 8,19]	0,0027*
1	56	14 (25,0)	NE [NE; NE]	64	11 (17,2)	NE [NE; NE]	1,41	[0,64; 3,19]	0,3917
Interaktion p-Wert									0,1503
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	13 (16,7)	NE [NE; NE]	77	8 (10,4)	NE [NE; NE]	1,62	[0,68; 4,09]	0,2769
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SOC: Endokrine Erkrankungen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	25 (25,3)	NE [NE; NE]	101	6 (5,9)	NE [NE; NE]	4,62	[2,02; 12,43]	0,0001*
Neu diagnostiziert	92	17 (18,5)	NE [NE; NE]	89	3 (3,4)	NE [NE; NE]	5,20	[1,74; 22,31]	0,0019*
Interaktion p-Wert									0,8766
Region									
Asien	54	13 (24,1)	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	7,51	[2,08; 48,06]	0,0011*
Rest der Welt	137	29 (21,2)	NE [NE; NE]	136	7 (5,1)	NE [NE; NE]	4,00	[1,85; 9,94]	0,0002*
Interaktion p-Wert									0,4510
Alter									
<65	101	26 (25,7)	NE [NE; NE]	98	4 (4,1)	NE [NE; NE]	6,93	[2,70; 23,50]	<0,0001*
>=65	90	16 (17,8)	NE [NE; NE]	92	5 (5,4)	NE [NE; NE]	3,09	[1,21; 9,44]	0,0175*
Interaktion p-Wert									0,2742
Abstammung									
Weiß	104	20 (19,2)	NE [NE; NE]	112	7 (6,3)	NE [NE; NE]	2,93	[1,29; 7,48]	0,0091*
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	14 (24,6)	NE [NE; NE]	58	2 (3,4)	NE [NE; NE]	8,12	[2,27; 51,71]	0,0005*
Andere	16	4 (25,0)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2177
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	24 (20,3)	NE [NE; NE]	111	7 (6,3)	NE [NE; NE]	3,32	[1,50; 8,34]	0,0023*
Unbekannt	52	16 (30,8)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	10,38	[2,95; 65,68]	<0,0001*
Interaktion p-Wert									0,1593
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SOC: Endokrine Erkrankungen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	26 (23,2)	NE [NE; NE]	122	5 (4,1)	NE [NE; NE]	5,44	[2,27; 16,13]	<0,0001*
Negativ	73	15 (20,5)	NE [NE; NE]	67	4 (6,0)	NE [NE; NE]	3,92	[1,42; 13,74]	0,0071*
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6597
Histologie									
Endometrioid	107	22 (20,6)	NE [NE; NE]	97	6 (6,2)	NE [NE; NE]	3,26	[1,40; 8,85]	0,0049*
Serös	42	12 (28,6)	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	7,72	[2,10; 49,69]	0,0011*
Andere	42	8 (19,0)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	8,96	[1,64;166,22]	0,0081*
Interaktion p-Wert									0,4730
Histologischer Grad									
High grade (G3)	77	23 (29,9)	NE [NE; NE]	82	5 (6,1)	NE [NE; NE]	4,79	[1,97; 14,28]	0,0003*
Low grade (G1+G2)	90	16 (17,8)	NE [NE; NE]	87	3 (3,4)	NE [NE; NE]	5,36	[1,78; 23,08]	0,0017*
Interaktion p-Wert									0,8873
ECOG Performance Status zu Baseline									
0	135	31 (23,0)	NE [NE; NE]	126	6 (4,8)	NE [NE; NE]	5,21	[2,33; 13,86]	<0,0001*
1	56	11 (19,6)	NE [NE; NE]	64	3 (4,7)	NE [NE; NE]	3,79	[1,18; 16,80]	0,0238*
Interaktion p-Wert									0,6915
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	13 (16,7)	NE [NE; NE]	77	3 (3,9)	NE [NE; NE]	4,15	[1,33; 18,16]	0,0125*
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hyperthyroidismus
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	6 (6,1)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	4 (4,3)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	5 (9,3)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	5 (3,6)	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	7 (6,9)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	3 (3,3)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	4 (3,8)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	5 (8,8)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	3 (2,5)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	6 (11,5)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hyperthyroidismus
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	7 (6,3)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	3 (4,1)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	7 (6,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	3 (7,1)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	3 (3,9)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	5 (5,6)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	6 (4,4)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	4 (7,1)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.1.2.2D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hypothyreose
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	17 (17,2)	NE [NE; NE]	101	3 (3,0)	NE [NE; NE]	6,20	[2,08; 26,59]	0,0005*
Neu diagnostiziert	92	14 (15,2)	NE [NE; NE]	89	3 (3,4)	NE [NE; NE]	4,17	[1,36; 18,11]	0,0109*
Interaktion p-Wert									0,6562
Region									
Asien	54	6 (11,1)	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	3,18	[0,73; 21,70]	0,1268
Rest der Welt	137	25 (18,2)	NE [NE; NE]	136	4 (2,9)	NE [NE; NE]	6,08	[2,35; 20,68]	<0,0001*
Interaktion p-Wert									0,5174
Alter									
<65	101	19 (18,8)	NE [NE; NE]	98	3 (3,1)	NE [NE; NE]	6,55	[2,23; 27,91]	0,0002*
>=65	90	12 (13,3)	NE [NE; NE]	92	3 (3,3)	NE [NE; NE]	3,83	[1,22; 16,84]	0,0203*
Interaktion p-Wert									0,5505
Abstammung									
Weiß	104	17 (16,3)	NE [NE; NE]	112	4 (3,6)	NE [NE; NE]	4,31	[1,59; 15,01]	0,0031*
Schwarz/Afroamerikanisch	13	2 (15,4)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	7 (12,3)	NE [NE; NE]	58	2 (3,4)	NE [NE; NE]	3,71	[0,90; 24,91]	0,0720
Andere	16	4 (25,0)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8785
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	19 (16,1)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	3,64	[1,46; 11,00]	0,0044*
Unbekannt	52	12 (23,1)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	15,29	[3,01;278,56]	0,0002*
Interaktion p-Wert									0,1671
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hypothyreose
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	18 (16,1)	NE [NE; NE]	122	4 (3,3)	NE [NE; NE]	4,54	[1,69; 15,74]	0,0019*
Negativ	73	12 (16,4)	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	6,32	[1,72; 40,64]	0,0037*
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7218
Histologie									
Endometrioid	107	14 (13,1)	NE [NE; NE]	97	5 (5,2)	NE [NE; NE]	2,39	[0,91; 7,41]	0,0770
Serös	42	9 (21,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	8 (19,0)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	9,07	[1,66;168,27]	0,0077*
Interaktion p-Wert									0,2168
Histologischer Grad									
High grade (G3)	77	21 (27,3)	NE [NE; NE]	82	4 (4,9)	NE [NE; NE]	5,43	[2,06; 18,62]	0,0003*
Low grade (G1+G2)	90	9 (10,0)	NE [NE; NE]	87	2 (2,3)	NE [NE; NE]	4,44	[1,14; 29,14]	0,0300*
Interaktion p-Wert									0,8345
ECOG Performance Status zu Baseline									
0	135	23 (17,0)	NE [NE; NE]	126	4 (3,2)	NE [NE; NE]	5,62	[2,16; 19,18]	0,0002*
1	56	8 (14,3)	NE [NE; NE]	64	2 (3,1)	NE [NE; NE]	4,19	[1,05; 27,78]	0,0426*
Interaktion p-Wert									0,7610
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	12 (15,4)	NE [NE; NE]	77	3 (3,9)	NE [NE; NE]	3,78	[1,19; 16,66]	0,0223*
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Vaginaler Ausfluss
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	5 (5,1)	NE [NE; NE]	101	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	7 (7,6)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	2 (3,7)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	10 (7,3)	NE [NE; NE]	136	2 (1,5)	NE [NE; NE]	4,83	[1,27; 31,43]	0,0187*
Interaktion p-Wert									NC
Alter									
<65	101	5 (5,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	7 (7,8)	NE [NE; NE]	92	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	7 (6,7)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	2 (3,5)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	3 (18,8)	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	9 (7,6)	NE [NE; NE]	111	2 (1,8)	NE [NE; NE]	4,26	[1,10; 27,98]	0,0351*
Unbekannt	52	2 (3,8)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Vaginaler Ausfluss
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	6 (5,4)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	6 (8,2)	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	5 (4,7)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	6 (14,3)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	6 (7,8)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	5 (5,6)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	7 (5,2)	NE [NE; NE]	126	2 (1,6)	NE [NE; NE]	NC	[NC]	NC
1	56	5 (8,9)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	6 (7,7)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.1.2.2D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Thrombozytopenie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	15 (15,2)	NE [NE; NE]	101	7 (6,9)	NE [NE; NE]	2,27	[0,96; 5,95]	0,0630
Neu diagnostiziert	92	16 (17,4)	NE [NE; NE]	89	7 (7,9)	NE [NE; NE]	2,24	[0,96; 5,84]	0,0632
Interaktion p-Wert									0,9853
Region									
Asien	54	4 (7,4)	NE [NE; NE]	54	4 (7,4)	NE [NE; NE]	1,03	[0,24; 4,35]	0,9683
Rest der Welt	137	27 (19,7)	NE [NE; NE]	136	10 (7,4)	NE [NE; NE]	2,75	[1,38; 5,98]	0,0037*
Interaktion p-Wert									0,2202
Alter									
<65	101	20 (19,8)	NE [NE; NE]	98	11 (11,2)	NE [NE; NE]	1,87	[0,91; 4,05]	0,0870
>=65	90	11 (12,2)	NE [NE; NE]	92	3 (3,3)	NE [NE; NE]	3,72	[1,16; 16,44]	0,0258*
Interaktion p-Wert									0,3477
Abstammung									
Weiß	104	19 (18,3)	NE [NE; NE]	112	7 (6,3)	NE [NE; NE]	3,01	[1,32; 7,70]	0,0079*
Schwarz/Afroamerikanisch	13	4 (30,8)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	3,10	[0,46; 60,63]	0,2648
Asiatisch	57	5 (8,8)	NE [NE; NE]	58	4 (6,9)	NE [NE; NE]	1,30	[0,35; 5,27]	0,6912
Andere	16	3 (18,8)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	0,91	[0,15; 6,94]	0,9223
Interaktion p-Wert									0,5594
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	18 (15,3)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	3,53	[1,41; 10,70]	0,0060*
Unbekannt	52	11 (21,2)	NE [NE; NE]	63	9 (14,3)	NE [NE; NE]	1,47	[0,61; 3,65]	0,3878
Interaktion p-Wert									0,1879
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Thrombozytopenie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	19 (17,0)	NE [NE; NE]	122	8 (6,6)	NE [NE; NE]	2,62	[1,19; 6,35]	0,0166*
Negativ	73	10 (13,7)	NE [NE; NE]	67	6 (9,0)	NE [NE; NE]	1,60	[0,59; 4,70]	0,3572
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4609
Histologie									
Endometrioid	107	17 (15,9)	NE [NE; NE]	97	9 (9,3)	NE [NE; NE]	1,66	[0,76; 3,90]	0,2088
Serös	42	6 (14,3)	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	3,90	[0,90; 26,61]	0,0702
Andere	42	8 (19,0)	NE [NE; NE]	41	3 (7,3)	NE [NE; NE]	3,03	[0,88; 13,83]	0,0813
Interaktion p-Wert									0,5441
Histologischer Grad									
High grade (G3)	77	16 (20,8)	NE [NE; NE]	82	6 (7,3)	NE [NE; NE]	2,81	[1,16; 7,84]	0,0218*
Low grade (G1+G2)	90	12 (13,3)	NE [NE; NE]	87	4 (4,6)	NE [NE; NE]	3,03	[1,06; 10,85]	0,0387*
Interaktion p-Wert									0,9201
ECOG Performance Status zu Baseline									
0	135	17 (12,6)	NE [NE; NE]	126	7 (5,6)	NE [NE; NE]	2,39	[1,03; 6,18]	0,0421*
1	56	14 (25,0)	NE [NE; NE]	64	7 (10,9)	NE [NE; NE]	2,24	[0,93; 5,91]	0,0718
Interaktion p-Wert									0,9211
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	12 (15,4)	NE [NE; NE]	77	7 (9,1)	NE [NE; NE]	1,71	[0,69; 4,59]	0,2536
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hypotonie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	5 (5,1)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	5 (5,4)	NE [NE; NE]	89	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	2 (3,7)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	8 (5,8)	NE [NE; NE]	136	2 (1,5)	NE [NE; NE]	3,68	[0,92; 24,45]	0,0672
Interaktion p-Wert									NC
Alter									
<65	101	5 (5,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	5 (5,6)	NE [NE; NE]	92	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	6 (5,8)	NE [NE; NE]	112	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	2 (3,5)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	1 (6,3)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	7 (5,9)	NE [NE; NE]	111	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	2 (3,8)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hypotonie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	6 (5,4)	NE [NE; NE]	122	2 (1,6)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	4 (5,5)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	3 (2,8)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	3 (7,1)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	4 (9,5)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	7 (9,1)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	2 (2,2)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	8 (5,9)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	2 (3,6)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	5 (6,4)	NE [NE; NE]	77	2 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SOC: Leber- und Gallenerkrankungen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	3 (3,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	7 (7,6)	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	4 (7,4)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	6 (4,4)	NE [NE; NE]	136	2 (1,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	4 (4,0)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	6 (6,7)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	5 (4,8)	NE [NE; NE]	112	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	4 (7,0)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	1 (6,3)	NE [NE; NE]	0,71	[0,03; 17,97]	0,8097
Nicht-HRRm	118	9 (7,6)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	8,50	[1,60;156,68]	0,0086*
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1642
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SOC: Leber- und Gallenerkrankungen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	8 (7,1)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	2 (2,7)	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	7 (6,5)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	2 (4,8)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	4 (5,2)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	6 (6,7)	NE [NE; NE]	87	2 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	10 (7,4)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	9,72	[1,86;178,40]	0,0040*
1	56	0	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	3 (27,3)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	4 (5,1)	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hypokaliaemie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	17 (17,2)	NE [NE; NE]	101	10 (9,9)	NE [NE; NE]	1,76	[0,82; 4,00]	0,1468
Neu diagnostiziert	92	11 (12,0)	NE [NE; NE]	89	5 (5,6)	NE [NE; NE]	2,12	[0,77; 6,74]	0,1490
Interaktion p-Wert									0,7838
Region									
Asien	54	5 (9,3)	NE [NE; NE]	54	4 (7,4)	NE [NE; NE]	1,29	[0,34; 5,22]	0,7025
Rest der Welt	137	23 (16,8)	NE [NE; NE]	136	11 (8,1)	NE [NE; NE]	2,07	[1,03; 4,42]	0,0404*
Interaktion p-Wert									0,5384
Alter									
<65	101	9 (8,9)	NE [NE; NE]	98	8 (8,2)	NE [NE; NE]	1,11	[0,42; 2,94]	0,8371
>=65	90	19 (21,1)	NE [NE; NE]	92	7 (7,6)	NE [NE; NE]	2,79	[1,22; 7,14]	0,0138*
Interaktion p-Wert									0,1563
Abstammung									
Weiß	104	18 (17,3)	NE [NE; NE]	112	8 (7,1)	NE [NE; NE]	2,45	[1,10; 5,97]	0,0281*
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	2 (25,0)	NE [NE; NE]	0,92	[0,15; 6,98]	0,9263
Asiatisch	57	5 (8,8)	NE [NE; NE]	58	5 (8,6)	NE [NE; NE]	1,04	[0,29; 3,74]	0,9508
Andere	16	2 (12,5)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4090
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	1 (6,3)	NE [NE; NE]	0,70	[0,03; 17,81]	0,8046
Nicht-HRRm	118	19 (16,1)	NE [NE; NE]	111	10 (9,0)	NE [NE; NE]	1,84	[0,88; 4,13]	0,1085
Unbekannt	52	8 (15,4)	NE [NE; NE]	63	4 (6,3)	NE [NE; NE]	2,42	[0,76; 9,05]	0,1363
Interaktion p-Wert									0,7273
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.1.2.2D.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first PT: Hypokaliaemie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	15 (13,4)	NE [NE; NE]	122	10 (8,2)	NE [NE; NE]	1,57	[0,71; 3,61]	0,2675
Negativ	73	9 (12,3)	NE [NE; NE]	67	5 (7,5)	NE [NE; NE]	1,75	[0,60; 5,69]	0,3071
Unbekannt	6	4 (66,7)	3,5 [1,1; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8750
Histologie									
Endometrioid	107	13 (12,1)	NE [NE; NE]	97	8 (8,2)	NE [NE; NE]	1,41	[0,59; 3,56]	0,4412
Serös	42	4 (9,5)	NE [NE; NE]	52	6 (11,5)	NE [NE; NE]	0,80	[0,21; 2,81]	0,7321
Andere	42	11 (26,2)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	13,12	[2,55;239,89]	0,0007*
Interaktion p-Wert									0,0183*
Histologischer Grad									
High grade (G3)	77	13 (16,9)	NE [NE; NE]	82	8 (9,8)	NE [NE; NE]	1,67	[0,70; 4,22]	0,2478
Low grade (G1+G2)	90	10 (11,1)	NE [NE; NE]	87	6 (6,9)	NE [NE; NE]	1,63	[0,60; 4,79]	0,3388
Interaktion p-Wert									0,9701
ECOG Performance Status zu Baseline									
0	135	16 (11,9)	NE [NE; NE]	126	8 (6,3)	NE [NE; NE]	1,92	[0,85; 4,75]	0,1204
1	56	12 (21,4)	NE [NE; NE]	64	7 (10,9)	NE [NE; NE]	1,90	[0,76; 5,11]	0,1701
Interaktion p-Wert									0,9837
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	10 (12,8)	NE [NE; NE]	77	5 (6,5)	NE [NE; NE]	2,08	[0,74; 6,66]	0,1693
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.2.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	37 (37,4)	NE [NE; NE]	101	32 (31,7)	NE [NE; NE]	1,23	[0,77; 1,98]	0,3943
Neu diagnostiziert	92	32 (34,8)	24,7 [15,6; NE]	89	26 (29,2)	NE [NE; NE]	1,05	[0,62; 1,77]	0,8662
Interaktion p-Wert									0,6533
Region									
Asien	54	21 (38,9)	NE [NE; NE]	54	19 (35,2)	NE [NE; NE]	1,13	[0,61; 2,13]	0,6928
Rest der Welt	137	48 (35,0)	24,7 [15,6; NE]	136	39 (28,7)	NE [NE; NE]	1,15	[0,75; 1,76]	0,5250
Interaktion p-Wert									0,9752
Alter									
<65	101	34 (33,7)	24,7 [14,1; NE]	98	26 (26,5)	NE [NE; NE]	1,28	[0,77; 2,16]	0,3346
>=65	90	35 (38,9)	NE [NE; NE]	92	32 (34,8)	NE [NE; NE]	1,01	[0,63; 1,64]	0,9622
Interaktion p-Wert									0,5037
Abstammung									
Weiß	104	35 (33,7)	24,7 [15,6; NE]	112	31 (27,7)	NE [NE; NE]	1,13	[0,70; 1,85]	0,6094
Schwarz/Afroamerikanisch	13	6 (46,2)	14,1 [1,3; NE]	8	2 (25,0)	NE [NE; NE]	2,17	[0,50; 14,83]	0,3169
Asiatisch	57	23 (40,4)	NE [NE; NE]	58	20 (34,5)	NE [NE; NE]	1,20	[0,66; 2,21]	0,5477
Andere	16	5 (31,3)	NE [NE; NE]	12	5 (41,7)	10,6 [0,6; NE]	0,58	[0,16; 2,07]	0,3859
Interaktion p-Wert									0,6032
HRR Mutationsstatus									
HRRm	21	8 (38,1)	NE [NE; NE]	16	4 (25,0)	NE [NE; NE]	1,45	[0,46; 5,45]	0,5339
Nicht-HRRm	118	43 (36,4)	24,7 [14,1; NE]	111	39 (35,1)	NE [NE; NE]	0,96	[0,62; 1,48]	0,8451
Unbekannt	52	18 (34,6)	NE [NE; NE]	63	15 (23,8)	NE [NE; NE]	1,53	[0,77; 3,08]	0,2227
Interaktion p-Wert									0,4757
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.2.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	41 (36,6)	24,7 [24,7; NE]	122	34 (27,9)	NE [NE; NE]	1,21	[0,77; 1,91]	0,4208
Negativ	73	24 (32,9)	NE [NE; NE]	67	24 (35,8)	NE [NE; NE]	0,93	[0,53; 1,65]	0,8103
Unbekannt	6	4 (66,7)	3,4 [1,8; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4897
Histologie									
Endometrioid	107	40 (37,4)	NE [NE; NE]	97	31 (32,0)	NE [NE; NE]	1,15	[0,72; 1,85]	0,5572
Serös	42	16 (38,1)	NE [NE; NE]	52	15 (28,8)	NE [NE; NE]	1,24	[0,61; 2,54]	0,5486
Andere	42	13 (31,0)	24,7 [24,7; NE]	41	12 (29,3)	NE [NE; NE]	0,98	[0,44; 2,18]	0,9625
Interaktion p-Wert									0,9066
Histologischer Grad									
High grade (G3)	77	29 (37,7)	24,7 [10,3; NE]	82	24 (29,3)	NE [NE; NE]	1,14	[0,66; 1,97]	0,6426
Low grade (G1+G2)	90	33 (36,7)	NE [NE; NE]	87	29 (33,3)	NE [NE; NE]	1,12	[0,68; 1,86]	0,6459
Interaktion p-Wert									0,9764
ECOG Performance Status zu Baseline									
0	135	50 (37,0)	24,7 [14,1; NE]	126	35 (27,8)	NE [NE; NE]	1,33	[0,87; 2,06]	0,1958
1	56	19 (33,9)	NE [NE; NE]	64	23 (35,9)	NE [NE; NE]	0,84	[0,45; 1,55]	0,5810
Interaktion p-Wert									0,2314
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	7 (63,6)	8,6 [2,1; NE]	10	2 (20,0)	NE [NE; NE]	3,00	[0,72; 20,16]	0,1379
IV	78	24 (30,8)	24,7 [24,7; NE]	77	23 (29,9)	NE [NE; NE]	0,90	[0,50; 1,60]	0,7127
Interaktion p-Wert									0,1305

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.2.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	14 (14,1)	NE [NE; NE]	101	7 (6,9)	NE [NE; NE]	2,08	[0,86; 5,48]	0,1036
Neu diagnostiziert	92	14 (15,2)	NE [NE; NE]	89	7 (7,9)	NE [NE; NE]	1,76	[0,73; 4,65]	0,2119
Interaktion p-Wert									0,7992
Region									
Asien	54	9 (16,7)	NE [NE; NE]	54	8 (14,8)	NE [NE; NE]	1,13	[0,43; 3,02]	0,7965
Rest der Welt	137	19 (13,9)	NE [NE; NE]	136	6 (4,4)	NE [NE; NE]	2,99	[1,26; 8,22]	0,0116*
Interaktion p-Wert									0,1459
Alter									
<65	101	17 (16,8)	NE [NE; NE]	98	6 (6,1)	NE [NE; NE]	2,78	[1,15; 7,71]	0,0217*
>=65	90	11 (12,2)	NE [NE; NE]	92	8 (8,7)	NE [NE; NE]	1,29	[0,52; 3,34]	0,5817
Interaktion p-Wert									0,2447
Abstammung									
Weiß	104	14 (13,5)	NE [NE; NE]	112	5 (4,5)	NE [NE; NE]	2,86	[1,09; 8,86]	0,0314*
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	10 (17,5)	NE [NE; NE]	58	8 (13,8)	NE [NE; NE]	1,26	[0,50; 3,31]	0,6206
Andere	16	3 (18,8)	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	1,78	[0,23; 36,12]	0,6010
Interaktion p-Wert									0,5018
HRR Mutationsstatus									
HRRm	21	5 (23,8)	NE [NE; NE]	16	2 (12,5)	NE [NE; NE]	1,79	[0,39; 12,54]	0,4695
Nicht-HRRm	118	17 (14,4)	NE [NE; NE]	111	10 (9,0)	NE [NE; NE]	1,55	[0,72; 3,51]	0,2661
Unbekannt	52	6 (11,5)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	3,56	[0,82; 24,32]	0,0920
Interaktion p-Wert									0,6350

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.2.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	17 (15,2)	NE [NE; NE]	122	10 (8,2)	NE [NE; NE]	1,70	[0,79; 3,87]	0,1753
Negativ	73	8 (11,0)	NE [NE; NE]	67	4 (6,0)	NE [NE; NE]	1,87	[0,59; 7,02]	0,2917
Unbekannt	6	3 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8958
Histologie									
Endometrioid	107	18 (16,8)	NE [NE; NE]	97	7 (7,2)	NE [NE; NE]	2,27	[0,99; 5,84]	0,0537
Serös	42	6 (14,3)	NE [NE; NE]	52	4 (7,7)	NE [NE; NE]	1,74	[0,50; 6,81]	0,3856
Andere	42	4 (9,5)	NE [NE; NE]	41	3 (7,3)	NE [NE; NE]	1,28	[0,28; 6,51]	0,7444
Interaktion p-Wert									0,8028
Histologischer Grad									
High grade (G3)	77	9 (11,7)	NE [NE; NE]	82	7 (8,5)	NE [NE; NE]	1,18	[0,44; 3,30]	0,7449
Low grade (G1+G2)	90	17 (18,9)	NE [NE; NE]	87	6 (6,9)	NE [NE; NE]	2,89	[1,20; 8,02]	0,0168*
Interaktion p-Wert									0,1923
ECOG Performance Status zu Baseline									
0	135	18 (13,3)	NE [NE; NE]	126	9 (7,1)	NE [NE; NE]	1,86	[0,86; 4,34]	0,1182
1	56	10 (17,9)	NE [NE; NE]	64	5 (7,8)	NE [NE; NE]	2,08	[0,74; 6,70]	0,1681
Interaktion p-Wert									0,8687
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	1 (10,0)	NE [NE; NE]	1,48	[0,14; 31,91]	0,7438
IV	78	11 (14,1)	NE [NE; NE]	77	6 (7,8)	NE [NE; NE]	1,67	[0,63; 4,85]	0,3058
Interaktion p-Wert									0,9296

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.2.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	38 (38,4)	NE [NE; NE]	101	33 (32,7)	NE [NE; NE]	1,22	[0,76; 1,95]	0,4122
Neu diagnostiziert	92	32 (34,8)	NE [NE; NE]	89	26 (29,2)	NE [NE; NE]	1,03	[0,61; 1,74]	0,9175
Interaktion p-Wert									0,6379
Region									
Asien	54	21 (38,9)	NE [NE; NE]	54	19 (35,2)	NE [NE; NE]	1,12	[0,60; 2,10]	0,7214
Rest der Welt	137	49 (35,8)	NE [NE; NE]	136	40 (29,4)	NE [NE; NE]	1,13	[0,74; 1,72]	0,5695
Interaktion p-Wert									0,9827
Alter									
<65	101	35 (34,7)	NE [NE; NE]	98	27 (27,6)	NE [NE; NE]	1,26	[0,77; 2,11]	0,3579
>=65	90	35 (38,9)	NE [NE; NE]	92	32 (34,8)	NE [NE; NE]	0,99	[0,62; 1,61]	0,9831
Interaktion p-Wert									0,4980
Abstammung									
Weiß	104	36 (34,6)	NE [NE; NE]	112	32 (28,6)	NE [NE; NE]	1,11	[0,69; 1,80]	0,6613
Schwarz/Afroamerikanisch	13	6 (46,2)	14,1 [1,3; NE]	8	2 (25,0)	NE [NE; NE]	2,24	[0,52; 15,31]	0,2947
Asiatisch	57	23 (40,4)	NE [NE; NE]	58	20 (34,5)	NE [NE; NE]	1,19	[0,65; 2,18]	0,5735
Andere	16	5 (31,3)	NE [NE; NE]	12	5 (41,7)	10,6 [0,6; NE]	0,57	[0,16; 2,06]	0,3800
Interaktion p-Wert									0,5835
HRR Mutationsstatus									
HRRm	21	8 (38,1)	NE [NE; NE]	16	4 (25,0)	NE [NE; NE]	1,42	[0,45; 5,34]	0,5585
Nicht-HRRm	118	44 (37,3)	NE [NE; NE]	111	40 (36,0)	NE [NE; NE]	0,94	[0,61; 1,45]	0,7837
Unbekannt	52	18 (34,6)	NE [NE; NE]	63	15 (23,8)	NE [NE; NE]	1,53	[0,77; 3,08]	0,2226
Interaktion p-Wert									0,4540
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.2.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	42 (37,5)	NE [NE; NE]	122	35 (28,7)	NE [NE; NE]	1,18	[0,75; 1,86]	0,4740
Negativ	73	24 (32,9)	NE [NE; NE]	67	24 (35,8)	NE [NE; NE]	0,93	[0,53; 1,65]	0,8095
Unbekannt	6	4 (66,7)	3,4 [1,8; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5263
Histologie									
Endometrioid	107	40 (37,4)	NE [NE; NE]	97	32 (33,0)	NE [NE; NE]	1,11	[0,70; 1,77]	0,6648
Serös	42	16 (38,1)	NE [NE; NE]	52	15 (28,8)	NE [NE; NE]	1,22	[0,60; 2,49]	0,5860
Andere	42	14 (33,3)	24,8 [24,7; NE]	41	12 (29,3)	NE [NE; NE]	1,04	[0,48; 2,29]	0,9206
Interaktion p-Wert									0,9559
Histologischer Grad									
High grade (G3)	77	30 (39,0)	24,8 [10,3; NE]	82	24 (29,3)	NE [NE; NE]	1,15	[0,68; 1,99]	0,6008
Low grade (G1+G2)	90	33 (36,7)	NE [NE; NE]	87	30 (34,5)	NE [NE; NE]	1,08	[0,66; 1,78]	0,7610
Interaktion p-Wert									0,8582
ECOG Performance Status zu Baseline									
0	135	50 (37,0)	NE [NE; NE]	126	35 (27,8)	NE [NE; NE]	1,31	[0,85; 2,03]	0,2184
1	56	20 (35,7)	NE [NE; NE]	64	24 (37,5)	23,1 [8,7; NE]	0,84	[0,46; 1,53]	0,5770
Interaktion p-Wert									0,2405
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	7 (63,6)	8,6 [2,1; NE]	10	2 (20,0)	NE [NE; NE]	3,14	[0,76; 21,09]	0,1193
IV	78	24 (30,8)	NE [NE; NE]	77	23 (29,9)	NE [NE; NE]	0,89	[0,50; 1,59]	0,6922
Interaktion p-Wert									0,1119

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.2.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	14 (14,1)	NE [NE; NE]	101	7 (6,9)	NE [NE; NE]	2,08	[0,87; 5,49]	0,1030
Neu diagnostiziert	92	14 (15,2)	NE [NE; NE]	89	7 (7,9)	NE [NE; NE]	1,76	[0,73; 4,66]	0,2090
Interaktion p-Wert									0,8015
Region									
Asien	54	9 (16,7)	NE [NE; NE]	54	8 (14,8)	NE [NE; NE]	1,14	[0,44; 3,03]	0,7889
Rest der Welt	137	19 (13,9)	NE [NE; NE]	136	6 (4,4)	NE [NE; NE]	3,00	[1,27; 8,23]	0,0115*
Interaktion p-Wert									0,1474
Alter									
<65	101	17 (16,8)	NE [NE; NE]	98	6 (6,1)	NE [NE; NE]	2,78	[1,16; 7,72]	0,0215*
>=65	90	11 (12,2)	NE [NE; NE]	92	8 (8,7)	NE [NE; NE]	1,29	[0,52; 3,35]	0,5766
Interaktion p-Wert									0,2458
Abstammung									
Weiß	104	14 (13,5)	NE [NE; NE]	112	5 (4,5)	NE [NE; NE]	2,87	[1,10; 8,88]	0,0309*
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	10 (17,5)	NE [NE; NE]	58	8 (13,8)	NE [NE; NE]	1,27	[0,50; 3,33]	0,6129
Andere	16	3 (18,8)	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	1,79	[0,23; 36,13]	0,6007
Interaktion p-Wert									0,5037
HRR Mutationsstatus									
HRRm	21	5 (23,8)	NE [NE; NE]	16	2 (12,5)	NE [NE; NE]	1,80	[0,39; 12,58]	0,4668
Nicht-HRRm	118	17 (14,4)	NE [NE; NE]	111	10 (9,0)	NE [NE; NE]	1,55	[0,72; 3,51]	0,2646
Unbekannt	52	6 (11,5)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	3,57	[0,82; 24,40]	0,0911
Interaktion p-Wert									0,6337

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.2.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	17 (15,2)	NE [NE; NE]	122	10 (8,2)	NE [NE; NE]	1,71	[0,79; 3,88]	0,1733
Negativ	73	8 (11,0)	NE [NE; NE]	67	4 (6,0)	NE [NE; NE]	1,88	[0,59; 7,04]	0,2895
Unbekannt	6	3 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8951
Histologie									
Endometrioid	107	18 (16,8)	NE [NE; NE]	97	7 (7,2)	NE [NE; NE]	2,27	[0,99; 5,84]	0,0532
Serös	42	6 (14,3)	NE [NE; NE]	52	4 (7,7)	NE [NE; NE]	1,74	[0,50; 6,81]	0,3847
Andere	42	4 (9,5)	NE [NE; NE]	41	3 (7,3)	NE [NE; NE]	1,29	[0,28; 6,55]	0,7374
Interaktion p-Wert									0,8056
Histologischer Grad									
High grade (G3)	77	9 (11,7)	NE [NE; NE]	82	7 (8,5)	NE [NE; NE]	1,18	[0,44; 3,30]	0,7444
Low grade (G1+G2)	90	17 (18,9)	NE [NE; NE]	87	6 (6,9)	NE [NE; NE]	2,90	[1,21; 8,05]	0,0165*
Interaktion p-Wert									0,1909
ECOG Performance Status zu Baseline									
0	135	18 (13,3)	NE [NE; NE]	126	9 (7,1)	NE [NE; NE]	1,86	[0,86; 4,34]	0,1181
1	56	10 (17,9)	NE [NE; NE]	64	5 (7,8)	NE [NE; NE]	2,10	[0,74; 6,75]	0,1635
Interaktion p-Wert									0,8602
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	1 (10,0)	NE [NE; NE]	1,50	[0,14; 32,27]	0,7362
IV	78	11 (14,1)	NE [NE; NE]	77	6 (7,8)	NE [NE; NE]	1,67	[0,64; 4,87]	0,3008
Interaktion p-Wert									0,9337

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.3.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first Therapieabbruch aufgrund von UE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	24 (24,2)	NE [NE; NE]	101	23 (22,8)	NE [NE; NE]	1,02	[0,58; 1,83]	0,9334
Neu diagnostiziert	92	23 (25,0)	NE [NE; NE]	89	14 (15,7)	NE [NE; NE]	1,47	[0,77; 2,94]	0,2466
Interaktion p-Wert									0,4140
Region									
Asien	54	12 (22,2)	NE [NE; NE]	54	9 (16,7)	NE [NE; NE]	1,33	[0,56; 3,27]	0,5109
Rest der Welt	137	35 (25,5)	NE [NE; NE]	136	28 (20,6)	NE [NE; NE]	1,14	[0,70; 1,90]	0,5938
Interaktion p-Wert									0,7628
Alter									
<65	101	21 (20,8)	NE [NE; NE]	98	17 (17,3)	NE [NE; NE]	1,14	[0,60; 2,19]	0,6901
>=65	90	26 (28,9)	NE [NE; NE]	92	20 (21,7)	NE [NE; NE]	1,25	[0,70; 2,27]	0,4498
Interaktion p-Wert									0,8306
Abstammung									
Weiß	104	28 (26,9)	NE [NE; NE]	112	22 (19,6)	NE [NE; NE]	1,28	[0,74; 2,27]	0,3797
Schwarz/Afroamerikanisch	13	2 (15,4)	NE [NE; NE]	8	2 (25,0)	NE [NE; NE]	0,55	[0,07; 4,55]	0,5481
Asiatisch	57	14 (24,6)	NE [NE; NE]	58	10 (17,2)	NE [NE; NE]	1,42	[0,64; 3,30]	0,3929
Andere	16	3 (18,8)	NE [NE; NE]	12	3 (25,0)	NE [NE; NE]	0,61	[0,11; 3,32]	0,5520
Interaktion p-Wert									0,6846
HRR Mutationsstatus									
HRRm	21	4 (19,0)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	32 (27,1)	NE [NE; NE]	111	27 (24,3)	NE [NE; NE]	1,06	[0,63; 1,78]	0,8274
Unbekannt	52	11 (21,2)	NE [NE; NE]	63	10 (15,9)	NE [NE; NE]	1,27	[0,53; 3,04]	0,5875
Interaktion p-Wert									0,7236
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.3.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first Therapieabbruch aufgrund von UE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	29 (25,9)	NE [NE; NE]	122	25 (20,5)	NE [NE; NE]	1,14	[0,67; 1,97]	0,6294
Negativ	73	16 (21,9)	NE [NE; NE]	67	12 (17,9)	NE [NE; NE]	1,22	[0,58; 2,65]	0,5949
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8811
Histologie									
Endometrioid	107	23 (21,5)	NE [NE; NE]	97	23 (23,7)	NE [NE; NE]	0,84	[0,47; 1,51]	0,5646
Serös	42	15 (35,7)	NE [NE; NE]	52	10 (19,2)	NE [NE; NE]	1,73	[0,78; 3,97]	0,1765
Andere	42	9 (21,4)	NE [NE; NE]	41	4 (9,8)	NE [NE; NE]	2,23	[0,73; 8,24]	0,1648
Interaktion p-Wert									0,1860
Histologischer Grad									
High grade (G3)	77	18 (23,4)	NE [NE; NE]	82	19 (23,2)	NE [NE; NE]	0,86	[0,45; 1,65]	0,6504
Low grade (G1+G2)	90	21 (23,3)	NE [NE; NE]	87	15 (17,2)	NE [NE; NE]	1,38	[0,72; 2,73]	0,3368
Interaktion p-Wert									0,3161
ECOG Performance Status zu Baseline									
0	135	36 (26,7)	NE [NE; NE]	126	20 (15,9)	NE [NE; NE]	1,70	[0,99; 2,98]	0,0533
1	56	11 (19,6)	NE [NE; NE]	64	17 (26,6)	NE [NE; NE]	0,60	[0,27; 1,27]	0,1862
Interaktion p-Wert									0,0278*
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	21 (26,9)	NE [NE; NE]	77	14 (18,2)	NE [NE; NE]	1,34	[0,68; 2,71]	0,3942
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.3.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first Therapieabbruch aufgrund von UE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	27 (27,3)	NE [NE; NE]	101	24 (23,8)	NE [NE; NE]	1,09	[0,63; 1,90]	0,7556
Neu diagnostiziert	92	23 (25,0)	NE [NE; NE]	89	13 (14,6)	NE [NE; NE]	1,56	[0,80; 3,18]	0,1910
Interaktion p-Wert									0,4180
Region									
Asien	54	13 (24,1)	NE [NE; NE]	54	10 (18,5)	NE [NE; NE]	1,28	[0,56; 3,01]	0,5529
Rest der Welt	137	37 (27,0)	NE [NE; NE]	136	27 (19,9)	NE [NE; NE]	1,24	[0,76; 2,05]	0,3987
Interaktion p-Wert									0,9425
Alter									
<65	101	21 (20,8)	NE [NE; NE]	98	16 (16,3)	NE [NE; NE]	1,19	[0,62; 2,32]	0,5939
>=65	90	29 (32,2)	NE [NE; NE]	92	21 (22,8)	NE [NE; NE]	1,31	[0,75; 2,33]	0,3439
Interaktion p-Wert									0,8305
Abstammung									
Weiß	104	31 (29,8)	NE [NE; NE]	112	22 (19,6)	NE [NE; NE]	1,41	[0,82; 2,47]	0,2151
Schwarz/Afroamerikanisch	13	2 (15,4)	NE [NE; NE]	8	2 (25,0)	NE [NE; NE]	0,52	[0,06; 4,31]	0,5139
Asiatisch	57	15 (26,3)	NE [NE; NE]	58	11 (19,0)	NE [NE; NE]	1,36	[0,63; 3,04]	0,4346
Andere	16	2 (12,5)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	0,60	[0,07; 5,01]	0,6126
Interaktion p-Wert									0,6831
HRR Mutationsstatus									
HRRm	21	4 (19,0)	NE [NE; NE]	16	1 (6,3)	NE [NE; NE]	2,76	[0,41; 54,07]	0,3204
Nicht-HRRm	118	35 (29,7)	NE [NE; NE]	111	26 (23,4)	NE [NE; NE]	1,19	[0,72; 2,00]	0,5000
Unbekannt	52	11 (21,2)	NE [NE; NE]	63	10 (15,9)	NE [NE; NE]	1,25	[0,53; 3,00]	0,6109
Interaktion p-Wert									0,7344
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.3.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first Therapieabbruch aufgrund von UE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	32 (28,6)	NE [NE; NE]	122	26 (21,3)	NE [NE; NE]	1,19	[0,71; 2,01]	0,5185
Negativ	73	16 (21,9)	NE [NE; NE]	67	11 (16,4)	NE [NE; NE]	1,33	[0,62; 2,95]	0,4609
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8064
Histologie									
Endometrioid	107	25 (23,4)	NE [NE; NE]	97	23 (23,7)	NE [NE; NE]	0,91	[0,51; 1,61]	0,7313
Serös	42	15 (35,7)	NE [NE; NE]	52	10 (19,2)	NE [NE; NE]	1,70	[0,77; 3,90]	0,1915
Andere	42	10 (23,8)	NE [NE; NE]	41	4 (9,8)	NE [NE; NE]	2,45	[0,82; 8,93]	0,1116
Interaktion p-Wert									0,2020
Histologischer Grad									
High grade (G3)	77	19 (24,7)	NE [NE; NE]	82	18 (22,0)	NE [NE; NE]	0,95	[0,50; 1,83]	0,8855
Low grade (G1+G2)	90	22 (24,4)	NE [NE; NE]	87	16 (18,4)	NE [NE; NE]	1,35	[0,71; 2,61]	0,3586
Interaktion p-Wert									0,4549
ECOG Performance Status zu Baseline									
0	135	39 (28,9)	NE [NE; NE]	126	19 (15,1)	NE [NE; NE]	1,92	[1,12; 3,39]	0,0165*
1	56	11 (19,6)	NE [NE; NE]	64	18 (28,1)	NE [NE; NE]	0,55	[0,25; 1,16]	0,1158
Interaktion p-Wert									0,0074*
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	21 (26,9)	NE [NE; NE]	77	13 (16,9)	NE [NE; NE]	1,47	[0,74; 3,02]	0,2721
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UE mit CTCAE Grad >=3
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	66 (66,7)	2,6 [2,1; 7,3]	101	58 (57,4)	4,4 [2,9; NE]	1,27	[0,89; 1,81]	0,1835
Neu diagnostiziert	92	63 (68,5)	4,2 [2,9; 6,9]	89	46 (51,7)	7,7 [2,3; NE]	1,29	[0,88; 1,90]	0,1866
Interaktion p-Wert									0,9530
Region									
Asien	54	38 (70,4)	2,2 [1,1; 3,4]	54	36 (66,7)	2,6 [0,8; 4,2]	1,00	[0,63; 1,58]	0,9965
Rest der Welt	137	91 (66,4)	5,1 [2,5; 7,7]	136	68 (50,0)	9,2 [3,7; NE]	1,42	[1,04; 1,95]	0,0286*
Interaktion p-Wert									0,2185
Alter									
<65	101	65 (64,4)	3,4 [2,2; 8,0]	98	54 (55,1)	5,3 [2,8; NE]	1,22	[0,85; 1,75]	0,2888
>=65	90	64 (71,1)	3,4 [2,1; 6,2]	92	50 (54,3)	4,7 [1,9; NE]	1,35	[0,93; 1,96]	0,1100
Interaktion p-Wert									0,6891
Abstammung									
Weiß	104	67 (64,4)	6,9 [2,8; 8,5]	112	58 (51,8)	8,3 [3,6; NE]	1,28	[0,90; 1,82]	0,1711
Schwarz/Afroamerikanisch	13	12 (92,3)	0,7 [0,3; 4,2]	8	2 (25,0)	NE [NE; NE]	7,20	[1,96; 46,29]	0,0017*
Asiatisch	57	40 (70,2)	2,2 [1,2; 3,4]	58	37 (63,8)	2,8 [1,0; 9,2]	1,08	[0,69; 1,70]	0,7228
Andere	16	9 (56,3)	6,9 [1,3; NE]	12	7 (58,3)	1,9 [0,9; NE]	0,79	[0,30; 2,22]	0,6469
Interaktion p-Wert									0,0340*
HRR Mutationsstatus									
HRRm	21	15 (71,4)	2,6 [0,8; 8,8]	16	6 (37,5)	NE [NE; NE]	2,43	[0,99; 6,82]	0,0535
Nicht-HRRm	118	82 (69,5)	3,4 [2,2; 7,2]	111	64 (57,7)	4,5 [2,5;12,2]	1,22	[0,88; 1,70]	0,2271
Unbekannt	52	32 (61,5)	3,4 [2,0; 8,3]	63	34 (54,0)	4,1 [2,8; NE]	1,16	[0,71; 1,88]	0,5546
Interaktion p-Wert									0,3419
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UE mit CTCAE Grad >=3
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	77 (68,8)	4,2 [2,1; 6,9]	122	65 (53,3)	4,7 [2,8; NE]	1,29	[0,93; 1,80]	0,1267
Negativ	73	47 (64,4)	3,1 [2,2; 7,9]	67	39 (58,2)	5,3 [2,8; NE]	1,16	[0,76; 1,78]	0,4893
Unbekannt	6	5 (83,3)	0,7 [0,1; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6961
Histologie									
Endometrioid	107	67 (62,6)	3,4 [2,2;10,0]	97	54 (55,7)	4,1 [2,1; NE]	1,05	[0,74; 1,51]	0,7823
Serös	42	32 (76,2)	3,1 [1,3; 6,9]	52	29 (55,8)	7,9 [2,8; NE]	1,62	[0,98; 2,69]	0,0613
Andere	42	30 (71,4)	3,4 [1,0; 6,2]	41	21 (51,2)	5,8 [2,1; NE]	1,63	[0,94; 2,88]	0,0846
Interaktion p-Wert									0,2625
Histologischer Grad									
High grade (G3)	77	56 (72,7)	4,1 [2,1; 6,8]	82	43 (52,4)	4,1 [1,4; NE]	1,37	[0,92; 2,04]	0,1216
Low grade (G1+G2)	90	53 (58,9)	5,1 [2,3;14,1]	87	48 (55,2)	7,9 [3,0; NE]	1,08	[0,73; 1,61]	0,6832
Interaktion p-Wert									0,4161
ECOG Performance Status zu Baseline									
0	135	87 (64,4)	4,2 [2,6; 7,7]	126	64 (50,8)	10,9 [3,1; NE]	1,32	[0,95; 1,82]	0,0935
1	56	42 (75,0)	2,2 [1,5; 6,2]	64	40 (62,5)	3,4 [1,9; 9,2]	1,26	[0,81; 1,95]	0,2989
Interaktion p-Wert									0,8699
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	8 (72,7)	8,0 [1,4; NE]	10	3 (30,0)	NE [NE; NE]	2,34	[0,68; 10,68]	0,1861
IV	78	52 (66,7)	3,7 [2,1; 6,9]	77	42 (54,5)	5,8 [2,1; NE]	1,19	[0,79; 1,79]	0,4123
Interaktion p-Wert									0,3196

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	32 (32,3)	NE [NE; NE]	101	19 (18,8)	NE [NE; NE]	1,84	[1,05; 3,31]	0,0317*
Neu diagnostiziert	92	30 (32,6)	NE [NE; NE]	89	20 (22,5)	NE [NE; NE]	1,45	[0,83; 2,60]	0,1913
Interaktion p-Wert									0,5620
Region									
Asien	54	20 (37,0)	NE [NE; NE]	54	14 (25,9)	NE [NE; NE]	1,60	[0,81; 3,23]	0,1754
Rest der Welt	137	42 (30,7)	NE [NE; NE]	136	25 (18,4)	NE [NE; NE]	1,69	[1,04; 2,80]	0,0357*
Interaktion p-Wert									0,9001
Alter									
<65	101	31 (30,7)	NE [NE; NE]	98	21 (21,4)	NE [NE; NE]	1,53	[0,88; 2,69]	0,1311
>=65	90	31 (34,4)	NE [NE; NE]	92	18 (19,6)	NE [NE; NE]	1,78	[1,01; 3,24]	0,0473*
Interaktion p-Wert									0,7064
Abstammung									
Weiß	104	32 (30,8)	NE [NE; NE]	112	22 (19,6)	NE [NE; NE]	1,54	[0,90; 2,69]	0,1146
Schwarz/Afroamerikanisch	13	4 (30,8)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	3,36	[0,50; 65,61]	0,2304
Asiatisch	57	21 (36,8)	NE [NE; NE]	58	14 (24,1)	NE [NE; NE]	1,71	[0,88; 3,44]	0,1153
Andere	16	5 (31,3)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	1,70	[0,37; 11,86]	0,5128
Interaktion p-Wert									0,9121
HRR Mutationsstatus									
HRRm	21	9 (42,9)	NE [NE; NE]	16	4 (25,0)	NE [NE; NE]	1,98	[0,64; 7,31]	0,2388
Nicht-HRRm	118	35 (29,7)	NE [NE; NE]	111	25 (22,5)	NE [NE; NE]	1,35	[0,81; 2,27]	0,2527
Unbekannt	52	18 (34,6)	NE [NE; NE]	63	10 (15,9)	NE [NE; NE]	2,27	[1,07; 5,11]	0,0329*
Interaktion p-Wert									0,5068

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	37 (33,0)	NE [NE; NE]	122	27 (22,1)	NE [NE; NE]	1,52	[0,93; 2,52]	0,0954
Negativ	73	22 (30,1)	NE [NE; NE]	67	12 (17,9)	NE [NE; NE]	1,76	[0,89; 3,67]	0,1075
Unbekannt	6	3 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7387
Histologie									
Endometrioid	107	34 (31,8)	NE [NE; NE]	97	18 (18,6)	NE [NE; NE]	1,74	[0,995; 3,15]	0,0519
Serös	42	10 (23,8)	NE [NE; NE]	52	12 (23,1)	NE [NE; NE]	1,01	[0,43; 2,34]	0,9807
Andere	42	18 (42,9)	NE [NE; NE]	41	9 (22,0)	NE [NE; NE]	2,31	[1,06; 5,38]	0,0344*
Interaktion p-Wert									0,3596
Histologischer Grad									
High grade (G3)	77	25 (32,5)	NE [NE; NE]	82	19 (23,2)	NE [NE; NE]	1,35	[0,75; 2,49]	0,3166
Low grade (G1+G2)	90	28 (31,1)	NE [NE; NE]	87	15 (17,2)	NE [NE; NE]	1,97	[1,07; 3,78]	0,0300*
Interaktion p-Wert									0,3968
ECOG Performance Status zu Baseline									
0	135	40 (29,6)	NE [NE; NE]	126	24 (19,0)	NE [NE; NE]	1,63	[0,99; 2,75]	0,0533
1	56	22 (39,3)	NE [NE; NE]	64	15 (23,4)	NE [NE; NE]	1,73	[0,91; 3,41]	0,0969
Interaktion p-Wert									0,8895
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	1 (10,0)	NE [NE; NE]	1,69	[0,16; 36,39]	0,6599
IV	78	27 (34,6)	NE [NE; NE]	77	19 (24,7)	NE [NE; NE]	1,44	[0,81; 2,64]	0,2158
Interaktion p-Wert									0,8994

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.1D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first G>=3 PT: Anaemie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	23 (23,2)	NE [NE; NE]	101	12 (11,9)	NE [NE; NE]	2,06	[1,04; 4,28]	0,0367*
Neu diagnostiziert	92	23 (25,0)	NE [NE; NE]	89	12 (13,5)	NE [NE; NE]	1,85	[0,94; 3,84]	0,0773
Interaktion p-Wert									0,8275
Region									
Asien	54	15 (27,8)	NE [NE; NE]	54	8 (14,8)	NE [NE; NE]	2,03	[0,88; 5,05]	0,0966
Rest der Welt	137	31 (22,6)	NE [NE; NE]	136	16 (11,8)	NE [NE; NE]	1,93	[1,07; 3,62]	0,0277*
Interaktion p-Wert									0,9276
Alter									
<65	101	21 (20,8)	NE [NE; NE]	98	14 (14,3)	NE [NE; NE]	1,51	[0,77; 3,03]	0,2293
>=65	90	25 (27,8)	NE [NE; NE]	92	10 (10,9)	NE [NE; NE]	2,60	[1,29; 5,69]	0,0070*
Interaktion p-Wert									0,2801
Abstammung									
Weiß	104	22 (21,2)	NE [NE; NE]	112	13 (11,6)	NE [NE; NE]	1,79	[0,91; 3,65]	0,0899
Schwarz/Afroamerikanisch	13	4 (30,8)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	3,29	[0,49; 64,38]	0,2385
Asiatisch	57	16 (28,1)	NE [NE; NE]	58	8 (13,8)	NE [NE; NE]	2,21	[0,97; 5,45]	0,0589
Andere	16	4 (25,0)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	1,32	[0,26; 9,53]	0,7450
Interaktion p-Wert									0,9015
HRR Mutationsstatus									
HRRm	21	7 (33,3)	NE [NE; NE]	16	3 (18,8)	NE [NE; NE]	1,94	[0,54; 9,00]	0,3195
Nicht-HRRm	118	27 (22,9)	NE [NE; NE]	111	16 (14,4)	NE [NE; NE]	1,62	[0,88; 3,08]	0,1184
Unbekannt	52	12 (23,1)	NE [NE; NE]	63	5 (7,9)	NE [NE; NE]	2,96	[1,10; 9,32]	0,0313*
Interaktion p-Wert									0,6127
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.1D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first G>=3 PT: Anaemie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	29 (25,9)	NE [NE; NE]	122	18 (14,8)	NE [NE; NE]	1,75	[0,98; 3,21]	0,0588
Negativ	73	14 (19,2)	NE [NE; NE]	67	6 (9,0)	NE [NE; NE]	2,27	[0,91; 6,40]	0,0801
Unbekannt	6	3 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6481
Histologie									
Endometrioid	107	22 (20,6)	NE [NE; NE]	97	10 (10,3)	NE [NE; NE]	1,98	[0,96; 4,37]	0,0643
Serös	42	9 (21,4)	NE [NE; NE]	52	8 (15,4)	NE [NE; NE]	1,40	[0,54; 3,74]	0,4838
Andere	42	15 (35,7)	NE [NE; NE]	41	6 (14,6)	NE [NE; NE]	2,84	[1,15; 7,96]	0,0226*
Interaktion p-Wert									0,5857
Histologischer Grad									
High grade (G3)	77	20 (26,0)	NE [NE; NE]	82	11 (13,4)	NE [NE; NE]	1,93	[0,94; 4,17]	0,0733
Low grade (G1+G2)	90	19 (21,1)	NE [NE; NE]	87	10 (11,5)	NE [NE; NE]	1,92	[0,91; 4,31]	0,0856
Interaktion p-Wert									0,9967
ECOG Performance Status zu Baseline									
0	135	32 (23,7)	NE [NE; NE]	126	14 (11,1)	NE [NE; NE]	2,26	[1,23; 4,37]	0,0081*
1	56	14 (25,0)	NE [NE; NE]	64	10 (15,6)	NE [NE; NE]	1,55	[0,69; 3,61]	0,2836
Interaktion p-Wert									0,4759
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	1 (10,0)	NE [NE; NE]	1,63	[0,16; 35,09]	0,6827
IV	78	21 (26,9)	NE [NE; NE]	77	11 (14,3)	NE [NE; NE]	1,95	[0,96; 4,20]	0,0650
Interaktion p-Wert									0,8893

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UE mit CTCAE Grad >=3
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	66 (66,7)	2,6 [2,1; 7,3]	101	59 (58,4)	4,4 [2,9;14,0]	1,25	[0,88; 1,78]	0,2168
Neu diagnostiziert	92	63 (68,5)	4,2 [2,9; 6,9]	89	46 (51,7)	7,7 [2,3; NE]	1,29	[0,88; 1,89]	0,1898
Interaktion p-Wert									0,9040
Region									
Asien	54	38 (70,4)	2,2 [1,1; 3,4]	54	37 (68,5)	2,6 [0,8; 4,2]	0,97	[0,62; 1,53]	0,9020
Rest der Welt	137	91 (66,4)	5,1 [2,5; 7,7]	136	68 (50,0)	9,2 [3,7; NE]	1,42	[1,04; 1,95]	0,0291*
Interaktion p-Wert									0,1810
Alter									
<65	101	65 (64,4)	3,4 [2,2; 8,0]	98	55 (56,1)	5,3 [2,8;14,0]	1,19	[0,83; 1,71]	0,3381
>=65	90	64 (71,1)	3,4 [2,1; 6,2]	92	50 (54,3)	4,7 [1,9; NE]	1,35	[0,93; 1,96]	0,1117
Interaktion p-Wert									0,6379
Abstammung									
Weiß	104	67 (64,4)	6,9 [2,8; 8,5]	112	58 (51,8)	8,3 [3,6; NE]	1,28	[0,90; 1,82]	0,1702
Schwarz/Afroamerikanisch	13	12 (92,3)	0,7 [0,3; 4,2]	8	2 (25,0)	NE [NE; NE]	7,19	[1,96; 46,25]	0,0017*
Asiatisch	57	40 (70,2)	2,2 [1,2; 3,4]	58	38 (65,5)	2,8 [1,0; 9,2]	1,05	[0,67; 1,65]	0,8228
Andere	16	9 (56,3)	6,9 [1,3; NE]	12	7 (58,3)	1,9 [0,9; NE]	0,79	[0,29; 2,21]	0,6384
Interaktion p-Wert									0,0308*
HRR Mutationsstatus									
HRRm	21	15 (71,4)	2,6 [0,8; 8,8]	16	6 (37,5)	NE [NE; NE]	2,43	[0,99; 6,83]	0,0530
Nicht-HRRm	118	82 (69,5)	3,4 [2,2; 7,2]	111	64 (57,7)	4,5 [2,5;12,2]	1,22	[0,88; 1,70]	0,2291
Unbekannt	52	32 (61,5)	3,4 [2,0; 8,3]	63	35 (55,6)	4,1 [2,8; NE]	1,12	[0,69; 1,81]	0,6452
Interaktion p-Wert									0,3200
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UE mit CTCAE Grad >=3
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	77 (68,8)	4,2 [2,1; 6,9]	122	66 (54,1)	4,7 [2,8; NE]	1,27	[0,92; 1,77]	0,1500
Negativ	73	47 (64,4)	3,1 [2,2; 7,9]	67	39 (58,2)	5,3 [2,8; NE]	1,16	[0,76; 1,78]	0,4988
Unbekannt	6	5 (83,3)	0,7 [0,1; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7294
Histologie									
Endometrioid	107	67 (62,6)	3,4 [2,2;10,0]	97	54 (55,7)	4,1 [2,1; NE]	1,05	[0,73; 1,51]	0,7913
Serös	42	32 (76,2)	3,1 [1,3; 6,9]	52	29 (55,8)	7,9 [2,8; NE]	1,61	[0,97; 2,68]	0,0628
Andere	42	30 (71,4)	3,4 [1,0; 6,2]	41	22 (53,7)	5,8 [2,1; NE]	1,56	[0,90; 2,73]	0,1116
Interaktion p-Wert									0,2909
Histologischer Grad									
High grade (G3)	77	56 (72,7)	4,1 [2,1; 6,8]	82	43 (52,4)	4,1 [1,4; NE]	1,36	[0,92; 2,04]	0,1253
Low grade (G1+G2)	90	53 (58,9)	5,1 [2,3;14,1]	87	49 (56,3)	7,9 [3,0; NE]	1,06	[0,72; 1,57]	0,7673
Interaktion p-Wert									0,3763
ECOG Performance Status zu Baseline									
0	135	87 (64,4)	4,2 [2,6; 7,7]	126	65 (51,6)	10,9 [3,1; NE]	1,29	[0,94; 1,79]	0,1139
1	56	42 (75,0)	2,2 [1,5; 6,2]	64	40 (62,5)	3,4 [1,9; 9,2]	1,26	[0,81; 1,94]	0,3022
Interaktion p-Wert									0,9133
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	8 (72,7)	8,0 [1,4; NE]	10	3 (30,0)	NE [NE; NE]	2,34	[0,68; 10,70]	0,1850
IV	78	52 (66,7)	3,7 [2,1; 6,9]	77	42 (54,5)	5,8 [2,1; NE]	1,19	[0,79; 1,79]	0,4060
Interaktion p-Wert									0,3197

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	32 (32,3)	NE [NE; NE]	101	19 (18,8)	NE [NE; NE]	1,84	[1,05; 3,30]	0,0326*
Neu diagnostiziert	92	31 (33,7)	NE [NE; NE]	89	20 (22,5)	NE [NE; NE]	1,49	[0,85; 2,65]	0,1626
Interaktion p-Wert									0,6046
Region									
Asien	54	20 (37,0)	NE [NE; NE]	54	14 (25,9)	NE [NE; NE]	1,59	[0,81; 3,22]	0,1779
Rest der Welt	137	43 (31,4)	NE [NE; NE]	136	25 (18,4)	NE [NE; NE]	1,71	[1,05; 2,84]	0,0296*
Interaktion p-Wert									0,8659
Alter									
<65	101	31 (30,7)	NE [NE; NE]	98	21 (21,4)	NE [NE; NE]	1,52	[0,88; 2,68]	0,1366
>=65	90	32 (35,6)	NE [NE; NE]	92	18 (19,6)	NE [NE; NE]	1,83	[1,04; 3,32]	0,0371*
Interaktion p-Wert									0,6504
Abstammung									
Weiß	104	33 (31,7)	NE [NE; NE]	112	22 (19,6)	NE [NE; NE]	1,58	[0,93; 2,75]	0,0925
Schwarz/Afroamerikanisch	13	4 (30,8)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	3,31	[0,49; 64,83]	0,2354
Asiatisch	57	21 (36,8)	NE [NE; NE]	58	14 (24,1)	NE [NE; NE]	1,70	[0,87; 3,43]	0,1180
Andere	16	5 (31,3)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	1,67	[0,36; 11,67]	0,5263
Interaktion p-Wert									0,9256
HRR Mutationsstatus									
HRRm	21	9 (42,9)	NE [NE; NE]	16	4 (25,0)	NE [NE; NE]	1,96	[0,64; 7,25]	0,2450
Nicht-HRRm	118	36 (30,5)	NE [NE; NE]	111	25 (22,5)	NE [NE; NE]	1,38	[0,83; 2,32]	0,2158
Unbekannt	52	18 (34,6)	NE [NE; NE]	63	10 (15,9)	NE [NE; NE]	2,26	[1,06; 5,08]	0,0344*
Interaktion p-Wert									0,5469

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	38 (33,9)	NE [NE; NE]	122	27 (22,1)	NE [NE; NE]	1,55	[0,95; 2,56]	0,0811
Negativ	73	22 (30,1)	NE [NE; NE]	67	12 (17,9)	NE [NE; NE]	1,76	[0,89; 3,67]	0,1080
Unbekannt	6	3 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7690
Histologie									
Endometrioid	107	34 (31,8)	NE [NE; NE]	97	18 (18,6)	NE [NE; NE]	1,73	[0,99; 3,13]	0,0545
Serös	42	11 (26,2)	NE [NE; NE]	52	12 (23,1)	NE [NE; NE]	1,10	[0,48; 2,51]	0,8196
Andere	42	18 (42,9)	NE [NE; NE]	41	9 (22,0)	NE [NE; NE]	2,30	[1,06; 5,36]	0,0352*
Interaktion p-Wert									0,4394
Histologischer Grad									
High grade (G3)	77	26 (33,8)	NE [NE; NE]	82	19 (23,2)	NE [NE; NE]	1,39	[0,77; 2,56]	0,2683
Low grade (G1+G2)	90	28 (31,1)	NE [NE; NE]	87	15 (17,2)	NE [NE; NE]	1,96	[1,06; 3,76]	0,0314*
Interaktion p-Wert									0,4400
ECOG Performance Status zu Baseline									
0	135	41 (30,4)	NE [NE; NE]	126	24 (19,0)	NE [NE; NE]	1,67	[1,01; 2,80]	0,0434*
1	56	22 (39,3)	NE [NE; NE]	64	15 (23,4)	NE [NE; NE]	1,72	[0,90; 3,38]	0,1022
Interaktion p-Wert									0,9409
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	1 (10,0)	NE [NE; NE]	1,63	[0,16; 35,11]	0,6827
IV	78	28 (35,9)	NE [NE; NE]	77	19 (24,7)	NE [NE; NE]	1,47	[0,82; 2,67]	0,1927
Interaktion p-Wert									0,9334

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.2D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first G>=3 PT: Anaemie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	23 (23,2)	NE [NE; NE]	101	12 (11,9)	NE [NE; NE]	2,05	[1,04; 4,27]	0,0377*
Neu diagnostiziert	92	24 (26,1)	NE [NE; NE]	89	12 (13,5)	NE [NE; NE]	1,90	[0,97; 3,94]	0,0612
Interaktion p-Wert									0,8805
Region									
Asien	54	15 (27,8)	NE [NE; NE]	54	8 (14,8)	NE [NE; NE]	2,03	[0,88; 5,04]	0,0974
Rest der Welt	137	32 (23,4)	NE [NE; NE]	136	16 (11,8)	NE [NE; NE]	1,98	[1,10; 3,70]	0,0220*
Interaktion p-Wert									0,9626
Alter									
<65	101	21 (20,8)	NE [NE; NE]	98	14 (14,3)	NE [NE; NE]	1,50	[0,77; 3,01]	0,2376
>=65	90	26 (28,9)	NE [NE; NE]	92	10 (10,9)	NE [NE; NE]	2,69	[1,34; 5,85]	0,0050*
Interaktion p-Wert									0,2462
Abstammung									
Weiß	104	23 (22,1)	NE [NE; NE]	112	13 (11,6)	NE [NE; NE]	1,86	[0,96; 3,78]	0,0681
Schwarz/Afroamerikanisch	13	4 (30,8)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	3,24	[0,48; 63,38]	0,2453
Asiatisch	57	16 (28,1)	NE [NE; NE]	58	8 (13,8)	NE [NE; NE]	2,20	[0,97; 5,43]	0,0600
Andere	16	4 (25,0)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	1,29	[0,25; 9,33]	0,7641
Interaktion p-Wert									0,9109
HRR Mutationsstatus									
HRRm	21	7 (33,3)	NE [NE; NE]	16	3 (18,8)	NE [NE; NE]	1,91	[0,53; 8,89]	0,3297
Nicht-HRRm	118	28 (23,7)	NE [NE; NE]	111	16 (14,4)	NE [NE; NE]	1,67	[0,92; 3,16]	0,0945
Unbekannt	52	12 (23,1)	NE [NE; NE]	63	5 (7,9)	NE [NE; NE]	2,94	[1,09; 9,24]	0,0327*
Interaktion p-Wert									0,6499
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.4.2.2D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first G>=3 PT: Anaemie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	30 (26,8)	NE [NE; NE]	122	18 (14,8)	NE [NE; NE]	1,79	[1,005; 3,27]	0,0481*
Negativ	73	14 (19,2)	NE [NE; NE]	67	6 (9,0)	NE [NE; NE]	2,27	[0,91; 6,40]	0,0802
Unbekannt	6	3 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6751
Histologie									
Endometrioid	107	22 (20,6)	NE [NE; NE]	97	10 (10,3)	NE [NE; NE]	1,96	[0,96; 4,34]	0,0669
Serös	42	10 (23,8)	NE [NE; NE]	52	8 (15,4)	NE [NE; NE]	1,54	[0,61; 4,03]	0,3621
Andere	42	15 (35,7)	NE [NE; NE]	41	6 (14,6)	NE [NE; NE]	2,83	[1,15; 7,93]	0,0230*
Interaktion p-Wert									0,6583
Histologischer Grad									
High grade (G3)	77	21 (27,3)	NE [NE; NE]	82	11 (13,4)	NE [NE; NE]	2,00	[0,98; 4,31]	0,0553
Low grade (G1+G2)	90	19 (21,1)	NE [NE; NE]	87	10 (11,5)	NE [NE; NE]	1,91	[0,91; 4,28]	0,0892
Interaktion p-Wert									0,9301
ECOG Performance Status zu Baseline									
0	135	33 (24,4)	NE [NE; NE]	126	14 (11,1)	NE [NE; NE]	2,31	[1,26; 4,46]	0,0060*
1	56	14 (25,0)	NE [NE; NE]	64	10 (15,6)	NE [NE; NE]	1,54	[0,69; 3,57]	0,2954
Interaktion p-Wert									0,4351
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	1 (10,0)	NE [NE; NE]	1,56	[0,15; 33,67]	0,7091
IV	78	22 (28,2)	NE [NE; NE]	77	11 (14,3)	NE [NE; NE]	2,00	[0,99; 4,30]	0,0532
Interaktion p-Wert									0,8486

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	66 (66,7)	3,4 [1,8; 5,3]	101	58 (57,4)	4,5 [2,2; NE]	1,24	[0,87; 1,77]	0,2283
Neu diagnostiziert	92	58 (63,0)	4,6 [1,3;10,6]	89	41 (46,1)	NE [NE; NE]	1,43	[0,96; 2,15]	0,0772
Interaktion p-Wert									0,6032
Region									
Asien	54	32 (59,3)	2,4 [0,9; NE]	54	29 (53,7)	4,7 [1,9; NE]	1,18	[0,71; 1,95]	0,5265
Rest der Welt	137	92 (67,2)	3,7 [2,2; 5,7]	136	70 (51,5)	7,1 [2,8; NE]	1,38	[1,01; 1,88]	0,0429*
Interaktion p-Wert									0,6024
Alter									
<65	101	68 (67,3)	3,0 [1,4; 7,7]	98	51 (52,0)	5,8 [3,7; NE]	1,40	[0,98; 2,03]	0,0656
>=65	90	56 (62,2)	3,7 [2,1; 6,1]	92	48 (52,2)	4,9 [2,2; NE]	1,23	[0,84; 1,81]	0,2964
Interaktion p-Wert									0,6193
Abstammung									
Weiß	104	67 (64,4)	3,4 [1,6; 7,8]	112	58 (51,8)	7,1 [2,8; NE]	1,34	[0,94; 1,90]	0,1052
Schwarz/Afroamerikanisch	13	8 (61,5)	7,7 [0,4; NE]	8	3 (37,5)	NE [NE; NE]	1,81	[0,52; 8,28]	0,3609
Asiatisch	57	35 (61,4)	2,2 [0,9; 8,3]	58	31 (53,4)	4,7 [1,9; NE]	1,23	[0,76; 2,01]	0,3933
Andere	16	13 (81,3)	4,2 [1,0; 9,9]	12	7 (58,3)	3,5 [0,2; NE]	1,15	[0,47; 3,06]	0,7668
Interaktion p-Wert									0,9425
HRR Mutationsstatus									
HRRm	21	13 (61,9)	6,5 [0,8; NE]	16	9 (56,3)	4,2 [0,9; NE]	1,06	[0,46; 2,57]	0,8912
Nicht-HRRm	118	77 (65,3)	3,0 [1,6; 5,1]	111	58 (52,3)	5,9 [2,3; NE]	1,34	[0,95; 1,89]	0,0912
Unbekannt	52	34 (65,4)	5,2 [1,4;11,5]	63	32 (50,8)	7,1 [2,1; NE]	1,38	[0,85; 2,24]	0,1946
Interaktion p-Wert									0,8667
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	76 (67,9)	3,4 [1,6; 5,8]	122	61 (50,0)	8,1 [3,3; NE]	1,47	[1,05; 2,06]	0,0256*
Negativ	73	44 (60,3)	4,4 [1,5;11,5]	67	37 (55,2)	4,9 [2,3; NE]	1,12	[0,72; 1,74]	0,6238
Unbekannt	6	4 (66,7)	2,8 [0,2; NE]	1	1 (100)	1,5 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3328
Histologie									
Endometrioid	107	66 (61,7)	4,4 [1,8; 9,9]	97	53 (54,6)	5,3 [2,2; NE]	1,14	[0,80; 1,64]	0,4731
Serös	42	29 (69,0)	3,4 [1,3; 8,3]	52	26 (50,0)	13,4 [2,6; NE]	1,49	[0,88; 2,54]	0,1414
Andere	42	29 (69,0)	2,8 [0,7; 7,7]	41	20 (48,8)	NE [NE; NE]	1,65	[0,94; 2,96]	0,0822
Interaktion p-Wert									0,4946
Histologischer Grad									
High grade (G3)	77	57 (74,0)	2,2 [1,3; 5,3]	82	42 (51,2)	7,1 [1,6; NE]	1,53	[1,03; 2,30]	0,0346*
Low grade (G1+G2)	90	50 (55,6)	6,9 [2,8; NE]	87	47 (54,0)	5,8 [2,2; NE]	1,02	[0,68; 1,52]	0,9294
Interaktion p-Wert									0,1546
ECOG Performance Status zu Baseline									
0	135	87 (64,4)	4,4 [1,8; 6,5]	126	74 (58,7)	3,7 [1,9;10,9]	1,10	[0,80; 1,50]	0,5602
1	56	37 (66,1)	2,8 [1,6;12,6]	64	25 (39,1)	NE [NE; NE]	1,99	[1,21; 3,35]	0,0071*
Interaktion p-Wert									0,0477*
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	9 (81,8)	1,3 [0,1;12,2]	10	1 (10,0)	NE [NE; NE]	14,49	[2,72;267,37]	0,0006*
IV	78	47 (60,3)	5,5 [1,4;16,8]	77	39 (50,6)	5,3 [2,1; NE]	1,14	[0,75; 1,76]	0,5369
Interaktion p-Wert									0,0022*

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	2 (2,2)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	4 (2,9)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	3 (3,3)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	1 (6,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	4 (3,4)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	2 (1,8)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	2 (2,7)	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	3 (7,1)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	3 (3,9)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	4 (3,0)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	21 (21,2)	NE [NE; NE]	101	21 (20,8)	NE [NE; NE]	1,01	[0,55; 1,87]	0,9633
Neu diagnostiziert	92	26 (28,3)	24,0 [20,5; NE]	89	19 (21,3)	NE [NE; NE]	1,28	[0,71; 2,34]	0,4166
Interaktion p-Wert									0,5931
Region									
Asien	54	15 (27,8)	NE [NE; NE]	54	17 (31,5)	NE [NE; NE]	0,93	[0,46; 1,87]	0,8398
Rest der Welt	137	32 (23,4)	NE [NE; NE]	136	23 (16,9)	NE [NE; NE]	1,32	[0,78; 2,29]	0,3055
Interaktion p-Wert									0,4326
Alter									
<65	101	28 (27,7)	NE [NE; NE]	98	19 (19,4)	NE [NE; NE]	1,53	[0,86; 2,78]	0,1493
>=65	90	19 (21,1)	NE [NE; NE]	92	21 (22,8)	NE [NE; NE]	0,82	[0,44; 1,54]	0,5396
Interaktion p-Wert									0,1527
Abstammung									
Weiß	104	26 (25,0)	24,0 [24,0; NE]	112	20 (17,9)	NE [NE; NE]	1,37	[0,76; 2,48]	0,2923
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	16 (28,1)	NE [NE; NE]	58	19 (32,8)	NE [NE; NE]	0,87	[0,44; 1,69]	0,6712
Andere	16	2 (12,5)	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	1,33	[0,13; 28,72]	0,8109
Interaktion p-Wert									0,5924
HRR Mutationsstatus									
HRRm	21	6 (28,6)	NE [NE; NE]	16	3 (18,8)	NE [NE; NE]	1,48	[0,39; 7,04]	0,5692
Nicht-HRRm	118	30 (25,4)	NE [NE; NE]	111	22 (19,8)	NE [NE; NE]	1,32	[0,77; 2,32]	0,3147
Unbekannt	52	11 (21,2)	NE [NE; NE]	63	15 (23,8)	NE [NE; NE]	0,79	[0,35; 1,72]	0,5559
Interaktion p-Wert									0,5270
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	29 (25,9)	NE [NE; NE]	122	24 (19,7)	NE [NE; NE]	1,23	[0,72; 2,14]	0,4476
Negativ	73	17 (23,3)	NE [NE; NE]	67	16 (23,9)	NE [NE; NE]	1,03	[0,52; 2,06]	0,9325
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6852
Histologie									
Endometrioid	107	25 (23,4)	NE [NE; NE]	97	21 (21,6)	NE [NE; NE]	1,06	[0,59; 1,91]	0,8432
Serös	42	11 (26,2)	NE [NE; NE]	52	10 (19,2)	NE [NE; NE]	1,28	[0,54; 3,08]	0,5696
Andere	42	11 (26,2)	24,0 [24,0; NE]	41	9 (22,0)	NE [NE; NE]	1,22	[0,51; 3,04]	0,6518
Interaktion p-Wert									0,9247
Histologischer Grad									
High grade (G3)	77	17 (22,1)	NE [NE; NE]	82	16 (19,5)	NE [NE; NE]	1,04	[0,52; 2,08]	0,9137
Low grade (G1+G2)	90	18 (20,0)	NE [NE; NE]	87	21 (24,1)	NE [NE; NE]	0,80	[0,42; 1,50]	0,4801
Interaktion p-Wert									0,5769
ECOG Performance Status zu Baseline									
0	135	33 (24,4)	NE [NE; NE]	126	35 (27,8)	NE [NE; NE]	0,88	[0,54; 1,41]	0,5922
1	56	14 (25,0)	NE [NE; NE]	64	5 (7,8)	NE [NE; NE]	3,04	[1,16; 9,42]	0,0226*
Interaktion p-Wert									0,0230*
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	7 (63,6)	4,7 [0,2; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	19 (24,4)	24,0 [20,5; NE]	77	19 (24,7)	NE [NE; NE]	0,85	[0,44; 1,62]	0,6165
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	33 (33,3)	NE [NE; NE]	101	30 (29,7)	NE [NE; NE]	1,16	[0,71; 1,92]	0,5488
Neu diagnostiziert	92	27 (29,3)	NE [NE; NE]	89	25 (28,1)	NE [NE; NE]	0,95	[0,55; 1,64]	0,8435
Interaktion p-Wert									0,5831
Region									
Asien	54	12 (22,2)	NE [NE; NE]	54	14 (25,9)	NE [NE; NE]	0,84	[0,38; 1,83]	0,6644
Rest der Welt	137	48 (35,0)	NE [NE; NE]	136	41 (30,1)	NE [NE; NE]	1,13	[0,74; 1,72]	0,5756
Interaktion p-Wert									0,5170
Alter									
<65	101	24 (23,8)	NE [NE; NE]	98	29 (29,6)	NE [NE; NE]	0,76	[0,44; 1,30]	0,3173
>=65	90	36 (40,0)	NE [NE; NE]	92	26 (28,3)	NE [NE; NE]	1,43	[0,87; 2,39]	0,1616
Interaktion p-Wert									0,0920
Abstammung									
Weiß	104	34 (32,7)	NE [NE; NE]	112	35 (31,3)	NE [NE; NE]	1,01	[0,63; 1,62]	0,9708
Schwarz/Afroamerikanisch	13	6 (46,2)	18,0 [0,4; NE]	8	1 (12,5)	NE [NE; NE]	5,21	[0,89; 98,45]	0,0697
Asiatisch	57	13 (22,8)	NE [NE; NE]	58	15 (25,9)	NE [NE; NE]	0,86	[0,41; 1,82]	0,7012
Andere	16	6 (37,5)	NE [NE; NE]	12	4 (33,3)	NE [NE; NE]	0,80	[0,23; 3,13]	0,7310
Interaktion p-Wert									0,3168
HRR Mutationsstatus									
HRRm	21	4 (19,0)	NE [NE; NE]	16	7 (43,8)	NE [NE; NE]	0,34	[0,09; 1,13]	0,0795
Nicht-HRRm	118	41 (34,7)	NE [NE; NE]	111	34 (30,6)	NE [NE; NE]	1,12	[0,71; 1,77]	0,6334
Unbekannt	52	15 (28,8)	NE [NE; NE]	63	14 (22,2)	NE [NE; NE]	1,32	[0,63; 2,77]	0,4550
Interaktion p-Wert									0,1487
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	35 (31,3)	NE [NE; NE]	122	36 (29,5)	NE [NE; NE]	0,99	[0,62; 1,58]	0,9632
Negativ	73	21 (28,8)	NE [NE; NE]	67	18 (26,9)	NE [NE; NE]	1,12	[0,60; 2,13]	0,7185
Unbekannt	6	4 (66,7)	8,1 [0,2; NE]	1	1 (100)	1,5 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7512
Histologie									
Endometrioid	107	32 (29,9)	NE [NE; NE]	97	28 (28,9)	NE [NE; NE]	1,02	[0,62; 1,71]	0,9319
Serös	42	13 (31,0)	NE [NE; NE]	52	17 (32,7)	NE [NE; NE]	0,88	[0,42; 1,80]	0,7236
Andere	42	15 (35,7)	18,0 [5,4; NE]	41	10 (24,4)	NE [NE; NE]	1,47	[0,67; 3,38]	0,3403
Interaktion p-Wert									0,6261
Histologischer Grad									
High grade (G3)	77	33 (42,9)	18,0 [8,3; NE]	82	25 (30,5)	NE [NE; NE]	1,30	[0,78; 2,21]	0,3208
Low grade (G1+G2)	90	22 (24,4)	NE [NE; NE]	87	23 (26,4)	NE [NE; NE]	0,95	[0,53; 1,71]	0,8655
Interaktion p-Wert									0,4327
ECOG Performance Status zu Baseline									
0	135	38 (28,1)	NE [NE; NE]	126	39 (31,0)	NE [NE; NE]	0,88	[0,56; 1,38]	0,5746
1	56	22 (39,3)	NE [NE; NE]	64	16 (25,0)	NE [NE; NE]	1,56	[0,82; 3,02]	0,1728
Interaktion p-Wert									0,1503
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	4 (36,4)	NE [NE; NE]	10	1 (10,0)	NE [NE; NE]	3,51	[0,52; 68,57]	0,2128
IV	78	21 (26,9)	NE [NE; NE]	77	23 (29,9)	NE [NE; NE]	0,81	[0,45; 1,48]	0,4986
Interaktion p-Wert									0,1631

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hepatische Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	2 (1,7)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hepatische Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	2 (1,9)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	1 (1,3)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hyperthyreose Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	4 (4,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	4 (4,3)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	4 (7,4)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	4 (2,9)	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	7 (6,9)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	4 (3,8)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	4 (7,0)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	3 (2,5)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	4 (7,7)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hyperthyreose Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	5 (4,5)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	3 (4,1)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	6 (5,6)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	2 (4,8)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	2 (2,6)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	4 (4,4)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	6 (4,4)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	2 (3,6)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hypothyreose Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	16 (16,2)	NE [NE; NE]	101	3 (3,0)	NE [NE; NE]	5,96	[1,98; 25,62]	0,0008*
Neu diagnostiziert	92	13 (14,1)	NE [NE; NE]	89	3 (3,4)	NE [NE; NE]	4,05	[1,31; 17,70]	0,0137*
Interaktion p-Wert									0,6685
Region									
Asien	54	6 (11,1)	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	3,21	[0,74; 21,92]	0,1234
Rest der Welt	137	23 (16,8)	NE [NE; NE]	136	4 (2,9)	NE [NE; NE]	5,83	[2,24; 19,90]	0,0001*
Interaktion p-Wert									0,5510
Alter									
<65	101	18 (17,8)	NE [NE; NE]	98	3 (3,1)	NE [NE; NE]	6,40	[2,17; 27,34]	0,0003*
>=65	90	11 (12,2)	NE [NE; NE]	92	3 (3,3)	NE [NE; NE]	3,63	[1,13; 16,07]	0,0288*
Interaktion p-Wert									0,5312
Abstammung									
Weiß	104	15 (14,4)	NE [NE; NE]	112	4 (3,6)	NE [NE; NE]	3,99	[1,45; 14,00]	0,0063*
Schwarz/Afroamerikanisch	13	2 (15,4)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	7 (12,3)	NE [NE; NE]	58	2 (3,4)	NE [NE; NE]	3,79	[0,92; 25,45]	0,0671
Andere	16	4 (25,0)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9587
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	18 (15,3)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	3,55	[1,41; 10,74]	0,0059*
Unbekannt	52	11 (21,2)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	14,54	[2,83;265,77]	0,0004*
Interaktion p-Wert									0,1770
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hypothyreose Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	17 (15,2)	NE [NE; NE]	122	4 (3,3)	NE [NE; NE]	4,51	[1,67; 15,69]	0,0022*
Negativ	73	11 (15,1)	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	5,80	[1,56; 37,52]	0,0067*
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7884
Histologie									
Endometrioid	107	12 (11,2)	NE [NE; NE]	97	5 (5,2)	NE [NE; NE]	2,12	[0,79; 6,68]	0,1401
Serös	42	9 (21,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	8 (19,0)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	9,31	[1,71;172,76]	0,0069*
Interaktion p-Wert									0,1699
Histologischer Grad									
High grade (G3)	77	21 (27,3)	NE [NE; NE]	82	4 (4,9)	NE [NE; NE]	5,57	[2,12; 19,11]	0,0002*
Low grade (G1+G2)	90	7 (7,8)	NE [NE; NE]	87	2 (2,3)	NE [NE; NE]	3,60	[0,87; 24,18]	0,0789
Interaktion p-Wert									0,6585
ECOG Performance Status zu Baseline									
0	135	21 (15,6)	NE [NE; NE]	126	4 (3,2)	NE [NE; NE]	5,29	[2,01; 18,13]	0,0003*
1	56	8 (14,3)	NE [NE; NE]	64	2 (3,1)	NE [NE; NE]	4,34	[1,09; 28,82]	0,0370*
Interaktion p-Wert									0,8389
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	11 (14,1)	NE [NE; NE]	77	3 (3,9)	NE [NE; NE]	3,66	[1,14; 16,19]	0,0278*
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.5.2.1D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	11 (11,1)	NE [NE; NE]	101	17 (16,8)	NE [NE; NE]	0,62	[0,28; 1,32]	0,2168
Neu diagnostiziert	92	15 (16,3)	NE [NE; NE]	89	10 (11,2)	NE [NE; NE]	1,34	[0,61; 3,08]	0,4736
Interaktion p-Wert									0,1705
Region									
Asien	54	7 (13,0)	NE [NE; NE]	54	7 (13,0)	NE [NE; NE]	0,96	[0,33; 2,79]	0,9324
Rest der Welt	137	19 (13,9)	NE [NE; NE]	136	20 (14,7)	NE [NE; NE]	0,87	[0,46; 1,64]	0,6685
Interaktion p-Wert									0,8823
Alter									
<65	101	14 (13,9)	NE [NE; NE]	98	15 (15,3)	NE [NE; NE]	0,85	[0,41; 1,78]	0,6687
>=65	90	12 (13,3)	NE [NE; NE]	92	12 (13,0)	NE [NE; NE]	0,95	[0,42; 2,13]	0,8917
Interaktion p-Wert									0,8514
Abstammung									
Weiß	104	14 (13,5)	NE [NE; NE]	112	16 (14,3)	NE [NE; NE]	0,87	[0,42; 1,80]	0,7141
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	2 (25,0)	NE [NE; NE]	0,27	[0,01; 2,82]	0,2662
Asiatisch	57	8 (14,0)	NE [NE; NE]	58	7 (12,1)	NE [NE; NE]	1,12	[0,40; 3,21]	0,8220
Andere	16	3 (18,8)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	0,97	[0,16; 7,36]	0,9716
Interaktion p-Wert									0,7438
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	1 (6,3)	NE [NE; NE]	1,36	[0,13; 29,36]	0,7970
Nicht-HRRm	118	15 (12,7)	NE [NE; NE]	111	19 (17,1)	NE [NE; NE]	0,69	[0,34; 1,35]	0,2781
Unbekannt	52	9 (17,3)	NE [NE; NE]	63	7 (11,1)	NE [NE; NE]	1,50	[0,56; 4,20]	0,4192
Interaktion p-Wert									0,4136

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	17 (15,2)	NE [NE; NE]	122	16 (13,1)	NE [NE; NE]	1,08	[0,54; 2,17]	0,8171
Negativ	73	9 (12,3)	NE [NE; NE]	67	11 (16,4)	NE [NE; NE]	0,70	[0,28; 1,69]	0,4270
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4420
Histologie									
Endometrioid	107	14 (13,1)	NE [NE; NE]	97	17 (17,5)	NE [NE; NE]	0,69	[0,33; 1,39]	0,2980
Serös	42	6 (14,3)	NE [NE; NE]	52	5 (9,6)	NE [NE; NE]	1,41	[0,42; 4,89]	0,5728
Andere	42	6 (14,3)	NE [NE; NE]	41	5 (12,2)	NE [NE; NE]	1,12	[0,34; 3,89]	0,8525
Interaktion p-Wert									0,5406
Histologischer Grad									
High grade (G3)	77	12 (15,6)	NE [NE; NE]	82	14 (17,1)	NE [NE; NE]	0,79	[0,36; 1,73]	0,5575
Low grade (G1+G2)	90	8 (8,9)	NE [NE; NE]	87	13 (14,9)	NE [NE; NE]	0,56	[0,22; 1,33]	0,1917
Interaktion p-Wert									0,5615
ECOG Performance Status zu Baseline									
0	135	19 (14,1)	NE [NE; NE]	126	21 (16,7)	NE [NE; NE]	0,79	[0,42; 1,47]	0,4566
1	56	7 (12,5)	NE [NE; NE]	64	6 (9,4)	NE [NE; NE]	1,24	[0,41; 3,86]	0,6983
Interaktion p-Wert									0,4800
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	12 (15,4)	NE [NE; NE]	77	10 (13,0)	NE [NE; NE]	1,09	[0,47; 2,60]	0,8359
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Myositis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Myositis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	1 (1,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	2 (1,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	2 (1,7)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	1 (1,3)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	1 (1,3)	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.11 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	5 (5,1)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	3 (3,3)	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	2 (3,7)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	6 (4,4)	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	6 (5,9)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	2 (2,2)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	6 (5,8)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	2 (3,5)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	5 (4,2)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.11 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	4 (3,6)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	4 (5,5)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	3 (2,8)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	4 (9,5)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	3 (3,9)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	5 (5,6)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	6 (4,4)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	2 (3,6)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.12 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Renale Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	0	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	0	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.12 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Renale Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	0	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	0	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.13 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Thyreoiditis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	4 (4,0)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	2 (2,2)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	4 (7,4)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	3 (3,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	3 (3,3)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	4 (7,0)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	4 (3,4)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.1D.13 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Thyreoiditis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	5 (4,5)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	4 (3,7)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	2 (2,6)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	3 (3,3)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	5 (3,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	1 (1,8)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	69 (69,7)	3,4 [1,8; 5,3]	101	60 (59,4)	4,5 [2,2;15,9]	1,27	[0,90; 1,80]	0,1729
Neu diagnostiziert	92	59 (64,1)	4,6 [1,3;10,6]	89	42 (47,2)	22,5 [3,7; NE]	1,44	[0,97; 2,15]	0,0712
Interaktion p-Wert									0,6507
Region									
Asien	54	34 (63,0)	2,4 [0,9;16,1]	54	30 (55,6)	4,7 [1,9; NE]	1,23	[0,75; 2,02]	0,4092
Rest der Welt	137	94 (68,6)	3,7 [2,2; 5,7]	136	72 (52,9)	7,1 [2,8; NE]	1,38	[1,02; 1,88]	0,0387*
Interaktion p-Wert									0,6952
Alter									
<65	101	69 (68,3)	3,0 [1,4; 7,7]	98	52 (53,1)	5,8 [3,7; NE]	1,42	[0,99; 2,04]	0,0564
>=65	90	59 (65,6)	3,7 [2,1; 6,1]	92	50 (54,3)	4,9 [2,2; NE]	1,25	[0,86; 1,83]	0,2395
Interaktion p-Wert									0,6437
Abstammung									
Weiß	104	68 (65,4)	3,4 [1,6; 7,8]	112	60 (53,6)	7,1 [2,8; NE]	1,32	[0,93; 1,87]	0,1204
Schwarz/Afroamerikanisch	13	9 (69,2)	7,7 [0,4;18,0]	8	3 (37,5)	NE [NE; NE]	2,10	[0,63; 9,49]	0,2390
Asiatisch	57	37 (64,9)	2,2 [0,9; 8,3]	58	32 (55,2)	4,7 [1,9; NE]	1,29	[0,80; 2,08]	0,2933
Andere	16	13 (81,3)	4,2 [1,0; 9,9]	12	7 (58,3)	3,5 [0,2; NE]	1,18	[0,48; 3,14]	0,7230
Interaktion p-Wert									0,8981
HRR Mutationsstatus									
HRRm	21	13 (61,9)	6,5 [0,8; NE]	16	9 (56,3)	4,2 [0,9; NE]	1,07	[0,46; 2,60]	0,8734
Nicht-HRRm	118	78 (66,1)	3,0 [1,6; 5,1]	111	59 (53,2)	5,9 [2,3; NE]	1,34	[0,96; 1,89]	0,0859
Unbekannt	52	37 (71,2)	5,2 [1,4;11,5]	63	34 (54,0)	7,1 [2,1; NE]	1,44	[0,90; 2,31]	0,1241
Interaktion p-Wert									0,8370
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	79 (70,5)	3,4 [1,6; 5,8]	122	62 (50,8)	8,1 [3,3; NE]	1,52	[1,09; 2,13]	0,0131*
Negativ	73	45 (61,6)	4,4 [1,5;11,5]	67	39 (58,2)	4,9 [2,3; NE]	1,09	[0,71; 1,69]	0,6830
Unbekannt	6	4 (66,7)	2,8 [0,2; NE]	1	1 (100)	1,5 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2341
Histologie									
Endometrioid	107	68 (63,6)	4,4 [1,8; 9,9]	97	56 (57,7)	5,3 [2,2;22,5]	1,12	[0,79; 1,60]	0,5332
Serös	42	30 (71,4)	3,4 [1,3; 8,3]	52	26 (50,0)	13,4 [2,6; NE]	1,57	[0,93; 2,68]	0,0914
Andere	42	30 (71,4)	2,8 [0,7; 7,7]	41	20 (48,8)	NE [NE; NE]	1,74	[0,996; 3,11]	0,0517
Interaktion p-Wert									0,3354
Histologischer Grad									
High grade (G3)	77	58 (75,3)	2,2 [1,3; 5,3]	82	44 (53,7)	7,1 [1,6; NE]	1,51	[1,02; 2,25]	0,0379*
Low grade (G1+G2)	90	52 (57,8)	6,9 [2,8;21,7]	87	48 (55,2)	5,8 [2,2; NE]	1,04	[0,70; 1,55]	0,8395
Interaktion p-Wert									0,1877
ECOG Performance Status zu Baseline									
0	135	88 (65,2)	4,4 [1,8; 6,5]	126	74 (58,7)	3,7 [1,9;10,9]	1,12	[0,83; 1,54]	0,4557
1	56	40 (71,4)	2,8 [1,6;12,6]	64	28 (43,8)	22,5 [5,9; NE]	1,94	[1,20; 3,17]	0,0067*
Interaktion p-Wert									0,0618
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	9 (81,8)	1,3 [0,1;12,2]	10	1 (10,0)	NE [NE; NE]	14,66	[2,75;270,34]	0,0006*
IV	78	48 (61,5)	5,5 [1,4;16,8]	77	40 (51,9)	5,3 [2,1; NE]	1,15	[0,75; 1,75]	0,5259
Interaktion p-Wert									0,0021*

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	3 (3,3)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	5 (3,6)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	4 (4,4)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	1 (6,3)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	1 (6,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	4 (3,4)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	2 (1,8)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	3 (4,1)	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	2 (1,9)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	3 (7,1)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	4 (5,2)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	5 (3,7)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	21 (21,2)	NE [NE; NE]	101	22 (21,8)	NE [NE; NE]	0,96	[0,53; 1,76]	0,9010
Neu diagnostiziert	92	26 (28,3)	NE [NE; NE]	89	19 (21,3)	NE [NE; NE]	1,28	[0,71; 2,35]	0,4073
Interaktion p-Wert									0,5026
Region									
Asien	54	15 (27,8)	NE [NE; NE]	54	17 (31,5)	NE [NE; NE]	0,93	[0,46; 1,87]	0,8466
Rest der Welt	137	32 (23,4)	NE [NE; NE]	136	24 (17,6)	NE [NE; NE]	1,26	[0,75; 2,17]	0,3851
Interaktion p-Wert									0,4965
Alter									
<65	101	28 (27,7)	NE [NE; NE]	98	19 (19,4)	NE [NE; NE]	1,52	[0,86; 2,77]	0,1520
>=65	90	19 (21,1)	NE [NE; NE]	92	22 (23,9)	NE [NE; NE]	0,79	[0,42; 1,46]	0,4456
Interaktion p-Wert									0,1243
Abstammung									
Weiß	104	26 (25,0)	NE [NE; NE]	112	21 (18,8)	NE [NE; NE]	1,29	[0,73; 2,32]	0,3801
Schwarz/Afroamerikanisch	13	3 (23,1)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	16 (28,1)	NE [NE; NE]	58	19 (32,8)	NE [NE; NE]	0,87	[0,44; 1,70]	0,6910
Andere	16	2 (12,5)	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	1,32	[0,13; 28,36]	0,8192
Interaktion p-Wert									0,6740
HRR Mutationsstatus									
HRRm	21	6 (28,6)	NE [NE; NE]	16	3 (18,8)	NE [NE; NE]	1,45	[0,38; 6,89]	0,5915
Nicht-HRRm	118	30 (25,4)	NE [NE; NE]	111	22 (19,8)	NE [NE; NE]	1,32	[0,77; 2,32]	0,3187
Unbekannt	52	11 (21,2)	NE [NE; NE]	63	16 (25,4)	NE [NE; NE]	0,75	[0,34; 1,60]	0,4612
Interaktion p-Wert									0,4608
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	29 (25,9)	NE [NE; NE]	122	24 (19,7)	NE [NE; NE]	1,23	[0,72; 2,13]	0,4551
Negativ	73	17 (23,3)	NE [NE; NE]	67	17 (25,4)	NE [NE; NE]	0,97	[0,49; 1,92]	0,9404
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5986
Histologie									
Endometrioid	107	25 (23,4)	NE [NE; NE]	97	22 (22,7)	NE [NE; NE]	1,01	[0,57; 1,80]	0,9739
Serös	42	11 (26,2)	NE [NE; NE]	52	10 (19,2)	NE [NE; NE]	1,29	[0,54; 3,10]	0,5615
Andere	42	11 (26,2)	NE [NE; NE]	41	9 (22,0)	NE [NE; NE]	1,22	[0,50; 3,03]	0,6576
Interaktion p-Wert									0,8758
Histologischer Grad									
High grade (G3)	77	17 (22,1)	NE [NE; NE]	82	17 (20,7)	NE [NE; NE]	0,97	[0,49; 1,92]	0,9397
Low grade (G1+G2)	90	18 (20,0)	NE [NE; NE]	87	21 (24,1)	NE [NE; NE]	0,80	[0,42; 1,50]	0,4798
Interaktion p-Wert									0,6696
ECOG Performance Status zu Baseline									
0	135	33 (24,4)	NE [NE; NE]	126	35 (27,8)	NE [NE; NE]	0,88	[0,54; 1,41]	0,5853
1	56	14 (25,0)	NE [NE; NE]	64	6 (9,4)	NE [NE; NE]	2,53	[1,01; 7,15]	0,0465*
Interaktion p-Wert									0,0439*
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	7 (63,6)	4,7 [0,2; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	19 (24,4)	NE [NE; NE]	77	19 (24,7)	NE [NE; NE]	0,86	[0,45; 1,65]	0,6551
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	34 (34,3)	29,9 [29,9; NE]	101	31 (30,7)	NE [NE; NE]	1,15	[0,70; 1,87]	0,5840
Neu diagnostiziert	92	29 (31,5)	NE [NE; NE]	89	26 (29,2)	NE [NE; NE]	0,95	[0,56; 1,62]	0,8389
Interaktion p-Wert									0,6032
Region									
Asien	54	14 (25,9)	NE [NE; NE]	54	15 (27,8)	NE [NE; NE]	0,90	[0,43; 1,88]	0,7854
Rest der Welt	137	49 (35,8)	NE [NE; NE]	136	42 (30,9)	NE [NE; NE]	1,09	[0,72; 1,66]	0,6689
Interaktion p-Wert									0,6541
Alter									
<65	101	27 (26,7)	NE [NE; NE]	98	30 (30,6)	NE [NE; NE]	0,80	[0,47; 1,35]	0,4076
>=65	90	36 (40,0)	NE [NE; NE]	92	27 (29,3)	NE [NE; NE]	1,36	[0,83; 2,26]	0,2276
Interaktion p-Wert									0,1519
Abstammung									
Weiß	104	35 (33,7)	NE [NE; NE]	112	36 (32,1)	NE [NE; NE]	0,99	[0,62; 1,58]	0,9578
Schwarz/Afroamerikanisch	13	6 (46,2)	18,0 [0,4; NE]	8	1 (12,5)	NE [NE; NE]	5,02	[0,86; 94,97]	0,0770
Asiatisch	57	15 (26,3)	NE [NE; NE]	58	16 (27,6)	NE [NE; NE]	0,92	[0,45; 1,87]	0,8178
Andere	16	6 (37,5)	NE [NE; NE]	12	4 (33,3)	NE [NE; NE]	0,77	[0,22; 3,00]	0,6843
Interaktion p-Wert									0,3432
HRR Mutationsstatus									
HRRm	21	5 (23,8)	NE [NE; NE]	16	7 (43,8)	NE [NE; NE]	0,39	[0,12; 1,24]	0,1094
Nicht-HRRm	118	42 (35,6)	NE [NE; NE]	111	35 (31,5)	NE [NE; NE]	1,10	[0,70; 1,73]	0,6812
Unbekannt	52	16 (30,8)	NE [NE; NE]	63	15 (23,8)	NE [NE; NE]	1,29	[0,63; 2,63]	0,4855
Interaktion p-Wert									0,2030
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	38 (33,9)	NE [NE; NE]	122	37 (30,3)	NE [NE; NE]	1,01	[0,64; 1,60]	0,9538
Negativ	73	21 (28,8)	NE [NE; NE]	67	19 (28,4)	NE [NE; NE]	1,05	[0,56; 1,98]	0,8699
Unbekannt	6	4 (66,7)	8,1 [0,2; NE]	1	1 (100)	1,5 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9219
Histologie									
Endometrioid	107	35 (32,7)	NE [NE; NE]	97	30 (30,9)	NE [NE; NE]	1,03	[0,63; 1,68]	0,9159
Serös	42	13 (31,0)	NE [NE; NE]	52	17 (32,7)	NE [NE; NE]	0,85	[0,40; 1,74]	0,6532
Andere	42	15 (35,7)	18,0 [5,4; NE]	41	10 (24,4)	NE [NE; NE]	1,45	[0,66; 3,33]	0,3595
Interaktion p-Wert									0,6125
Histologischer Grad									
High grade (G3)	77	33 (42,9)	18,0 [8,3; NE]	82	26 (31,7)	22,5 [22,5; NE]	1,21	[0,73; 2,05]	0,4582
Low grade (G1+G2)	90	24 (26,7)	NE [NE; NE]	87	24 (27,6)	NE [NE; NE]	0,98	[0,55; 1,73]	0,9413
Interaktion p-Wert									0,5800
ECOG Performance Status zu Baseline									
0	135	41 (30,4)	NE [NE; NE]	126	39 (31,0)	NE [NE; NE]	0,94	[0,60; 1,45]	0,7647
1	56	22 (39,3)	NE [NE; NE]	64	18 (28,1)	22,5 [16,4; NE]	1,34	[0,72; 2,53]	0,3576
Interaktion p-Wert									0,3550
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	4 (36,4)	NE [NE; NE]	10	1 (10,0)	NE [NE; NE]	3,35	[0,49; 65,45]	0,2320
IV	78	23 (29,5)	NE [NE; NE]	77	24 (31,2)	22,5 [22,5; NE]	0,82	[0,46; 1,46]	0,4971
Interaktion p-Wert									0,1784

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hepatische Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	2 (1,7)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hepatische Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	2 (1,9)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	1 (1,3)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hyperthyreose Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	6 (6,1)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	4 (4,3)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	5 (9,3)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	5 (3,6)	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	7 (6,9)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	3 (3,3)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	4 (3,8)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	5 (8,8)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	3 (2,5)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	6 (11,5)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hyperthyreose Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	7 (6,3)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	3 (4,1)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	7 (6,5)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	3 (7,1)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	3 (3,9)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	5 (5,6)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	6 (4,4)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	4 (7,1)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hypothyreose Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	17 (17,2)	NE [NE; NE]	101	3 (3,0)	NE [NE; NE]	6,20	[2,08; 26,59]	0,0005*
Neu diagnostiziert	92	14 (15,2)	NE [NE; NE]	89	3 (3,4)	NE [NE; NE]	4,17	[1,36; 18,11]	0,0109*
Interaktion p-Wert									0,6562
Region									
Asien	54	6 (11,1)	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	3,18	[0,73; 21,70]	0,1268
Rest der Welt	137	25 (18,2)	NE [NE; NE]	136	4 (2,9)	NE [NE; NE]	6,08	[2,35; 20,68]	<0,0001*
Interaktion p-Wert									0,5174
Alter									
<65	101	19 (18,8)	NE [NE; NE]	98	3 (3,1)	NE [NE; NE]	6,55	[2,23; 27,91]	0,0002*
>=65	90	12 (13,3)	NE [NE; NE]	92	3 (3,3)	NE [NE; NE]	3,83	[1,22; 16,84]	0,0203*
Interaktion p-Wert									0,5505
Abstammung									
Weiß	104	17 (16,3)	NE [NE; NE]	112	4 (3,6)	NE [NE; NE]	4,31	[1,59; 15,01]	0,0031*
Schwarz/Afroamerikanisch	13	2 (15,4)	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	7 (12,3)	NE [NE; NE]	58	2 (3,4)	NE [NE; NE]	3,71	[0,90; 24,91]	0,0720
Andere	16	4 (25,0)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8785
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	19 (16,1)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	3,64	[1,46; 11,00]	0,0044*
Unbekannt	52	12 (23,1)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	15,29	[3,01;278,56]	0,0002*
Interaktion p-Wert									0,1671
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Hypothyreose Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	18 (16,1)	NE [NE; NE]	122	4 (3,3)	NE [NE; NE]	4,54	[1,69; 15,74]	0,0019*
Negativ	73	12 (16,4)	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	6,32	[1,72; 40,64]	0,0037*
Unbekannt	6	1 (16,7)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7218
Histologie									
Endometrioid	107	14 (13,1)	NE [NE; NE]	97	5 (5,2)	NE [NE; NE]	2,39	[0,91; 7,41]	0,0770
Serös	42	9 (21,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	8 (19,0)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	9,07	[1,66;168,27]	0,0077*
Interaktion p-Wert									0,2168
Histologischer Grad									
High grade (G3)	77	21 (27,3)	NE [NE; NE]	82	4 (4,9)	NE [NE; NE]	5,43	[2,06; 18,62]	0,0003*
Low grade (G1+G2)	90	9 (10,0)	NE [NE; NE]	87	2 (2,3)	NE [NE; NE]	4,44	[1,14; 29,14]	0,0300*
Interaktion p-Wert									0,8345
ECOG Performance Status zu Baseline									
0	135	23 (17,0)	NE [NE; NE]	126	4 (3,2)	NE [NE; NE]	5,62	[2,16; 19,18]	0,0002*
1	56	8 (14,3)	NE [NE; NE]	64	2 (3,1)	NE [NE; NE]	4,19	[1,05; 27,78]	0,0426*
Interaktion p-Wert									0,7610
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	12 (15,4)	NE [NE; NE]	77	3 (3,9)	NE [NE; NE]	3,78	[1,19; 16,66]	0,0223*
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	11 (11,1)	NE [NE; NE]	101	18 (17,8)	NE [NE; NE]	0,58	[0,27; 1,22]	0,1531
Neu diagnostiziert	92	15 (16,3)	NE [NE; NE]	89	10 (11,2)	NE [NE; NE]	1,33	[0,60; 3,06]	0,4884
Interaktion p-Wert									0,1383
Region									
Asien	54	7 (13,0)	NE [NE; NE]	54	7 (13,0)	NE [NE; NE]	0,95	[0,33; 2,79]	0,9299
Rest der Welt	137	19 (13,9)	NE [NE; NE]	136	21 (15,4)	NE [NE; NE]	0,82	[0,44; 1,53]	0,5301
Interaktion p-Wert									0,8061
Alter									
<65	101	14 (13,9)	NE [NE; NE]	98	16 (16,3)	NE [NE; NE]	0,79	[0,38; 1,63]	0,5236
>=65	90	12 (13,3)	NE [NE; NE]	92	12 (13,0)	NE [NE; NE]	0,94	[0,42; 2,11]	0,8747
Interaktion p-Wert									0,7581
Abstammung									
Weiß	104	14 (13,5)	NE [NE; NE]	112	17 (15,2)	NE [NE; NE]	0,82	[0,40; 1,66]	0,5740
Schwarz/Afroamerikanisch	13	1 (7,7)	NE [NE; NE]	8	2 (25,0)	NE [NE; NE]	0,25	[0,01; 2,63]	0,2417
Asiatisch	57	8 (14,0)	NE [NE; NE]	58	7 (12,1)	NE [NE; NE]	1,12	[0,40; 3,19]	0,8297
Andere	16	3 (18,8)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	0,97	[0,16; 7,37]	0,9726
Interaktion p-Wert									0,7101
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	1 (6,3)	NE [NE; NE]	1,33	[0,13; 28,67]	0,8126
Nicht-HRRm	118	15 (12,7)	NE [NE; NE]	111	19 (17,1)	NE [NE; NE]	0,68	[0,34; 1,34]	0,2653
Unbekannt	52	9 (17,3)	NE [NE; NE]	63	8 (12,7)	NE [NE; NE]	1,30	[0,50; 3,48]	0,5842
Interaktion p-Wert									0,5151

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	17 (15,2)	NE [NE; NE]	122	16 (13,1)	NE [NE; NE]	1,06	[0,53; 2,13]	0,8619
Negativ	73	9 (12,3)	NE [NE; NE]	67	12 (17,9)	NE [NE; NE]	0,65	[0,26; 1,53]	0,3240
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3798
Histologie									
Endometrioid	107	14 (13,1)	NE [NE; NE]	97	18 (18,6)	NE [NE; NE]	0,64	[0,31; 1,29]	0,2120
Serös	42	6 (14,3)	NE [NE; NE]	52	5 (9,6)	NE [NE; NE]	1,40	[0,42; 4,85]	0,5819
Andere	42	6 (14,3)	NE [NE; NE]	41	5 (12,2)	NE [NE; NE]	1,12	[0,34; 3,88]	0,8562
Interaktion p-Wert									0,4726
Histologischer Grad									
High grade (G3)	77	12 (15,6)	NE [NE; NE]	82	14 (17,1)	NE [NE; NE]	0,79	[0,36; 1,71]	0,5444
Low grade (G1+G2)	90	8 (8,9)	NE [NE; NE]	87	14 (16,1)	NE [NE; NE]	0,51	[0,20; 1,20]	0,1237
Interaktion p-Wert									0,4672
ECOG Performance Status zu Baseline									
0	135	19 (14,1)	NE [NE; NE]	126	22 (17,5)	NE [NE; NE]	0,75	[0,40; 1,38]	0,3513
1	56	7 (12,5)	NE [NE; NE]	64	6 (9,4)	NE [NE; NE]	1,23	[0,41; 3,83]	0,7094
Interaktion p-Wert									0,4335
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	12 (15,4)	NE [NE; NE]	77	10 (13,0)	NE [NE; NE]	1,11	[0,48; 2,63]	0,8152
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Myositis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Myositis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	3 (2,2)	NE [NE; NE]	136	2 (1,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	2 (2,0)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	3 (2,9)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	3 (2,5)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.10 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	2 (1,8)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	2 (2,6)	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	1 (1,8)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	1 (1,3)	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.11 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	6 (6,1)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	3 (3,3)	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	3 (5,6)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	6 (4,4)	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	6 (5,9)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	3 (3,3)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	6 (5,8)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	3 (5,3)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	6 (5,1)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.11 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	5 (4,5)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	4 (5,5)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	3 (2,8)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Andere	42	5 (11,9)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	3 (3,9)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	5 (5,6)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	6 (4,4)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	3 (5,4)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.5.2.2D.12 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Renale Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	0	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	0	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.12 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Renale Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	0	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	1 (1,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	0	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.13 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Thyreoiditis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	4 (4,0)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	2 (2,2)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	4 (7,4)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	3 (3,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	3 (3,3)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	4 (7,0)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	1 (4,8)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	4 (3,4)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.5.2.2D.13 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI GT: Thyreoiditis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	5 (4,5)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	4 (3,7)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	2 (2,6)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	3 (3,3)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	5 (3,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	1 (1,8)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	12 (12,1)	NE [NE; NE]	101	9 (8,9)	NE [NE; NE]	1,42	[0,60; 3,48]	0,4250
Neu diagnostiziert	92	5 (5,4)	NE [NE; NE]	89	5 (5,6)	NE [NE; NE]	0,87	[0,24; 3,13]	0,8250
Interaktion p-Wert									0,5256
Region									
Asien	54	4 (7,4)	NE [NE; NE]	54	4 (7,4)	NE [NE; NE]	1,00	[0,24; 4,25]	0,9948
Rest der Welt	137	13 (9,5)	NE [NE; NE]	136	10 (7,4)	NE [NE; NE]	1,24	[0,54; 2,90]	0,6103
Interaktion p-Wert									0,7995
Alter									
<65	101	6 (5,9)	NE [NE; NE]	98	9 (9,2)	NE [NE; NE]	0,62	[0,21; 1,73]	0,3657
>=65	90	11 (12,2)	NE [NE; NE]	92	5 (5,4)	NE [NE; NE]	2,21	[0,80; 7,00]	0,1275
Interaktion p-Wert									0,0867
Abstammung									
Weiß	104	11 (10,6)	NE [NE; NE]	112	8 (7,1)	NE [NE; NE]	1,42	[0,58; 3,67]	0,4452
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	5 (8,8)	NE [NE; NE]	58	4 (6,9)	NE [NE; NE]	1,27	[0,33; 5,11]	0,7245
Andere	16	0	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8864
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	11 (9,3)	NE [NE; NE]	111	10 (9,0)	NE [NE; NE]	1,01	[0,43; 2,42]	0,9838
Unbekannt	52	4 (7,7)	NE [NE; NE]	63	4 (6,3)	NE [NE; NE]	1,17	[0,28; 4,94]	0,8266
Interaktion p-Wert									0,8605
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	10 (8,9)	NE [NE; NE]	122	8 (6,6)	NE [NE; NE]	1,30	[0,51; 3,41]	0,5788
Negativ	73	5 (6,8)	NE [NE; NE]	67	6 (9,0)	NE [NE; NE]	0,76	[0,22; 2,54]	0,6554
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4880
Histologie									
Endometrioid	107	8 (7,5)	NE [NE; NE]	97	9 (9,3)	NE [NE; NE]	0,77	[0,29; 2,01]	0,5854
Serös	42	5 (11,9)	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	3,09	[0,67; 21,58]	0,1528
Andere	42	4 (9,5)	NE [NE; NE]	41	3 (7,3)	NE [NE; NE]	1,29	[0,28; 6,53]	0,7403
Interaktion p-Wert									0,3215
Histologischer Grad									
High grade (G3)	77	5 (6,5)	NE [NE; NE]	82	6 (7,3)	NE [NE; NE]	0,77	[0,22; 2,57]	0,6704
Low grade (G1+G2)	90	9 (10,0)	NE [NE; NE]	87	8 (9,2)	NE [NE; NE]	1,12	[0,43; 2,99]	0,8099
Interaktion p-Wert									0,6296
ECOG Performance Status zu Baseline									
0	135	14 (10,4)	NE [NE; NE]	126	9 (7,1)	NE [NE; NE]	1,44	[0,63; 3,46]	0,3868
1	56	3 (5,4)	NE [NE; NE]	64	5 (7,8)	NE [NE; NE]	0,64	[0,13; 2,60]	0,5325
Interaktion p-Wert									0,3281
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	3 (3,8)	NE [NE; NE]	77	5 (6,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	2 (2,2)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	2 (1,7)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	2 (4,8)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	2 (2,6)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	1 (1,0)	NE [NE; NE]	101	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	0	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	0	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	2 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.6.2.1D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	3 (3,0)	NE [NE; NE]	101	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	3 (3,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	4 (2,9)	NE [NE; NE]	136	3 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	4 (4,1)	NE [NE; NE]	NC	[NC]	NC
>=65	90	3 (3,3)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	3 (2,9)	NE [NE; NE]	112	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	2 (3,4)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	3 (2,5)	NE [NE; NE]	111	4 (3,6)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	2 (1,8)	NE [NE; NE]	122	3 (2,5)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	4 (3,7)	NE [NE; NE]	97	3 (3,1)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	2 (2,4)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	4 (4,4)	NE [NE; NE]	87	3 (3,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	4 (3,2)	NE [NE; NE]	NC	[NC]	NC
1	56	2 (3,6)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	1 (1,3)	NE [NE; NE]	77	3 (3,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.6.2.1D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	6 (6,1)	NE [NE; NE]	101	4 (4,0)	NE [NE; NE]	1,52	[0,43; 5,96]	0,5117
Neu diagnostiziert	92	0	NE [NE; NE]	89	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	2 (3,7)	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	4 (2,9)	NE [NE; NE]	136	5 (3,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	4 (4,1)	NE [NE; NE]	NC	[NC]	NC
>=65	90	5 (5,6)	NE [NE; NE]	92	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	4 (3,8)	NE [NE; NE]	112	4 (3,6)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	2 (3,5)	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	4 (3,4)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	2 (3,8)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	3 (2,7)	NE [NE; NE]	122	4 (3,3)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	3 (4,1)	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	3 (2,8)	NE [NE; NE]	97	4 (4,1)	NE [NE; NE]	NC	[NC]	NC
Serös	42	2 (4,8)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	2 (4,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	3 (3,9)	NE [NE; NE]	82	4 (4,9)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	2 (2,2)	NE [NE; NE]	87	2 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	6 (4,4)	NE [NE; NE]	126	3 (2,4)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	3 (4,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	2 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Myositis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Myositis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Neue primäre Malignität
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	0	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	0	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Neue primäre Malignität
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	0	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	0	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	3 (3,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.1D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	2 (1,8)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	2 (4,8)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	3 (3,3)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	1 (1,8)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	12 (12,1)	NE [NE; NE]	101	9 (8,9)	NE [NE; NE]	1,43	[0,60; 3,50]	0,4178
Neu diagnostiziert	92	5 (5,4)	NE [NE; NE]	89	5 (5,6)	NE [NE; NE]	0,87	[0,24; 3,13]	0,8279
Interaktion p-Wert									0,5231
Region									
Asien	54	4 (7,4)	NE [NE; NE]	54	4 (7,4)	NE [NE; NE]	1,00	[0,24; 4,23]	0,9993
Rest der Welt	137	13 (9,5)	NE [NE; NE]	136	10 (7,4)	NE [NE; NE]	1,25	[0,55; 2,92]	0,5981
Interaktion p-Wert									0,7890
Alter									
<65	101	6 (5,9)	NE [NE; NE]	98	9 (9,2)	NE [NE; NE]	0,63	[0,21; 1,74]	0,3719
>=65	90	11 (12,2)	NE [NE; NE]	92	5 (5,4)	NE [NE; NE]	2,21	[0,80; 7,01]	0,1267
Interaktion p-Wert									0,0878
Abstammung									
Weiß	104	11 (10,6)	NE [NE; NE]	112	8 (7,1)	NE [NE; NE]	1,43	[0,58; 3,70]	0,4377
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	5 (8,8)	NE [NE; NE]	58	4 (6,9)	NE [NE; NE]	1,26	[0,33; 5,11]	0,7253
Andere	16	0	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8801
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	11 (9,3)	NE [NE; NE]	111	10 (9,0)	NE [NE; NE]	1,01	[0,43; 2,42]	0,9851
Unbekannt	52	4 (7,7)	NE [NE; NE]	63	4 (6,3)	NE [NE; NE]	1,18	[0,28; 4,98]	0,8173
Interaktion p-Wert									0,8519
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	10 (8,9)	NE [NE; NE]	122	8 (6,6)	NE [NE; NE]	1,31	[0,52; 3,43]	0,5670
Negativ	73	5 (6,8)	NE [NE; NE]	67	6 (9,0)	NE [NE; NE]	0,76	[0,22; 2,53]	0,6529
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4796
Histologie									
Endometrioid	107	8 (7,5)	NE [NE; NE]	97	9 (9,3)	NE [NE; NE]	0,76	[0,29; 1,99]	0,5767
Serös	42	5 (11,9)	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	3,13	[0,68; 21,86]	0,1479
Andere	42	4 (9,5)	NE [NE; NE]	41	3 (7,3)	NE [NE; NE]	1,31	[0,29; 6,66]	0,7201
Interaktion p-Wert									0,3102
Histologischer Grad									
High grade (G3)	77	5 (6,5)	NE [NE; NE]	82	6 (7,3)	NE [NE; NE]	0,78	[0,23; 2,60]	0,6831
Low grade (G1+G2)	90	9 (10,0)	NE [NE; NE]	87	8 (9,2)	NE [NE; NE]	1,12	[0,43; 2,99]	0,8120
Interaktion p-Wert									0,6404
ECOG Performance Status zu Baseline									
0	135	14 (10,4)	NE [NE; NE]	126	9 (7,1)	NE [NE; NE]	1,45	[0,63; 3,47]	0,3816
1	56	3 (5,4)	NE [NE; NE]	64	5 (7,8)	NE [NE; NE]	0,64	[0,13; 2,61]	0,5356
Interaktion p-Wert									0,3278
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	3 (3,8)	NE [NE; NE]	77	5 (6,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	2 (2,2)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	2 (1,7)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	2 (4,8)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	2 (2,6)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	1 (1,0)	NE [NE; NE]	101	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	0	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	0	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	2 (2,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.6.2.2D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	3 (3,0)	NE [NE; NE]	101	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	3 (3,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	4 (2,9)	NE [NE; NE]	136	3 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	4 (4,1)	NE [NE; NE]	NC	[NC]	NC
>=65	90	3 (3,3)	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	3 (2,9)	NE [NE; NE]	112	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	2 (3,4)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	3 (2,5)	NE [NE; NE]	111	4 (3,6)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	2 (1,8)	NE [NE; NE]	122	3 (2,5)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	4 (3,7)	NE [NE; NE]	97	3 (3,1)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	2 (2,4)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	4 (4,4)	NE [NE; NE]	87	3 (3,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	4 (3,2)	NE [NE; NE]	NC	[NC]	NC
1	56	2 (3,6)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	1 (1,3)	NE [NE; NE]	77	3 (3,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.6.2.2D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	6 (6,1)	NE [NE; NE]	101	5 (5,0)	NE [NE; NE]	1,18	[0,35; 4,09]	0,7885
Neu diagnostiziert	92	0	NE [NE; NE]	89	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	2 (3,7)	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	1,91	[0,18; 41,11]	0,5870
Rest der Welt	137	4 (2,9)	NE [NE; NE]	136	6 (4,4)	NE [NE; NE]	0,57	[0,14; 2,02]	0,3853
Interaktion p-Wert									0,3700
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	5 (5,1)	NE [NE; NE]	NC	[NC]	NC
>=65	90	5 (5,6)	NE [NE; NE]	92	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	4 (3,8)	NE [NE; NE]	112	5 (4,5)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	2 (3,5)	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	4 (3,4)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	2 (3,8)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.6.2.2D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	3 (2,7)	NE [NE; NE]	122	4 (3,3)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	3 (4,1)	NE [NE; NE]	67	3 (4,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	3 (2,8)	NE [NE; NE]	97	5 (5,2)	NE [NE; NE]	NC	[NC]	NC
Serös	42	2 (4,8)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	2 (4,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	3 (3,9)	NE [NE; NE]	82	4 (4,9)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	2 (2,2)	NE [NE; NE]	87	3 (3,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	6 (4,4)	NE [NE; NE]	126	4 (3,2)	NE [NE; NE]	1,33	[0,38; 5,21]	0,6591
1	56	0	NE [NE; NE]	64	3 (4,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	2 (2,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Myositis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Myositis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Neue primäre Malignität
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	0	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	0	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Neue primäre Malignität
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	0	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	0	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	3 (3,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.6.2.2D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first UESI G>=3 GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	2 (1,8)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	2 (4,8)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	3 (3,3)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	1 (1,8)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.7.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	8 (8,1)	NE [NE; NE]	101	7 (6,9)	NE [NE; NE]	1,17	[0,42; 3,35]	0,7552
Neu diagnostiziert	92	4 (4,3)	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	3,63	[0,54; 70,92]	0,1995
Interaktion p-Wert									0,3293
Region									
Asien	54	2 (3,7)	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	0,99	[0,12; 8,26]	0,9934
Rest der Welt	137	10 (7,3)	NE [NE; NE]	136	6 (4,4)	NE [NE; NE]	1,60	[0,59; 4,70]	0,3563
Interaktion p-Wert									0,6719
Alter									
<65	101	5 (5,0)	NE [NE; NE]	98	2 (2,0)	NE [NE; NE]	2,42	[0,52; 16,90]	0,2667
>=65	90	7 (7,8)	NE [NE; NE]	92	6 (6,5)	NE [NE; NE]	1,13	[0,38; 3,51]	0,8263
Interaktion p-Wert									0,4386
Abstammung									
Weiß	104	10 (9,6)	NE [NE; NE]	112	6 (5,4)	NE [NE; NE]	1,73	[0,64; 5,09]	0,2800
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	2 (3,5)	NE [NE; NE]	58	2 (3,4)	NE [NE; NE]	1,00	[0,12; 8,32]	0,9986
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6256
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	7 (5,9)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	1,29	[0,41; 4,34]	0,6660
Unbekannt	52	3 (5,8)	NE [NE; NE]	63	3 (4,8)	NE [NE; NE]	1,17	[0,22; 6,34]	0,8454
Interaktion p-Wert									0,9270
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	6 (5,4)	NE [NE; NE]	122	4 (3,3)	NE [NE; NE]	1,56	[0,45; 6,10]	0,4857
Negativ	73	4 (5,5)	NE [NE; NE]	67	4 (6,0)	NE [NE; NE]	0,92	[0,22; 3,89]	0,9045
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5791
Histologie									
Endometrioid	107	7 (6,5)	NE [NE; NE]	97	3 (3,1)	NE [NE; NE]	2,08	[0,58; 9,67]	0,2682
Serös	42	2 (4,8)	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	1,18	[0,14; 9,85]	0,8675
Andere	42	3 (7,1)	NE [NE; NE]	41	3 (7,3)	NE [NE; NE]	0,94	[0,17; 5,09]	0,9421
Interaktion p-Wert									0,7383
Histologischer Grad									
High grade (G3)	77	3 (3,9)	NE [NE; NE]	82	4 (4,9)	NE [NE; NE]	0,71	[0,14; 3,23]	0,6545
Low grade (G1+G2)	90	8 (8,9)	NE [NE; NE]	87	3 (3,4)	NE [NE; NE]	2,69	[0,78; 12,28]	0,1214
Interaktion p-Wert									0,1844
ECOG Performance Status zu Baseline									
0	135	9 (6,7)	NE [NE; NE]	126	7 (5,6)	NE [NE; NE]	1,18	[0,44; 3,30]	0,7408
1	56	3 (5,4)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	3,27	[0,42; 66,13]	0,2678
Interaktion p-Wert									0,3958
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	0	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	1 (1,3)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	1 (1,3)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.7.2.1D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	0	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	0	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	0	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	0	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.7.2.1D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	4 (4,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	3 (2,2)	NE [NE; NE]	136	3 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	3 (3,3)	NE [NE; NE]	92	4 (4,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	3 (2,9)	NE [NE; NE]	112	3 (2,7)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	2 (1,7)	NE [NE; NE]	111	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	3 (2,5)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	3 (2,8)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	2 (4,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	2 (2,4)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	3 (3,3)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	3 (2,4)	NE [NE; NE]	NC	[NC]	NC
1	56	2 (3,6)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	1 (1,3)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Hepatische Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	1 (1,0)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Hepatische Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	0	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.7.2.1D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	2 (1,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	3 (2,7)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	1 (0,9)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	2 (2,1)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	2 (2,6)	NE [NE; NE]	82	2 (2,4)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	3 (2,4)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Myositis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Myositis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	1 (1,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	3 (3,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.1D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	2 (1,8)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	2 (4,8)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	3 (3,3)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	1 (1,8)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.7.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	9 (9,1)	NE [NE; NE]	101	7 (6,9)	NE [NE; NE]	1,35	[0,50; 3,78]	0,5512
Neu diagnostiziert	92	4 (4,3)	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	3,60	[0,53; 70,45]	0,2020
Interaktion p-Wert									0,3959
Region									
Asien	54	2 (3,7)	NE [NE; NE]	54	2 (3,7)	NE [NE; NE]	1,00	[0,12; 8,31]	0,9975
Rest der Welt	137	11 (8,0)	NE [NE; NE]	136	6 (4,4)	NE [NE; NE]	1,77	[0,67; 5,15]	0,2487
Interaktion p-Wert									0,6084
Alter									
<65	101	6 (5,9)	NE [NE; NE]	98	2 (2,0)	NE [NE; NE]	2,93	[0,67; 19,98]	0,1575
>=65	90	7 (7,8)	NE [NE; NE]	92	6 (6,5)	NE [NE; NE]	1,14	[0,38; 3,53]	0,8169
Interaktion p-Wert									0,3244
Abstammung									
Weiß	104	11 (10,6)	NE [NE; NE]	112	6 (5,4)	NE [NE; NE]	1,92	[0,73; 5,58]	0,1872
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	2 (3,5)	NE [NE; NE]	58	2 (3,4)	NE [NE; NE]	1,00	[0,12; 8,31]	0,9976
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5594
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	8 (6,8)	NE [NE; NE]	111	5 (4,5)	NE [NE; NE]	1,48	[0,49; 4,88]	0,4897
Unbekannt	52	3 (5,8)	NE [NE; NE]	63	3 (4,8)	NE [NE; NE]	1,20	[0,22; 6,46]	0,8270
Interaktion p-Wert									0,8325
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.1 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	7 (6,3)	NE [NE; NE]	122	4 (3,3)	NE [NE; NE]	1,84	[0,55; 7,01]	0,3219
Negativ	73	4 (5,5)	NE [NE; NE]	67	4 (6,0)	NE [NE; NE]	0,92	[0,22; 3,91]	0,9121
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4661
Histologie									
Endometrioid	107	7 (6,5)	NE [NE; NE]	97	3 (3,1)	NE [NE; NE]	2,11	[0,59; 9,77]	0,2614
Serös	42	2 (4,8)	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	1,18	[0,14; 9,82]	0,8699
Andere	42	4 (9,5)	NE [NE; NE]	41	3 (7,3)	NE [NE; NE]	1,27	[0,28; 6,44]	0,7547
Interaktion p-Wert									0,8407
Histologischer Grad									
High grade (G3)	77	4 (5,2)	NE [NE; NE]	82	4 (4,9)	NE [NE; NE]	0,95	[0,23; 4,03]	0,9448
Low grade (G1+G2)	90	8 (8,9)	NE [NE; NE]	87	3 (3,4)	NE [NE; NE]	2,73	[0,79; 12,46]	0,1161
Interaktion p-Wert									0,2772
ECOG Performance Status zu Baseline									
0	135	9 (6,7)	NE [NE; NE]	126	7 (5,6)	NE [NE; NE]	1,20	[0,45; 3,36]	0,7175
1	56	4 (7,1)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	4,31	[0,64; 84,35]	0,1416
Interaktion p-Wert									0,2622
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	2 (18,2)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	2 (2,6)	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.2 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	0	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	1 (1,3)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	1 (1,3)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.7.2.2D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	0	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	0	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.3 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	0	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	0	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Nutzenbewertung nach AMNOG

Table 4.3.7.2.2D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	4 (4,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	3 (2,2)	NE [NE; NE]	136	3 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	3 (3,3)	NE [NE; NE]	92	4 (4,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	3 (2,9)	NE [NE; NE]	112	3 (2,7)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	2 (1,7)	NE [NE; NE]	111	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	2 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.4 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	3 (2,5)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	2 (33,3)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	3 (2,8)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	2 (3,8)	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	2 (4,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	2 (2,4)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	3 (3,3)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	3 (2,4)	NE [NE; NE]	NC	[NC]	NC
1	56	2 (3,6)	NE [NE; NE]	64	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	1 (1,3)	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Hepatische Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	1 (1,0)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.5 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Hepatische Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	0	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	2 (2,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	1 (1,9)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	2 (1,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	1 (1,0)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	2 (2,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	2 (1,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	1 (1,7)	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	3 (2,7)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.6 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
PD-L1 Expression									
Positiv	112	1 (0,9)	NE [NE; NE]	122	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	2 (3,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	2 (2,1)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	1 (2,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	2 (2,6)	NE [NE; NE]	82	2 (2,4)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	3 (2,4)	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	1 (1,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Myositis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	0	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	1 (0,7)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	0	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	1 (1,1)	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	1 (1,0)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	0	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	1 (1,9)	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.7 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Myositis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	1 (0,9)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	0	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	1 (2,4)	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	0	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	0	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	0	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	0	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	0	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	1 (0,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	2 (2,0)	NE [NE; NE]	98	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	1 (0,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	0	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	0	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	2 (1,7)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	1 (1,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.8 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	2 (1,8)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	0	NE [NE; NE]	67	1 (1,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	1 (1,0)	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	1 (2,4)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	1 (1,3)	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	1 (1,1)	NE [NE; NE]	87	1 (1,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	1 (0,7)	NE [NE; NE]	126	1 (0,8)	NE [NE; NE]	NC	[NC]	NC
1	56	1 (1,8)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	0	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Krankheitsstatus									
Rezidivierend	99	2 (2,0)	NE [NE; NE]	101	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	92	1 (1,1)	NE [NE; NE]	89	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	54	1 (1,9)	NE [NE; NE]	54	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	137	2 (1,5)	NE [NE; NE]	136	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	101	3 (3,0)	NE [NE; NE]	98	0	NE [NE; NE]	NC	[NC]	NC
>=65	90	0	NE [NE; NE]	92	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	104	2 (1,9)	NE [NE; NE]	112	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	13	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	57	1 (1,8)	NE [NE; NE]	58	0	NE [NE; NE]	NC	[NC]	NC
Andere	16	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	21	2 (9,5)	NE [NE; NE]	16	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	118	1 (0,8)	NE [NE; NE]	111	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	52	0	NE [NE; NE]	63	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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Table 4.3.7.2.2D.9 DUO-E (pMMR Durva/Ola): Summary of subgroup analysis of time to first SUESI GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab + Olaparib (N=191)			CTx (N=190)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Positiv	112	2 (1,8)	NE [NE; NE]	122	0	NE [NE; NE]	NC	[NC]	NC
Negativ	73	1 (1,4)	NE [NE; NE]	67	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	6	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	107	1 (0,9)	NE [NE; NE]	97	0	NE [NE; NE]	NC	[NC]	NC
Serös	42	0	NE [NE; NE]	52	0	NE [NE; NE]	NC	[NC]	NC
Andere	42	2 (4,8)	NE [NE; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	77	0	NE [NE; NE]	82	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	90	3 (3,3)	NE [NE; NE]	87	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	135	2 (1,5)	NE [NE; NE]	126	0	NE [NE; NE]	NC	[NC]	NC
1	56	1 (1,8)	NE [NE; NE]	64	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	11	1 (9,1)	NE [NE; NE]	10	0	NE [NE; NE]	NC	[NC]	NC
IV	78	0	NE [NE; NE]	77	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

Time to event of AE is defined as the time from first dose of study treatment to first onset of the respective AE or the time to censoring if the AE has not occurred by 30 days (Olaparib/placebo) or 90 days (Durvalumab/placebo) following discontinuation of study treatment, before administration of subsequent cancer therapy or death, whichever comes first. All AEs are coded using MedDRA version 25.1. Includes AEs with onset date on or after the date of first dose and up to and including + 30 days/+ 90 days following discontinuation of study treatment. Analysis done if >=10 patients at each subgroup level and >=10 events in at least one subgroup level combined for both arms. Analysis done for SOC and PT only if main effect for that SOC or PT is statistically significant at 5% level. [a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached. [b] Estimated from main effects of unstratified Cox proportional hazard model including trt., subgroup and subgroup-by-trt. interaction.
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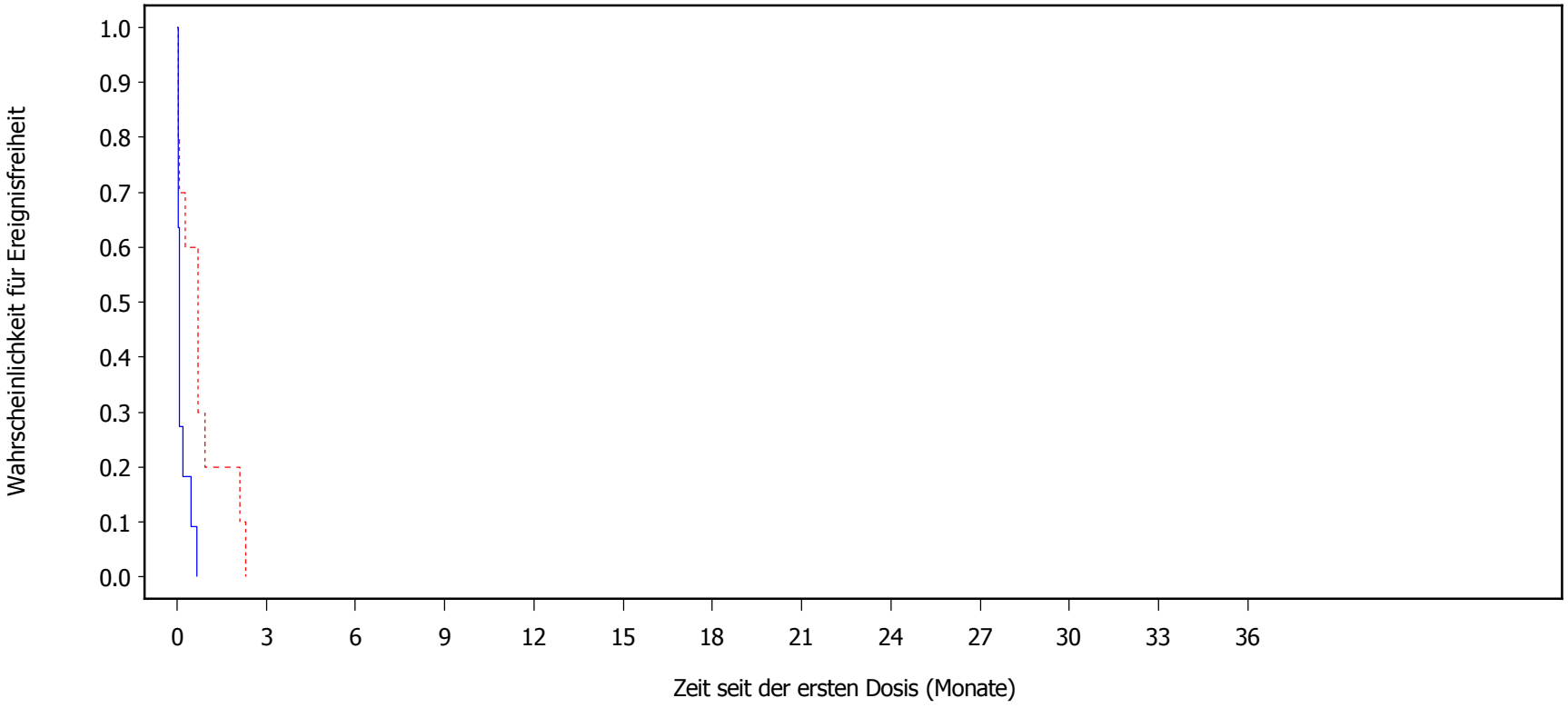
Figure 4.4.1.2.1D.1 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE for FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen=III
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

11	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
10	0	0	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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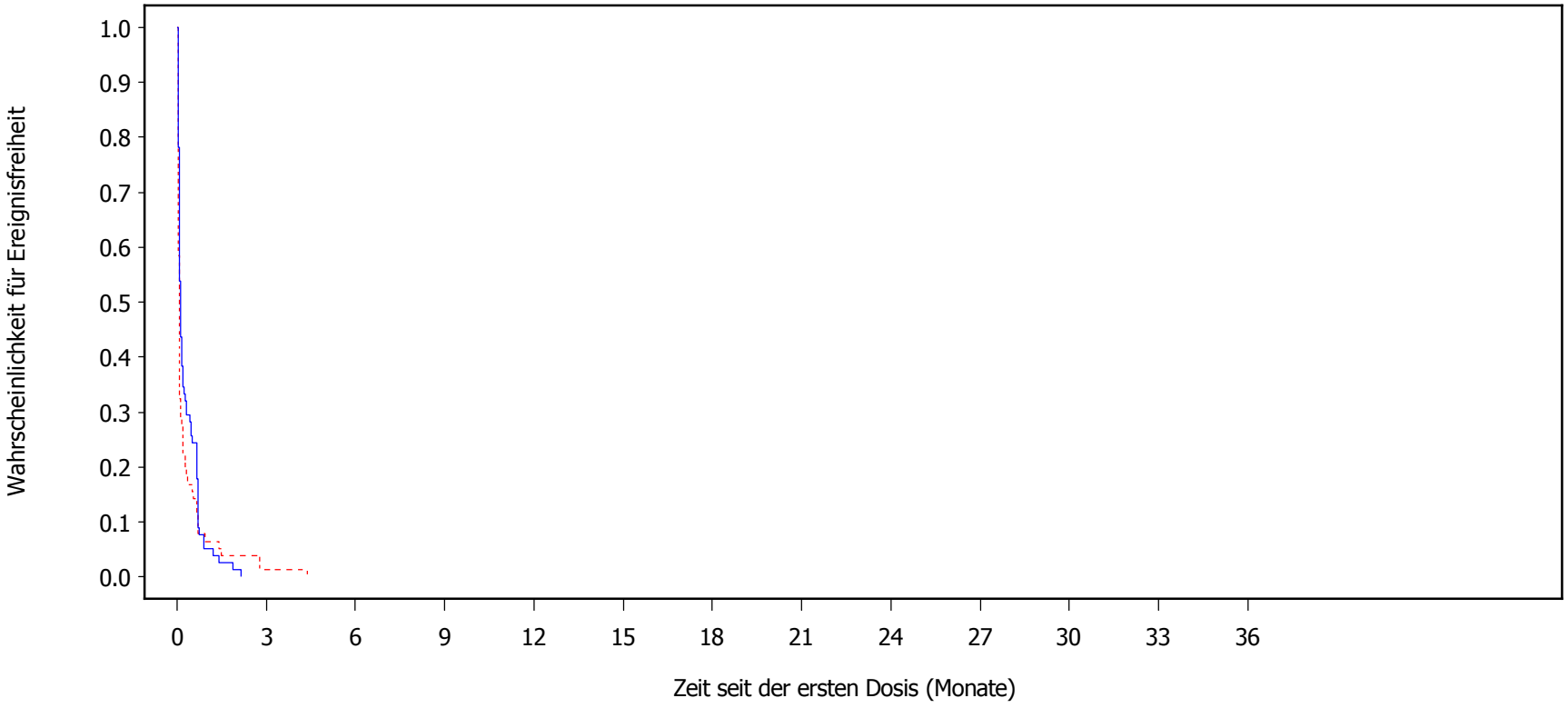
Figure 4.4.1.2.1D.2 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE for FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen=IV
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

78	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
77	1	0	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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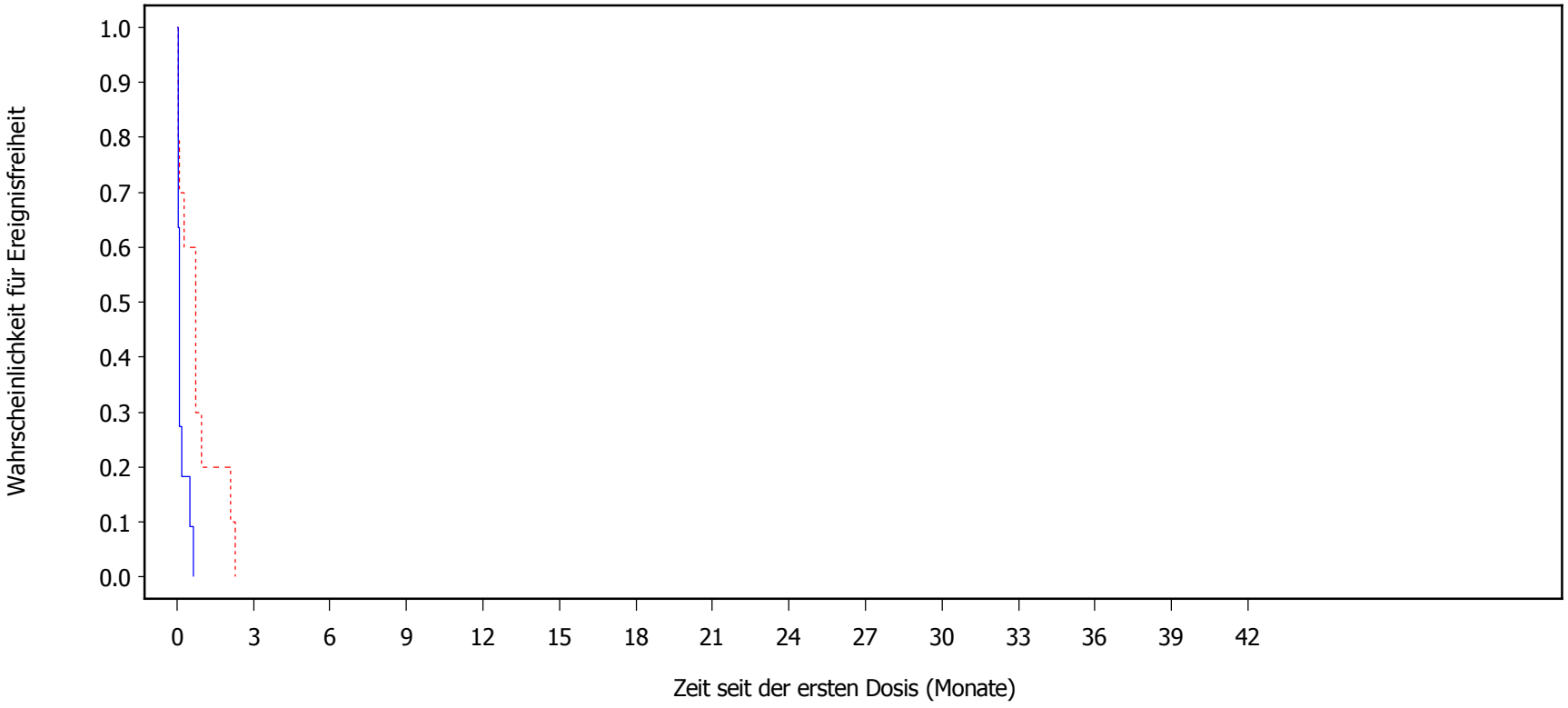
Figure 4.4.1.2.2D.1 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE for FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen=III
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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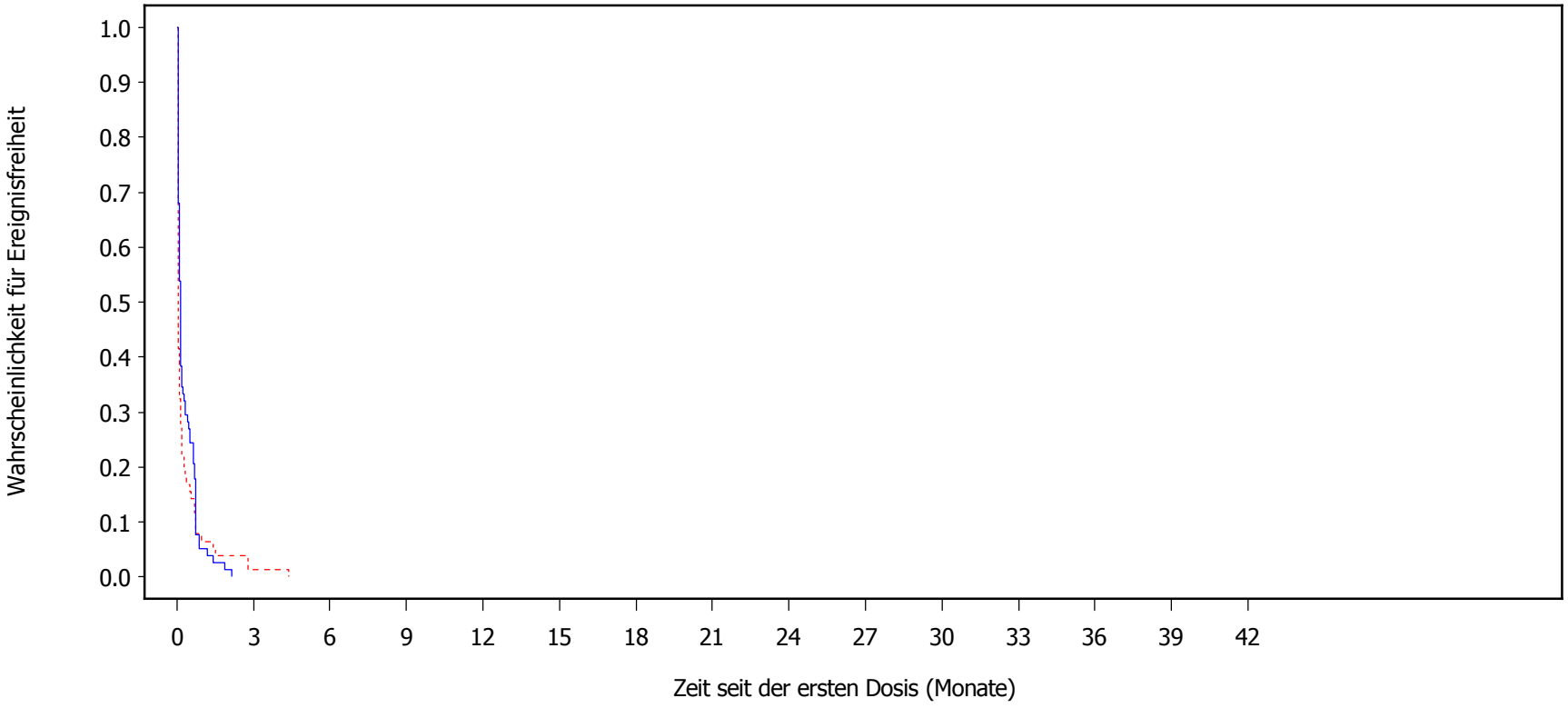
Figure 4.4.1.2.2D.2 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE for FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen=IV
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

78	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
77	1	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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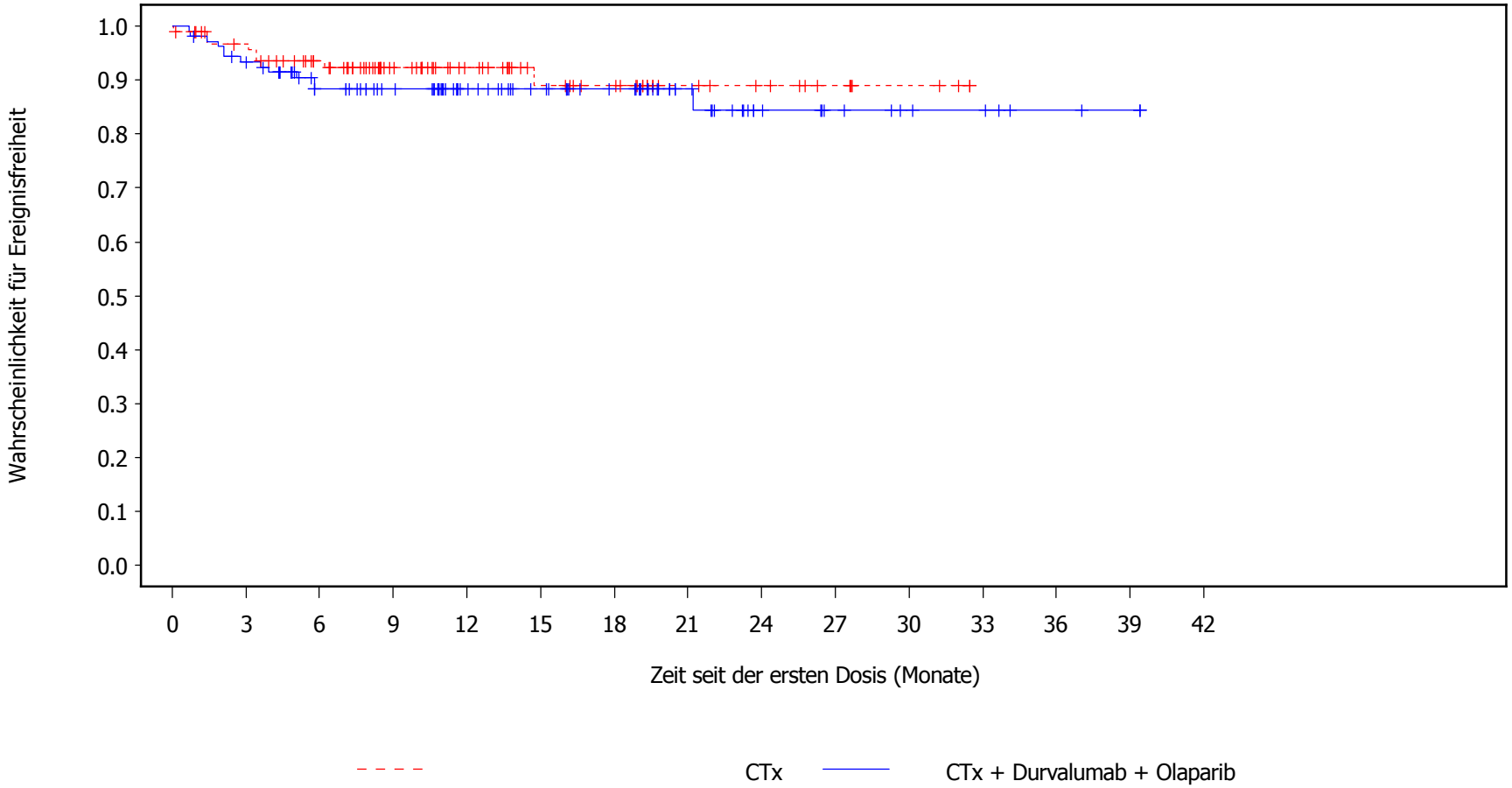
Figure 4.4.1.2.2D.3 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of PT: Hypokaliaemie for Histologie=Endometrioid
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

107	98	81	71	55	46	38	24	13	9	6	5	2	1	0	CTx + Durvalumab + Olaparib
97	88	75	54	39	28	24	13	10	6	3	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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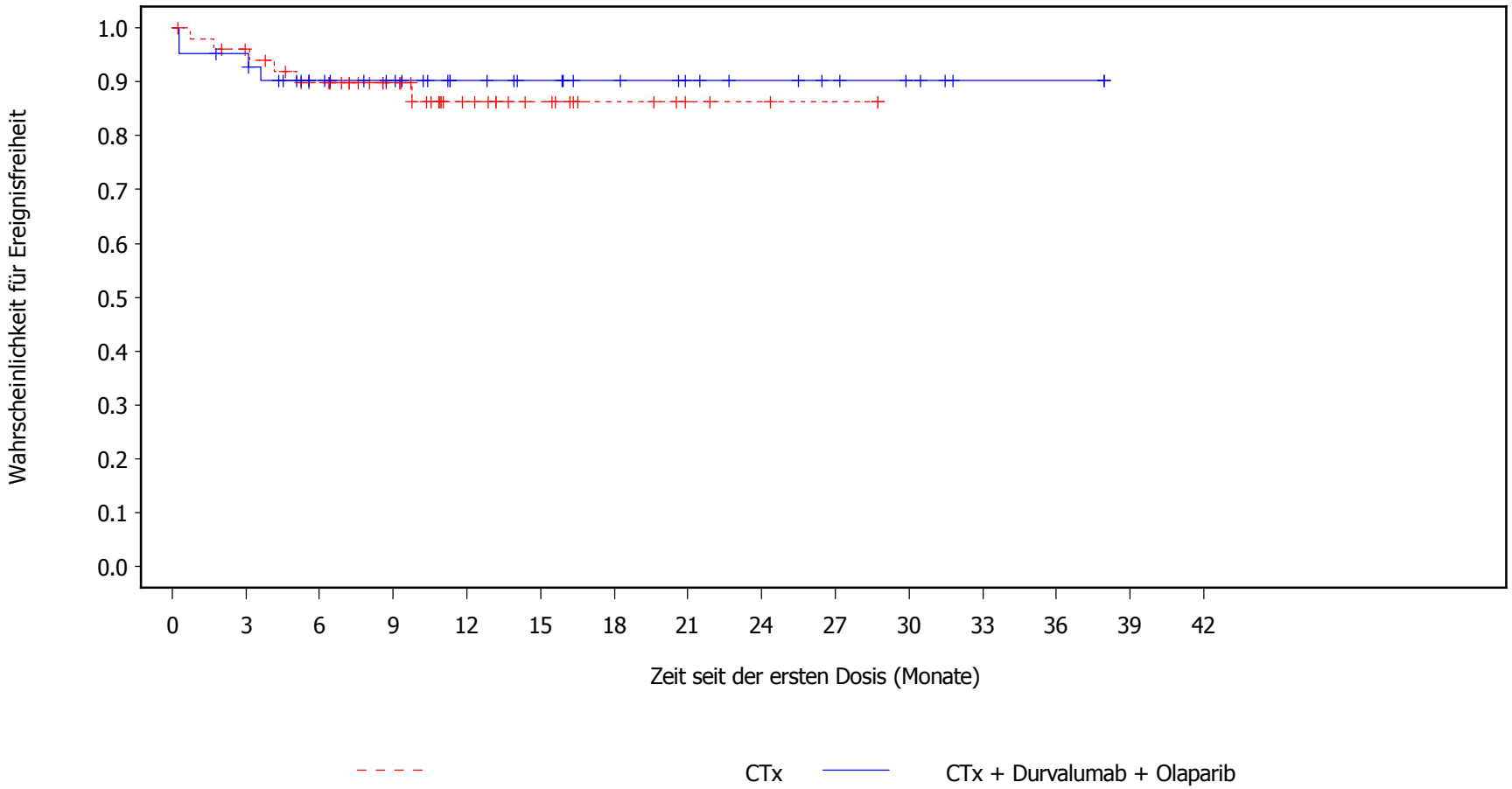
Figure 4.4.1.2.2D.4 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of PT: Hypokaliaemie for Histologie=Serös
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

42	39	30	26	19	16	13	10	8	6	4	1	1	0	0	CTx + Durvalumab + Olaparib
52	47	40	29	17	11	6	3	2	1	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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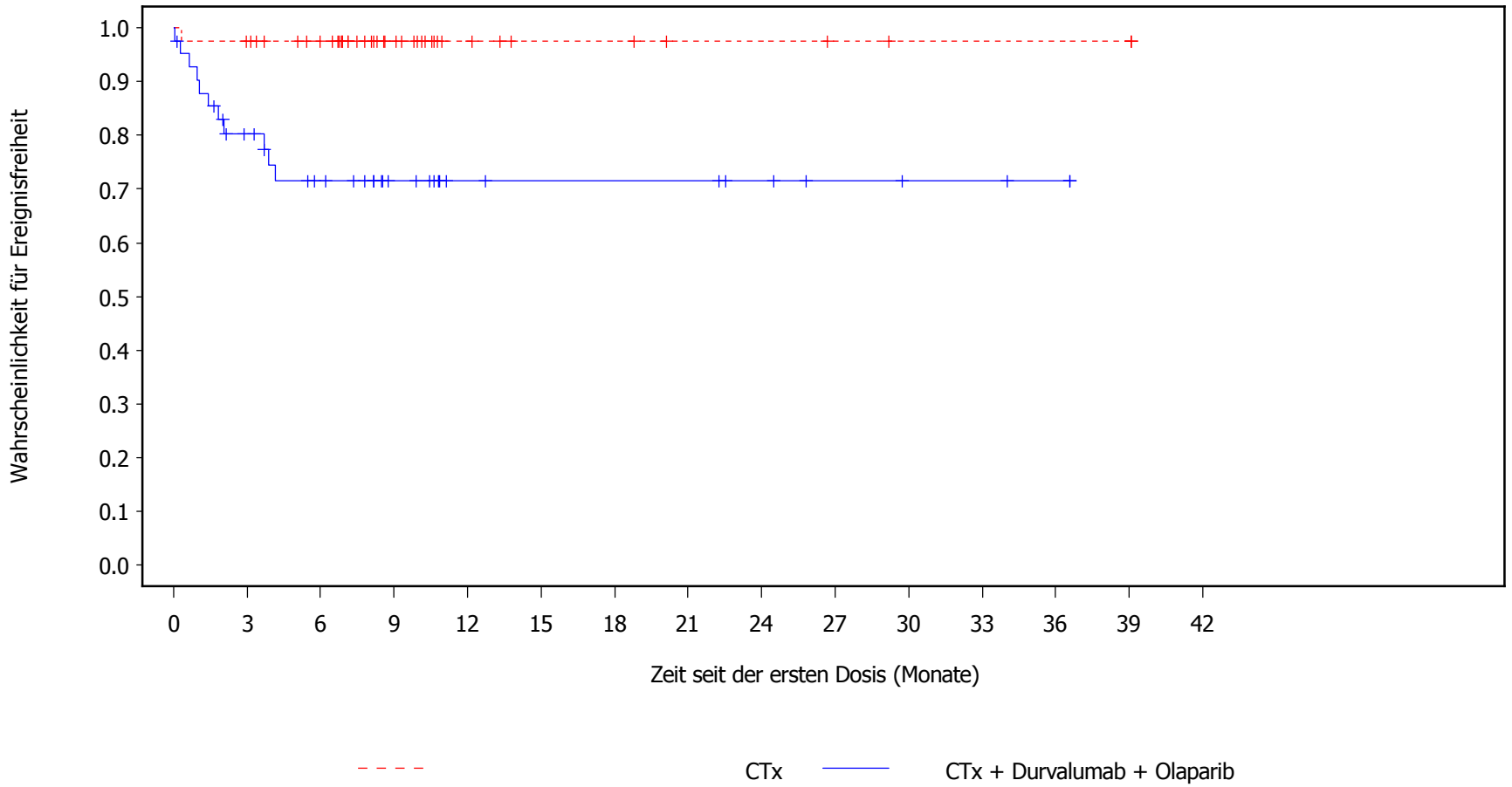
Figure 4.4.1.2.2D.5 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of PT: Hypokaliaemie for Histologie=Andere
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

42	29	22	14	8	7	7	7	5	3	2	2	1	0	0	CTx + Durvalumab + Olaparib
41	39	33	18	8	5	5	3	3	2	1	1	1	1	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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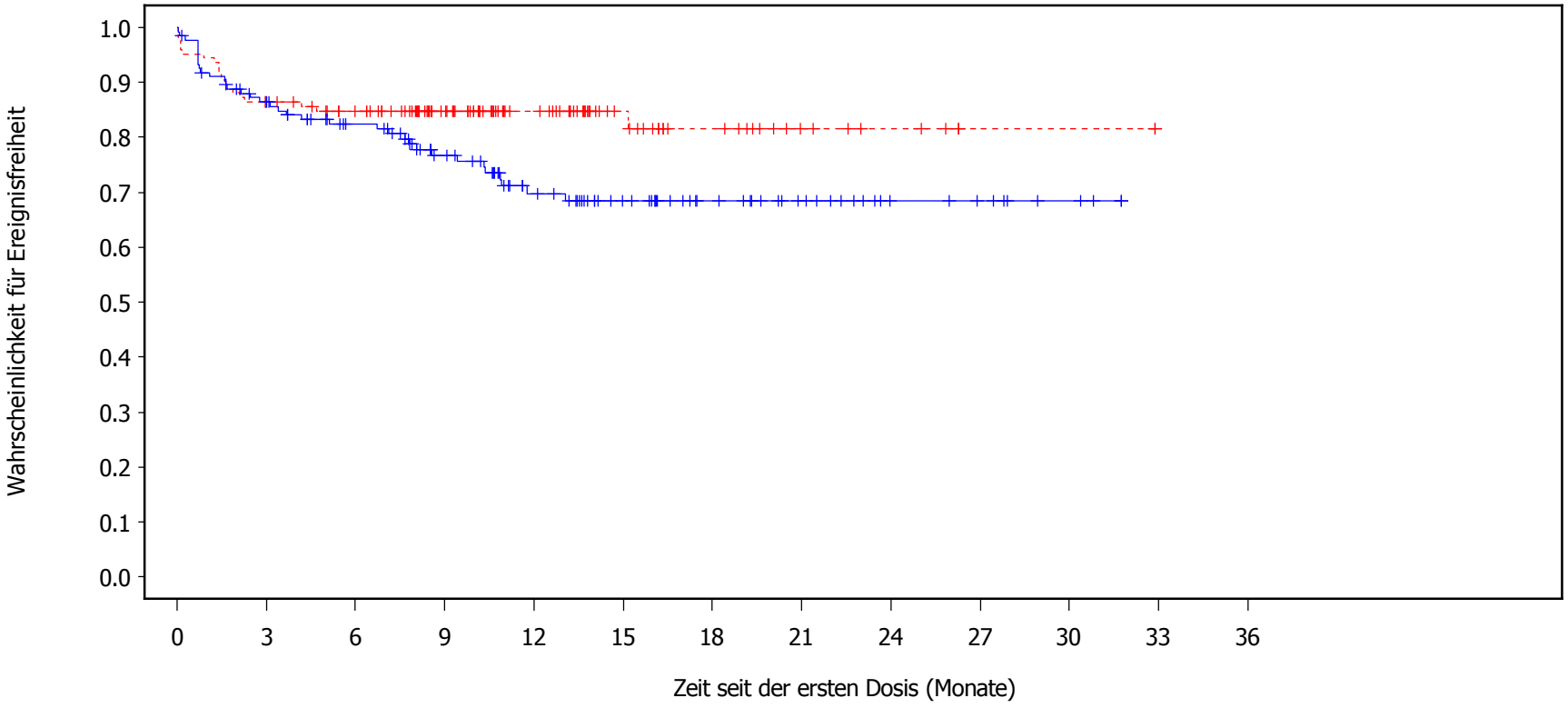
Figure 4.4.3.2.1D.1 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of Therapieabbruch aufgrund von UE for ECOG Performance Status zu Baseline=0
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

135	111	94	74	53	38	26	18	9	7	3	0	0	CTx + Durvalumab + Olaparib
126	107	97	72	47	26	16	8	5	1	1	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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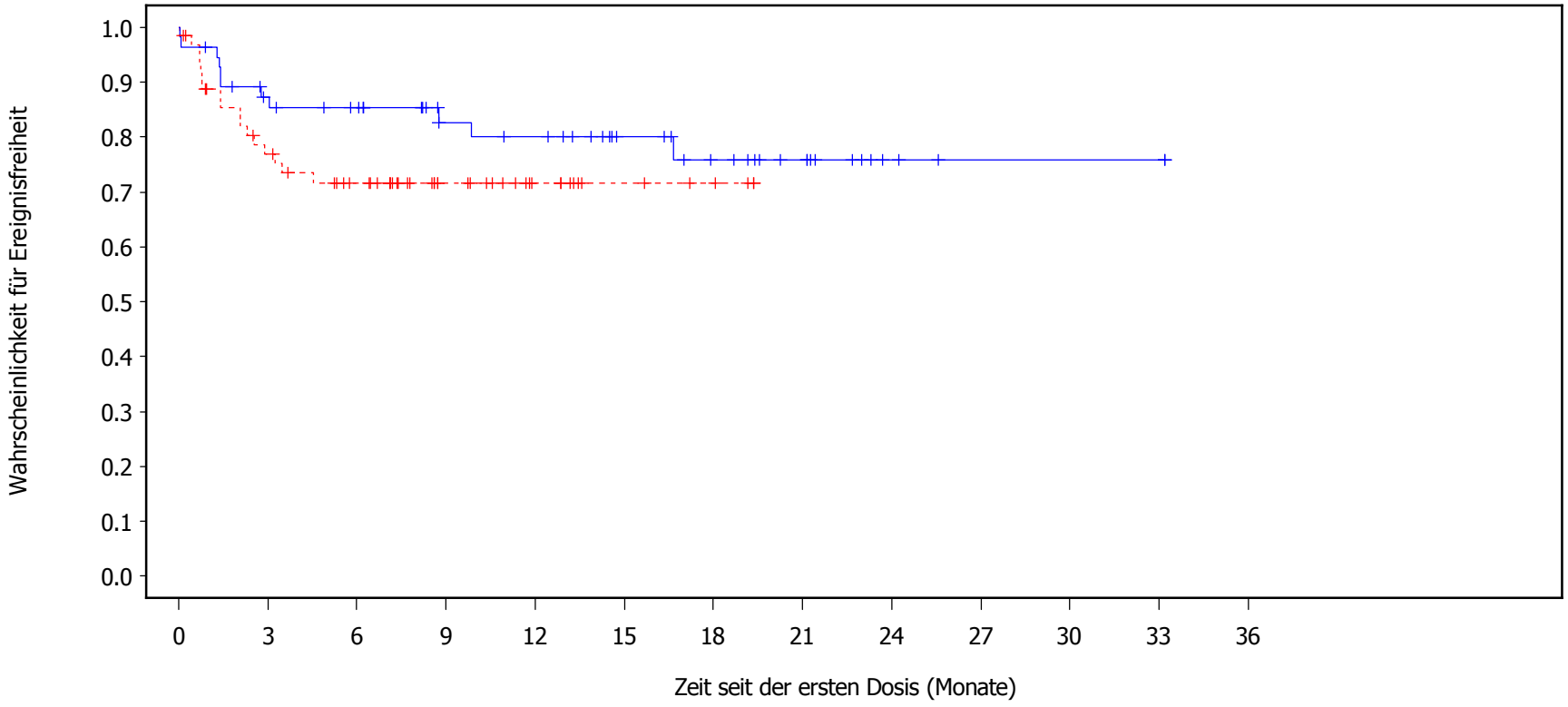
Figure 4.4.3.2.1D.2 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of Therapieabbruch aufgrund von UE for ECOG Performance Status zu Baseline=1
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

56	45	41	31	29	21	16	11	3	1	1	1	0	CTx + Durvalumab + Olaparib
64	45	36	20	11	5	3	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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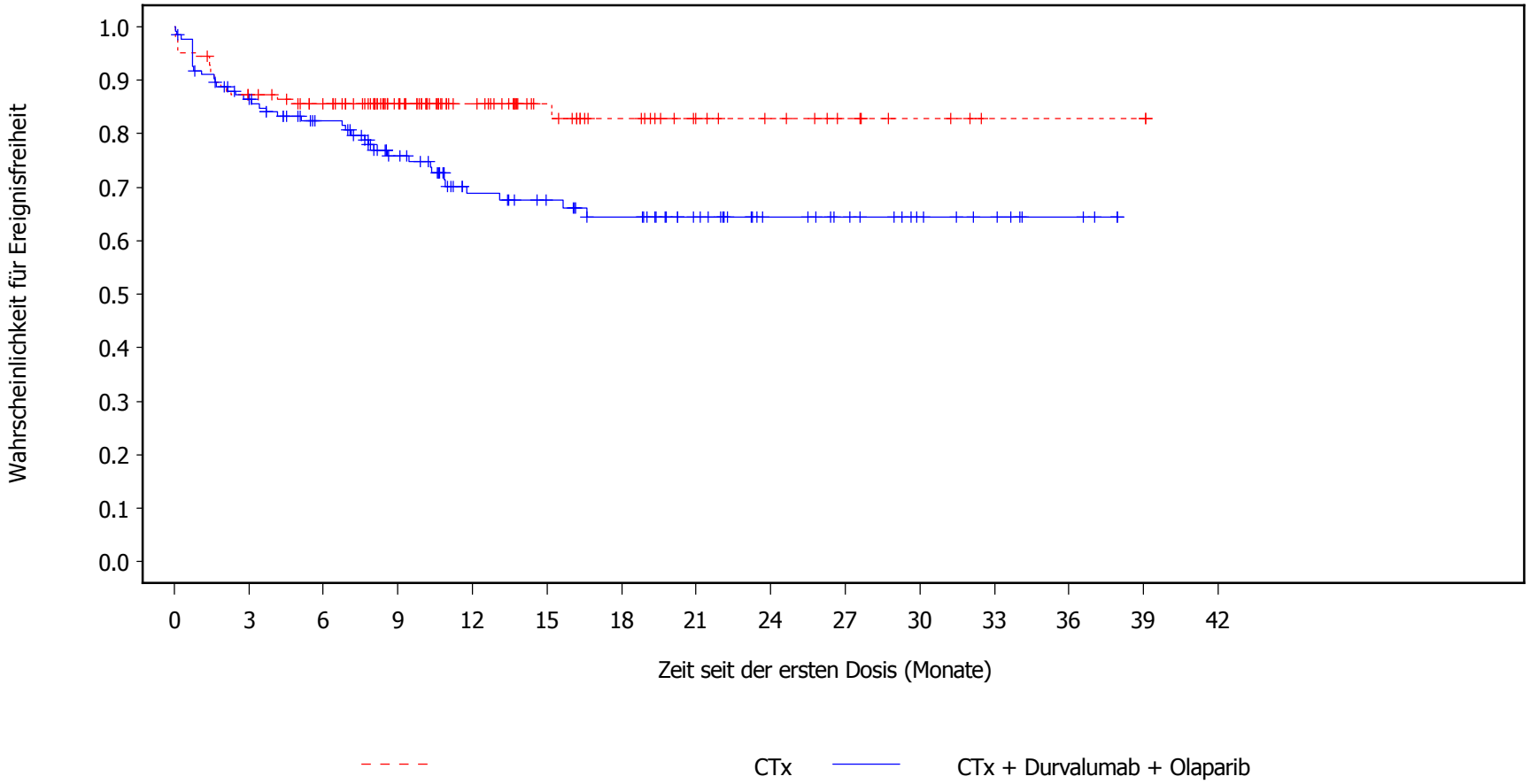
Figure 4.4.3.2.2D.1 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of Therapieabbruch aufgrund von UE for ECOG Performance Status zu Baseline=0
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

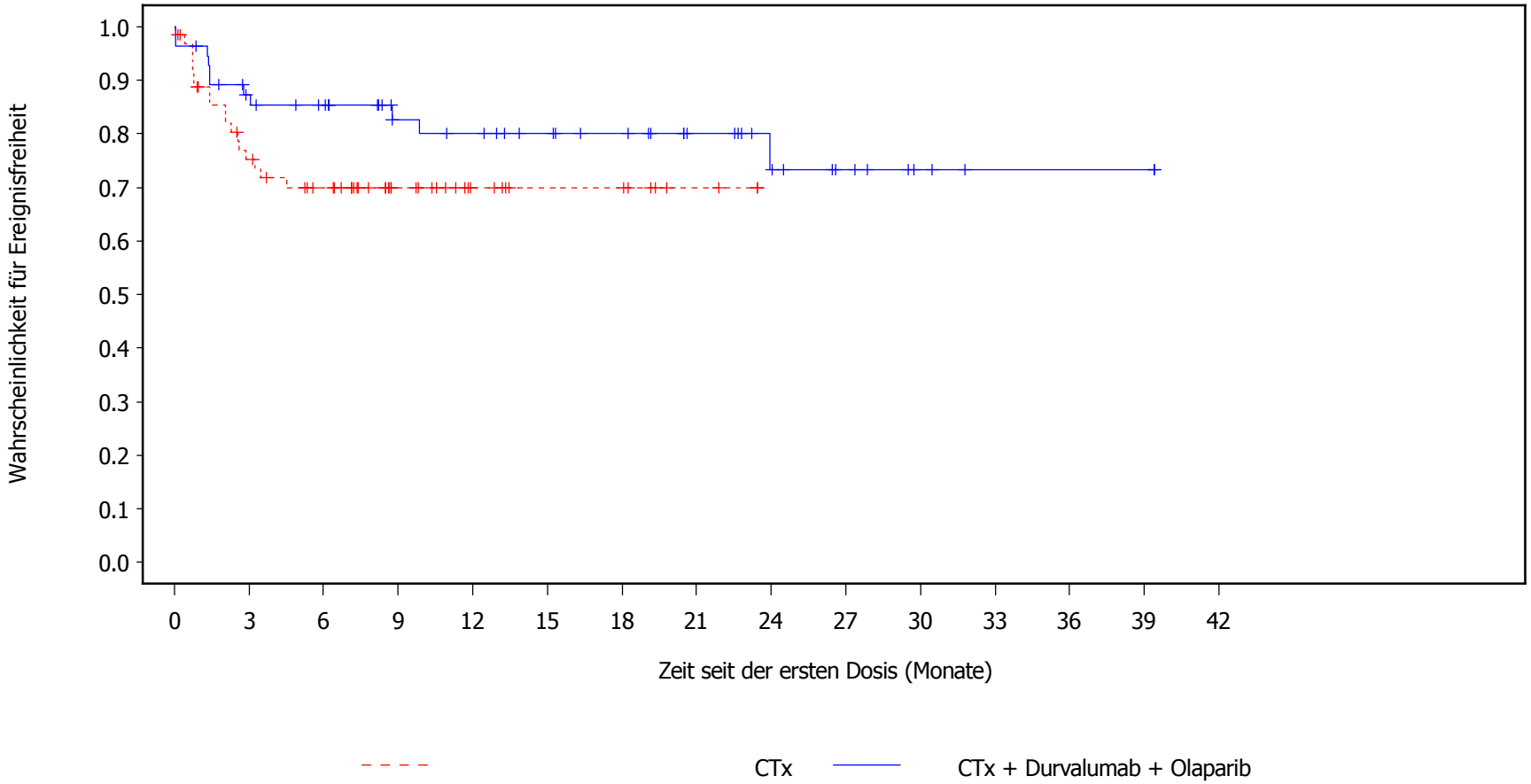
135	111	94	73	52	46	40	30	20	16	10	7	3	0	0	CTx + Durvalumab + Olaparib
126	107	97	72	47	31	22	14	11	7	4	1	1	1	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc2.sas gttesubaedc2xaa 29MAY2024:15:58

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.3.2.2D.2 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of Therapieabbruch aufgrund von UE for ECOG Performance Status zu Baseline=1
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

56	45	41	31	29	25	22	16	11	7	3	1	1	1	0	CTx + Durvalumab + Olaparib
64	44	36	20	11	7	7	2	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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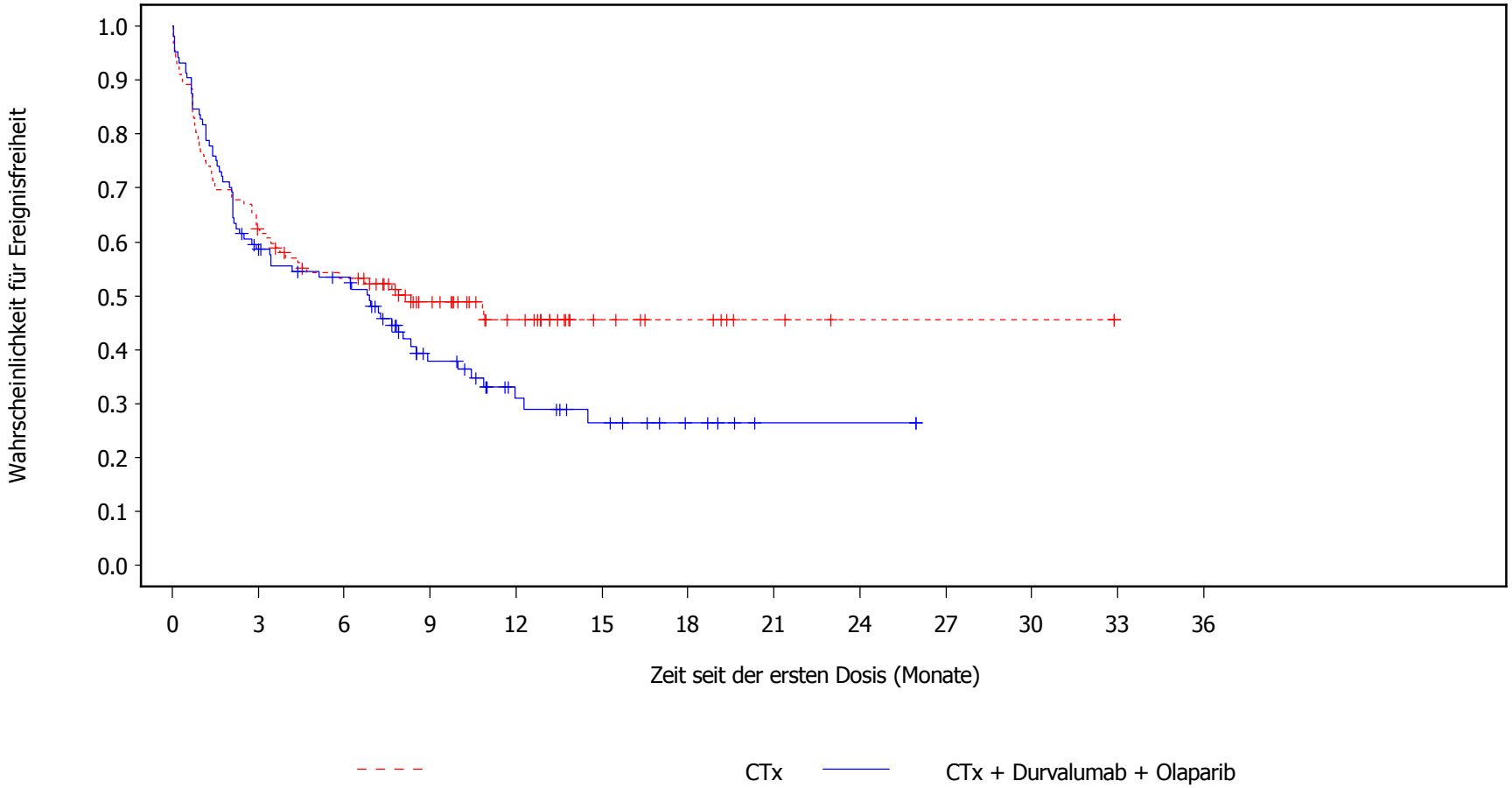
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.2.1D.1 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Abstammung=Weiß
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

104	59	50	26	15	10	5	1	1	0	0	0	0	CTx + Durvalumab + Olaparib
112	69	56	38	24	10	7	3	1	1	1	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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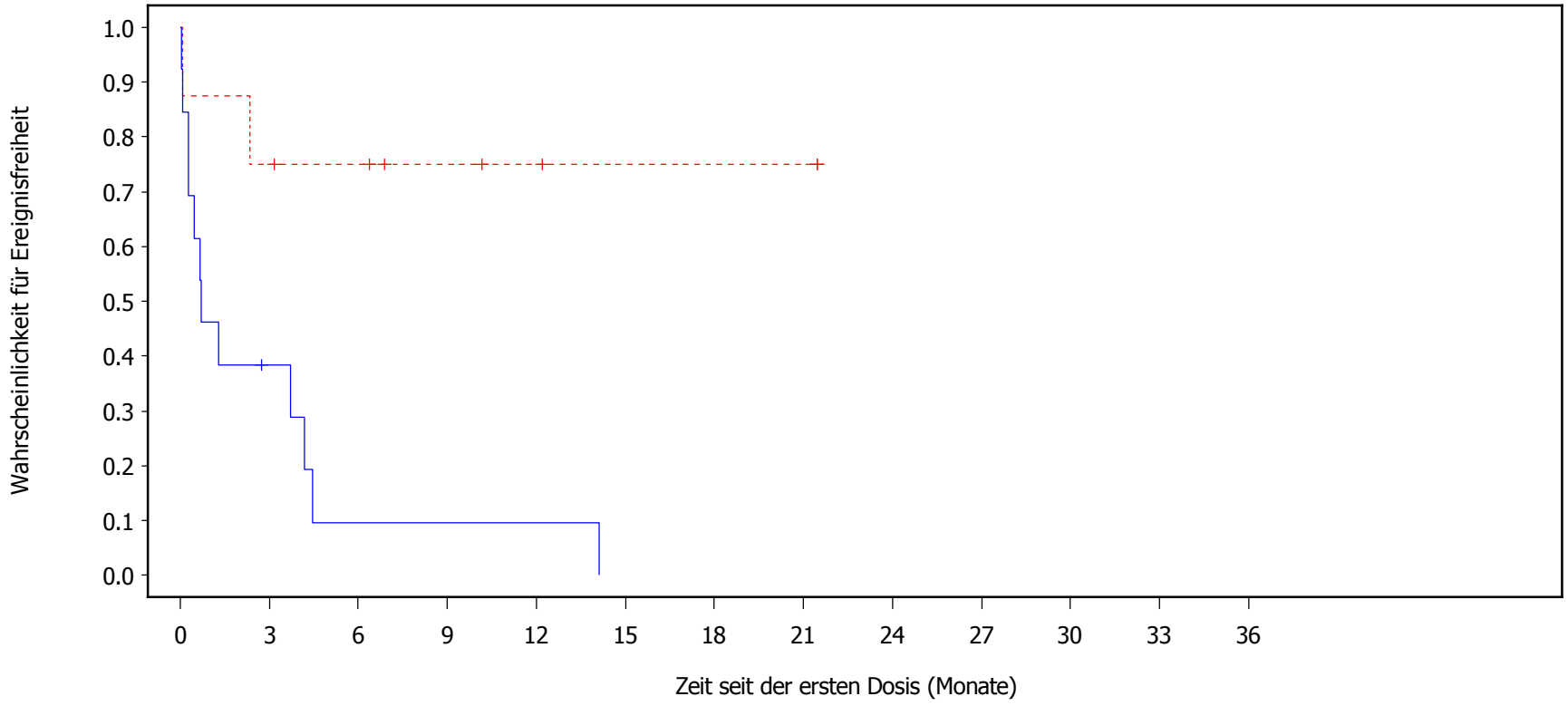
Figure 4.4.4.2.1D.2 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Abstammung=Schwarz/Afroamerikanisch
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

13	4	1	1	1	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
8	6	5	3	2	1	1	1	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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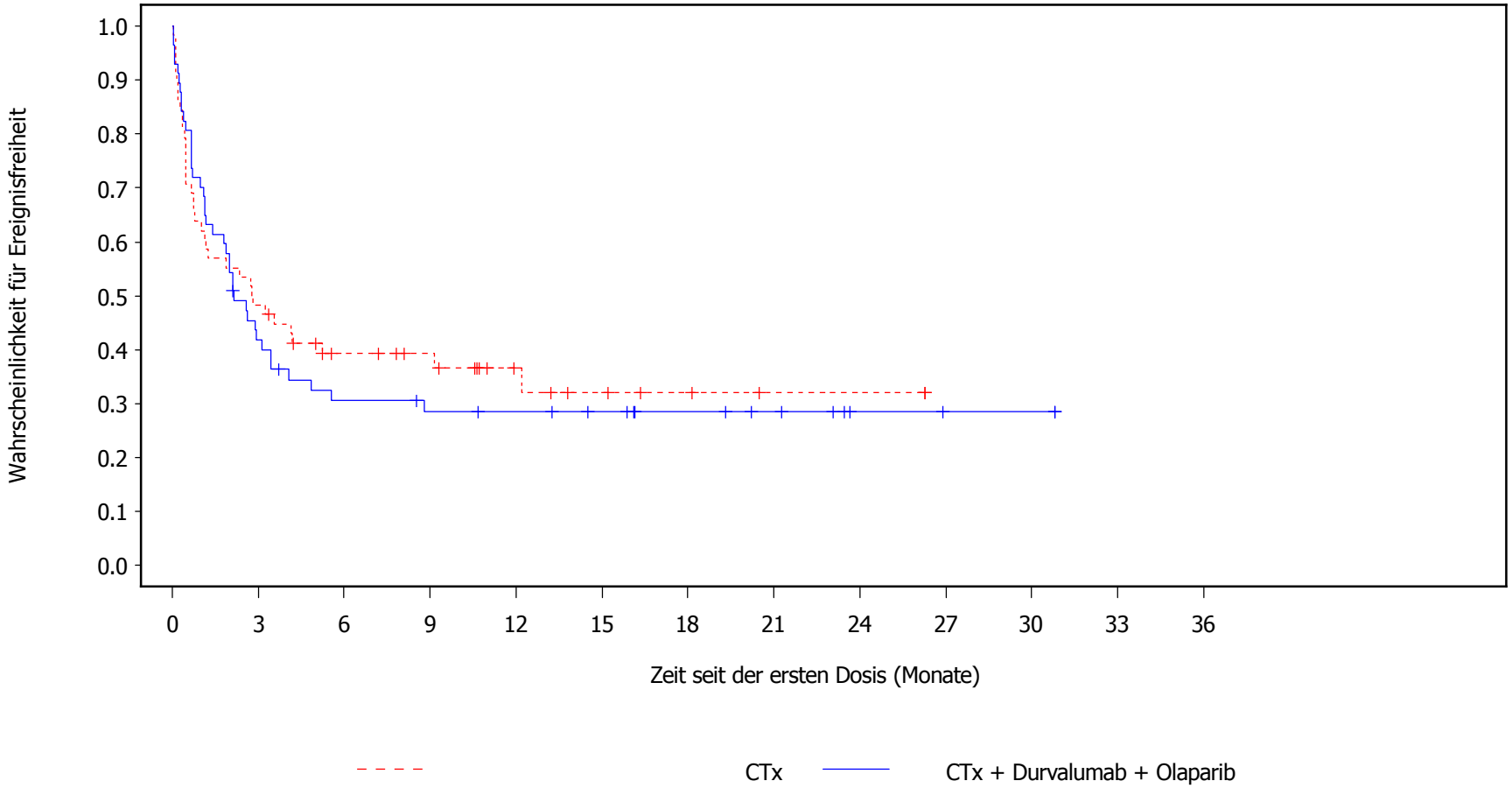
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.2.1D.3 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Abstammung=Asiatisch
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

57	23	16	14	13	11	8	6	2	1	1	0	0	CTx + Durvalumab + Olaparib
58	28	18	15	8	5	3	1	1	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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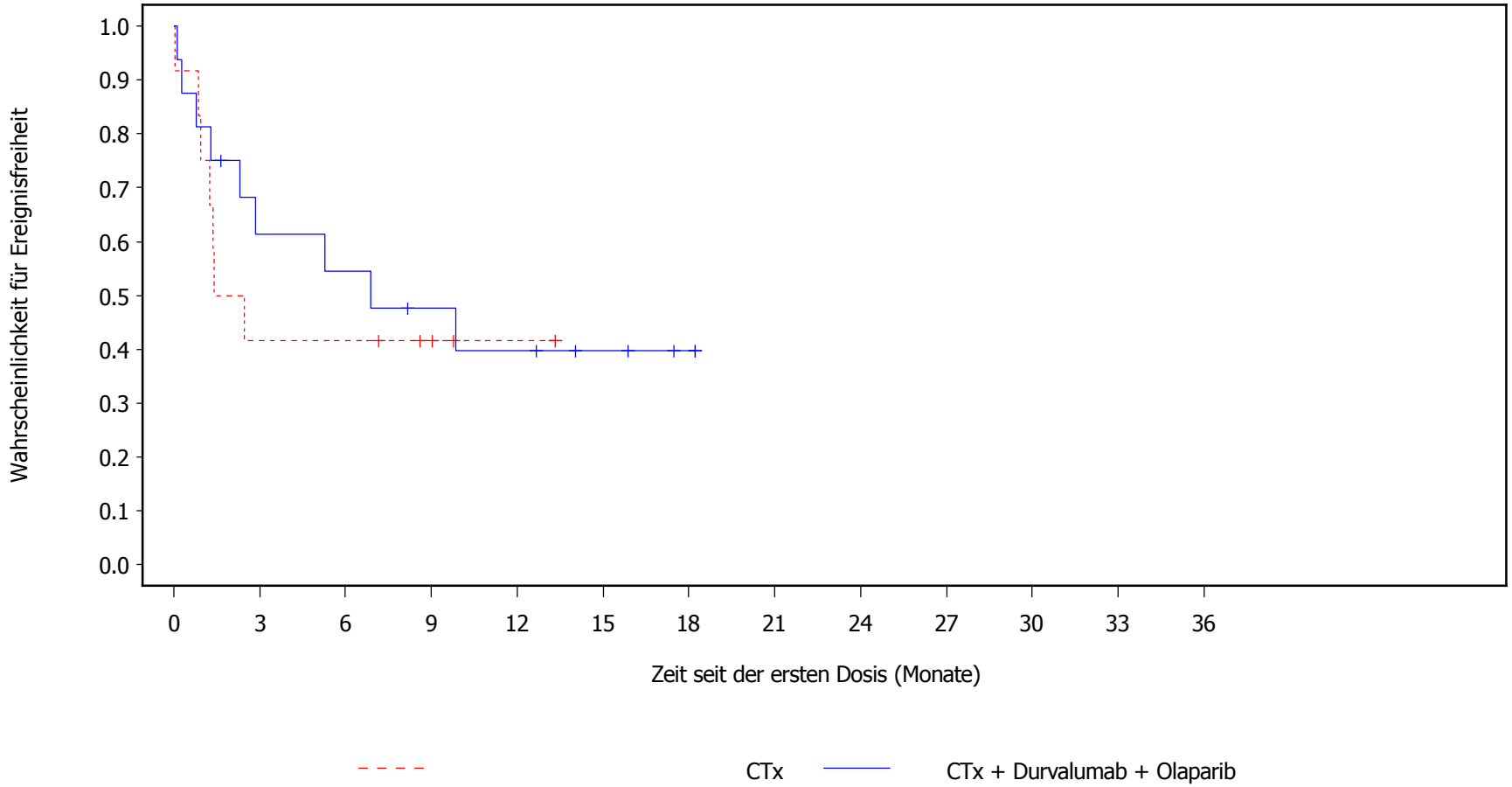
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.2.1D.4 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Abstammung=Andere
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

16	9	8	6	5	3	1	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
12	5	5	3	1	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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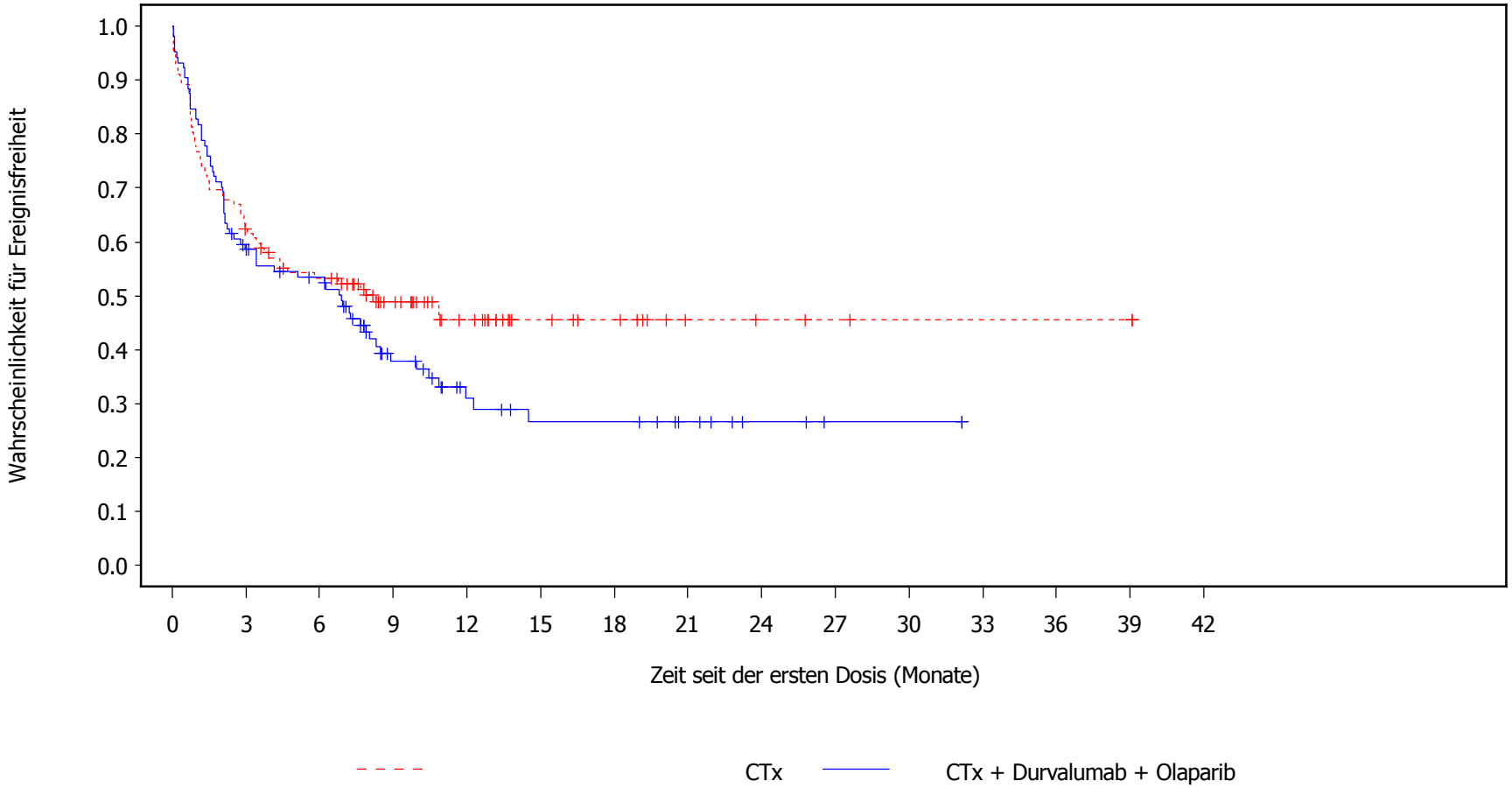
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.2.2D.1 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Abstammung=Weiß
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

104	59	50	26	15	11	11	7	3	1	1	0	0	0	0	CTx + Durvalumab + Olaparib
112	69	56	38	24	13	10	4	3	2	1	1	1	1	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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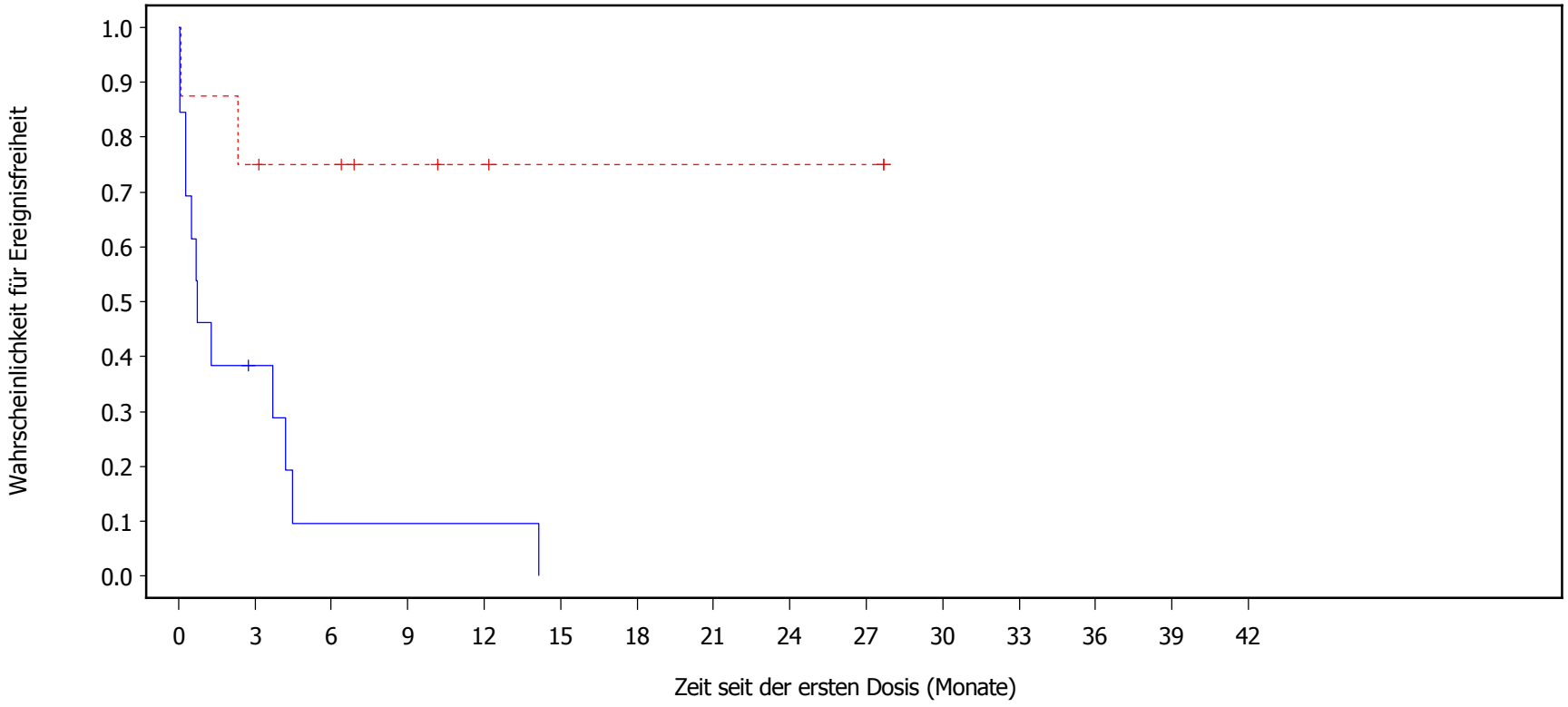
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.2.2D.2 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Abstammung=Schwarz/Afroamerikanisch
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

13	4	1	1	1	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
8	6	5	3	2	1	1	1	1	1	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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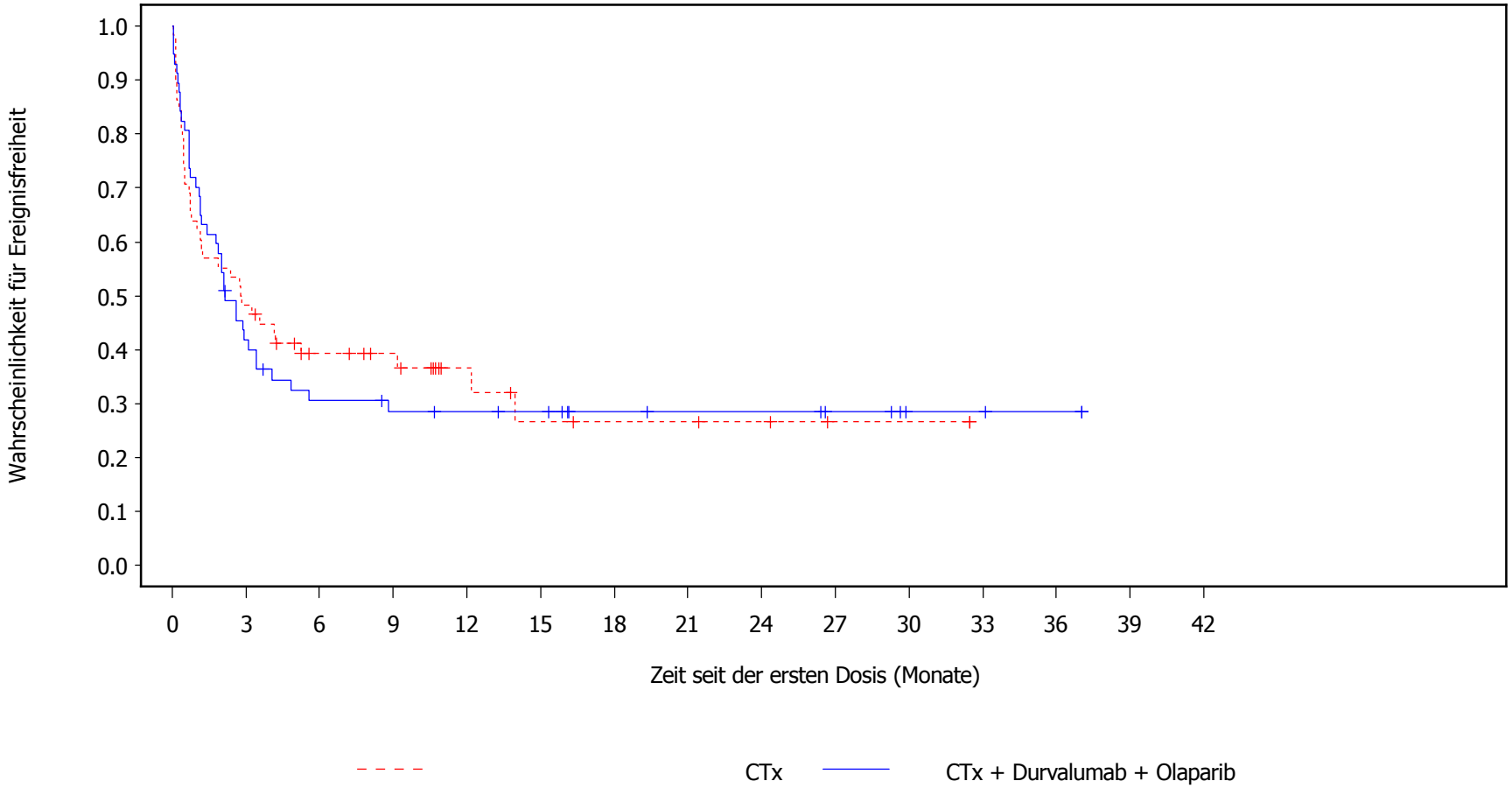
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.2.2D.3 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Abstammung=Asiatisch
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

57	23	16	14	13	12	8	7	7	5	2	2	1	0	0	CTx + Durvalumab + Olaparib
58	28	18	15	8	5	4	4	3	1	1	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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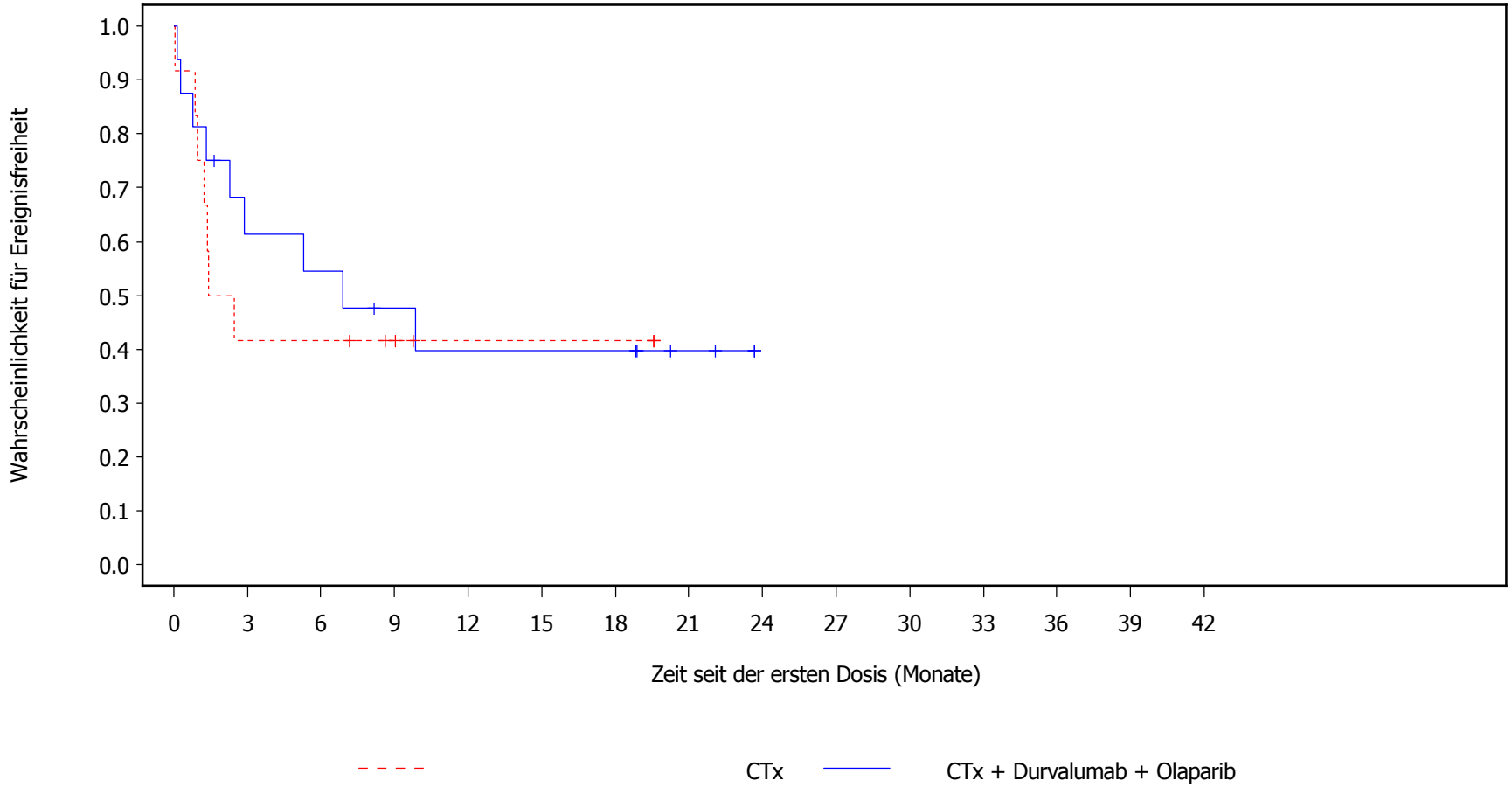
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.2.2D.4 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Abstammung=Andere
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

16	9	8	6	5	5	5	2	0	0	0	0	0	0	0	CTx + Durvalumab + Olaparib
12	5	5	3	1	1	1	0	0	0	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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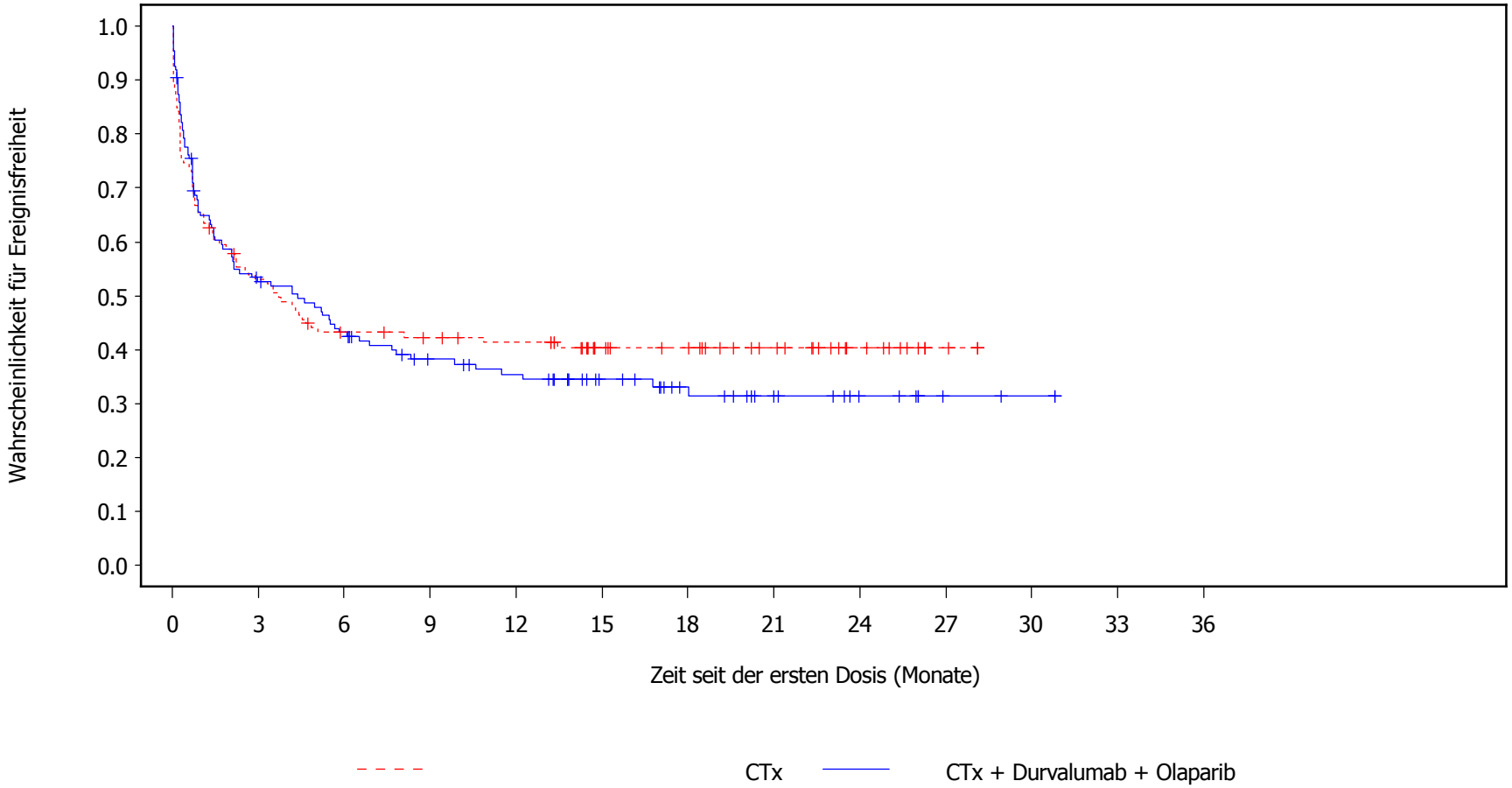
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.5.2.1D.1 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UESI for ECOG Performance Status zu Baseline=0
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

135	68	55	43	38	27	19	12	7	2	1	0	0	CTx + Durvalumab + Olaparib
126	65	51	48	45	31	27	19	10	2	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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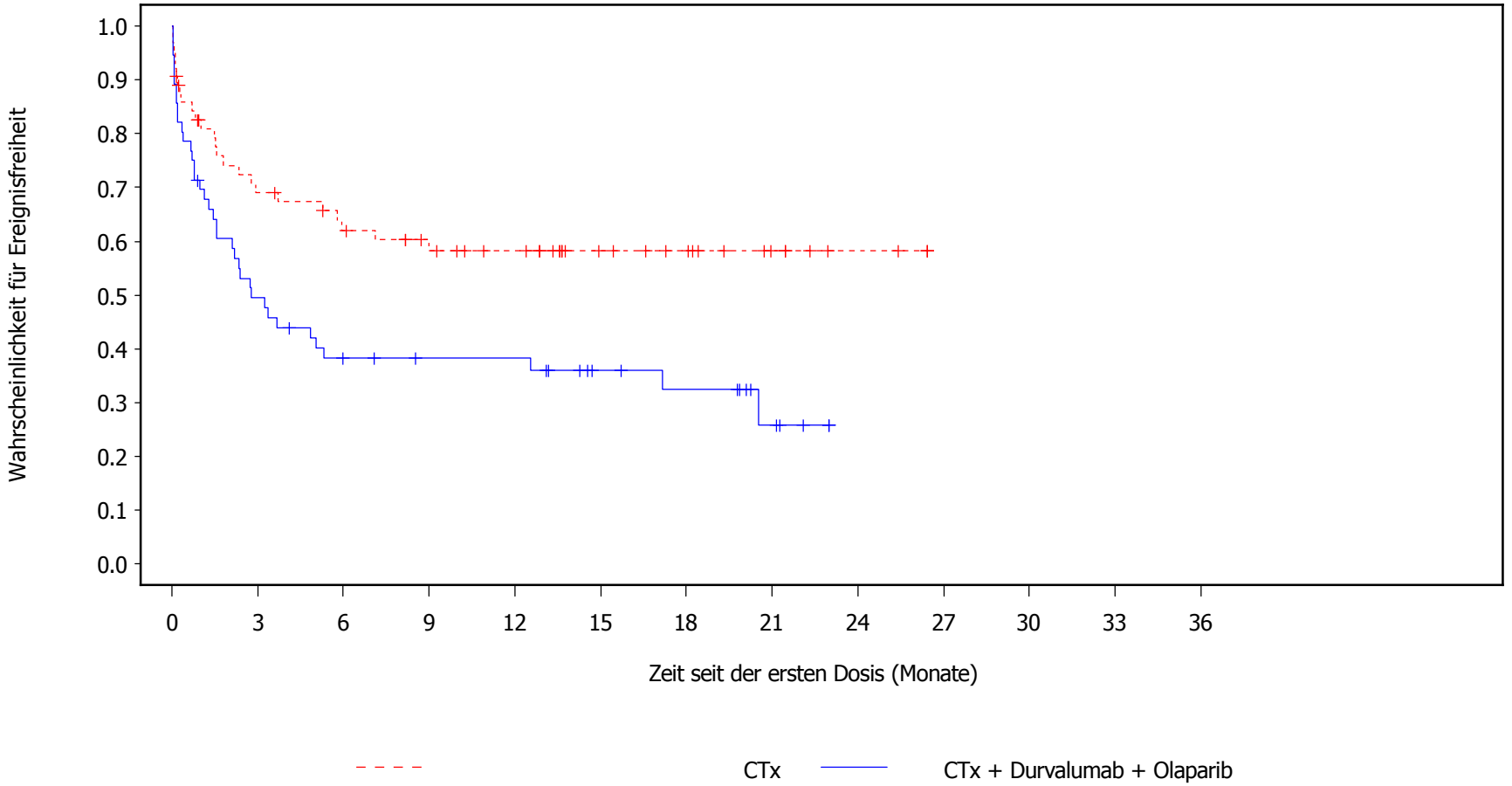
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.5.2.1D.2 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UESI for ECOG Performance Status zu Baseline=1
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

56	27	19	17	17	11	9	4	0	0	0	0	0	CTx + Durvalumab + Olaparib
64	41	35	30	25	15	12	6	2	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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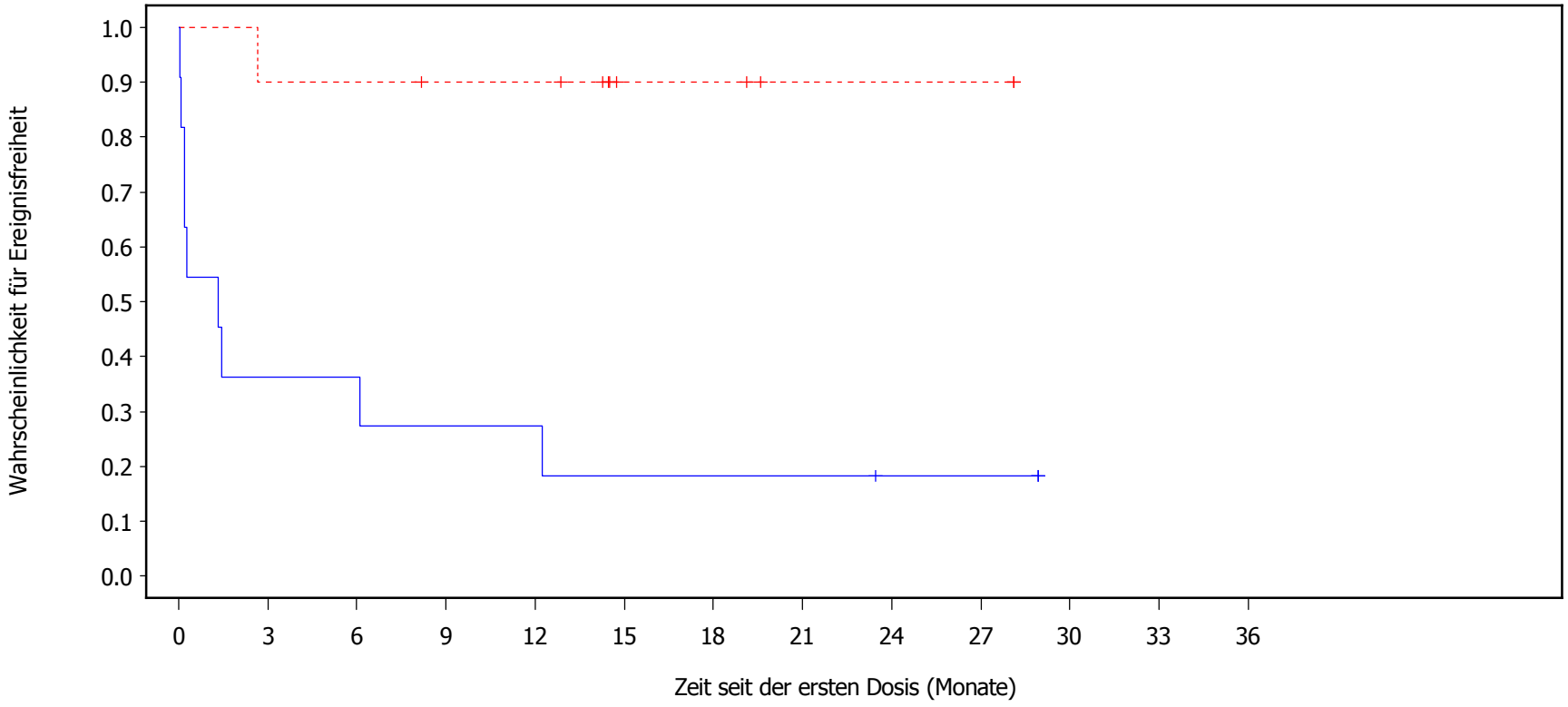
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.5.2.1D.3 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UESI for FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen=III
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

11	4	4	3	3	2	2	2	1	1	0	0	0	CTx + Durvalumab + Olaparib
10	9	9	8	8	3	3	1	1	1	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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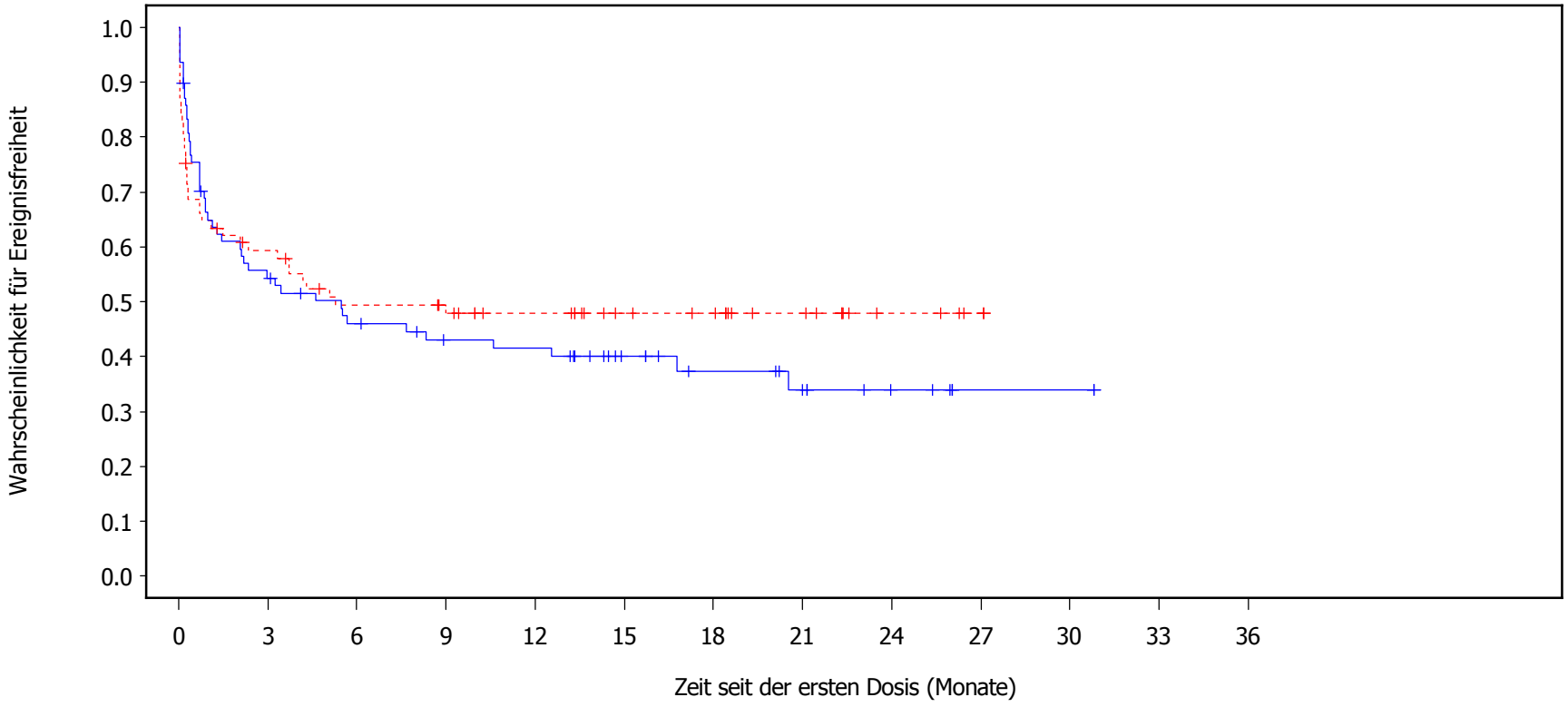
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.5.2.1D.4 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UESI for FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen=IV
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

78	41	33	28	27	18	13	9	5	1	1	0	0	CTx + Durvalumab + Olaparib
77	43	34	32	26	19	17	11	4	1	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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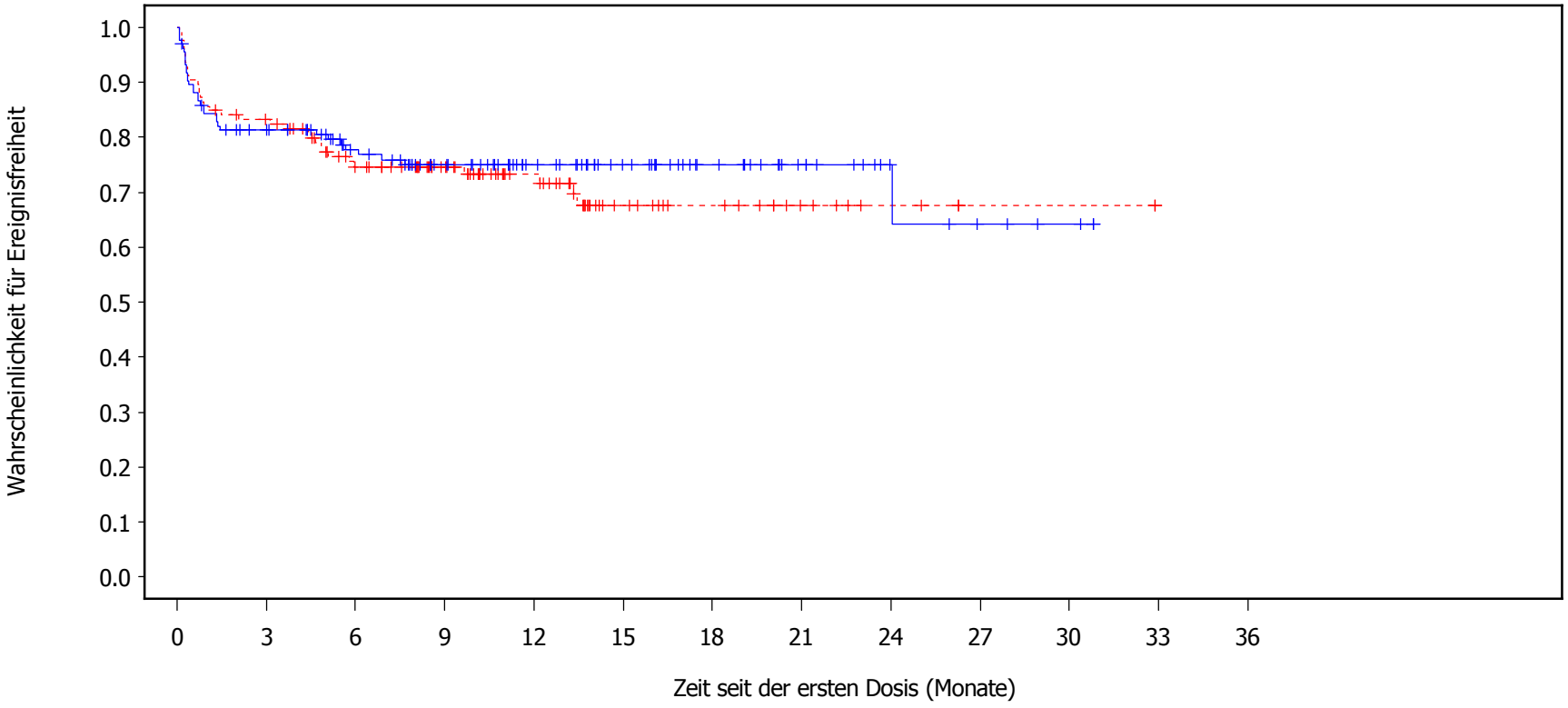
Figure 4.4.5.2.1D.5 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UESI GT: Dermatitis/Hautausschlag for ECOG Performance Status zu Baseline=0
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

135	104	84	67	50	36	24	15	7	4	2	0	0	CTx + Durvalumab + Olaparib
126	102	81	64	43	21	15	8	4	1	1	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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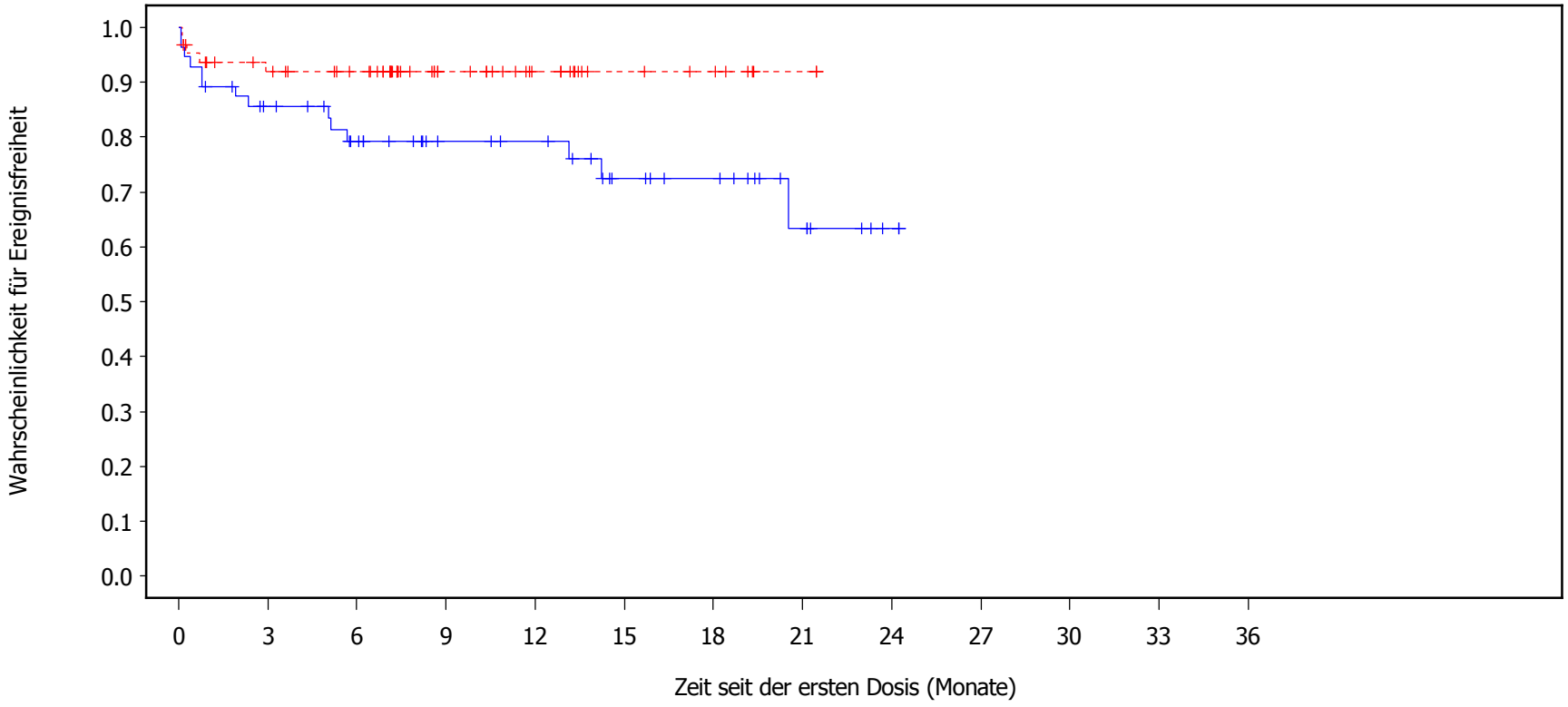
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.5.2.1D.6 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UESI GT: Dermatitis/Hautausschlag for ECOG Performance Status zu Baseline=1
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

56	44	36	27	25	17	14	7	1	0	0	0	0	CTx + Durvalumab + Olaparib
64	53	47	25	16	8	6	1	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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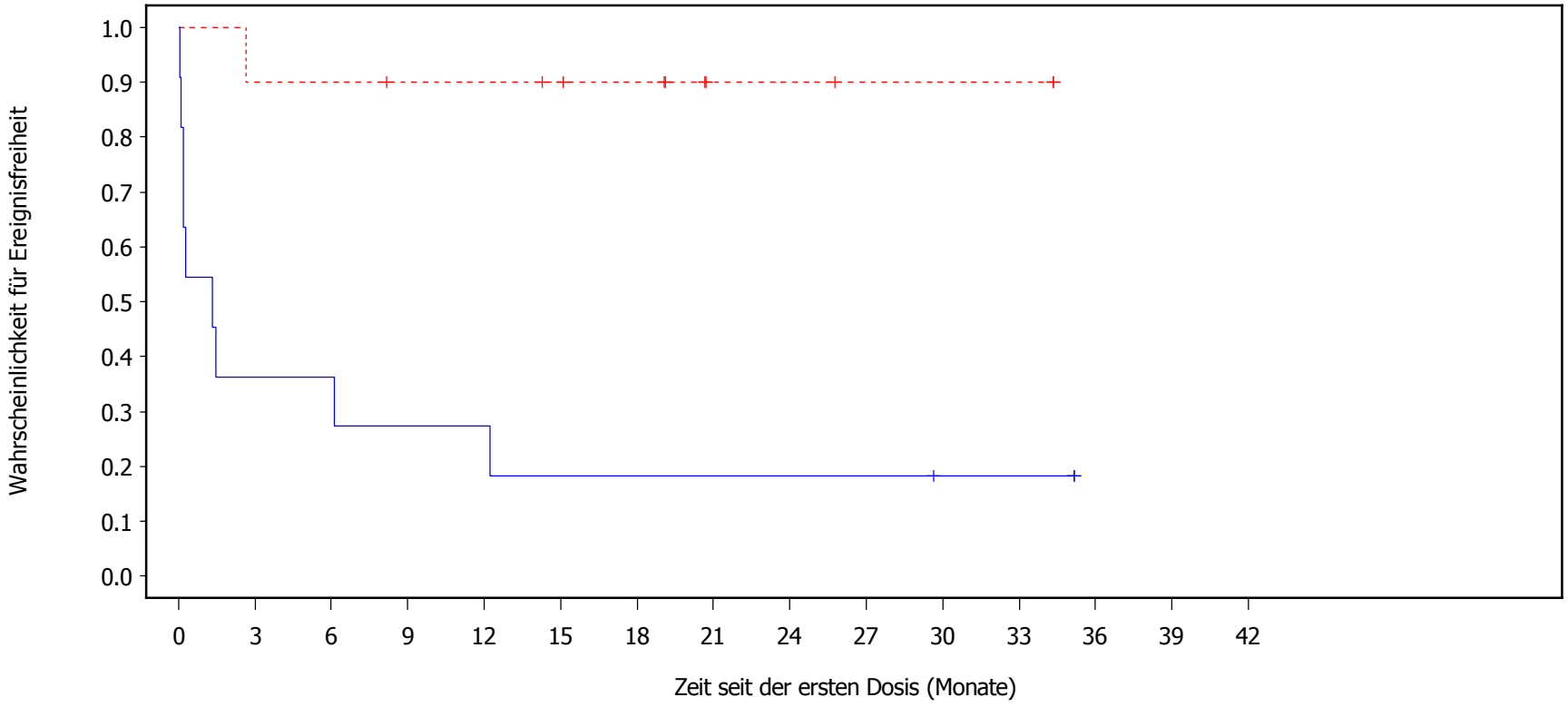
Figure 4.4.5.2.2D.1 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UESI for FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen=III
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

11	4	4	3	3	2	2	2	2	2	1	1	0	0	0	CTx + Durvalumab + Olaparib
10	9	9	8	8	7	6	2	2	1	1	1	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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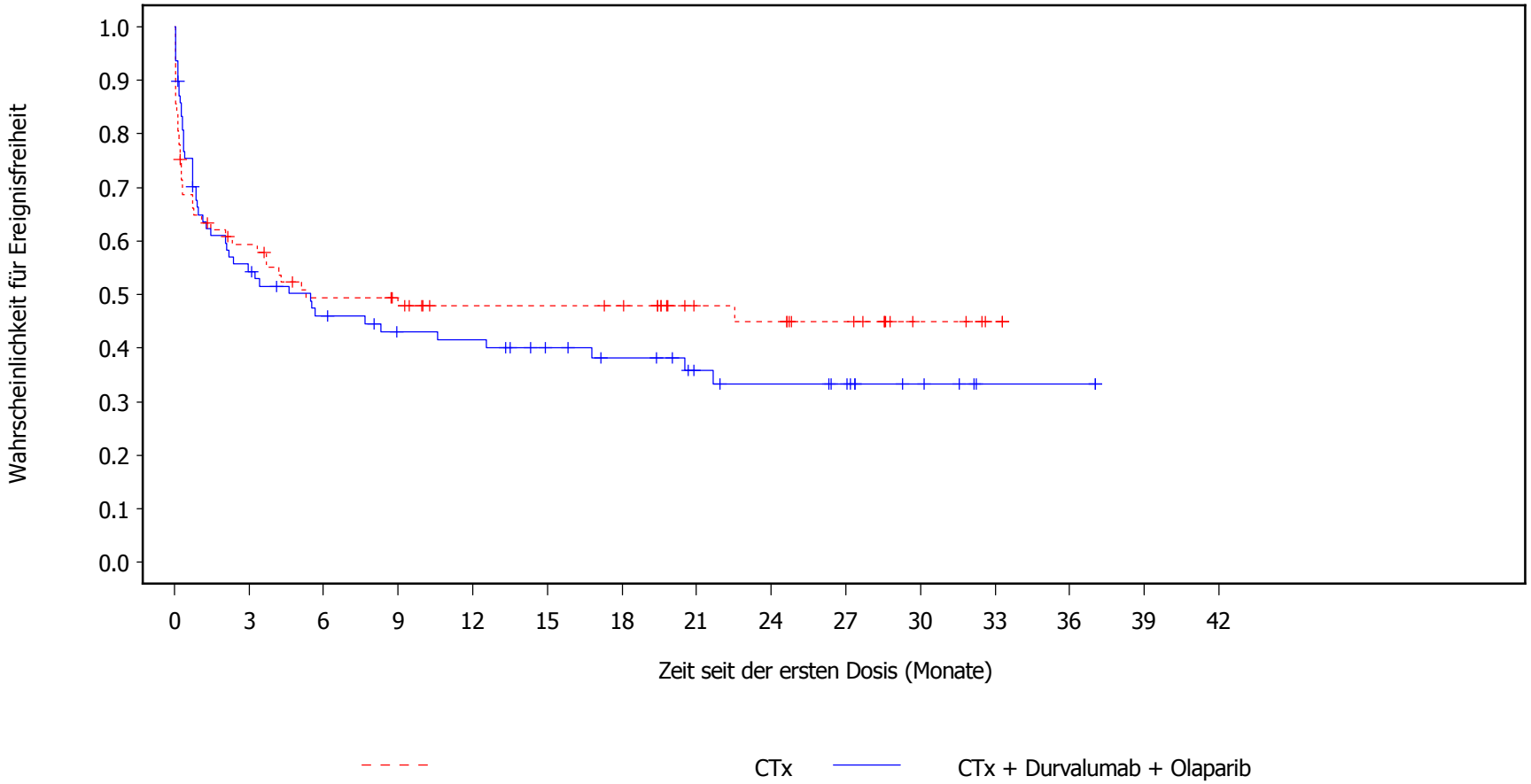
Figure 4.4.5.2.2D.2 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UESI for FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen=IV
Safety Analysis Set, DCO 18OCT2023



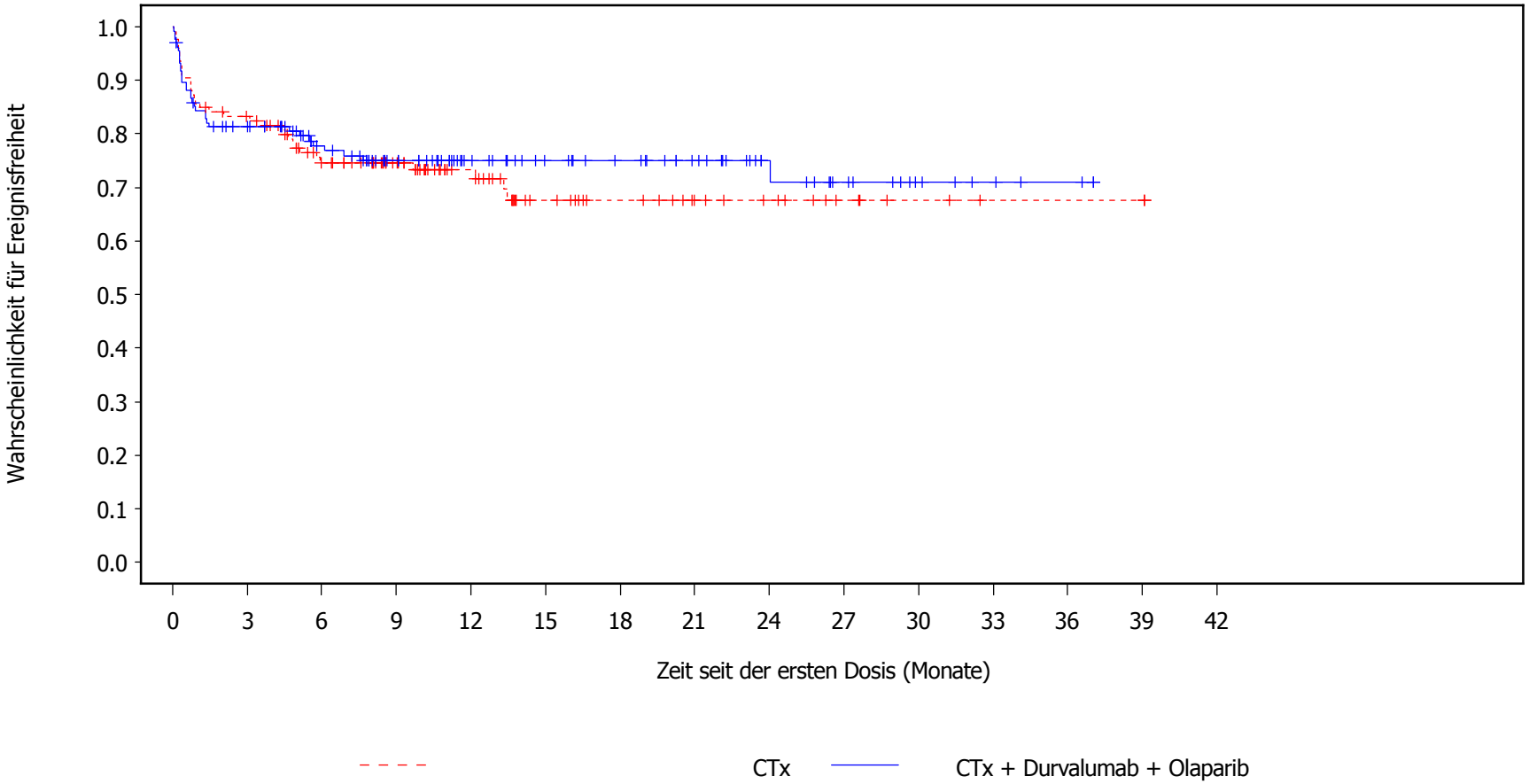
Anzahl an Patienten unter Risiko:

78	41	33	28	27	22	19	14	12	10	5	1	1	0	0	CTx + Durvalumab + Olaparib
77	43	34	32	26	26	25	16	15	11	4	1	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc2.sas gttesubaedc2zab 29MAY2024:15:58

Figure 4.4.5.2.2D.3 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UESI GT: Dermatitis/Hautausschlag for ECOG Performance Status zu Baseline=0
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

135	104	84	67	50	41	36	29	19	13	7	4	2	0	0	CTx + Durvalumab + Olaparib
126	102	81	64	43	26	20	14	11	6	3	1	1	1	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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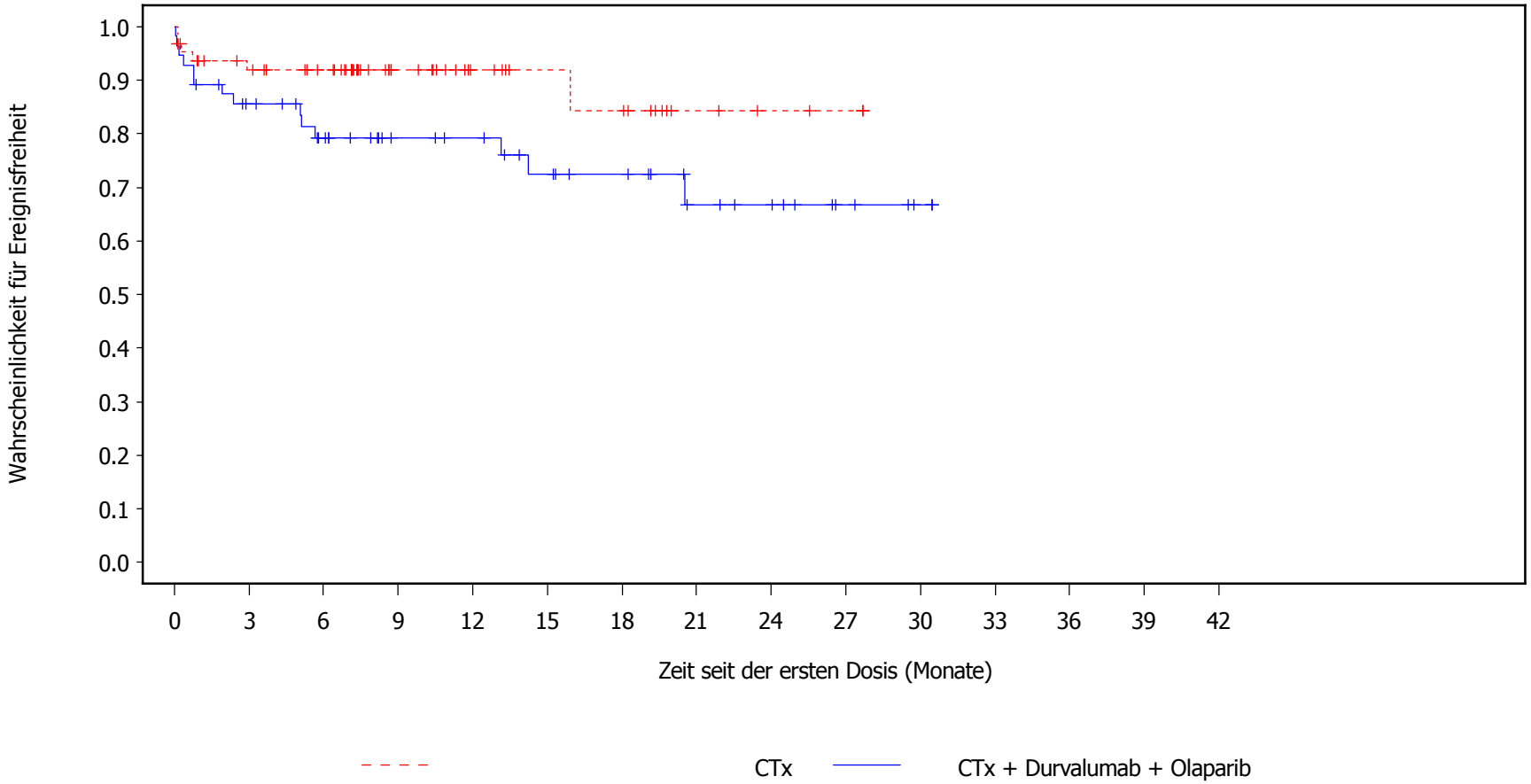
Figure 4.4.5.2.2D.4 DUO-E (pMMR Durva/Ola) Subgroup Analysis: Kaplan-Meier plot of UESI GT: Dermatitis/Hautausschlag for ECOG Performance Status zu Baseline=1
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

56	44	36	27	25	20	17	11	9	4	1	0	0	0	0	CTx + Durvalumab + Olaparib
64	53	47	25	16	12	11	4	2	1	0	0	0	0	0	CTx

Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc2.sas gttesubaedc2zad 29MAY2024:15:58