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® als Monotherapie beim Endometriumkarzinom mit Mismatch-Reparatur-Defizienz (dMMR)

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 1.1.1.1D DUO-E (dMMR Durva): Summary of observation period (months) for efficacy endpoints
Patients with dMMR tumour status , DCO 12APR2023

		CTx + Durvalumab (N=46)	CTx (N=49)
Gesamtüberleben	n	46	49
	Mediane	18,37	15,51
	Min	1,0	2,3
	Max	31,9	28,8
Progressionsfreies Überleben	n	46	49
	Mediane	12,44	6,70
	Min	0,0	0,0
	Max	29,1	26,4
Progressionsfreies Überleben 2	n	46	49
	Mediane	15,23	10,55
	Min	0,0	2,1
	Max	29,1	26,4
Zeit bis zur ersten nachfolgenden Krebstherapie od. Tod	n	46	49
	Mediane	15,62	8,05
	Min	0,7	2,3
	Max	31,9	27,4
Zeit bis zur zweiten nachfolgenden Krebstherapie od. Tod	n	46	49
	Mediane	17,49	13,24
	Min	0,7	2,3
	Max	31,9	28,8
Zeit bis zum Absetzen der Therapie od. Tod	n	46	49
	Mediane	14,62	6,70
	Min	0,0	0,1
	Max	31,9	27,4

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 2.1.1 DUO-E (dMMR Durva): Summary of observation period (months) for PRO endpoints
Patients with dMMR tumour status, DCO 12APR2023

		CTx + Durvalumab (N=46)	CTx (N=49)
EORTC QLQ-C30	n	46	49
	Mediane	12,40	5,06
	Min	0,0	0,0
	Max	31,1	27,1
EORTC QLQ-EN24	n	46	49
	Mediane	10,05	5,06
	Min	0,0	0,0
	Max	31,1	27,1
EQ-5D visuelle Analogskala	n	46	49
	Mediane	8,26	5,06
	Min	0,0	0,0
	Max	31,1	27,1
PGIS	n	46	49
	Mediane	6,01	4,83
	Min	0,0	0,0
	Max	31,1	27,1
PGIC	n	46	49
	Mediane	12,40	6,83
	Min	0,0	0,0
	Max	31,1	27,1
PGI-TT	n	46	49
	Mediane	5,14	4,83
	Min	0,0	0,0
	Max	31,1	27,1

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 3.1.1.1D DUO-E (dMMR Durva): Summary of observation period (months) for safety outcomes
Patients with dMMR tumour status, DCO 12APR2023

		CTx + Durvalumab (N=44)	CTx (N=46)
AE/AESI (excl. NPM and MDS/AML) [a]	n	44	46
	Mediane	14,62	7,43
	Min	0,7	0,7
	Max	31,7	27,4
AESI: NPM and MDS/AML [b]	n	44	46
	Mediane	18,37	15,47
	Min	1,0	2,1
	Max	31,7	28,8

[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 1.1.1.2D DUO-E (dMMR Durva): Summary of observation period (months) for overall survival
Patients with dMMR tumour status , DCO 18OCT2023

		CTx + Durvalumab (N=46)	CTx (N=49)
Gesamtüberleben	n	46	49
	Mediane	24,48	19,88
	Min	1,0	2,3
	Max	38,1	35,1

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 3.1.1.2D DUO-E (dMMR Durva): Summary of observation period (months) for safety outcomes
Patients with dMMR tumour status, DCO 18OCT2023

		CTx + Durvalumab (N=44)	CTx (N=46)
AE/AESI (excl. NPM and MDS/AML) [a]	n	44	46
	Mediane	20,24	7,43
	Min	0,7	0,7
	Max	37,9	33,6
AESI: NPM and MDS/AML [b]	n	44	46
	Mediane	24,48	19,78
	Min	1,0	2,1
	Max	37,9	35,0

[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 1.2.1.1.2D DUO-E (dMMR Durva): Summary of analysis of overall survival (OS)
Patients with dMMR tumour status, DCO 18OCT2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	46	9 (19,6)	NE [NE; NE]	49	19 (38,8)	NE [NE; NE]	0,41	[0,17; 0,88]	0,0218*

[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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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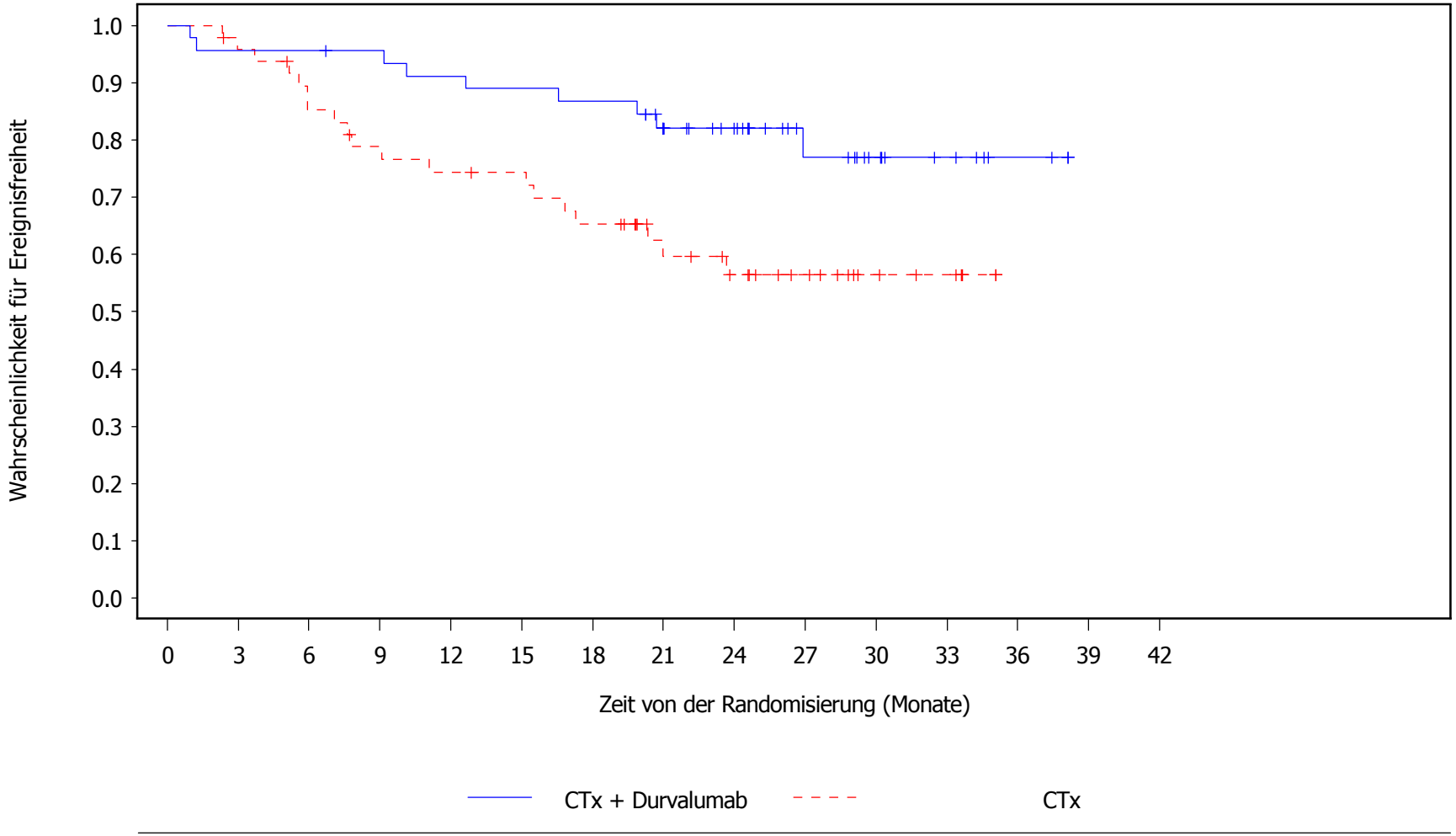
Figure 1.3.1.1.2D DUO-E (dMMR Durva): Kaplan-Meier plot of overall survival (OS)
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

46	44	44	43	41	40	39	31	25	15	10	6	2	0	0	CTx + Durvalumab
49	46	40	36	34	33	29	21	17	12	6	4	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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Table 1.2.3.1 DUO-E (dMMR Durva): Summary of analysis of second progression-free survival by investigator
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	46	10 (21,7)	NE [NE; NE]	49	20 (40,8)	15,2 [11,1; NE]	0,33	[0,15; 0,71]	0,0039*

[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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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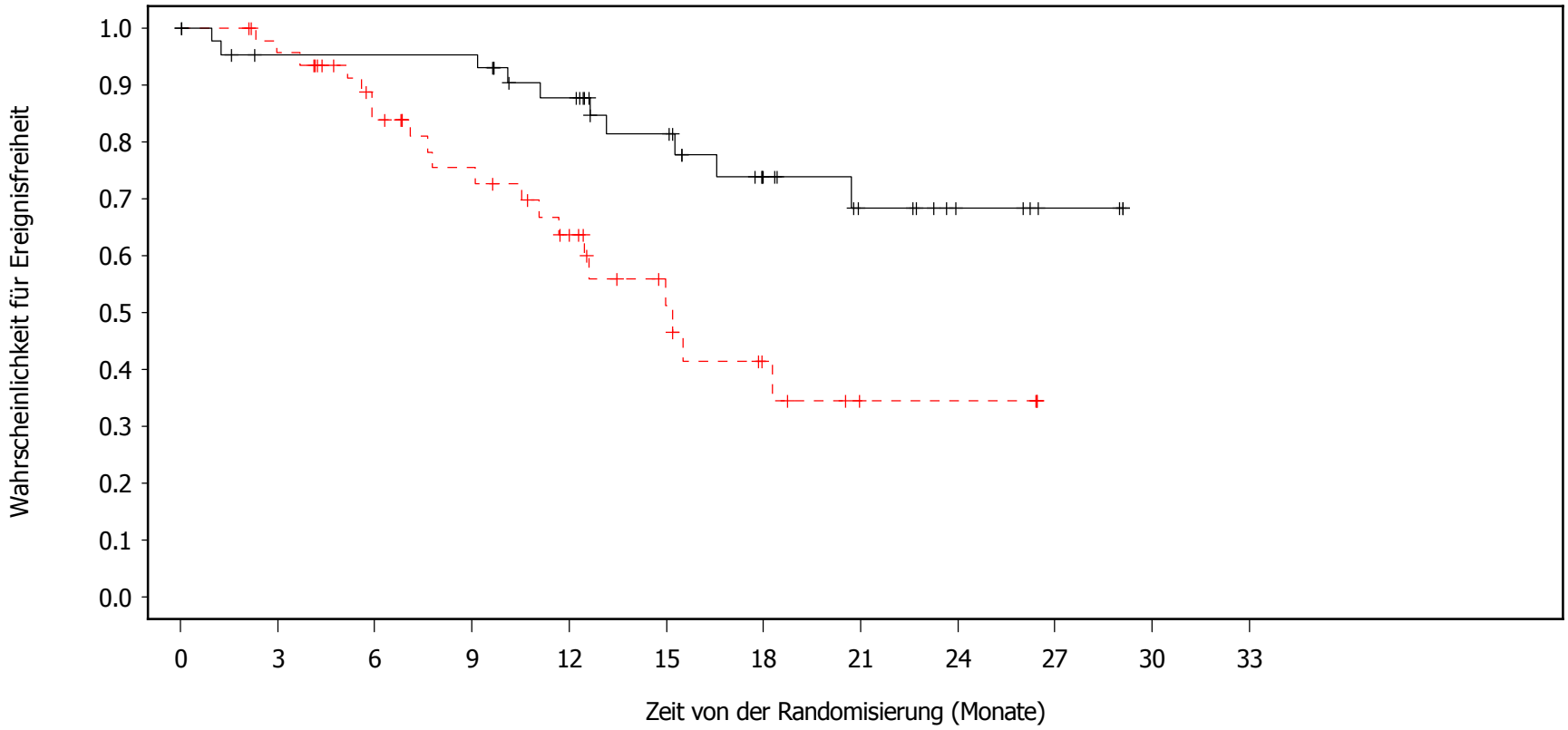
Figure 1.3.3.1 DUO-E (dMMR Durva): Kaplan-Meier plot of second progression-free survival by investigator
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

46	40	40	40	33	25	16	10	5	2	0	0	CTx + Durvalumab
49	45	34	27	19	11	6	2	2	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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Table 1.2.4.1 DUO-E (dMMR Durva): Summary of analysis of time to first subsequent cancer therapy or death
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	46	16 (34,8)	NE [NE; NE]	49	28 (57,1)	8,8 [7,4; NE]	0,43	[0,22; 0,79]	0,0069*

[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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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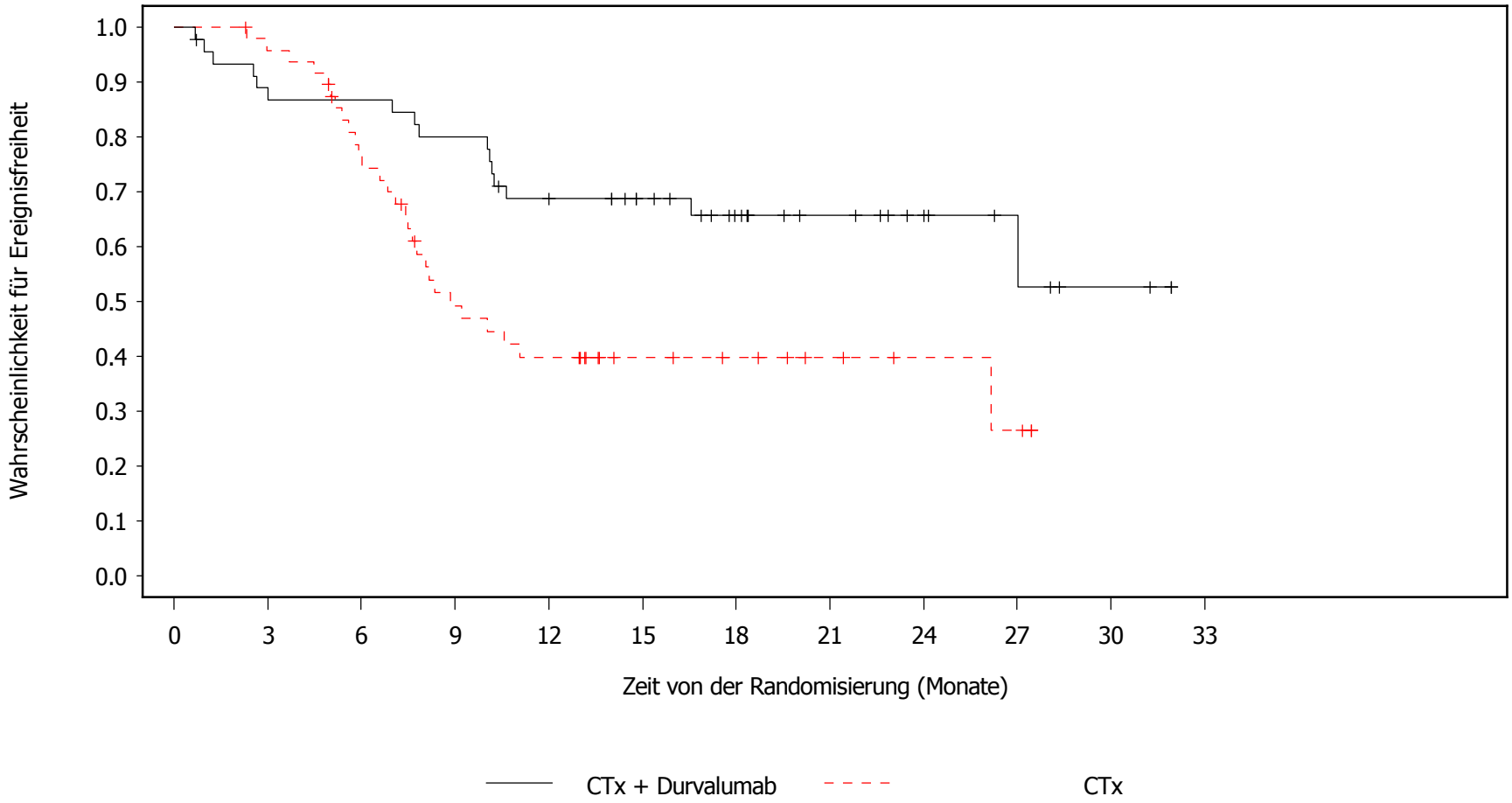
Figure 1.3.4.1 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first subsequent cancer therapy or death
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

46	40	39	36	29	24	17	12	8	5	2	0	CTx + Durvalumab
49	46	35	21	17	10	8	5	3	2	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Table 1.2.5.1 DUO-E (dMMR Durva): Summary of analysis of time to second subsequent cancer therapy or death
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	46	9 (19,6)	NE [NE; NE]	49	21 (42,9)	16,9 [15,2; NE]	0,38	[0,17; 0,82]	0,0137*

[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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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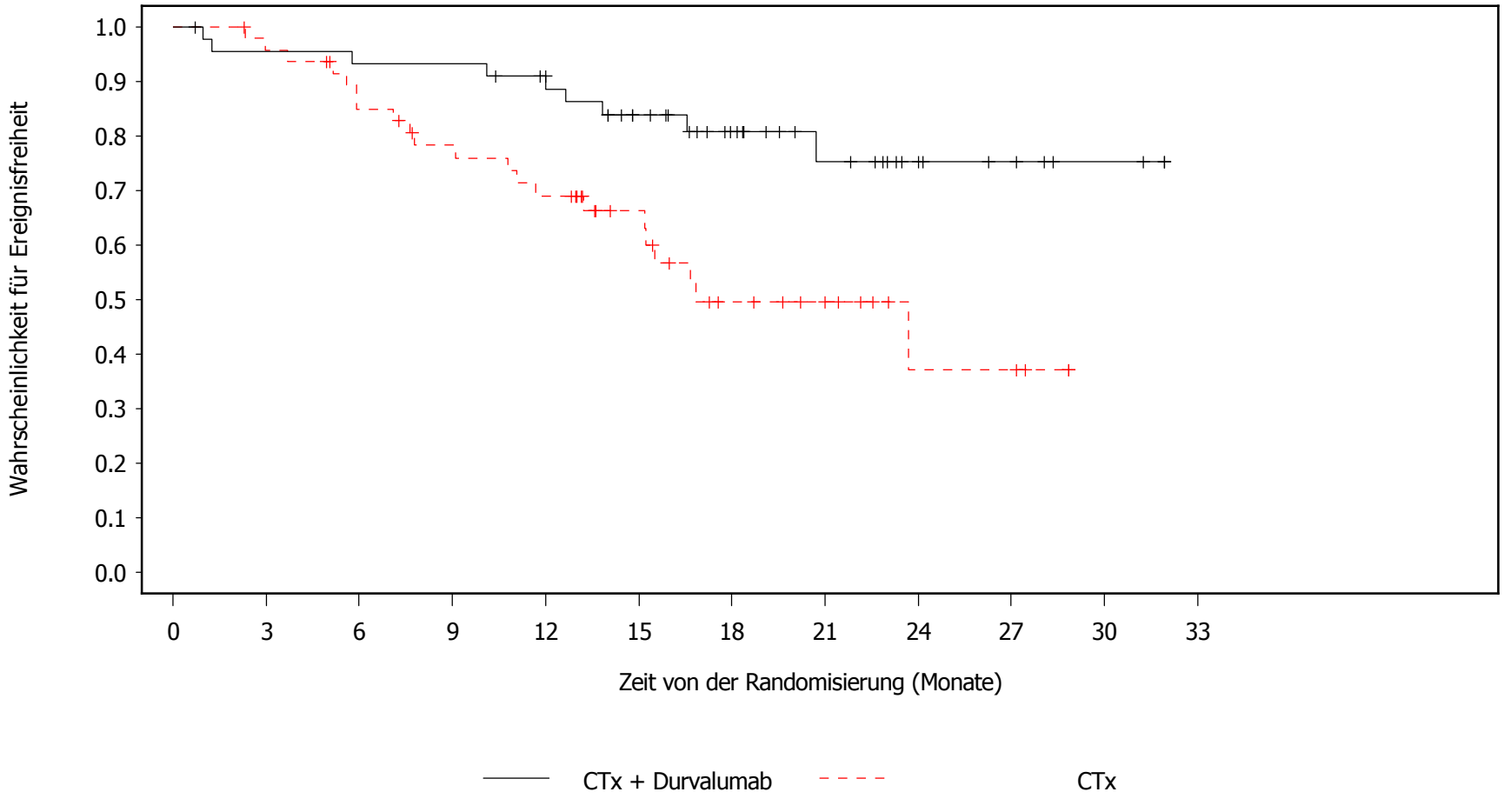
Figure 1.3.5.1 DUO-E (dMMR Durva): Kaplan-Meier plot of time to second subsequent cancer therapy or death
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

46	43	42	42	38	30	21	14	8	5	2	0	CTx + Durvalumab
49	46	39	34	30	21	12	8	3	3	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Table 1.2.6.1 DUO-E (dMMR Durva): Summary of analysis of time to study treatment discontinuation or death
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	46	22 (47,8)	21,2 [9,3; NE]	49	37 (75,5)	6,7 [5,1; 7,9]	0,44	[0,25; 0,75]	0,0022*

[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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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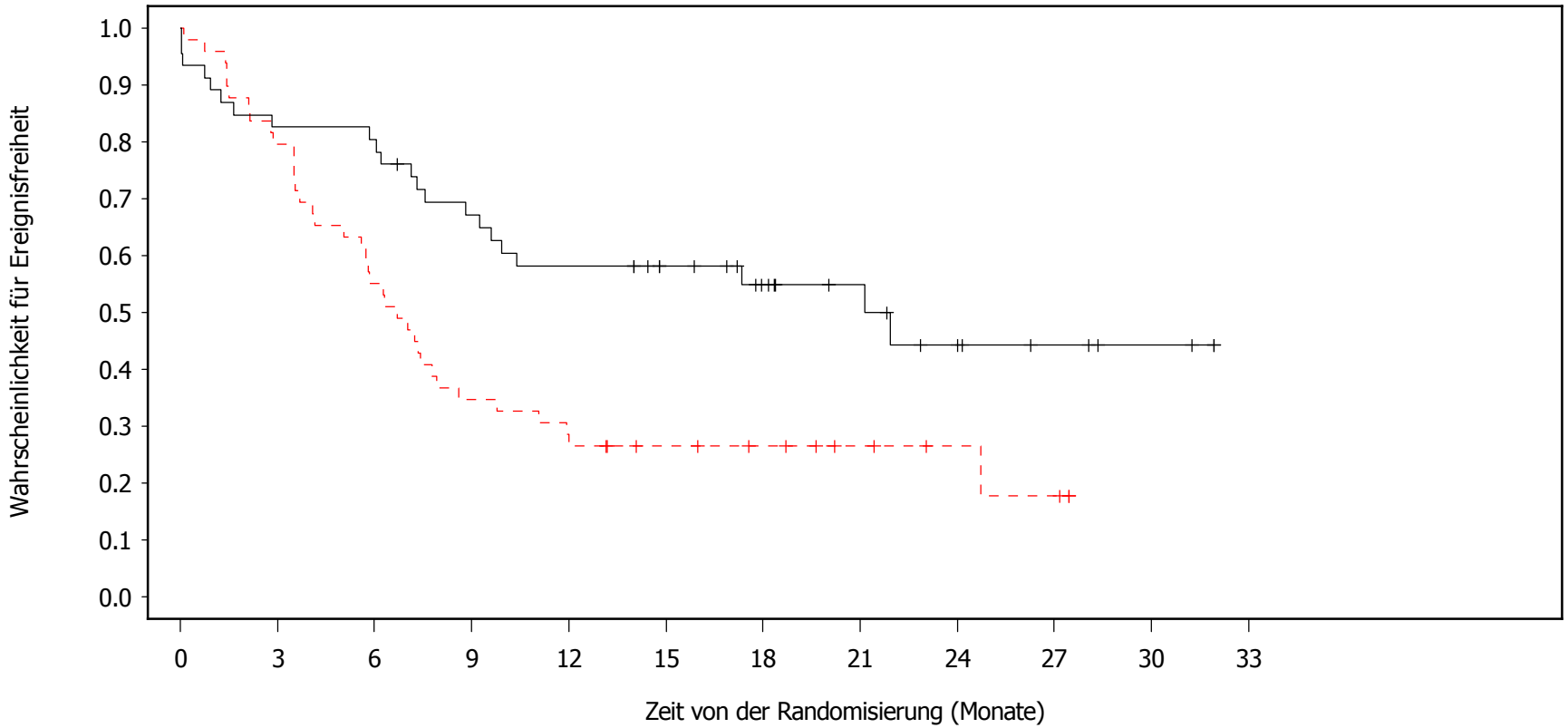
Figure 1.3.6.1 DUO-E (dMMR Durva): Kaplan-Meier plot of time to study treatment discontinuation or death
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

46	38	37	30	26	21	15	11	7	4	2	0	CTx + Durvalumab
49	39	27	17	14	10	8	5	3	2	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Table 2.2.6.1 DUO-E (dMMR Durva): Summary of analysis of time to first deterioration in PGI-TT
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	46	29 (63,0)	0,8 [0,7; 1,3]	49	31 (63,3)	1,3 [0,7; 2,1]	1,56	[0,88; 2,79]	0,1219

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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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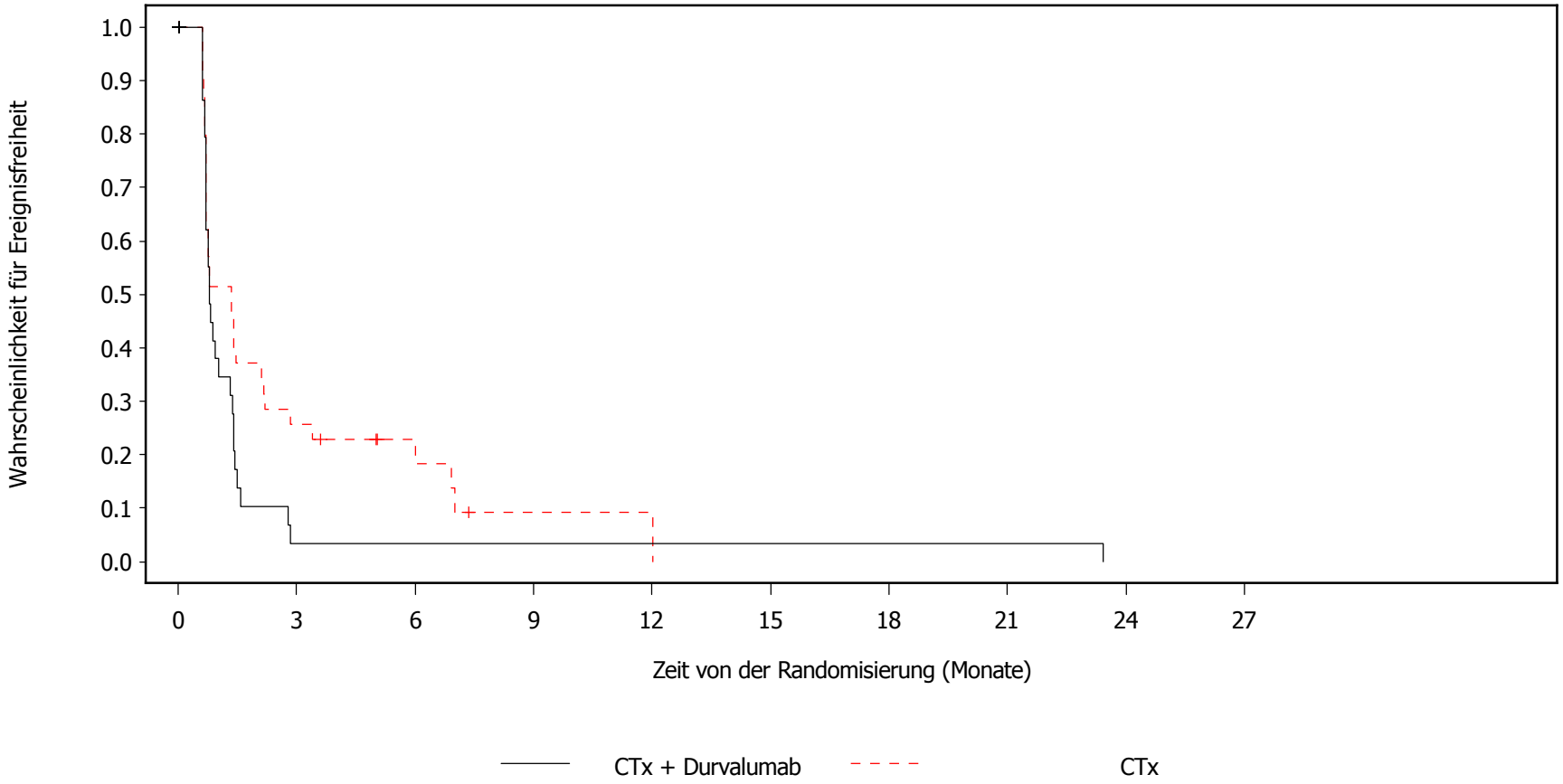
Figure 2.3.6.1.1 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - PGI-TT
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

46	1	1	1	1	1	1	1	0	0	CTx + Durvalumab
49	9	5	1	1	0	0	0	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.

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Table 2.4.1.1.1 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-C30 Allgemeine over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	67,89 (20,426)	-8,27 (3,470)	36	71,53 (20,254)	-3,51 (3,389)	-4,75 [-14,462; 4,956]	0,3322
Tag 43 (Woche 6)	33	67,42 (20,662)	-4,63 (2,805)	34	73,77 (21,135)	-5,40 (2,766)	0,78 [-7,122; 8,678]	0,8448
Tag 64 (Woche 9)	33	66,92 (20,675)	-6,11 (2,960)	34	75,98 (19,437)	-8,09 (2,942)	1,98 [-6,408; 10,371]	0,6392
Tag 85 (Woche 12)	30	66,67 (21,554)	-7,61 (3,069)	29	77,01 (19,372)	-12,81 (3,130)	5,21 [-3,630; 14,042]	0,2439
Tag 106 (Woche 15)	28	66,07 (21,508)	-10,36 (3,194)	31	77,42 (19,268)	-10,56 (3,180)	0,20 [-8,899; 9,294]	0,9656
Tag 127 (Woche 18)	29	68,39 (21,522)	-11,73 (3,519)	26	74,04 (18,001)	-12,51 (3,652)	0,78 [-9,424; 10,986]	0,8789
Tag 155 (Woche 22)	24	68,40 (21,560)	-4,18 (2,710)	21	72,22 (20,299)	-6,81 (2,837)	2,63 [-5,248; 10,507]	0,5071
Tag 183 (Woche 26)	29	67,24 (21,238)	-0,57 (2,365)	20	70,83 (21,203)	-9,48 (2,640)	8,91 [1,807; 16,013]	0,0147*
Tag 211 (Woche 30)	27	67,90 (21,768)	-0,34 (2,452)	21	74,21 (20,566)	-4,81 (2,698)	4,47 [-2,850; 11,797]	0,2271
Tag 239 (Woche 34)	22	68,56 (23,978)	0,88 (2,379)	15	72,78 (21,238)	-8,03 (2,741)	8,91 [1,592; 16,235]	0,0180*
Tag 267 (Woche 38)	24	67,01 (23,245)	-0,26 (3,289)	17	72,06 (20,821)	-7,81 (3,741)	7,55 [-2,480; 17,587]	0,1370
Tag 295 (Woche 42)	25	68,00 (22,526)	1,65 (3,486)	16	67,71 (21,054)	-14,27 (4,099)	15,92 [5,102; 26,735]	0,0047*
Tag 323 (Woche 46)	23	66,30 (23,230)	-4,44 (3,681)	17	69,61 (21,838)	-10,21 (4,160)	5,78 [-5,366; 16,919]	0,3035
Tag 351 (Woche 50)	22	68,18 (21,306)	-1,53 (2,862)	15	68,89 (21,238)	-10,93 (3,321)	9,40 [0,590; 18,201]	0,0370*
Durchschnitt über alle Visiten	37	67,34 (19,777)	-4,11 (2,165)	38	73,03 (20,726)	-8,95 (2,236)	4,84 [-1,410; 11,090]	0,1269
Hedges' g SMD							0,36 [-0,101; 0,812]	0,1272

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	74,51 (15,437)	-0,56 (3,341)	36	84,63 (14,934)	-5,66 (3,262)	5,10 [-4,470; 14,675]	0,2913
Tag 43 (Woche 6)	33	74,14 (15,253)	0,69 (2,979)	34	86,67 (13,633)	-9,37 (2,938)	10,06 [1,427; 18,690]	0,0231*
Tag 64 (Woche 9)	33	73,33 (14,907)	-1,99 (3,571)	34	86,67 (14,213)	-16,42 (3,522)	14,43 [4,057; 24,799]	0,0071*
Tag 85 (Woche 12)	30	74,67 (15,202)	-4,11 (3,742)	29	87,13 (13,793)	-17,60 (3,787)	13,49 [2,488; 24,500]	0,0170*
Tag 106 (Woche 15)	28	73,57 (16,074)	-7,74 (3,838)	31	87,31 (13,373)	-17,45 (3,832)	9,71 [-1,539; 20,953]	0,0896
Tag 127 (Woche 18)	29	74,25 (16,205)	-5,66 (3,576)	26	86,67 (12,927)	-16,59 (3,702)	10,93 [0,264; 21,593]	0,0447*
Tag 155 (Woche 22)	24	74,44 (17,547)	-4,40 (3,151)	21	87,30 (11,908)	-11,03 (3,309)	6,63 [-2,864; 16,114]	0,1674
Tag 183 (Woche 26)	29	74,25 (16,008)	-5,95 (3,776)	20	84,67 (15,001)	-15,09 (4,107)	9,14 [-2,375; 20,648]	0,1175
Tag 211 (Woche 30)	27	76,05 (16,357)	0,14 (2,855)	21	85,40 (14,999)	-8,01 (3,097)	8,15 [-0,515; 16,810]	0,0648
Tag 239 (Woche 34)	22	74,55 (17,045)	3,25 (2,800)	15	84,89 (14,793)	-8,27 (3,140)	11,51 [2,846; 20,177]	0,0101*
Tag 267 (Woche 38)	24	75,56 (16,758)	3,13 (2,851)	17	85,49 (13,991)	-10,18 (3,211)	13,31 [4,472; 22,143]	0,0038*
Tag 295 (Woche 42)	25	75,73 (17,520)	-0,47 (3,103)	16	84,58 (13,924)	-10,46 (3,567)	9,99 [0,284; 19,694]	0,0439*
Tag 323 (Woche 46)	23	75,94 (17,025)	-1,99 (3,509)	17	85,49 (13,991)	-9,91 (3,933)	7,92 [-2,920; 18,769]	0,1487
Tag 351 (Woche 50)	22	74,24 (18,088)	1,64 (3,565)	15	86,22 (12,716)	-14,43 (4,028)	16,07 [4,907; 27,242]	0,0058*
Durchschnitt über alle Visiten	37	74,77 (15,165)	-1,72 (2,618)	38	84,91 (14,596)	-12,18 (2,679)	10,46 [2,729; 18,191]	0,0089*
Hedges' g SMD							0,64 [0,173; 1,103]	0,0071*

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	74,51 (22,931)	-1,19 (4,979)	36	80,09 (24,501)	-7,93 (4,819)	6,75 [-7,105; 20,596]	0,3347
Tag 43 (Woche 6)	33	73,74 (23,581)	-3,22 (4,456)	34	85,78 (18,410)	-6,28 (4,362)	3,06 [-9,506; 15,636]	0,6282
Tag 64 (Woche 9)	33	73,23 (23,176)	-8,01 (4,590)	34	83,82 (23,386)	-13,20 (4,479)	5,19 [-7,697; 18,079]	0,4245
Tag 85 (Woche 12)	30	75,56 (22,630)	-7,91 (4,525)	29	86,21 (22,302)	-13,59 (4,550)	5,68 [-7,248; 18,609]	0,3836
Tag 106 (Woche 15)	28	75,60 (23,343)	-14,83 (5,052)	31	86,56 (21,696)	-14,02 (4,969)	-0,81 [-15,084; 13,463]	0,9101
Tag 127 (Woche 18)	29	78,16 (22,318)	-11,01 (4,947)	26	84,62 (23,534)	-21,32 (5,084)	10,31 [-3,924; 24,551]	0,1528
Tag 155 (Woche 22)	24	76,39 (24,533)	-10,46 (4,916)	21	88,10 (15,936)	-10,60 (5,178)	0,14 [-14,310; 14,597]	0,9842
Tag 183 (Woche 26)	29	74,14 (24,635)	-10,30 (5,428)	20	87,50 (16,109)	-15,69 (6,031)	5,39 [-11,060; 21,832]	0,5152
Tag 211 (Woche 30)	27	77,78 (24,019)	-4,50 (4,529)	21	85,71 (23,738)	-5,19 (4,937)	0,70 [-12,758; 14,156]	0,9178
Tag 239 (Woche 34)	22	78,03 (25,400)	3,78 (4,564)	15	88,89 (14,996)	-10,95 (5,282)	14,73 [0,666; 28,785]	0,0404*
Tag 267 (Woche 38)	24	77,08 (22,954)	-2,77 (5,023)	17	83,33 (25,685)	-10,84 (5,664)	8,07 [-7,142; 23,286]	0,2929
Tag 295 (Woche 42)	25	76,67 (24,533)	-1,69 (4,919)	16	79,17 (26,874)	-15,09 (5,696)	13,39 [-1,702; 28,487]	0,0810
Tag 323 (Woche 46)	23	77,54 (23,360)	-1,49 (4,325)	17	80,39 (26,507)	-11,59 (4,840)	10,10 [-2,918; 23,119]	0,1259
Tag 351 (Woche 50)	22	74,24 (25,054)	1,27 (4,405)	15	80,00 (27,603)	-17,00 (4,974)	18,26 [4,895; 31,627]	0,0084*
Durchschnitt über alle Visiten	37	74,77 (22,778)	-5,17 (3,568)	38	81,14 (24,252)	-12,38 (3,630)	7,21 [-2,999; 17,422]	0,1633
Hedges' g SMD							0,32 [-0,132; 0,780]	0,1639

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	70,59 (19,703)	-0,86 (3,073)	36	78,47 (16,351)	6,64 (3,035)	-7,49 [-16,218; 1,229]	0,0911
Tag 43 (Woche 6)	33	70,45 (19,330)	4,22 (3,017)	34	79,41 (15,656)	4,21 (3,006)	0,01 [-8,611; 8,634]	0,9979
Tag 64 (Woche 9)	33	70,45 (19,330)	4,16 (3,701)	34	79,90 (16,038)	2,38 (3,705)	1,78 [-8,826; 12,387]	0,7388
Tag 85 (Woche 12)	30	71,67 (19,525)	4,66 (3,053)	29	80,17 (16,277)	4,58 (3,112)	0,08 [-8,736; 8,902]	0,9851
Tag 106 (Woche 15)	28	67,56 (19,022)	-0,66 (3,713)	31	80,38 (15,745)	4,05 (3,689)	-4,71 [-15,371; 5,953]	0,3812
Tag 127 (Woche 18)	29	70,11 (19,985)	1,25 (3,601)	26	78,85 (17,034)	3,62 (3,701)	-2,37 [-12,831; 8,100]	0,6532
Tag 155 (Woche 22)	24	72,92 (19,543)	4,78 (3,261)	21	79,37 (16,376)	3,30 (3,396)	1,49 [-8,047; 11,020]	0,7561
Tag 183 (Woche 26)	29	70,11 (19,226)	2,52 (3,922)	20	78,75 (18,824)	0,27 (4,253)	2,25 [-9,456; 13,954]	0,7027
Tag 211 (Woche 30)	27	70,37 (18,965)	3,02 (3,410)	21	78,97 (18,375)	6,93 (3,659)	-3,91 [-14,031; 6,204]	0,4430
Tag 239 (Woche 34)	22	70,83 (20,372)	7,28 (3,245)	15	76,67 (20,940)	6,66 (3,606)	0,62 [-9,174; 10,416]	0,8996
Tag 267 (Woche 38)	24	68,40 (19,502)	4,89 (3,694)	17	77,94 (19,530)	3,28 (4,057)	1,61 [-9,514; 12,735]	0,7733
Tag 295 (Woche 42)	25	70,00 (20,127)	0,77 (3,816)	16	75,52 (19,357)	6,41 (4,296)	-5,64 [-17,230; 5,950]	0,3346
Tag 323 (Woche 46)	23	68,12 (18,404)	-0,34 (4,335)	17	75,00 (18,865)	1,54 (4,745)	-1,88 [-14,832; 11,069]	0,7725
Tag 351 (Woche 50)	22	68,94 (20,279)	1,24 (4,024)	15	76,67 (17,873)	5,68 (4,544)	-4,44 [-16,704; 7,833]	0,4724
Durchschnitt über alle Visiten	37	70,50 (18,901)	2,64 (2,862)	38	78,95 (16,063)	4,25 (2,936)	-1,61 [-9,911; 6,683]	0,6991
Hedges' g SMD							-0,09 [-0,543; 0,363]	0,6971

[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 2.4.1.1.5 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-C30 Funktionsskala: Kognition over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	85,29 (15,766)	-4,65 (3,112)	36	86,11 (15,685)	0,82 (3,029)	-5,46 [-14,123; 3,198]	0,2126
Tag 43 (Woche 6)	33	84,85 (15,791)	-4,52 (2,788)	34	89,71 (12,985)	-2,26 (2,755)	-2,26 [-10,120; 5,598]	0,5675
Tag 64 (Woche 9)	33	85,86 (15,658)	-6,51 (3,451)	34	88,73 (14,047)	-8,94 (3,409)	2,43 [-7,265; 12,122]	0,6187
Tag 85 (Woche 12)	30	87,22 (14,306)	-6,62 (3,465)	29	90,23 (13,000)	-7,11 (3,513)	0,49 [-9,375; 10,351]	0,9214
Tag 106 (Woche 15)	28	84,52 (16,310)	-11,42 (3,608)	31	90,32 (12,747)	-9,40 (3,541)	-2,02 [-12,182; 8,139]	0,6922
Tag 127 (Woche 18)	29	86,21 (16,103)	-9,80 (3,200)	26	87,82 (15,317)	-11,83 (3,304)	2,04 [-7,170; 11,247]	0,6595
Tag 155 (Woche 22)	24	84,03 (16,652)	-9,03 (3,006)	21	89,68 (13,412)	-5,40 (3,145)	-3,62 [-12,408; 5,163]	0,4116
Tag 183 (Woche 26)	29	83,91 (16,356)	-12,22 (3,321)	20	89,17 (14,585)	-7,07 (3,710)	-5,16 [-15,161; 4,851]	0,3068
Tag 211 (Woche 30)	27	85,19 (15,562)	-9,30 (2,880)	21	89,68 (14,411)	-5,49 (3,149)	-3,80 [-12,360; 4,753]	0,3777
Tag 239 (Woche 34)	22	87,12 (13,542)	-10,16 (2,756)	15	90,00 (12,280)	-6,54 (3,189)	-3,62 [-12,052; 4,819]	0,3941
Tag 267 (Woche 38)	24	84,72 (16,966)	-8,76 (3,055)	17	88,24 (15,326)	-11,98 (3,471)	3,22 [-6,052; 12,496]	0,4897
Tag 295 (Woche 42)	25	83,33 (16,667)	-7,10 (3,080)	16	84,38 (17,710)	-7,45 (3,614)	0,34 [-9,145; 9,828]	0,9428
Tag 323 (Woche 46)	23	83,33 (17,408)	-10,75 (3,724)	17	85,29 (17,562)	-6,74 (4,228)	-4,01 [-15,270; 7,257]	0,4792
Tag 351 (Woche 50)	22	81,82 (16,988)	-12,53 (3,495)	15	85,56 (17,668)	-6,78 (4,072)	-5,75 [-16,492; 4,993]	0,2878
Durchschnitt über alle Visiten	37	85,14 (15,607)	-8,81 (2,307)	38	86,84 (15,576)	-6,87 (2,375)	-1,94 [-8,563; 4,680]	0,5601
Hedges' g SMD							-0,13 [-0,587; 0,319]	0,5624

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	72,55 (22,051)	-6,07 (4,636)	36	80,56 (21,269)	-1,39 (4,489)	-4,68 [-17,639; 8,283]	0,4741
Tag 43 (Woche 6)	33	72,22 (21,517)	-1,93 (3,862)	34	84,31 (17,857)	0,65 (3,797)	-2,58 [-13,543; 8,388]	0,6407
Tag 64 (Woche 9)	33	73,23 (22,024)	-0,15 (4,732)	34	84,31 (17,857)	-8,09 (4,681)	7,93 [-5,542; 21,403]	0,2442
Tag 85 (Woche 12)	30	73,33 (22,574)	-3,53 (4,169)	29	84,48 (18,328)	-6,78 (4,217)	3,26 [-8,751; 15,268]	0,5901
Tag 106 (Woche 15)	28	72,02 (22,705)	-8,96 (4,778)	31	84,41 (18,225)	-5,88 (4,691)	-3,08 [-16,670; 10,519]	0,6532
Tag 127 (Woche 18)	29	73,56 (21,137)	-10,23 (4,438)	26	82,05 (18,811)	-11,62 (4,581)	1,39 [-11,504; 14,279]	0,8306
Tag 155 (Woche 22)	24	75,00 (21,423)	-3,68 (4,708)	21	84,13 (17,059)	-3,68 (4,963)	0,01 [-13,869; 13,880]	0,9994
Tag 183 (Woche 26)	29	73,56 (20,662)	-2,95 (3,934)	20	86,67 (16,754)	-0,92 (4,456)	-2,03 [-14,123; 10,070]	0,7391
Tag 211 (Woche 30)	27	73,46 (20,806)	0,33 (3,664)	21	84,92 (18,185)	1,85 (4,018)	-1,52 [-12,570; 9,531]	0,7846
Tag 239 (Woche 34)	22	74,24 (21,656)	1,92 (4,107)	15	85,56 (17,668)	0,86 (4,749)	1,06 [-11,735; 13,850]	0,8691
Tag 267 (Woche 38)	24	72,22 (21,795)	2,26 (4,466)	17	83,33 (18,634)	-5,71 (5,009)	7,97 [-5,665; 21,609]	0,2473
Tag 295 (Woche 42)	25	72,00 (21,365)	2,92 (3,641)	16	82,29 (18,727)	-3,16 (4,154)	6,08 [-5,125; 17,283]	0,2825
Tag 323 (Woche 46)	23	72,46 (21,678)	-5,02 (4,835)	17	83,33 (18,634)	-6,89 (5,310)	1,87 [-12,693; 16,441]	0,7980
Tag 351 (Woche 50)	22	72,73 (20,922)	2,07 (4,289)	15	84,44 (17,213)	-3,81 (4,886)	5,89 [-7,419; 19,192]	0,3784
Durchschnitt über alle Visiten	37	72,97 (21,642)	-2,36 (3,148)	38	80,70 (21,056)	-3,90 (3,196)	1,54 [-7,519; 10,601]	0,7355
Hedges' g SMD							0,08 [-0,374; 0,531]	0,7341

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	34,64 (18,905)	6,31 (3,388)	36	28,09 (18,109)	6,58 (3,278)	-0,27 [-9,732; 9,198]	0,9554
Tag 43 (Woche 6)	33	34,34 (19,117)	2,23 (3,471)	34	24,84 (17,313)	9,29 (3,409)	-7,07 [-16,889; 2,754]	0,1557
Tag 64 (Woche 9)	33	34,34 (19,117)	3,39 (3,489)	34	24,51 (17,252)	15,65 (3,444)	-12,26 [-22,169; -2,347]	0,0161*
Tag 85 (Woche 12)	30	32,22 (17,102)	7,16 (3,800)	29	22,22 (15,992)	14,12 (3,908)	-6,96 [-17,996; 4,082]	0,2127
Tag 106 (Woche 15)	28	34,92 (20,222)	12,47 (4,303)	31	21,86 (15,578)	15,84 (4,318)	-3,37 [-15,783; 9,048]	0,5902
Tag 127 (Woche 18)	29	34,48 (20,216)	16,83 (4,466)	26	24,36 (14,061)	18,17 (4,661)	-1,34 [-14,468; 11,789]	0,8390
Tag 155 (Woche 22)	24	34,72 (21,811)	4,09 (4,302)	21	24,87 (17,179)	10,13 (4,533)	-6,04 [-18,748; 6,671]	0,3453
Tag 183 (Woche 26)	29	34,87 (20,080)	3,18 (3,433)	20	26,11 (18,123)	11,98 (3,834)	-8,80 [-19,227; 1,631]	0,0967
Tag 211 (Woche 30)	27	32,10 (18,318)	-3,56 (3,428)	21	23,81 (16,587)	7,61 (3,819)	-11,16 [-21,554; -0,771]	0,0357*
Tag 239 (Woche 34)	22	34,34 (19,064)	-3,48 (3,237)	15	25,93 (18,624)	8,73 (3,728)	-12,21 [-22,232; -2,185]	0,0179*
Tag 267 (Woche 38)	24	35,19 (22,621)	-0,44 (4,281)	17	24,18 (18,524)	9,96 (4,904)	-10,40 [-23,647; 2,855]	0,1216
Tag 295 (Woche 42)	25	34,67 (22,064)	1,89 (4,375)	16	26,39 (18,976)	11,73 (5,128)	-9,85 [-23,476; 3,781]	0,1537
Tag 323 (Woche 46)	23	35,75 (22,462)	-1,19 (3,763)	17	25,49 (18,743)	11,15 (4,247)	-12,34 [-23,846; -0,838]	0,0359*
Tag 351 (Woche 50)	22	35,35 (22,909)	1,16 (4,104)	15	24,44 (17,916)	12,03 (4,768)	-10,87 [-23,691; 1,947]	0,0947
Durchschnitt über alle Visiten	37	33,63 (18,608)	3,58 (2,732)	38	26,90 (18,382)	11,64 (2,839)	-8,07 [-16,040; -0,092]	0,0475*
Hedges' g SMD							-0,47 [-0,927; -0,008]	0,0459*

[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 2.4.1.1.8 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-C30 Übelkeit und Erbrechen over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	6,37 (11,616)	3,99 (2,745)	36	4,17 (9,237)	4,21 (2,648)	-0,23 [-7,849; 7,392]	0,9525
Tag 43 (Woche 6)	33	6,57 (11,740)	6,31 (2,867)	34	4,41 (9,454)	3,78 (2,788)	2,53 [-5,439; 10,503]	0,5289
Tag 64 (Woche 9)	33	6,06 (11,650)	5,48 (2,755)	34	2,94 (7,644)	7,25 (2,703)	-1,76 [-9,491; 5,969]	0,6511
Tag 85 (Woche 12)	30	5,56 (11,015)	4,93 (2,831)	29	2,30 (5,849)	5,22 (2,873)	-0,30 [-8,391; 7,800]	0,9421
Tag 106 (Woche 15)	28	5,36 (11,161)	6,70 (2,646)	31	2,15 (5,680)	5,61 (2,606)	1,09 [-6,360; 8,535]	0,7718
Tag 127 (Woche 18)	29	5,75 (11,159)	7,93 (2,733)	26	3,85 (8,573)	4,32 (2,840)	3,61 [-4,282; 11,498]	0,3646
Tag 155 (Woche 22)	24	6,25 (11,849)	0,89 (1,645)	21	3,97 (8,983)	-0,36 (1,734)	1,25 [-3,558; 6,054]	0,6046
Tag 183 (Woche 26)	29	6,32 (11,281)	3,40 (2,115)	20	4,17 (9,169)	0,27 (2,417)	3,13 [-3,316; 9,579]	0,3347
Tag 211 (Woche 30)	27	3,70 (8,439)	-1,70 (2,344)	21	2,38 (5,976)	2,11 (2,647)	-3,81 [-10,898; 3,284]	0,2855
Tag 239 (Woche 34)	22	3,79 (8,807)	-0,51 (1,915)	15	2,22 (5,864)	2,66 (2,287)	-3,17 [-9,154; 2,819]	0,2923
Tag 267 (Woche 38)	24	4,17 (10,132)	0,05 (2,282)	17	1,96 (5,535)	5,33 (2,716)	-5,29 [-12,442; 1,865]	0,1431
Tag 295 (Woche 42)	25	4,67 (10,229)	1,39 (1,798)	16	4,17 (9,623)	3,66 (2,195)	-2,27 [-7,983; 3,447]	0,4285
Tag 323 (Woche 46)	23	5,07 (10,583)	0,01 (1,969)	17	3,92 (9,372)	2,84 (2,318)	-2,83 [-8,939; 3,277]	0,3565
Tag 351 (Woche 50)	22	5,30 (10,772)	-1,61 (1,454)	15	3,33 (9,344)	3,28 (1,761)	-4,89 [-9,491; -0,286]	0,0378*
Durchschnitt über alle Visiten	37	6,31 (11,352)	2,66 (1,378)	38	3,95 (9,033)	3,58 (1,432)	-0,92 [-4,899; 3,052]	0,6446
Hedges' g SMD							-0,11 [-0,559; 0,347]	0,6461

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	29,41 (26,924)	0,81 (4,349)	36	22,69 (24,609)	1,85 (4,243)	-1,04 [-13,218; 11,132]	0,8648
Tag 43 (Woche 6)	33	31,31 (26,272)	-1,15 (3,488)	34	18,63 (23,125)	-4,59 (3,443)	3,45 [-6,419; 13,315]	0,4884
Tag 64 (Woche 9)	33	30,30 (26,827)	-6,08 (4,190)	34	20,59 (24,638)	2,99 (4,138)	-9,07 [-20,885; 2,745]	0,1304
Tag 85 (Woche 12)	30	28,33 (27,034)	-4,46 (4,598)	29	18,97 (21,234)	3,55 (4,668)	-8,01 [-21,159; 5,138]	0,2287
Tag 106 (Woche 15)	28	30,95 (28,224)	1,76 (4,608)	31	17,74 (21,053)	2,00 (4,557)	-0,24 [-13,306; 12,826]	0,9709
Tag 127 (Woche 18)	29	28,74 (26,688)	4,61 (4,401)	26	21,15 (23,361)	5,59 (4,564)	-0,98 [-13,713; 11,750]	0,8782
Tag 155 (Woche 22)	24	27,78 (24,899)	1,76 (4,181)	21	22,22 (25,459)	-1,65 (4,394)	3,41 [-8,765; 15,584]	0,5777
Tag 183 (Woche 26)	29	28,74 (24,759)	0,11 (4,000)	20	20,83 (26,422)	0,85 (4,505)	-0,75 [-12,848; 11,354]	0,9023
Tag 211 (Woche 30)	27	25,31 (24,621)	-4,43 (3,740)	21	18,25 (21,670)	-2,96 (4,156)	-1,47 [-12,678; 9,737]	0,7939
Tag 239 (Woche 34)	22	28,03 (25,915)	-8,40 (3,551)	15	22,22 (23,288)	-1,19 (4,087)	-7,21 [-18,129; 3,702]	0,1905
Tag 267 (Woche 38)	24	31,94 (29,861)	-2,84 (3,498)	17	20,59 (23,221)	2,57 (3,973)	-5,42 [-16,111; 5,280]	0,3146
Tag 295 (Woche 42)	25	28,67 (25,694)	-2,53 (5,021)	16	27,08 (27,131)	4,89 (5,889)	-7,42 [-23,005; 8,156]	0,3427
Tag 323 (Woche 46)	23	31,88 (28,829)	-6,48 (4,274)	17	26,47 (26,391)	4,85 (4,829)	-11,33 [-24,267; 1,598]	0,0846
Tag 351 (Woche 50)	22	31,82 (25,670)	-4,62 (4,731)	15	24,44 (25,871)	2,06 (5,468)	-6,68 [-21,292; 7,929]	0,3617
Durchschnitt über alle Visiten	37	28,38 (26,313)	-2,28 (2,985)	38	21,93 (24,232)	1,49 (3,078)	-3,77 [-12,364; 4,824]	0,3848
Hedges' g SMD							-0,20 [-0,655; 0,253]	0,3858

[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 2.4.1.1.10 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-C30 Dyspnoe over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	17,65 (18,776)	0,19 (3,407)	36	10,19 (17,493)	2,75 (3,315)	-2,56 [-12,153; 7,034]	0,5960
Tag 43 (Woche 6)	33	16,16 (18,858)	1,85 (3,185)	34	7,84 (16,532)	3,40 (3,181)	-1,55 [-10,630; 7,533]	0,7348
Tag 64 (Woche 9)	33	17,17 (18,858)	8,01 (3,822)	34	8,82 (17,034)	7,26 (3,801)	0,74 [-10,138; 11,620]	0,8923
Tag 85 (Woche 12)	30	15,56 (19,045)	6,01 (3,873)	29	9,20 (17,586)	7,65 (3,961)	-1,63 [-12,773; 9,504]	0,7706
Tag 106 (Woche 15)	28	17,86 (19,207)	13,65 (4,250)	31	8,60 (17,144)	10,27 (4,170)	3,39 [-8,643; 15,418]	0,5764
Tag 127 (Woche 18)	29	16,09 (19,150)	9,87 (3,959)	26	7,69 (14,322)	13,13 (4,191)	-3,26 [-14,892; 8,371]	0,5779
Tag 155 (Woche 22)	24	16,67 (17,025)	4,94 (3,618)	21	9,52 (18,687)	8,95 (3,840)	-4,00 [-14,679; 6,670]	0,4555
Tag 183 (Woche 26)	29	18,39 (19,078)	6,30 (4,124)	20	8,33 (18,337)	3,48 (4,727)	2,82 [-9,929; 15,577]	0,6590
Tag 211 (Woche 30)	27	17,28 (19,327)	3,63 (3,722)	21	9,52 (18,687)	4,09 (4,134)	-0,46 [-11,712; 10,785]	0,9346
Tag 239 (Woche 34)	22	19,70 (19,678)	0,39 (4,001)	15	11,11 (20,574)	6,36 (4,590)	-5,97 [-18,363; 6,420]	0,3367
Tag 267 (Woche 38)	24	16,67 (19,659)	5,34 (4,156)	17	11,76 (20,211)	9,65 (4,778)	-4,31 [-17,058; 8,440]	0,5014
Tag 295 (Woche 42)	25	17,33 (19,532)	1,23 (4,695)	16	12,50 (20,638)	12,90 (5,595)	-11,66 [-26,389; 3,061]	0,1180
Tag 323 (Woche 46)	23	14,49 (16,896)	4,29 (3,946)	17	11,76 (20,211)	4,52 (4,556)	-0,23 [-12,362; 11,896]	0,9695
Tag 351 (Woche 50)	22	19,70 (19,678)	11,70 (5,078)	15	11,11 (20,574)	4,36 (5,923)	7,34 [-8,485; 23,162]	0,3558
Durchschnitt über alle Visiten	37	17,12 (18,628)	5,53 (2,534)	38	9,65 (17,169)	7,05 (2,665)	-1,53 [-8,928; 5,877]	0,6825
Hedges' g SMD							-0,09 [-0,548; 0,358]	0,6819

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	34,31 (27,810)	2,48 (4,540)	36	28,70 (25,389)	-6,73 (4,456)	9,21 [-3,505; 21,917]	0,1531
Tag 43 (Woche 6)	33	36,36 (26,827)	0,97 (4,200)	34	26,47 (25,662)	-8,24 (4,176)	9,21 [-2,675; 21,093]	0,1267
Tag 64 (Woche 9)	33	35,35 (27,562)	-5,20 (4,746)	34	26,47 (25,662)	-1,77 (4,737)	-3,43 [-16,867; 10,001]	0,6119
Tag 85 (Woche 12)	30	34,44 (28,343)	-2,85 (5,372)	29	26,44 (24,200)	-2,89 (5,496)	0,04 [-15,381; 15,466]	0,9956
Tag 106 (Woche 15)	28	38,10 (28,276)	3,94 (4,682)	31	24,73 (24,294)	-3,41 (4,644)	7,35 [-5,953; 20,649]	0,2742
Tag 127 (Woche 18)	29	35,63 (28,074)	1,85 (4,330)	26	28,21 (24,390)	1,04 (4,551)	0,80 [-11,792; 13,400]	0,8990
Tag 155 (Woche 22)	24	37,50 (28,340)	2,54 (4,626)	21	26,98 (24,987)	-1,97 (4,923)	4,51 [-9,117; 18,138]	0,5103
Tag 183 (Woche 26)	29	37,93 (27,781)	1,30 (4,724)	20	28,33 (27,091)	-5,61 (5,409)	6,91 [-7,543; 21,366]	0,3428
Tag 211 (Woche 30)	27	37,04 (28,244)	-0,46 (4,652)	21	26,98 (24,987)	-4,03 (5,201)	3,57 [-10,487; 17,617]	0,6138
Tag 239 (Woche 34)	22	37,88 (29,628)	-3,78 (4,233)	15	31,11 (26,627)	-2,95 (4,950)	-0,83 [-13,945; 12,294]	0,9000
Tag 267 (Woche 38)	24	37,50 (26,580)	-6,78 (3,995)	17	29,41 (26,040)	-1,78 (4,646)	-5,00 [-17,357; 7,359]	0,4207
Tag 295 (Woche 42)	25	41,33 (27,689)	-3,82 (5,381)	16	35,42 (25,730)	-4,47 (6,397)	0,65 [-16,053; 17,354]	0,9381
Tag 323 (Woche 46)	23	36,23 (26,425)	-0,28 (5,300)	17	35,29 (24,918)	-0,76 (6,170)	0,48 [-15,797; 16,761]	0,9529
Tag 351 (Woche 50)	22	42,42 (29,424)	-0,01 (6,079)	15	33,33 (25,198)	0,83 (7,135)	-0,84 [-19,667; 17,989]	0,9290
Durchschnitt über alle Visiten	37	34,23 (26,628)	-0,72 (2,996)	38	27,19 (25,534)	-3,05 (3,179)	2,33 [-6,411; 11,073]	0,5967
Hedges' g SMD							0,12 [-0,331; 0,575]	0,5981

[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 2.4.1.1.12 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-C30 Appetitverlust over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	27,45 (27,793)	0,68 (4,338)	36	13,89 (21,639)	-0,35 (4,226)	1,03 [-11,273; 13,333]	0,8679
Tag 43 (Woche 6)	33	28,28 (27,790)	-0,94 (4,022)	34	9,80 (17,465)	0,99 (4,028)	-1,93 [-13,629; 9,776]	0,7436
Tag 64 (Woche 9)	33	28,28 (27,790)	-3,28 (4,126)	34	11,76 (19,903)	7,16 (4,101)	-10,43 [-22,342; 1,473]	0,0849
Tag 85 (Woche 12)	30	25,56 (27,240)	0,66 (4,708)	29	9,20 (17,586)	7,12 (4,928)	-6,45 [-20,391; 7,484]	0,3591
Tag 106 (Woche 15)	28	29,76 (27,725)	1,07 (4,984)	31	9,68 (17,625)	7,87 (4,935)	-6,80 [-21,319; 7,715]	0,3531
Tag 127 (Woche 18)	29	29,89 (28,653)	4,42 (4,823)	26	11,54 (20,960)	1,03 (5,024)	3,39 [-10,951; 17,738]	0,6378
Tag 155 (Woche 22)	24	26,39 (27,766)	-7,99 (3,989)	21	7,94 (17,965)	-2,81 (4,366)	-5,18 [-17,406; 7,047]	0,3992
Tag 183 (Woche 26)	29	31,03 (28,074)	-9,36 (4,005)	20	10,00 (19,041)	6,77 (4,573)	-16,13 [-28,758; -3,503]	0,0132*
Tag 211 (Woche 30)	27	29,63 (26,688)	-13,27 (3,903)	21	11,11 (19,245)	6,04 (4,329)	-19,31 [-31,349; -7,273]	0,0021*
Tag 239 (Woche 34)	22	30,30 (28,930)	-15,57 (3,269)	15	11,11 (16,265)	4,10 (3,805)	-19,67 [-30,094; -9,241]	0,0004*
Tag 267 (Woche 38)	24	26,39 (27,766)	-10,00 (4,544)	17	11,76 (20,211)	4,42 (5,302)	-14,42 [-28,802; -0,046]	0,0493*
Tag 295 (Woche 42)	25	29,33 (27,756)	-7,07 (5,399)	16	16,67 (24,343)	3,81 (6,350)	-10,87 [-27,916; 6,166]	0,2051
Tag 323 (Woche 46)	23	27,54 (27,802)	-8,29 (4,342)	17	17,65 (23,914)	1,17 (4,931)	-9,46 [-22,823; 3,898]	0,1609
Tag 351 (Woche 50)	22	30,30 (27,039)	-13,35 (4,323)	15	17,78 (24,774)	1,16 (5,011)	-14,50 [-27,968; -1,039]	0,0353*
Durchschnitt über alle Visiten	37	27,93 (26,659)	-5,88 (2,682)	38	14,04 (21,409)	3,46 (2,803)	-9,34 [-17,277; -1,401]	0,0218*
Hedges' g SMD							-0,55 [-1,011; -0,088]	0,0196*

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	20,59 (27,235)	4,60 (4,815)	36	17,59 (23,212)	1,03 (4,678)	3,58 [-9,813; 16,965]	0,5961
Tag 43 (Woche 6)	33	21,21 (27,409)	3,50 (4,302)	34	16,67 (22,096)	11,91 (4,219)	-8,41 [-20,451; 3,630]	0,1679
Tag 64 (Woche 9)	33	20,20 (27,562)	6,45 (4,780)	34	13,73 (20,297)	10,63 (4,733)	-4,18 [-17,637; 9,283]	0,5379
Tag 85 (Woche 12)	30	16,67 (24,369)	3,84 (5,494)	29	13,79 (20,925)	11,99 (5,602)	-8,15 [-23,813; 7,521]	0,3027
Tag 106 (Woche 15)	28	21,43 (28,995)	2,98 (5,044)	31	13,98 (20,681)	16,87 (4,928)	-13,89 [-28,019; 0,233]	0,0538
Tag 127 (Woche 18)	29	19,54 (27,483)	5,55 (5,026)	26	12,82 (19,037)	18,24 (5,289)	-12,69 [-27,318; 1,947]	0,0880
Tag 155 (Woche 22)	24	19,44 (27,657)	-6,01 (3,848)	21	17,46 (22,655)	5,23 (4,072)	-11,24 [-22,487; 0,008]	0,0502
Tag 183 (Woche 26)	29	19,54 (27,483)	3,87 (4,475)	20	16,67 (20,233)	7,00 (5,177)	-3,13 [-16,838; 10,578]	0,6495
Tag 211 (Woche 30)	27	16,05 (23,334)	-3,14 (4,351)	21	14,29 (19,920)	6,49 (4,878)	-9,63 [-22,656; 3,393]	0,1446
Tag 239 (Woche 34)	22	16,67 (22,420)	-2,90 (4,097)	15	17,78 (21,331)	3,45 (4,834)	-6,35 [-19,053; 6,362]	0,3213
Tag 267 (Woche 38)	24	23,61 (30,263)	-1,08 (3,774)	17	17,65 (20,809)	5,74 (4,372)	-6,82 [-18,433; 4,786]	0,2435
Tag 295 (Woche 42)	25	21,33 (28,674)	-1,38 (4,001)	16	18,75 (20,972)	4,64 (4,839)	-6,02 [-18,635; 6,592]	0,3422
Tag 323 (Woche 46)	23	26,09 (30,078)	4,72 (5,290)	17	17,65 (20,809)	12,62 (6,083)	-7,90 [-24,131; 8,334]	0,3329
Tag 351 (Woche 50)	22	24,24 (29,424)	-1,48 (6,093)	15	15,56 (21,331)	9,77 (7,267)	-11,25 [-30,481; 7,980]	0,2443
Durchschnitt über alle Visiten	37	18,92 (26,690)	1,39 (2,720)	38	17,54 (22,907)	8,97 (2,877)	-7,58 [-15,495; 0,341]	0,0604
Hedges' g SMD							-0,44 [-0,895; 0,021]	0,0616

[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 2.4.1.1.14 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-C30 Diarrhö over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	5,88 (12,898)	3,71 (3,011)	36	8,33 (16,667)	1,64 (2,934)	2,07 [-6,333; 10,465]	0,6252
Tag 43 (Woche 6)	33	6,06 (13,056)	2,86 (3,166)	34	7,84 (16,532)	5,40 (3,121)	-2,54 [-11,413; 6,333]	0,5700
Tag 64 (Woche 9)	33	6,06 (13,056)	7,52 (3,488)	34	5,88 (12,898)	2,62 (3,439)	4,91 [-4,872; 14,687]	0,3201
Tag 85 (Woche 12)	30	6,67 (13,561)	9,76 (3,814)	29	4,60 (11,698)	5,19 (3,881)	4,56 [-6,319; 15,448]	0,4050
Tag 106 (Woche 15)	28	7,14 (13,929)	3,54 (3,204)	31	4,30 (11,359)	1,76 (3,118)	1,78 [-7,187; 10,751]	0,6922
Tag 127 (Woche 18)	29	6,90 (13,742)	8,85 (4,126)	26	6,41 (13,397)	4,49 (4,330)	4,36 [-7,629; 16,344]	0,4693
Tag 155 (Woche 22)	24	6,94 (13,828)	0,62 (2,931)	21	7,94 (14,548)	2,41 (3,113)	-1,79 [-10,394; 6,821]	0,6779
Tag 183 (Woche 26)	29	6,90 (13,742)	6,09 (3,895)	20	8,33 (14,809)	4,89 (4,554)	1,20 [-10,813; 13,210]	0,8421
Tag 211 (Woche 30)	27	7,41 (14,122)	8,66 (4,361)	21	6,35 (13,412)	0,85 (4,875)	7,81 [-5,284; 20,904]	0,2374
Tag 239 (Woche 34)	22	7,58 (14,298)	7,95 (3,665)	15	4,44 (11,729)	1,71 (4,358)	6,24 [-5,243; 17,731]	0,2797
Tag 267 (Woche 38)	24	5,56 (12,690)	0,44 (2,871)	17	3,92 (11,070)	5,50 (3,375)	-5,06 [-13,951; 3,830]	0,2579
Tag 295 (Woche 42)	25	6,67 (13,608)	0,27 (2,311)	16	6,25 (13,437)	-2,19 (2,826)	2,46 [-4,886; 9,802]	0,5040
Tag 323 (Woche 46)	23	5,80 (12,918)	2,45 (2,827)	17	5,88 (13,098)	-0,61 (3,287)	3,06 [-5,671; 11,783]	0,4842
Tag 351 (Woche 50)	22	7,58 (14,298)	1,04 (3,028)	15	6,67 (13,801)	2,65 (3,659)	-1,61 [-11,207; 7,987]	0,7363
Durchschnitt über alle Visiten	37	5,41 (12,456)	4,55 (1,890)	38	7,89 (16,319)	2,59 (1,988)	1,96 [-3,518; 7,439]	0,4774
Hedges' g SMD							0,16 [-0,290; 0,617]	0,4805

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	34	21,57 (32,703)	11,07 (4,496)	36	14,81 (23,155)	4,13 (4,414)	6,94 [-5,669; 19,559]	0,2758
Tag 43 (Woche 6)	33	24,24 (32,567)	1,99 (2,820)	34	13,73 (18,564)	0,25 (2,790)	1,74 [-6,246; 9,723]	0,6651
Tag 64 (Woche 9)	33	24,24 (32,567)	0,88 (3,665)	34	12,75 (18,376)	1,61 (3,637)	-0,73 [-11,116; 9,659]	0,8892
Tag 85 (Woche 12)	30	24,44 (33,828)	1,21 (3,926)	29	13,79 (18,934)	1,78 (3,973)	-0,57 [-11,795; 10,657]	0,9198
Tag 106 (Woche 15)	28	26,19 (34,375)	0,16 (3,346)	31	13,98 (18,805)	-0,53 (3,252)	0,69 [-8,705; 10,088]	0,8837
Tag 127 (Woche 18)	29	19,54 (30,234)	4,92 (3,657)	26	15,38 (19,392)	5,13 (3,819)	-0,20 [-10,778; 10,373]	0,9696
Tag 155 (Woche 22)	24	23,61 (31,819)	-0,42 (3,527)	21	15,87 (20,053)	-1,10 (3,700)	0,69 [-9,620; 10,990]	0,8945
Tag 183 (Woche 26)	29	22,99 (30,993)	5,17 (4,115)	20	13,33 (16,754)	-0,62 (4,683)	5,79 [-6,768; 18,338]	0,3604
Tag 211 (Woche 30)	27	22,22 (32,026)	2,53 (3,460)	21	12,70 (16,587)	0,69 (3,818)	1,84 [-8,535; 12,206]	0,7246
Tag 239 (Woche 34)	22	19,70 (31,971)	0,90 (3,876)	15	15,56 (17,213)	1,79 (4,501)	-0,88 [-12,859; 11,092]	0,8827
Tag 267 (Woche 38)	24	25,00 (32,969)	-1,83 (3,691)	17	15,69 (17,150)	2,52 (4,192)	-4,35 [-15,630; 6,934]	0,4427
Tag 295 (Woche 42)	25	24,00 (32,660)	-0,54 (3,554)	16	14,58 (17,078)	-1,18 (4,181)	0,63 [-10,458; 11,720]	0,9094
Tag 323 (Woche 46)	23	26,09 (33,267)	3,11 (4,739)	17	13,73 (16,910)	4,01 (5,282)	-0,89 [-15,290; 13,505]	0,9014
Tag 351 (Woche 50)	22	27,27 (33,549)	4,54 (4,255)	15	11,11 (16,265)	2,29 (4,899)	2,25 [-11,008; 15,499]	0,7349
Durchschnitt über alle Visiten	37	21,62 (31,639)	2,41 (2,593)	38	14,91 (22,855)	1,48 (2,669)	0,92 [-6,537; 8,385]	0,8058
Hedges' g SMD							0,06 [-0,396; 0,509]	0,8061

[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.

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Table 2.4.2.1.1 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-EN24 Sexuelles Interesse over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	90,32 (19,614)	3,11 (2,360)	35	98,10 (7,850)	-1,91 (2,268)	5,02 [-1,616; 11,652]	0,1359
Tag 43 (Woche 6)	29	88,51 (20,463)	0,06 (2,403)	33	95,96 (13,838)	1,87 (2,241)	-1,81 [-8,439; 4,818]	0,5873
Tag 64 (Woche 9)	30	88,89 (20,216)	-0,21 (2,722)	33	95,96 (13,838)	-0,59 (2,571)	0,37 [-7,175; 7,920]	0,9219
Tag 85 (Woche 12)	27	90,12 (20,286)	3,37 (2,255)	29	97,70 (8,596)	2,17 (2,188)	1,20 [-5,181; 7,573]	0,7088
Tag 106 (Woche 15)	25	92,00 (17,427)	-2,05 (2,463)	31	95,70 (14,252)	1,33 (2,264)	-3,38 [-10,108; 3,345]	0,3187
Tag 127 (Woche 18)	27	90,12 (20,286)	0,33 (2,244)	26	97,44 (9,058)	3,57 (2,255)	-3,24 [-9,710; 3,232]	0,3200
Tag 155 (Woche 22)	21	92,06 (17,965)	0,91 (2,100)	21	98,41 (7,274)	2,40 (2,119)	-1,49 [-7,548; 4,560]	0,6223
Tag 183 (Woche 26)	26	88,46 (20,960)	-0,58 (2,825)	20	98,33 (7,454)	-0,89 (3,054)	0,31 [-8,213; 8,833]	0,9421
Tag 211 (Woche 30)	23	88,41 (21,576)	-0,71 (2,273)	21	98,41 (7,274)	1,51 (2,324)	-2,22 [-8,914; 4,482]	0,5079
Tag 239 (Woche 34)	19	89,47 (22,368)	-0,87 (3,043)	15	97,78 (8,607)	-1,61 (3,311)	0,75 [-8,417; 9,912]	0,8705
Tag 267 (Woche 38)	20	90,00 (19,041)	-3,54 (3,839)	17	98,04 (8,085)	-1,88 (4,108)	-1,66 [-13,220; 9,892]	0,7727
Tag 295 (Woche 42)	22	90,91 (18,349)	-1,97 (2,464)	16	97,92 (8,333)	-3,44 (2,793)	1,47 [-6,134; 9,075]	0,6987
Tag 323 (Woche 46)	20	90,00 (19,041)	-5,99 (4,855)	17	98,04 (8,085)	1,34 (5,245)	-7,33 [-22,082; 7,423]	0,3204
Tag 351 (Woche 50)	19	89,47 (19,413)	-1,50 (3,262)	15	100,0 (0,000)	1,02 (3,537)	-2,52 [-12,547; 7,499]	0,6114
Durchschnitt über alle Visiten	34	89,22 (19,627)	-0,69 (1,665)	37	96,40 (13,109)	0,35 (1,676)	-1,04 [-5,821; 3,743]	0,6662
Hedges' g SMD							-0,10 [-0,569; 0,363]	0,6645

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	95,70 (11,359)	0,29 (3,585)	35	98,10 (7,850)	-1,91 (3,452)	2,20 [-8,039; 12,445]	0,6629
Tag 43 (Woche 6)	29	95,40 (11,698)	0,86 (1,221)	33	97,98 (8,077)	1,73 (1,167)	-0,88 [-4,253; 2,500]	0,6071
Tag 64 (Woche 9)	30	95,56 (11,525)	-1,72 (1,846)	33	97,98 (8,077)	0,11 (1,799)	-1,83 [-6,990; 3,335]	0,4827
Tag 85 (Woche 12)	27	97,53 (8,896)	-0,51 (1,966)	29	97,70 (8,596)	0,56 (1,950)	-1,07 [-6,610; 4,468]	0,7005
Tag 106 (Woche 15)	25	96,00 (11,055)	0,79 (1,713)	31	97,85 (8,324)	1,53 (1,609)	-0,73 [-5,446; 3,980]	0,7569
Tag 127 (Woche 18)	27	93,83 (13,195)	1,13 (1,833)	26	97,44 (9,058)	-0,41 (1,811)	1,54 [-3,659; 6,731]	0,5559
Tag 155 (Woche 22)	21	95,24 (11,952)	2,52 (0,916)	21	98,41 (7,274)	1,74 (0,911)	0,78 [-1,814; 3,381]	0,5486
Tag 183 (Woche 26)	26	94,87 (12,265)	1,93 (1,247)	20	96,67 (10,260)	0,54 (1,337)	1,39 [-2,269; 5,053]	0,4503
Tag 211 (Woche 30)	23	94,20 (12,918)	-2,09 (2,067)	21	96,83 (10,026)	0,23 (2,109)	-2,32 [-8,270; 3,636]	0,4379
Tag 239 (Woche 34)	19	94,74 (12,488)	-2,23 (2,450)	15	95,56 (11,729)	-1,14 (2,631)	-1,09 [-8,365; 6,184]	0,7634
Tag 267 (Woche 38)	20	95,00 (12,212)	-2,95 (4,418)	17	96,08 (11,070)	0,12 (4,550)	-3,07 [-16,125; 9,984]	0,6332
Tag 295 (Woche 42)	22	95,45 (11,708)	-0,07 (1,620)	16	95,83 (11,386)	0,91 (1,684)	-0,99 [-5,689; 3,718]	0,6760
Tag 323 (Woche 46)	20	95,00 (12,212)	-3,93 (2,452)	17	96,08 (11,070)	-1,29 (2,548)	-2,65 [-9,770; 4,476]	0,4592
Tag 351 (Woche 50)	19	94,74 (12,488)	1,01 (1,301)	15	100,0 (0,000)	0,58 (1,387)	0,43 [-3,386; 4,241]	0,8238
Durchschnitt über alle Visiten	34	95,10 (11,983)	-0,36 (1,398)	37	98,20 (7,641)	0,23 (1,375)	-0,59 [-4,533; 3,350]	0,7653
Hedges' g SMD							-0,07 [-0,537; 0,395]	0,7659

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	11,83 (20,725)	5,02 (4,089)	35	15,71 (22,846)	4,22 (3,858)	0,80 [-10,450; 12,041]	0,8881
Tag 43 (Woche 6)	29	11,49 (21,410)	1,95 (3,186)	33	13,64 (21,431)	6,74 (3,002)	-4,79 [-13,541; 3,957]	0,2780
Tag 64 (Woche 9)	30	11,11 (21,142)	4,99 (3,182)	33	12,63 (21,258)	8,92 (3,034)	-3,92 [-12,684; 4,841]	0,3752
Tag 85 (Woche 12)	27	9,88 (19,204)	0,05 (3,094)	29	12,64 (22,118)	11,72 (2,975)	-11,68 [-20,242; -3,110]	0,0083*
Tag 106 (Woche 15)	25	8,00 (16,750)	6,97 (3,526)	31	12,90 (21,820)	9,05 (3,249)	-2,08 [-11,641; 7,482]	0,6656
Tag 127 (Woche 18)	27	11,11 (21,681)	6,33 (3,267)	26	12,18 (15,317)	13,50 (3,273)	-7,17 [-16,415; 2,069]	0,1258
Tag 155 (Woche 22)	21	14,29 (23,738)	7,79 (3,513)	21	14,29 (24,316)	9,08 (3,506)	-1,28 [-11,243; 8,674]	0,7968
Tag 183 (Woche 26)	26	12,82 (22,265)	5,68 (3,251)	20	17,50 (25,058)	6,25 (3,563)	-0,57 [-10,224; 9,093]	0,9072
Tag 211 (Woche 30)	23	12,32 (23,147)	5,17 (3,331)	21	15,87 (24,987)	4,13 (3,471)	1,04 [-8,604; 10,684]	0,8298
Tag 239 (Woche 34)	19	14,91 (24,780)	3,96 (3,782)	15	16,67 (28,868)	3,89 (4,164)	0,06 [-11,266; 11,391]	0,9912
Tag 267 (Woche 38)	20	13,33 (24,543)	8,67 (3,850)	17	15,69 (27,304)	6,91 (4,159)	1,76 [-9,695; 13,211]	0,7581
Tag 295 (Woche 42)	22	12,88 (23,532)	3,77 (3,895)	16	17,71 (27,534)	7,15 (4,465)	-3,38 [-15,332; 8,568]	0,5714
Tag 323 (Woche 46)	20	13,33 (24,543)	5,56 (3,912)	17	16,67 (27,003)	3,18 (4,318)	2,37 [-9,358; 14,107]	0,6856
Tag 351 (Woche 50)	19	14,04 (25,008)	13,44 (3,789)	15	16,67 (28,172)	5,22 (4,288)	8,22 [-3,350; 19,793]	0,1587
Durchschnitt über alle Visiten	34	11,76 (20,321)	5,67 (2,159)	37	14,86 (22,493)	7,14 (2,184)	-1,47 [-7,611; 4,665]	0,6333
Hedges' g SMD							-0,11 [-0,578; 0,354]	0,6362

[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 gmmrmpraar 27MAR2024:14:53

Table 2.4.2.1.4 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-EN24 Urologische Symptome over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	18,01 (15,679)	3,37 (3,303)	35	14,29 (13,940)	0,28 (3,129)	3,09 [-6,019; 12,207]	0,5004
Tag 43 (Woche 6)	29	18,10 (16,071)	2,12 (3,087)	33	12,63 (13,521)	2,09 (2,939)	0,03 [-8,510; 8,576]	0,9939
Tag 64 (Woche 9)	30	17,78 (16,042)	3,37 (3,068)	33	12,63 (13,521)	4,59 (2,953)	-1,22 [-9,759; 7,315]	0,7763
Tag 85 (Woche 12)	27	16,67 (15,331)	4,16 (3,410)	29	12,36 (12,914)	0,28 (3,317)	3,89 [-5,655; 13,430]	0,4189
Tag 106 (Woche 15)	25	17,33 (16,653)	4,39 (3,382)	31	12,10 (12,700)	1,28 (3,217)	3,12 [-6,262; 12,493]	0,5093
Tag 127 (Woche 18)	27	19,44 (15,845)	2,35 (3,180)	26	15,38 (13,883)	0,62 (3,143)	1,73 [-7,228; 10,683]	0,7014
Tag 155 (Woche 22)	21	17,46 (15,569)	0,90 (2,946)	21	14,68 (14,168)	0,38 (2,924)	0,52 [-7,830; 8,870]	0,9011
Tag 183 (Woche 26)	26	17,63 (15,515)	2,96 (2,760)	20	13,75 (14,120)	-2,18 (2,918)	5,14 [-2,920; 13,205]	0,2071
Tag 211 (Woche 30)	23	15,94 (14,194)	2,61 (2,254)	21	11,90 (12,520)	-4,39 (2,332)	7,00 [0,494; 13,505]	0,0354*
Tag 239 (Woche 34)	19	17,98 (14,504)	3,67 (2,899)	15	12,22 (13,681)	-4,31 (3,099)	7,99 [-0,563; 16,536]	0,0666
Tag 267 (Woche 38)	20	17,08 (15,407)	0,23 (2,122)	17	13,24 (13,196)	0,18 (2,245)	0,05 [-6,162; 6,257]	0,9879
Tag 295 (Woche 42)	22	17,05 (14,880)	2,39 (2,545)	16	16,15 (14,741)	0,93 (2,779)	1,46 [-6,085; 9,010]	0,6999
Tag 323 (Woche 46)	20	18,33 (17,227)	8,23 (2,923)	17	15,20 (14,801)	1,13 (3,106)	7,10 [-1,460; 15,652]	0,1024
Tag 351 (Woche 50)	19	17,11 (15,829)	3,66 (3,428)	15	13,89 (14,996)	1,43 (3,745)	2,23 [-7,996; 12,447]	0,6641
Durchschnitt über alle Visiten	34	17,16 (15,344)	3,17 (2,147)	37	13,51 (13,938)	0,16 (2,128)	3,01 [-3,053; 9,070]	0,3254
Hedges' g SMD							0,23 [-0,234; 0,701]	0,3274

[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 gmmrmpraas 27MAR2024:14:53

Table 2.4.2.1.5 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-EN24 Gastrointestinale Symptome over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	12,69 (9,941)	-0,87 (2,246)	35	12,95 (12,726)	0,31 (2,118)	-1,18 [-7,348; 4,987]	0,7034
Tag 43 (Woche 6)	29	14,25 (9,876)	-0,39 (1,723)	33	12,93 (13,117)	-1,30 (1,625)	0,91 [-3,814; 5,641]	0,7009
Tag 64 (Woche 9)	30	13,33 (10,057)	1,78 (2,218)	33	12,12 (12,185)	0,74 (2,122)	1,04 [-5,089; 7,167]	0,7361
Tag 85 (Woche 12)	27	12,84 (9,415)	-1,47 (2,117)	29	12,87 (12,716)	4,72 (2,044)	-6,19 [-12,068; -0,310]	0,0394*
Tag 106 (Woche 15)	25	12,80 (10,169)	0,50 (2,242)	31	12,26 (12,543)	1,40 (2,086)	-0,90 [-7,018; 5,209]	0,7687
Tag 127 (Woche 18)	27	13,33 (9,957)	0,44 (2,232)	26	14,87 (12,265)	1,52 (2,249)	-1,09 [-7,421; 5,244]	0,7323
Tag 155 (Woche 22)	21	12,38 (10,389)	-2,46 (1,835)	21	13,97 (12,632)	-0,78 (1,830)	-1,68 [-6,892; 3,531]	0,5200
Tag 183 (Woche 26)	26	14,10 (10,554)	0,89 (2,128)	20	13,00 (11,337)	1,42 (2,313)	-0,54 [-6,819; 5,746]	0,8651
Tag 211 (Woche 30)	23	11,59 (9,892)	-0,92 (2,198)	21	13,02 (11,051)	0,92 (2,269)	-1,83 [-8,150; 4,482]	0,5636
Tag 239 (Woche 34)	19	13,33 (9,686)	-2,39 (2,506)	15	14,67 (12,137)	-0,92 (2,757)	-1,47 [-8,960; 6,014]	0,6942
Tag 267 (Woche 38)	20	12,00 (10,728)	0,21 (2,587)	17	13,33 (12,019)	2,83 (2,777)	-2,61 [-10,239; 5,010]	0,4943
Tag 295 (Woche 42)	22	12,42 (10,347)	-1,22 (1,952)	16	14,17 (11,895)	0,41 (2,221)	-1,64 [-7,575; 4,302]	0,5827
Tag 323 (Woche 46)	20	12,00 (10,728)	3,84 (2,269)	17	14,12 (11,519)	1,56 (2,480)	2,27 [-4,506; 9,055]	0,5028
Tag 351 (Woche 50)	19	12,98 (10,994)	-1,12 (1,859)	15	12,44 (10,945)	1,29 (2,089)	-2,41 [-8,069; 3,242]	0,3934
Durchschnitt über alle Visiten	34	12,75 (10,033)	-0,23 (1,353)	37	12,25 (12,719)	1,01 (1,361)	-1,24 [-5,064; 2,589]	0,5212
Hedges' g SMD							-0,15 [-0,617; 0,315]	0,5252

[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 gmmrmpraat 27MAR2024:14:53

Table 2.4.2.1.6 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	16,67 (23,570)	19,09 (5,322)	35	7,62 (19,530)	16,63 (4,962)	2,46 [-12,192; 17,117]	0,7385
Tag 43 (Woche 6)	29	16,09 (22,040)	18,99 (5,470)	33	5,05 (11,399)	21,35 (5,146)	-2,36 [-17,582; 12,860]	0,7582
Tag 64 (Woche 9)	30	15,00 (22,037)	15,59 (5,389)	33	4,04 (10,232)	23,35 (5,174)	-7,77 [-22,939; 7,408]	0,3113
Tag 85 (Woche 12)	27	17,28 (22,400)	21,33 (5,791)	29	3,45 (9,322)	27,03 (5,587)	-5,70 [-22,190; 10,795]	0,4928
Tag 106 (Woche 15)	25	13,33 (18,634)	18,98 (5,298)	31	4,30 (10,513)	23,85 (5,054)	-4,87 [-19,772; 10,027]	0,5164
Tag 127 (Woche 18)	27	17,28 (22,872)	23,20 (5,145)	26	5,13 (11,323)	20,95 (5,048)	2,25 [-12,455; 16,953]	0,7612
Tag 155 (Woche 22)	21	15,87 (23,849)	19,68 (4,987)	21	1,59 (5,013)	22,88 (5,009)	-3,20 [-17,741; 11,342]	0,6617
Tag 183 (Woche 26)	26	14,74 (21,770)	19,56 (4,691)	20	3,33 (8,719)	20,91 (4,991)	-1,35 [-15,376; 12,684]	0,8486
Tag 211 (Woche 30)	23	15,94 (22,740)	16,85 (4,760)	21	3,17 (8,529)	18,52 (4,922)	-1,66 [-15,746; 12,418]	0,8141
Tag 239 (Woche 34)	19	16,67 (24,216)	10,57 (4,268)	15	3,33 (9,344)	21,62 (4,576)	-11,05 [-23,949; 1,856]	0,0919
Tag 267 (Woche 38)	20	17,50 (23,863)	8,89 (5,219)	17	2,94 (8,810)	17,63 (5,519)	-8,74 [-24,435; 6,963]	0,2702
Tag 295 (Woche 42)	22	16,67 (23,002)	14,25 (5,300)	16	3,13 (9,065)	15,30 (5,824)	-1,05 [-17,301; 15,194]	0,8973
Tag 323 (Woche 46)	20	19,17 (23,740)	18,89 (6,648)	17	2,94 (8,810)	18,38 (7,102)	0,51 [-19,816; 20,833]	0,9601
Tag 351 (Woche 50)	19	16,67 (24,216)	11,90 (6,289)	15	1,11 (4,303)	18,35 (7,077)	-6,45 [-26,244; 13,349]	0,5155
Durchschnitt über alle Visiten	34	16,67 (22,845)	16,98 (3,754)	37	7,21 (19,060)	20,48 (3,742)	-3,50 [-14,325; 7,329]	0,5216
Hedges' g SMD							-0,15 [-0,621; 0,312]	0,5153

[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 gmmrmpraau 27MAR2024:14:53

Table 2.4.2.1.7 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-EN24 Rücken- und Beckenschmerzen over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	26,88 (26,415)	-4,78 (4,366)	35	23,81 (27,501)	-4,27 (4,120)	-0,51 [-12,498; 11,478]	0,9326
Tag 43 (Woche 6)	29	27,59 (26,828)	-1,77 (4,002)	33	21,21 (26,112)	-7,29 (3,786)	5,52 [-5,514; 16,554]	0,3215
Tag 64 (Woche 9)	30	26,67 (25,371)	-2,09 (4,367)	33	21,21 (26,112)	-0,06 (4,200)	-2,03 [-14,160; 10,101]	0,7393
Tag 85 (Woche 12)	27	27,16 (26,209)	-4,75 (4,764)	29	21,84 (27,133)	4,54 (4,620)	-9,29 [-22,590; 4,005]	0,1674
Tag 106 (Woche 15)	25	25,33 (22,111)	0,04 (5,087)	31	21,51 (26,595)	-1,33 (4,725)	1,37 [-12,518; 15,268]	0,8438
Tag 127 (Woche 18)	27	25,93 (28,244)	2,03 (4,674)	26	23,08 (26,279)	-0,50 (4,724)	2,53 [-10,762; 15,828]	0,7046
Tag 155 (Woche 22)	21	30,16 (27,698)	-7,32 (4,617)	21	28,57 (28,452)	-2,88 (4,601)	-4,44 [-17,455; 8,578]	0,4974
Tag 183 (Woche 26)	26	30,77 (26,538)	-2,43 (4,450)	20	21,67 (22,361)	2,58 (4,880)	-5,01 [-18,328; 8,303]	0,4541
Tag 211 (Woche 30)	23	27,54 (23,894)	0,76 (4,903)	21	19,05 (22,537)	4,79 (5,168)	-4,03 [-18,381; 10,319]	0,5760
Tag 239 (Woche 34)	19	28,07 (25,491)	-5,76 (4,484)	15	24,44 (23,458)	4,34 (4,943)	-10,10 [-23,585; 3,386]	0,1382
Tag 267 (Woche 38)	20	28,33 (22,361)	1,21 (5,292)	17	23,53 (22,866)	-1,27 (5,708)	2,49 [-13,253; 18,224]	0,7518
Tag 295 (Woche 42)	22	28,79 (23,672)	3,73 (4,500)	16	27,08 (21,837)	-1,45 (5,116)	5,18 [-8,554; 18,923]	0,4505
Tag 323 (Woche 46)	20	26,67 (23,195)	0,12 (4,326)	17	25,49 (22,140)	6,42 (4,733)	-6,30 [-19,290; 6,692]	0,3324
Tag 351 (Woche 50)	19	28,07 (25,491)	0,47 (5,397)	15	24,44 (23,458)	4,07 (6,036)	-3,60 [-19,989; 12,783]	0,6592
Durchschnitt über alle Visiten	34	26,47 (25,662)	-1,47 (2,626)	37	23,42 (27,063)	0,55 (2,671)	-2,02 [-9,517; 5,486]	0,5933
Hedges' g SMD							-0,13 [-0,592; 0,340]	0,5959

[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 gmmrmpraav 27MAR2024:14:53

Table 2.4.2.1.8 DUO-E (dMMR Durva): Analysis of change from baseline in EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	10,75 (15,840)	12,98 (4,663)	35	9,52 (15,278)	18,45 (4,404)	-5,46 [-18,258; 7,329]	0,3974
Tag 43 (Woche 6)	29	10,34 (15,694)	23,88 (5,207)	33	9,09 (15,076)	20,46 (4,935)	3,42 [-10,894; 17,741]	0,6349
Tag 64 (Woche 9)	30	10,00 (15,536)	26,67 (5,245)	33	8,08 (14,506)	37,12 (5,035)	-10,45 [-24,957; 4,050]	0,1551
Tag 85 (Woche 12)	27	11,11 (16,013)	31,44 (5,841)	29	8,05 (14,516)	42,53 (5,666)	-11,09 [-27,343; 5,153]	0,1777
Tag 106 (Woche 15)	25	6,67 (13,608)	39,01 (5,424)	31	7,53 (14,167)	48,37 (5,115)	-9,37 [-24,143; 5,410]	0,2106
Tag 127 (Woche 18)	27	11,11 (16,013)	45,10 (5,926)	26	10,26 (15,689)	48,50 (5,923)	-3,41 [-20,125; 13,306]	0,6856
Tag 155 (Woche 22)	21	11,11 (16,102)	48,95 (5,454)	21	11,11 (16,102)	44,53 (5,440)	4,43 [-10,967; 19,818]	0,5679
Tag 183 (Woche 26)	26	12,82 (16,538)	41,27 (5,638)	20	13,33 (16,754)	32,00 (6,000)	9,27 [-7,108; 25,656]	0,2628
Tag 211 (Woche 30)	23	11,59 (16,233)	39,33 (5,461)	21	11,11 (16,102)	26,17 (5,641)	13,16 [-2,537; 28,858]	0,0988
Tag 239 (Woche 34)	19	8,77 (15,080)	33,02 (6,099)	15	15,56 (17,213)	36,41 (6,669)	-3,40 [-21,648; 14,857]	0,7099
Tag 267 (Woche 38)	20	10,00 (15,672)	32,83 (5,742)	17	13,73 (16,910)	36,72 (6,210)	-3,89 [-20,859; 13,083]	0,6478
Tag 295 (Woche 42)	22	10,61 (15,891)	31,99 (6,278)	16	14,58 (17,078)	27,63 (7,125)	4,36 [-14,715; 23,437]	0,6480
Tag 323 (Woche 46)	20	10,00 (15,672)	27,45 (6,721)	17	13,73 (16,910)	30,90 (7,444)	-3,45 [-23,668; 16,768]	0,7327
Tag 351 (Woche 50)	19	10,53 (15,919)	38,16 (6,872)	15	11,11 (16,265)	29,28 (7,780)	8,88 [-12,073; 29,833]	0,3973
Durchschnitt über alle Visiten	34	11,76 (16,169)	33,72 (3,865)	37	9,01 (15,008)	34,22 (3,919)	-0,50 [-11,502; 10,502]	0,9280
Hedges' g SMD							-0,02 [-0,487; 0,444]	0,9286

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	15,05 (20,797)	14,27 (5,767)	35	13,33 (21,693)	17,19 (5,438)	-2,92 [-18,738; 12,899]	0,7139
Tag 43 (Woche 6)	29	17,24 (21,121)	14,06 (4,350)	33	11,11 (19,837)	13,59 (4,103)	0,47 [-11,496; 12,431]	0,9381
Tag 64 (Woche 9)	30	15,56 (20,960)	16,81 (4,441)	33	10,10 (19,516)	16,21 (4,259)	0,60 [-11,705; 12,910]	0,9225
Tag 85 (Woche 12)	27	13,58 (19,080)	15,69 (5,302)	29	9,20 (19,713)	20,73 (5,160)	-5,03 [-19,829; 9,760]	0,4992
Tag 106 (Woche 15)	25	16,00 (21,773)	20,39 (5,728)	31	9,68 (19,614)	20,27 (5,391)	0,12 [-15,630; 15,875]	0,9877
Tag 127 (Woche 18)	27	16,05 (21,424)	20,78 (5,001)	26	11,54 (20,960)	15,12 (5,012)	5,66 [-8,511; 19,840]	0,4278
Tag 155 (Woche 22)	21	17,46 (22,655)	13,48 (5,840)	21	12,70 (22,301)	17,32 (5,810)	-3,84 [-20,396; 12,710]	0,6435
Tag 183 (Woche 26)	26	17,95 (21,563)	15,84 (5,308)	20	10,00 (19,041)	14,30 (5,722)	1,54 [-14,231; 17,306]	0,8457
Tag 211 (Woche 30)	23	15,94 (22,178)	13,85 (4,772)	21	7,94 (17,965)	11,22 (5,001)	2,63 [-11,343; 16,596]	0,7075
Tag 239 (Woche 34)	19	17,54 (23,223)	12,02 (4,682)	15	11,11 (20,574)	16,45 (5,102)	-4,43 [-18,496; 9,641]	0,5285
Tag 267 (Woche 38)	20	16,67 (22,942)	14,54 (5,510)	17	9,80 (19,596)	15,30 (5,954)	-0,76 [-17,151; 15,630]	0,9261
Tag 295 (Woche 42)	22	16,67 (22,420)	19,61 (5,833)	16	12,50 (20,638)	18,88 (6,584)	0,73 [-16,964; 18,421]	0,9345
Tag 323 (Woche 46)	20	18,33 (22,878)	9,77 (4,949)	17	11,76 (20,211)	23,10 (5,391)	-13,34 [-28,107; 1,434]	0,0757
Tag 351 (Woche 50)	19	15,79 (23,223)	15,74 (5,978)	15	11,11 (20,574)	19,86 (6,701)	-4,12 [-22,257; 14,009]	0,6494
Durchschnitt über alle Visiten	34	14,71 (20,418)	15,49 (3,301)	37	12,61 (21,302)	17,11 (3,346)	-1,62 [-11,038; 7,796]	0,7323
Hedges' g SMD							-0,08 [-0,547; 0,385]	0,7337

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	9,68 (19,614)	59,89 (6,859)	35	3,81 (10,760)	69,49 (6,484)	-9,60 [-28,668; 9,464]	0,3179
Tag 43 (Woche 6)	29	12,64 (22,562)	66,48 (7,339)	33	4,04 (11,048)	57,66 (6,876)	8,82 [-11,554; 29,194]	0,3902
Tag 64 (Woche 9)	30	12,22 (22,289)	51,02 (7,739)	33	4,04 (11,048)	59,04 (7,341)	-8,02 [-29,585; 13,546]	0,4606
Tag 85 (Woche 12)	27	11,11 (22,646)	52,39 (8,076)	29	3,45 (10,331)	41,26 (7,791)	11,13 [-11,509; 33,776]	0,3304
Tag 106 (Woche 15)	25	8,00 (17,427)	50,19 (7,576)	31	4,30 (11,359)	39,14 (7,140)	11,05 [-9,838; 31,937]	0,2956
Tag 127 (Woche 18)	27	11,11 (20,672)	46,11 (7,517)	26	5,13 (12,265)	34,19 (7,473)	11,91 [-9,415; 33,238]	0,2694
Tag 155 (Woche 22)	21	11,11 (21,943)	40,05 (8,633)	21	1,59 (7,274)	30,66 (8,706)	9,39 [-15,537; 34,311]	0,4544
Tag 183 (Woche 26)	26	11,54 (22,983)	16,41 (6,957)	20	3,33 (10,260)	8,30 (7,490)	8,11 [-12,621; 28,837]	0,4371
Tag 211 (Woche 30)	23	8,70 (20,640)	4,49 (5,267)	21	3,17 (10,026)	1,98 (5,539)	2,51 [-12,913; 17,924]	0,7465
Tag 239 (Woche 34)	19	7,02 (21,020)	6,66 (4,402)	15	4,44 (11,729)	-0,21 (4,833)	6,87 [-6,263; 20,004]	0,2999
Tag 267 (Woche 38)	20	11,67 (22,361)	3,41 (5,294)	17	3,92 (11,070)	5,50 (5,733)	-2,10 [-17,883; 13,691]	0,7914
Tag 295 (Woche 42)	22	10,61 (21,544)	8,69 (5,429)	16	4,17 (11,386)	2,32 (6,177)	6,37 [-10,222; 22,959]	0,4456
Tag 323 (Woche 46)	20	11,67 (22,361)	0,87 (4,871)	17	3,92 (11,070)	9,35 (5,394)	-8,47 [-23,259; 6,316]	0,2546
Tag 351 (Woche 50)	19	12,28 (22,800)	-2,35 (7,027)	15	2,22 (8,607)	11,86 (7,946)	-14,21 [-36,058; 7,639]	0,1955
Durchschnitt über alle Visiten	34	11,76 (21,528)	28,88 (3,505)	37	3,60 (10,493)	26,47 (3,532)	2,41 [-7,621; 12,444]	0,6336
Hedges' g SMD							0,11 [-0,352; 0,580]	0,6327

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	31	10,75 (23,392)	8,38 (4,205)	35	5,71 (15,094)	13,22 (3,962)	-4,84 [-16,442; 6,762]	0,4079
Tag 43 (Woche 6)	29	11,49 (24,030)	17,01 (5,328)	33	6,06 (15,489)	20,80 (5,021)	-3,79 [-18,469; 10,897]	0,6088
Tag 64 (Woche 9)	30	11,11 (23,705)	14,17 (5,004)	33	4,04 (11,048)	23,10 (4,793)	-8,93 [-22,864; 5,012]	0,2056
Tag 85 (Woche 12)	27	7,41 (14,122)	24,24 (5,658)	29	3,45 (10,331)	28,22 (5,563)	-3,97 [-19,847; 11,899]	0,6186
Tag 106 (Woche 15)	25	10,67 (24,944)	15,99 (5,094)	31	3,23 (10,018)	20,82 (4,843)	-4,82 [-18,988; 9,345]	0,4989
Tag 127 (Woche 18)	27	12,35 (24,717)	17,72 (5,981)	26	5,13 (12,265)	20,66 (5,984)	-2,94 [-20,014; 14,141]	0,7320
Tag 155 (Woche 22)	21	14,29 (27,021)	4,48 (4,527)	21	4,76 (11,952)	6,60 (4,487)	-2,11 [-15,035; 10,811]	0,7442
Tag 183 (Woche 26)	26	12,82 (25,081)	5,78 (3,806)	20	6,67 (13,680)	1,77 (4,057)	4,00 [-7,189; 15,198]	0,4771
Tag 211 (Woche 30)	23	10,14 (23,430)	3,74 (3,431)	21	4,76 (11,952)	3,78 (3,560)	-0,04 [-9,975; 9,891]	0,9932
Tag 239 (Woche 34)	19	12,28 (25,363)	3,94 (3,251)	15	2,22 (8,607)	0,87 (3,551)	3,07 [-6,674; 12,816]	0,5307
Tag 267 (Woche 38)	20	13,33 (27,359)	7,50 (4,592)	17	3,92 (11,070)	9,86 (4,905)	-2,37 [-15,949; 11,213]	0,7283
Tag 295 (Woche 42)	22	13,64 (26,546)	2,17 (3,313)	16	6,25 (13,437)	8,61 (3,696)	-6,44 [-16,462; 3,582]	0,2031
Tag 323 (Woche 46)	20	13,33 (27,359)	5,93 (4,607)	17	5,88 (13,098)	3,81 (5,012)	2,13 [-11,658; 15,910]	0,7578
Tag 351 (Woche 50)	19	14,04 (27,924)	-0,71 (3,555)	15	4,44 (11,729)	6,57 (3,966)	-7,28 [-18,128; 3,571]	0,1831
Durchschnitt über alle Visiten	34	11,76 (23,039)	9,31 (2,979)	37	5,41 (14,727)	12,05 (2,965)	-2,74 [-11,200; 5,725]	0,5204
Hedges' g SMD							-0,15 [-0,619; 0,314]	0,5208

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

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	29	68,86 (17,192)	-6,53 (4,073)	35	72,77 (18,198)	0,48 (3,715)	-7,02 [-18,100; 4,066]	0,2098
Tag 43 (Woche 6)	27	68,74 (17,593)	-4,78 (3,846)	33	75,12 (17,601)	-2,69 (3,521)	-2,09 [-12,600; 8,428]	0,6924
Tag 64 (Woche 9)	27	68,78 (17,673)	-3,60 (3,204)	33	75,79 (16,987)	-5,99 (2,946)	2,39 [-6,363; 11,146]	0,5872
Tag 85 (Woche 12)	25	66,88 (17,709)	-3,03 (3,240)	29	76,72 (16,490)	-6,44 (3,016)	3,41 [-5,532; 12,357]	0,4490
Tag 106 (Woche 15)	22	68,73 (18,045)	-6,95 (3,326)	31	77,23 (16,136)	-5,66 (3,011)	-1,29 [-10,341; 7,758]	0,7766
Tag 127 (Woche 18)	25	68,96 (18,749)	-4,72 (3,484)	26	76,08 (17,013)	-10,33 (3,348)	5,61 [-4,129; 15,345]	0,2540
Tag 155 (Woche 22)	20	70,35 (17,129)	-3,54 (3,401)	21	74,10 (18,292)	-6,35 (3,273)	2,80 [-6,677; 12,283]	0,5567
Tag 183 (Woche 26)	24	69,04 (17,773)	-0,06 (3,002)	20	74,95 (17,884)	-7,81 (3,065)	7,75 [-0,879; 16,386]	0,0774
Tag 211 (Woche 30)	21	70,67 (17,993)	-0,24 (3,063)	21	77,19 (15,848)	-2,56 (3,042)	2,32 [-6,382; 11,022]	0,5954
Tag 239 (Woche 34)	17	68,24 (18,863)	4,24 (3,183)	15	74,00 (16,296)	-4,19 (3,240)	8,43 [-0,762; 17,627]	0,0713
Tag 267 (Woche 38)	18	70,61 (19,110)	2,63 (3,686)	17	74,47 (15,500)	-8,12 (3,714)	10,75 [0,180; 21,318]	0,0464*
Tag 295 (Woche 42)	21	70,62 (17,996)	-0,06 (3,582)	16	70,63 (17,150)	-7,20 (3,812)	7,14 [-3,402; 17,687]	0,1792
Tag 323 (Woche 46)	19	70,21 (18,287)	-2,10 (3,808)	17	71,82 (17,325)	-6,66 (3,917)	4,56 [-6,460; 15,575]	0,4092
Tag 351 (Woche 50)	19	73,53 (15,728)	-0,70 (2,955)	15	73,07 (16,888)	-3,95 (3,164)	3,26 [-5,471; 11,985]	0,4562
Durchschnitt über alle Visiten	32	69,31 (16,668)	-2,10 (2,542)	37	73,62 (18,059)	-5,53 (2,419)	3,43 [-3,623; 10,485]	0,3345
Hedges' g SMD							0,23 [-0,242; 0,708]	0,3362

[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 2.4.4.1.1 DUO-E (dMMR Durva): Analysis of change from baseline in PGIS over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	28	2,57 (1,526)	0,50 (0,255)	32	2,00 (1,191)	0,19 (0,233)	0,30 [-0,394; 1,002]	0,3867
Tag 43 (Woche 6)	25	2,52 (1,610)	0,19 (0,232)	31	1,74 (0,999)	0,47 (0,212)	-0,28 [-0,920; 0,361]	0,3865
Tag 64 (Woche 9)	26	2,58 (1,579)	0,19 (0,244)	31	1,74 (0,999)	0,49 (0,226)	-0,30 [-0,979; 0,377]	0,3786
Tag 85 (Woche 12)	23	2,52 (1,563)	0,20 (0,255)	28	1,75 (1,005)	0,54 (0,236)	-0,33 [-1,045; 0,378]	0,3511
Tag 106 (Woche 15)	22	2,32 (1,492)	0,47 (0,250)	29	1,76 (1,023)	0,53 (0,230)	-0,06 [-0,750; 0,629]	0,8610
Tag 127 (Woche 18)	24	2,63 (1,583)	0,01 (0,265)	24	1,79 (0,977)	0,66 (0,257)	-0,65 [-1,406; 0,106]	0,0904
Tag 155 (Woche 22)	19	2,42 (1,465)	0,20 (0,258)	19	1,84 (1,015)	0,60 (0,254)	-0,40 [-1,134; 0,343]	0,2870
Tag 183 (Woche 26)	22	2,50 (1,472)	-0,32 (0,221)	18	2,00 (1,138)	0,30 (0,229)	-0,62 [-1,268; 0,028]	0,0602
Tag 211 (Woche 30)	20	2,30 (1,380)	-0,33 (0,210)	20	1,95 (1,099)	0,27 (0,209)	-0,60 [-1,195; 0,003]	0,0512
Tag 239 (Woche 34)	16	2,44 (1,459)	-0,49 (0,207)	14	2,14 (1,027)	0,39 (0,214)	-0,89 [-1,493; -0,286]	0,0048*
Tag 267 (Woche 38)	18	2,50 (1,543)	-0,46 (0,212)	16	1,94 (1,063)	0,56 (0,221)	-1,02 [-1,644; -0,396]	0,0019*
Tag 295 (Woche 42)	19	2,32 (1,493)	-0,24 (0,232)	14	2,07 (1,072)	0,51 (0,257)	-0,75 [-1,448; -0,044]	0,0377*
Tag 323 (Woche 46)	18	2,56 (1,723)	0,18 (0,229)	15	2,07 (1,033)	0,56 (0,247)	-0,37 [-1,059; 0,313]	0,2793
Tag 351 (Woche 50)	17	2,35 (1,539)	0,12 (0,250)	14	1,93 (0,917)	0,80 (0,277)	-0,68 [-1,434; 0,083]	0,0795
Durchschnitt über alle Visiten	30	2,50 (1,503)	0,02 (0,159)	35	1,91 (1,173)	0,49 (0,154)	-0,47 [-0,924; -0,024]	0,0394*
Hedges' g SMD							-0,52 [-1,021; -0,028]	0,0385*

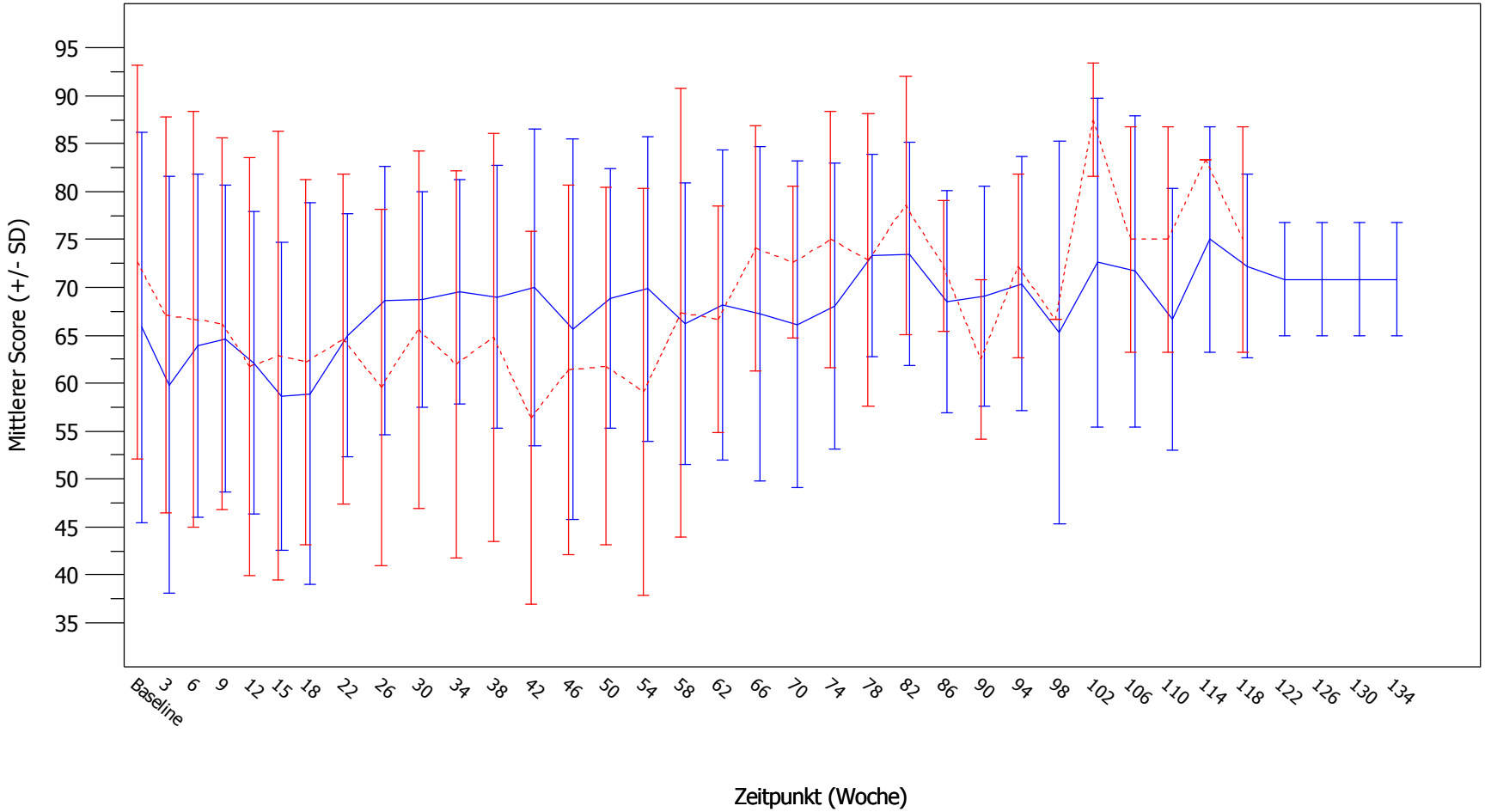
[a] = Number of patients with change from baseline used for MMRM analysis at each timepoint. [b] = Mean baseline for patients with change from baseline used for MMRM analysis at each timepoint. Treatment difference is calculated from a mixed model for repeated measures (MMRM) analysis of the change from 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 gmmrmprabb 27MAR2024:14:53

Table 2.4.5.1.1 DUO-E (dMMR Durva): Analysis of change from baseline in PGI-TT over time (mixed model for repeated measures), Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)			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)	28	1,29 (0,535)	1,23 (0,199)	32	1,34 (0,745)	0,77 (0,185)	0,46 [-0,083; 1,006]	0,0950
Tag 43 (Woche 6)	25	1,24 (0,523)	1,08 (0,194)	31	1,35 (0,755)	0,83 (0,176)	0,25 [-0,273; 0,775]	0,3429
Tag 64 (Woche 9)	26	1,19 (0,402)	1,00 (0,209)	31	1,35 (0,755)	1,23 (0,193)	-0,24 [-0,806; 0,334]	0,4113
Tag 85 (Woche 12)	22	1,32 (0,568)	1,22 (0,199)	28	1,36 (0,780)	1,12 (0,181)	0,11 [-0,433; 0,644]	0,6967
Tag 106 (Woche 15)	22	1,27 (0,550)	1,56 (0,221)	29	1,38 (0,775)	1,41 (0,199)	0,15 [-0,449; 0,744]	0,6228
Tag 127 (Woche 18)	22	1,23 (0,528)	1,51 (0,214)	24	1,46 (0,833)	1,29 (0,203)	0,21 [-0,380; 0,807]	0,4748
Tag 155 (Woche 22)	18	1,22 (0,548)	1,06 (0,200)	19	1,42 (0,838)	0,69 (0,192)	0,37 [-0,188; 0,933]	0,1879
Tag 183 (Woche 26)	21	1,29 (0,561)	0,74 (0,210)	18	1,33 (0,686)	0,87 (0,214)	-0,13 [-0,736; 0,467]	0,6560
Tag 211 (Woche 30)	20	1,30 (0,571)	0,99 (0,198)	20	1,30 (0,657)	0,79 (0,196)	0,20 [-0,358; 0,760]	0,4741
Durchschnitt über alle Visiten	30	1,27 (0,521)	1,15 (0,147)	35	1,34 (0,725)	1,00 (0,138)	0,15 [-0,250; 0,557]	0,4502
Hedges' g SMD							0,19 [-0,302; 0,676]	0,4535

[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 gmmrmprabc 27MAR2024:14:53

Figure 2.5.1.1.1 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Allgemeine Lebensqualität/Gesundheitsszustand across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



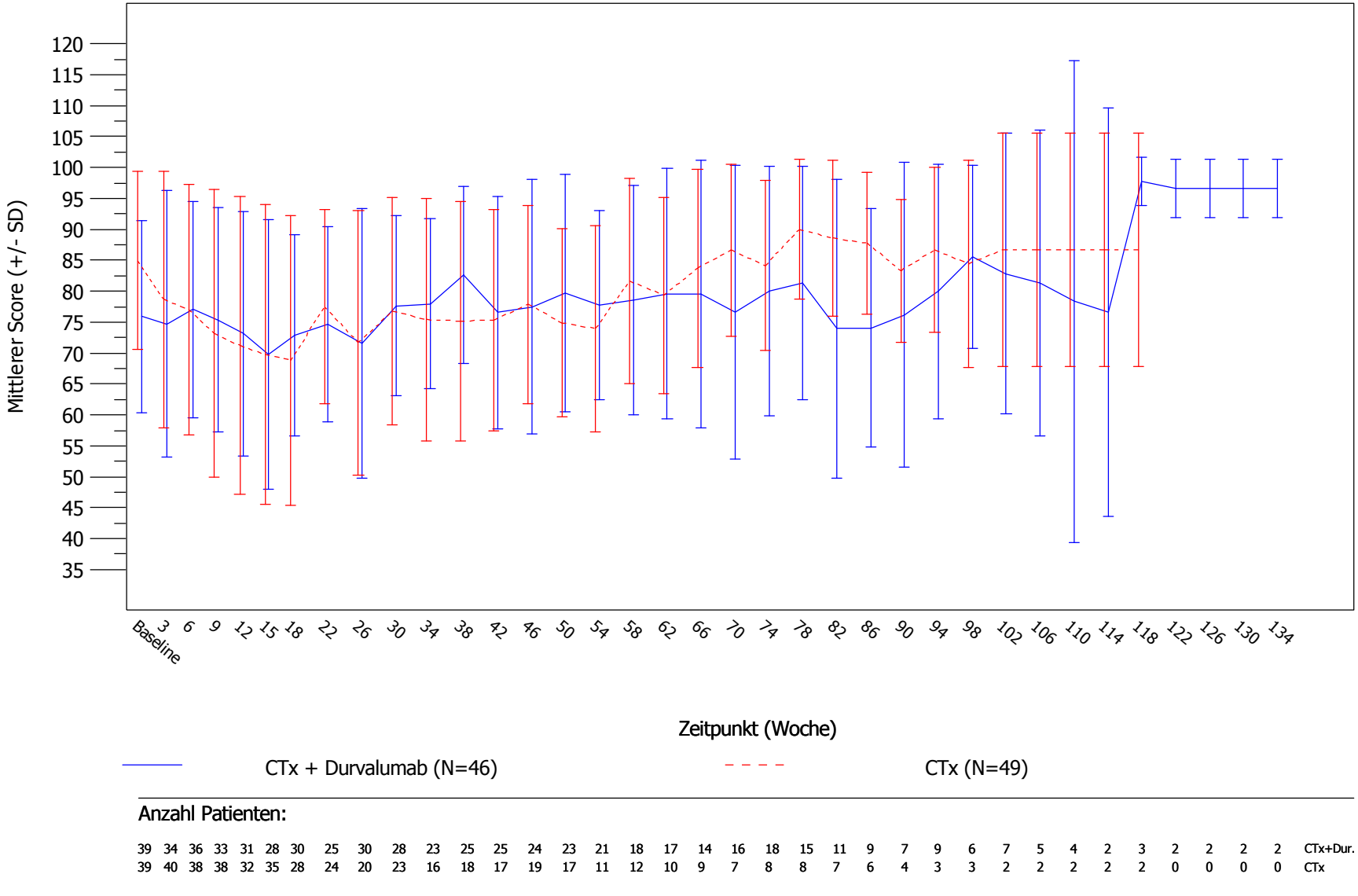
Anzahl Patienten:

39	34	36	33	31	28	30	25	30	28	23	25	25	24	23	21	18	17	14	16	18	15	11	9	7	9	6	7	5	4	2	3	2	2	2	2	CTx+Dur.
39	40	38	38	32	35	28	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG

Figure 2.5.1.1.2 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Funktionsskala: Körper across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

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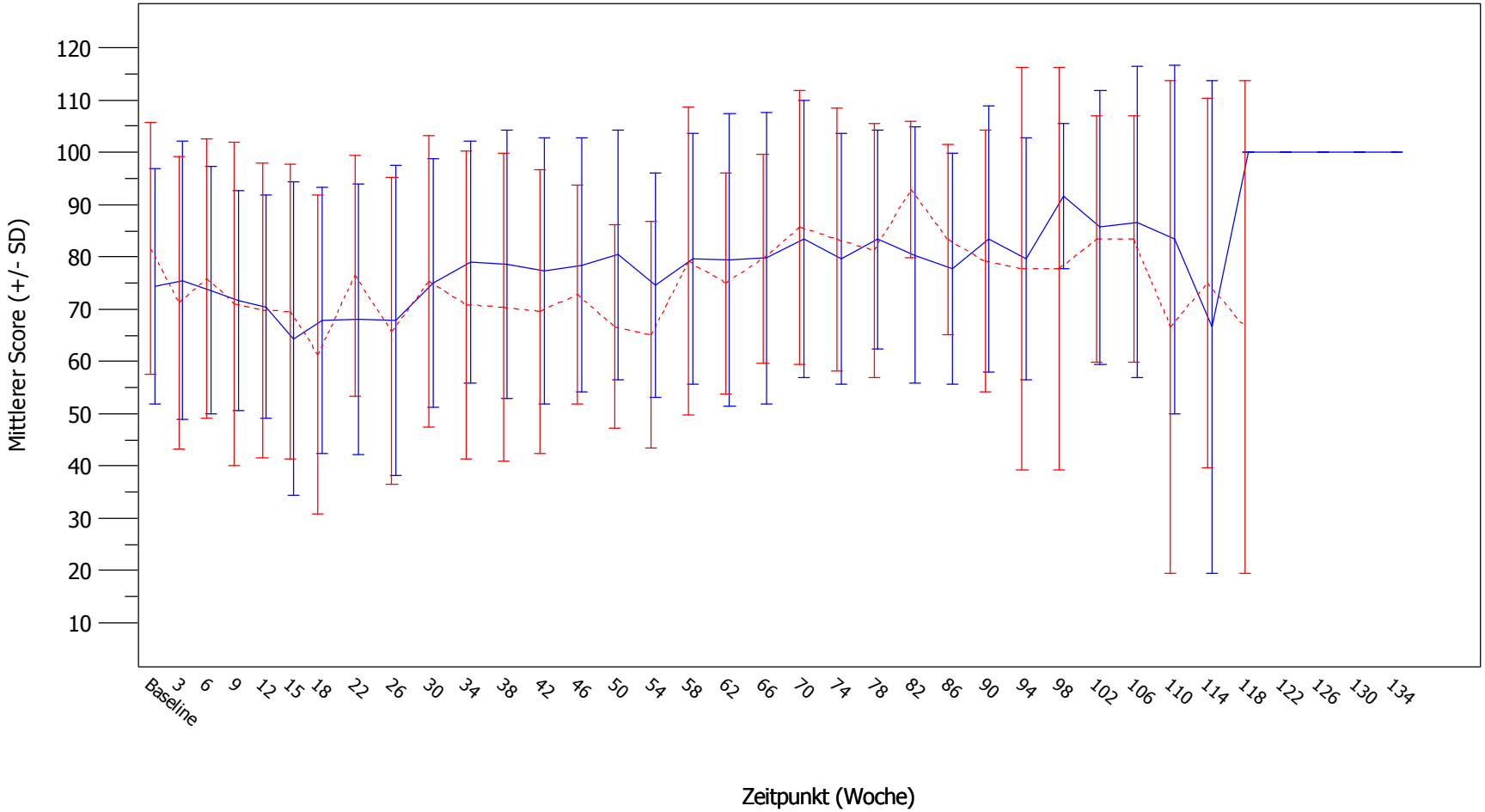
Figure 2.5.1.1.3 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Funktionsskala: Rolle across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

39	34	36	33	31	28	30	25	30	28	23	25	25	24	23	21	18	17	14	16	18	15	11	9	7	9	6	7	5	4	2	3	2	2	2	2	CTx+Dur.
39	40	38	38	32	35	28	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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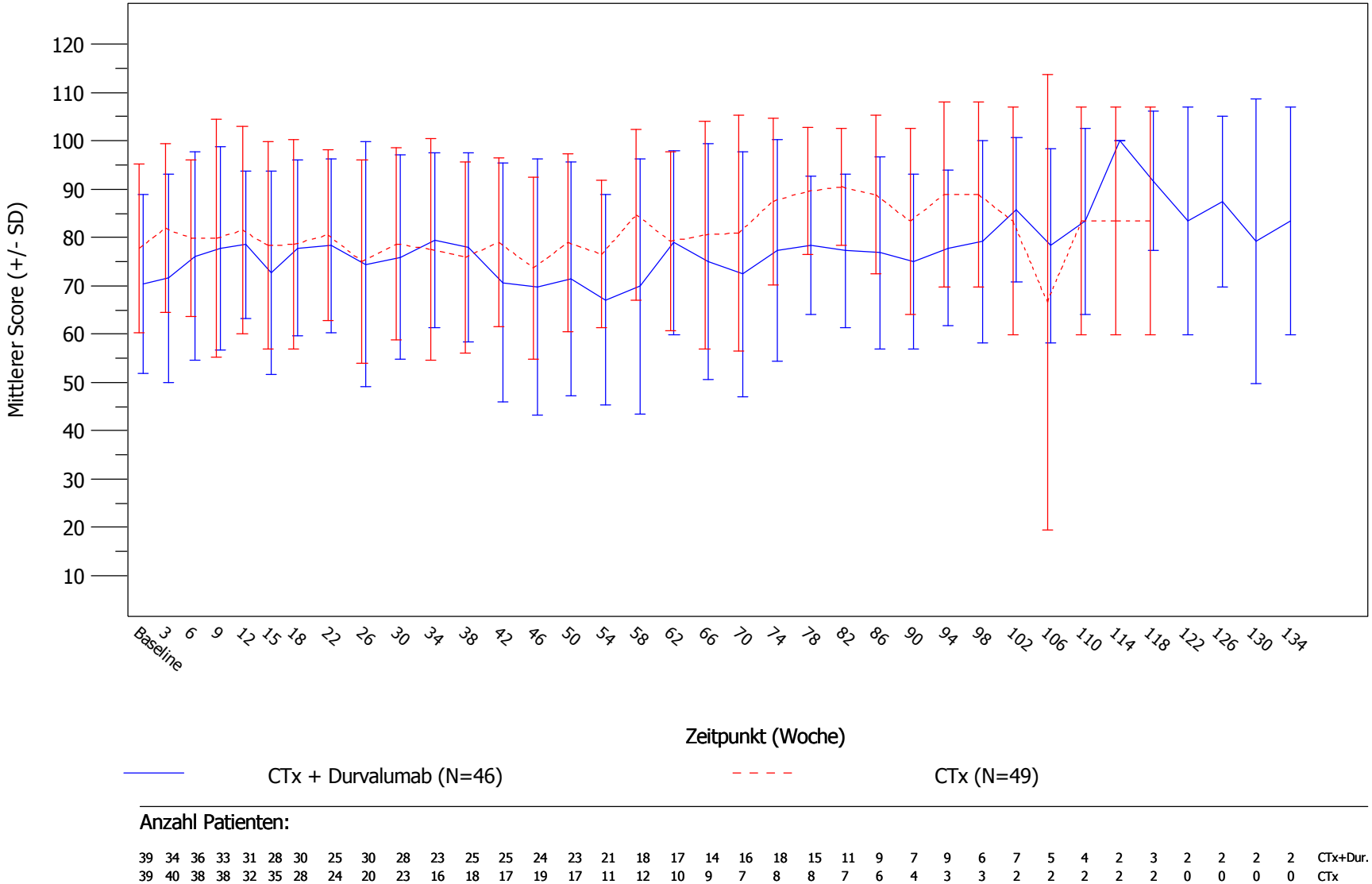
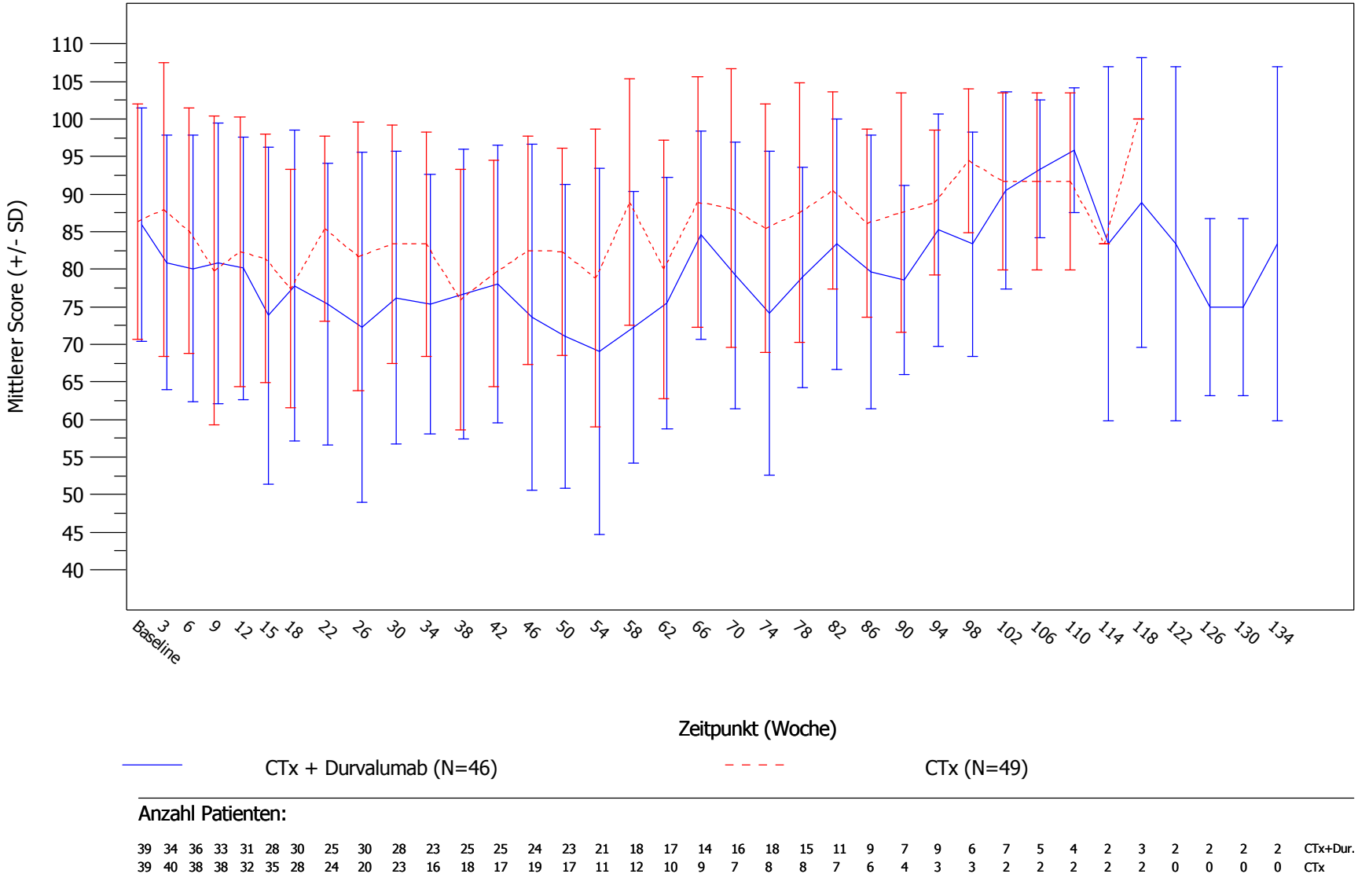
Figure 2.5.1.1.4 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Funktionsskala: Emotionalität across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

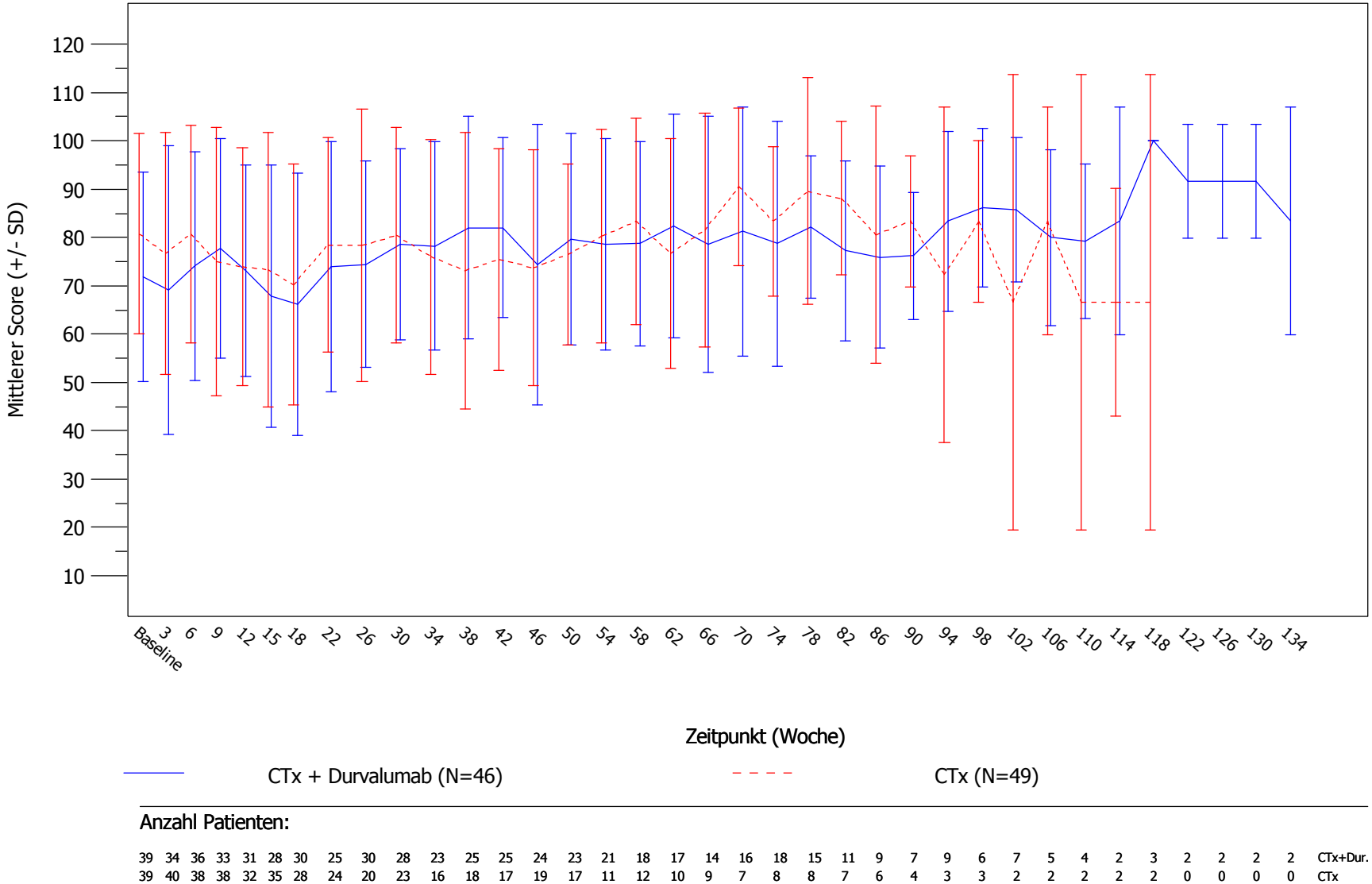
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/fmeanpr.sas gfmeanpraad 13MAR2024:16:00

Figure 2.5.1.1.5 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Funktionsskala: Kognition across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

Figure 2.5.1.1.6 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Funktionsskala: Sozial across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

39	34	36	33	31	28	30	25	30	28	23	25	25	24	23	21	18	17	14	16	18	15	11	9	7	9	6	7	5	4	2	3	2	2	2	2	CTx+Dur.
39	40	38	38	32	35	28	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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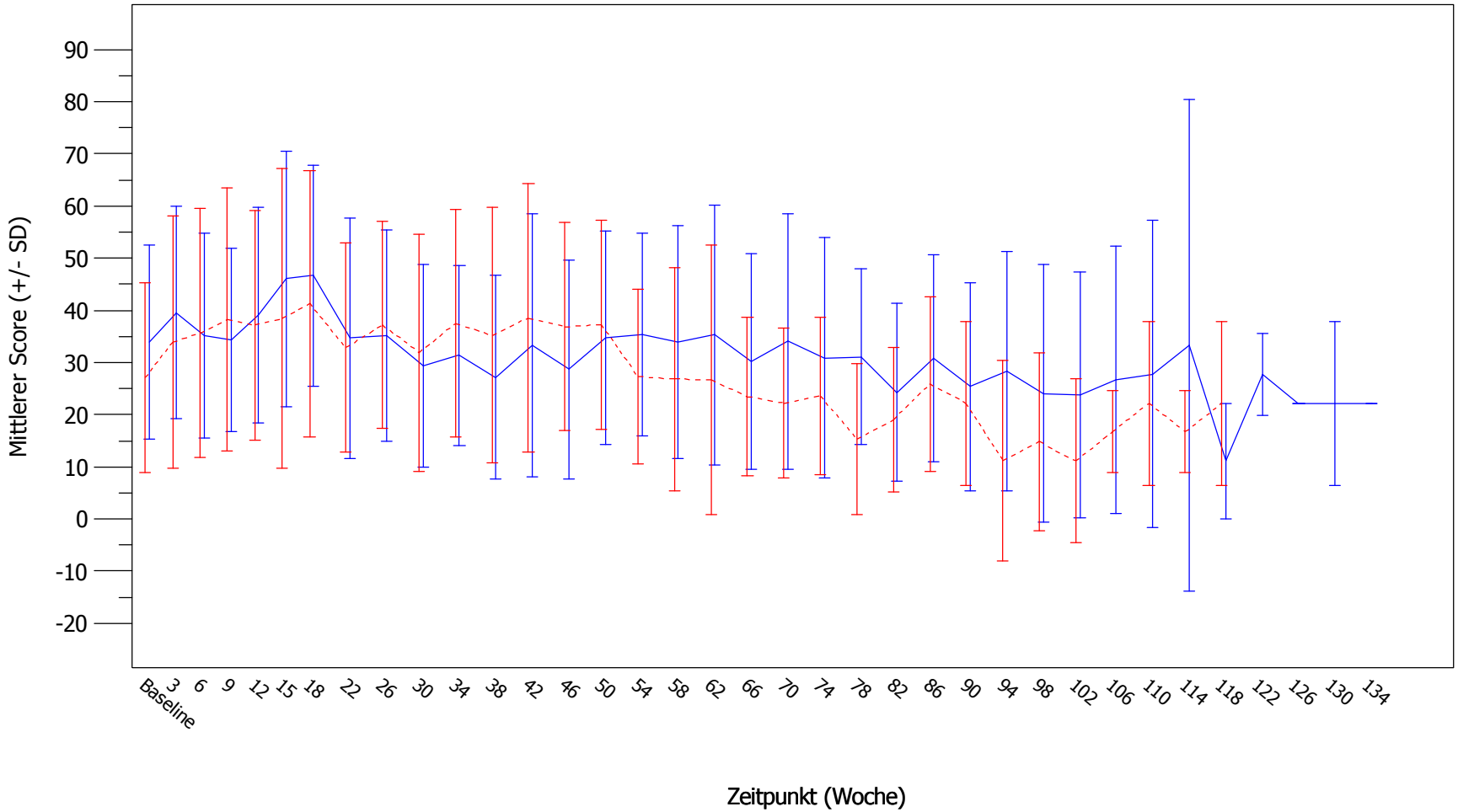
Figure 2.5.1.1.7 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Fatigue across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



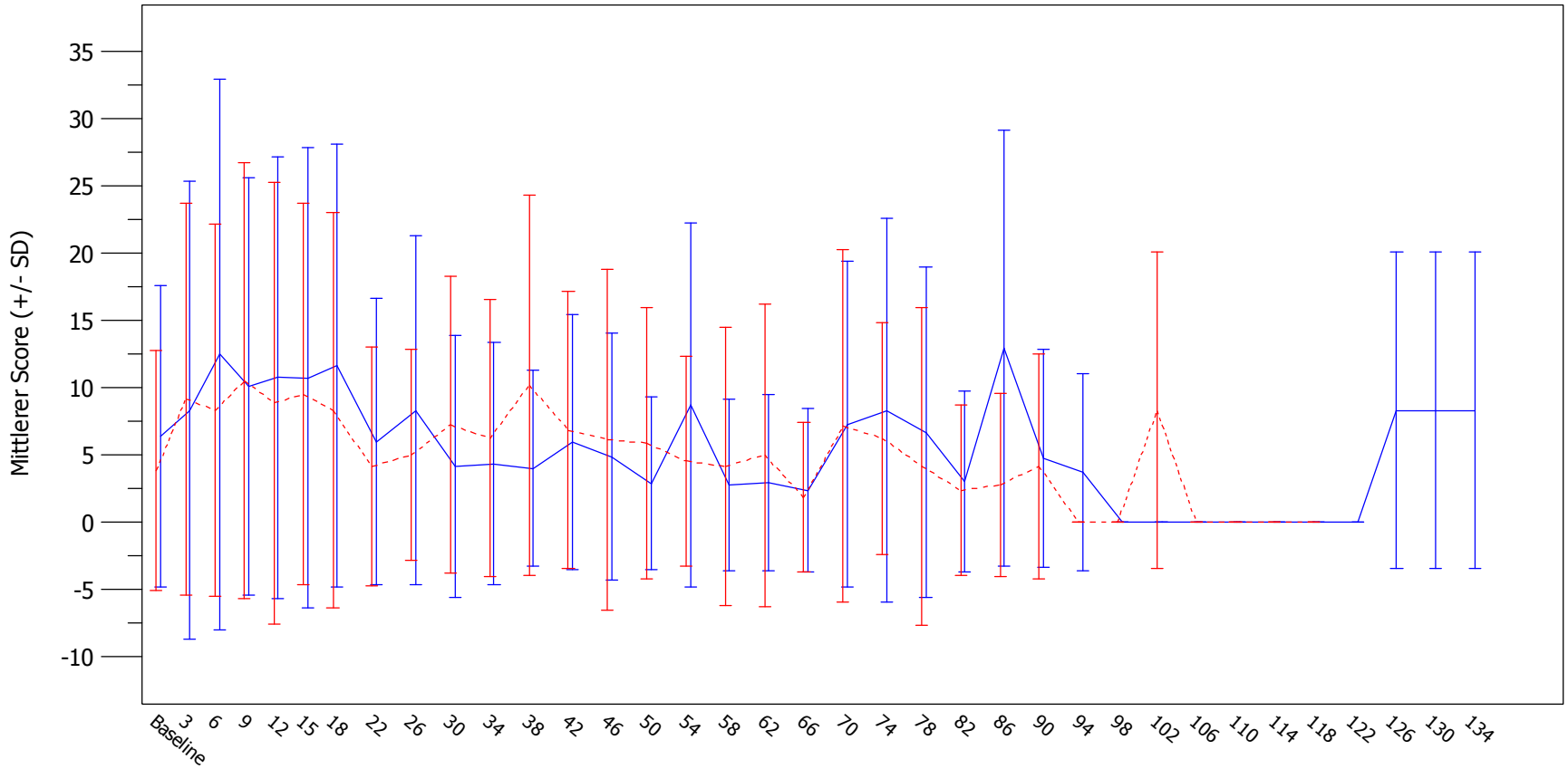
Anzahl Patienten:

39	34	36	33	31	28	30	25	30	28	23	25	25	24	23	21	18	17	14	16	18	15	11	9	7	9	6	7	5	4	2	3	2	2	2	2	CTx+Dur.
39	40	38	38	32	35	28	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.1.1.8 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Übelkeit und Erbrechen across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

39	34	36	33	31	28	30	25	30	28	23	25	25	24	23	21	18	17	14	16	18	15	11	9	7	9	6	7	5	4	2	3	2	2	2	2	CTx+Dur.
39	40	38	38	32	35	28	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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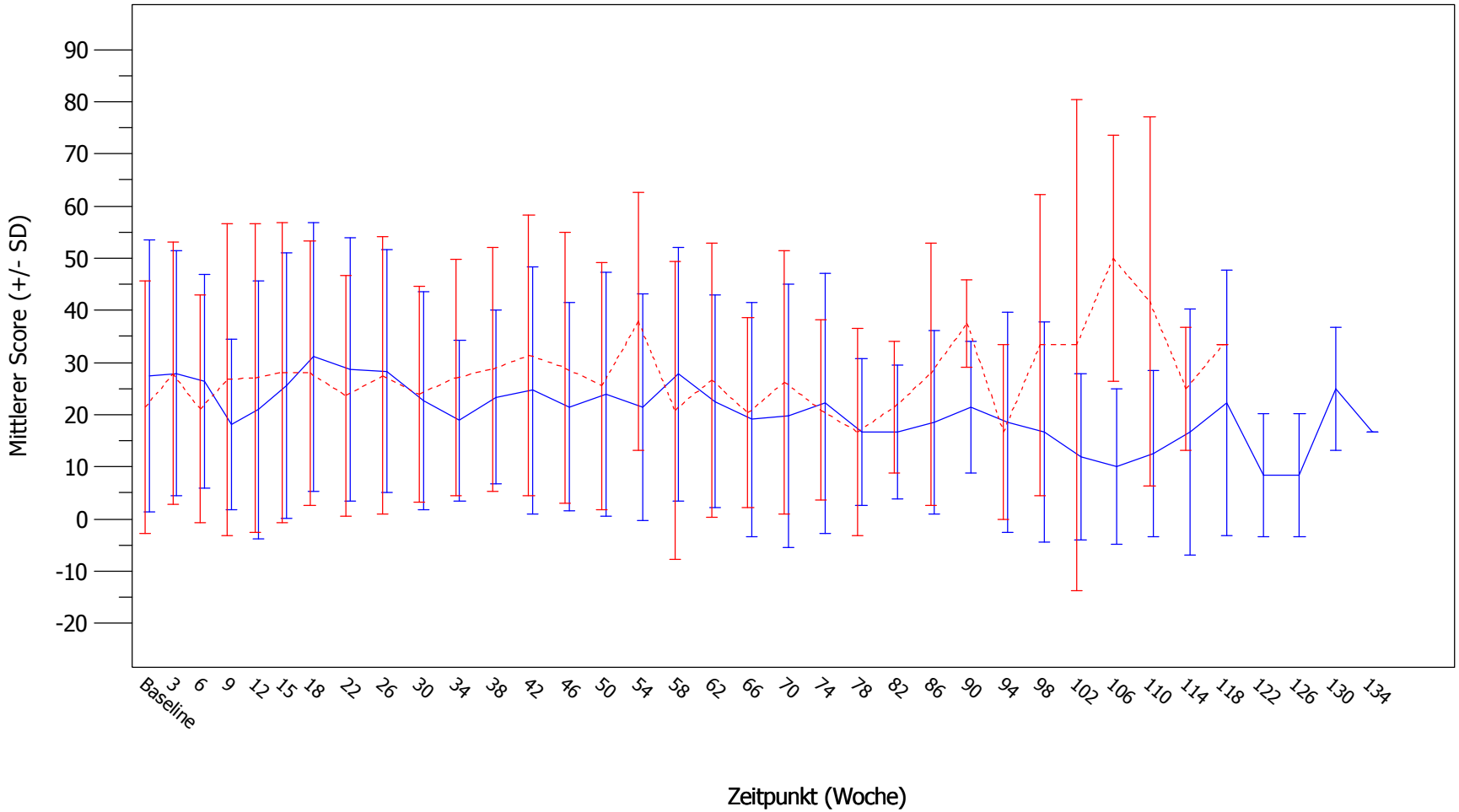
Figure 2.5.1.1.9 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Schmerzen across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

39	34	36	33	31	28	30	25	30	28	23	25	25	24	23	21	18	17	14	16	18	15	11	9	7	9	6	7	5	4	2	3	2	2	2	2	CTx+Dur.
39	40	38	38	32	35	28	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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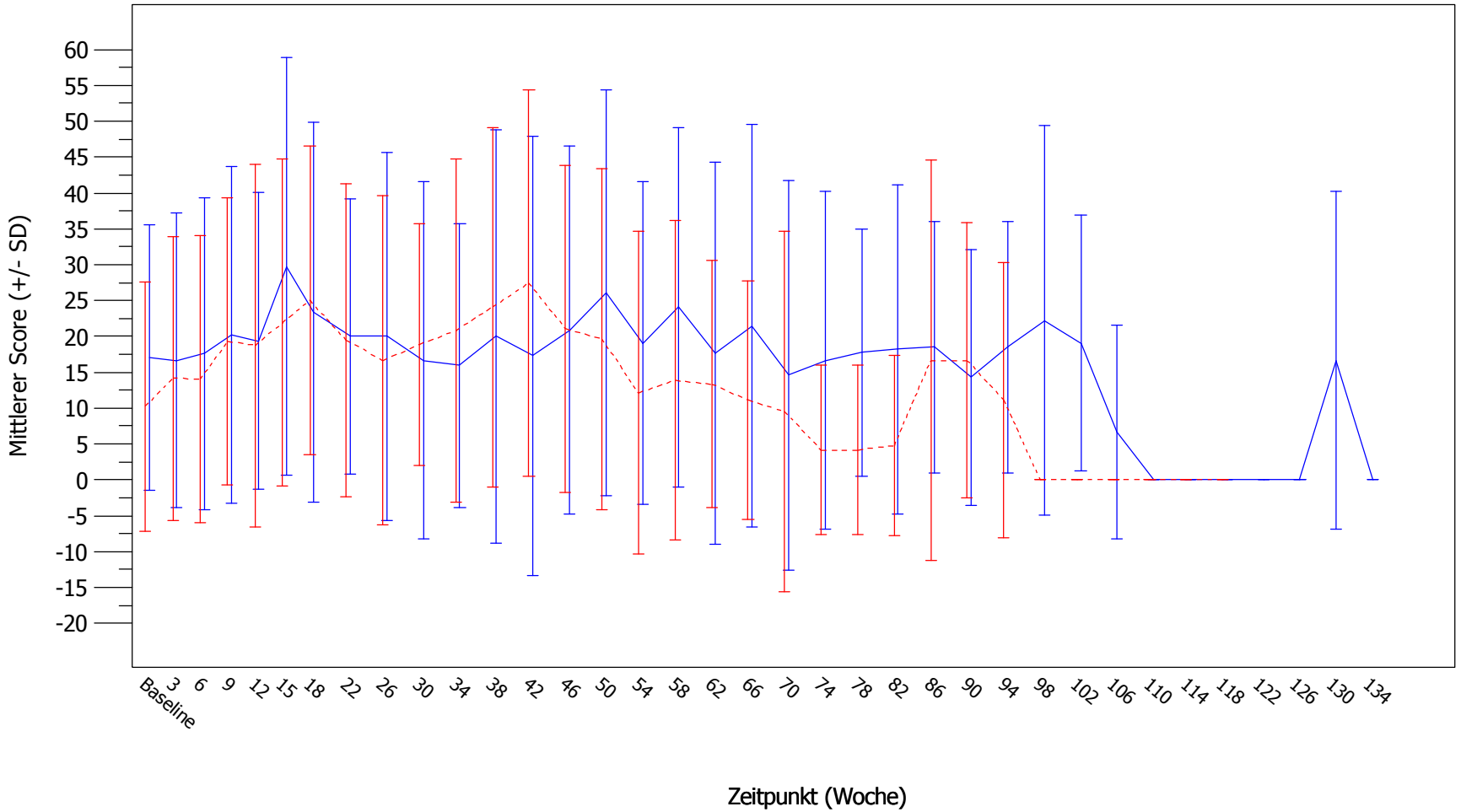
Figure 2.5.1.1.10 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Dyspnoe across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023

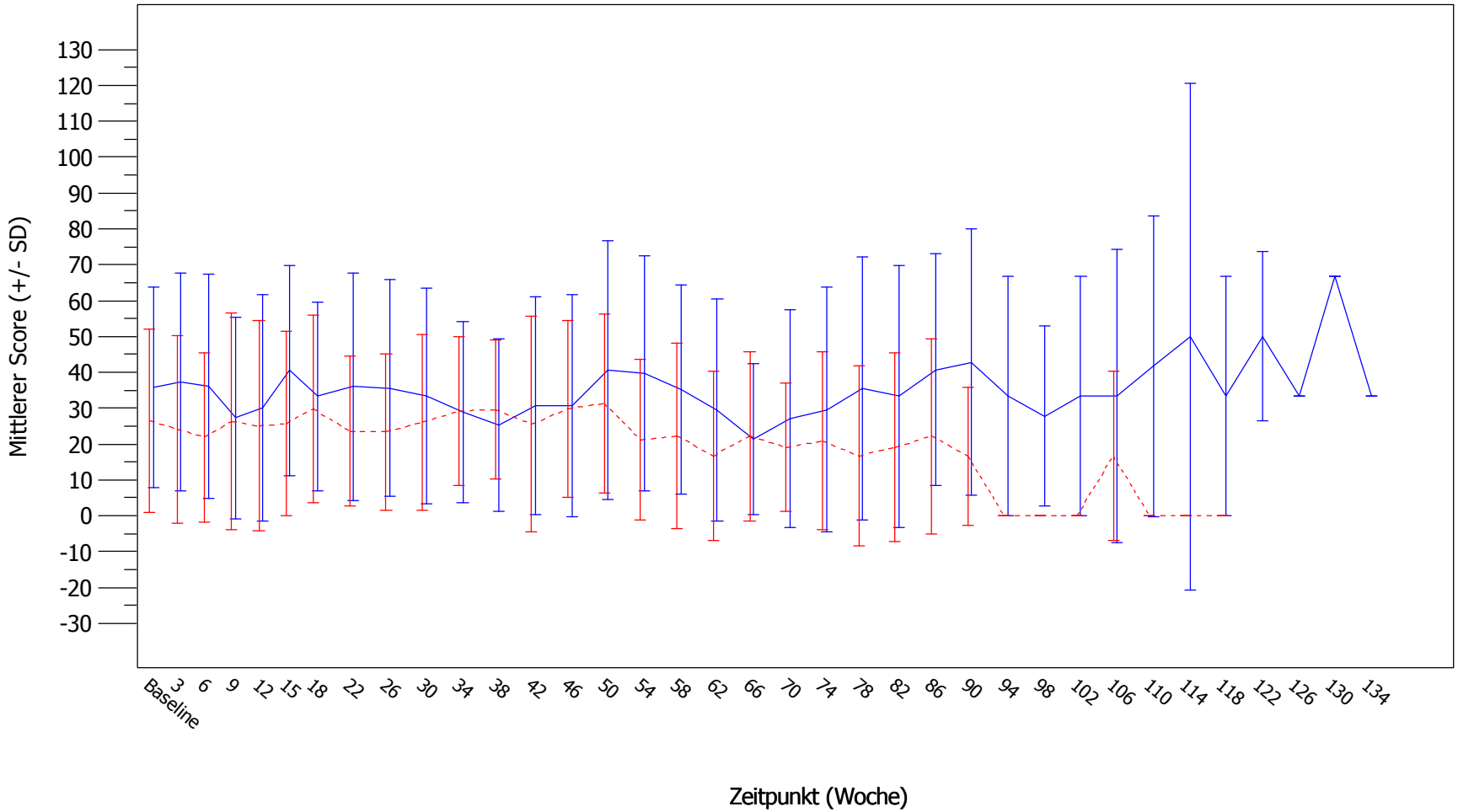


Anzahl Patienten:

39	34	36	33	31	28	30	25	30	28	23	25	25	24	23	21	18	17	14	16	18	15	11	9	7	9	6	7	5	4	2	3	2	2	2	2	CTx+Dur.
39	40	38	38	32	35	28	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

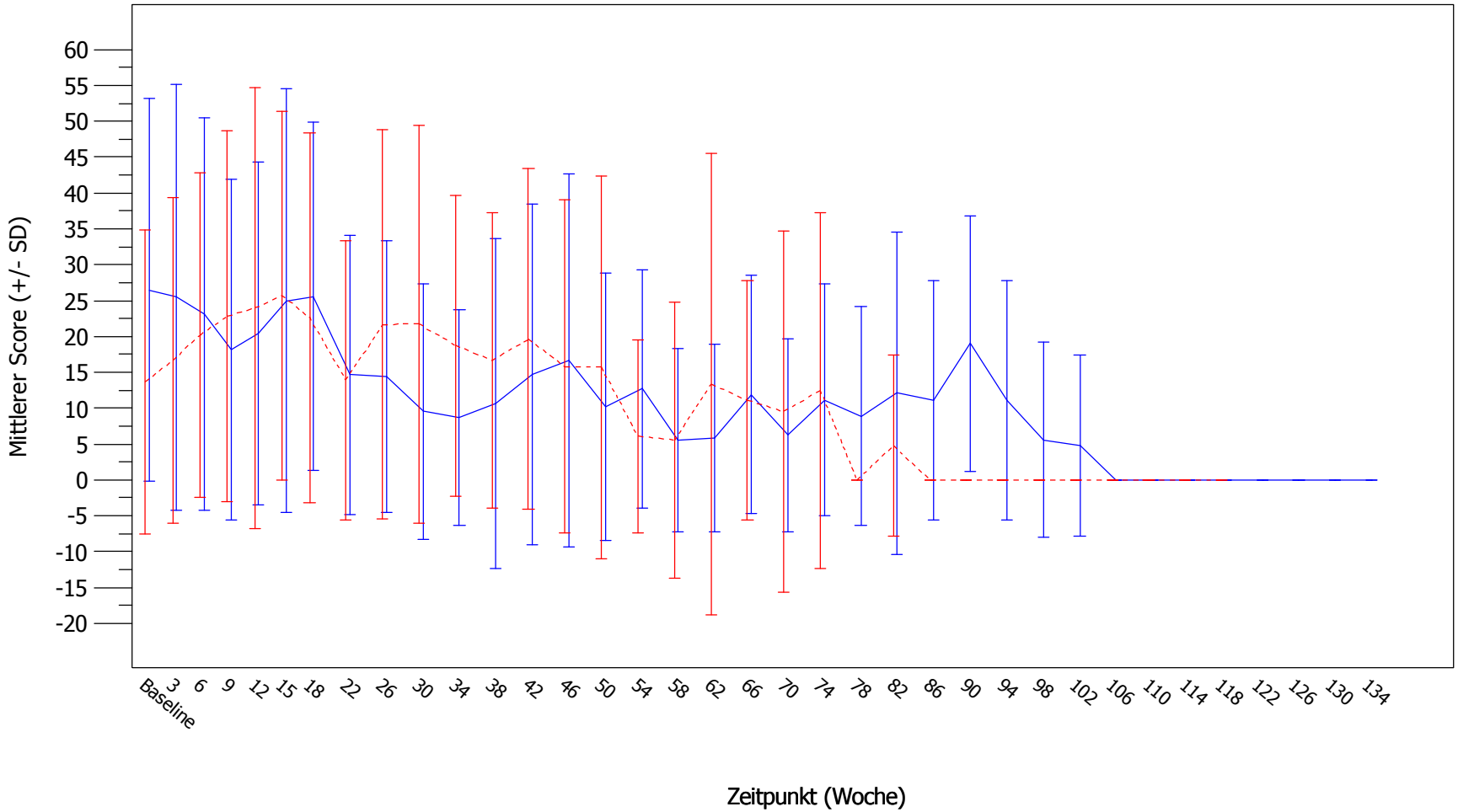
Figure 2.5.1.1.11 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Schlaflosigkeit across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.1.1.12 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Appetitverlust across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



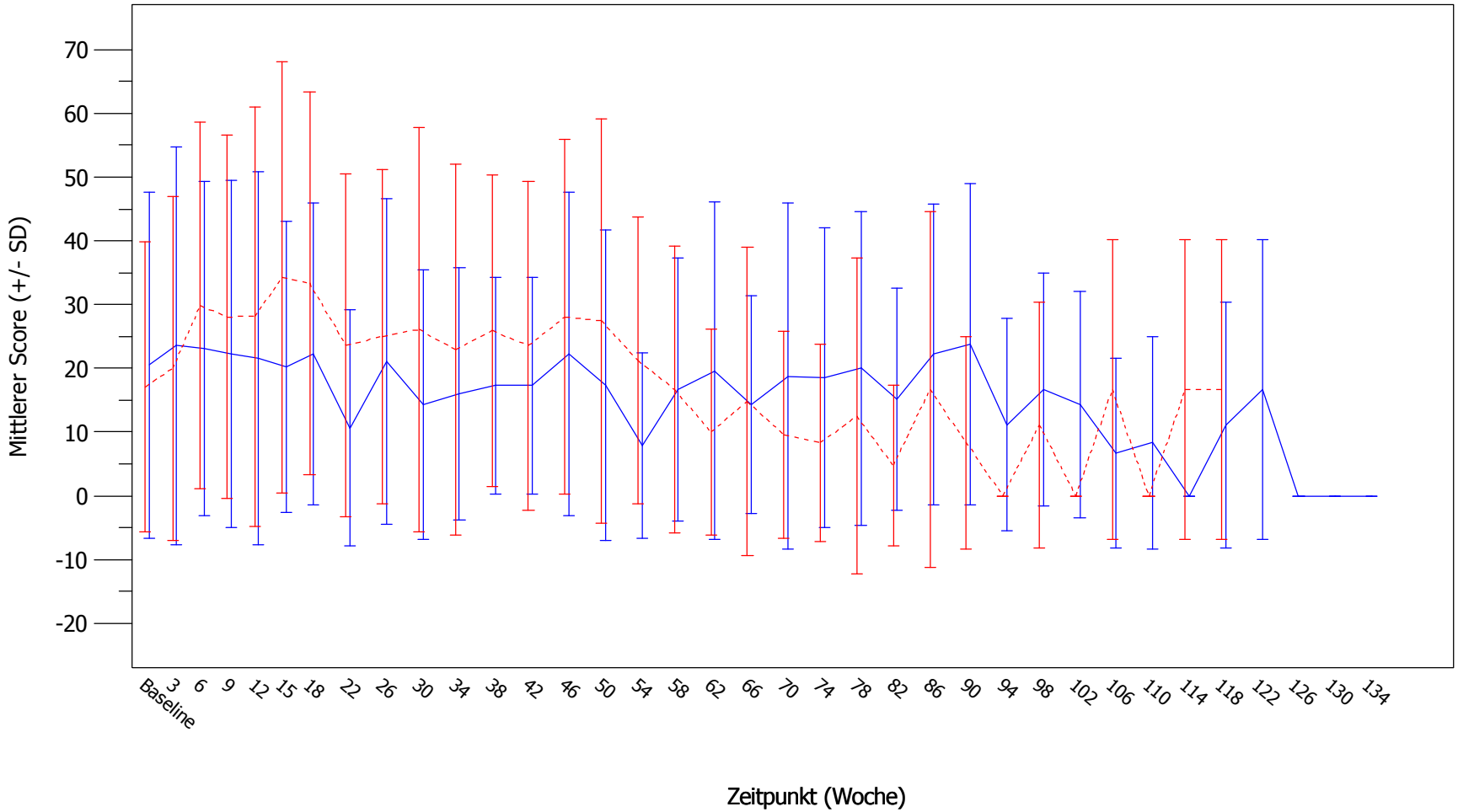
Anzahl Patienten:

39	34	36	33	31	28	30	25	30	28	23	25	25	24	23	21	18	17	14	16	18	15	11	9	7	9	6	7	5	4	2	3	2	2	2	2	CTx+Dur.
39	40	38	38	32	35	28	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.1.1.13 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Verstopfung across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023

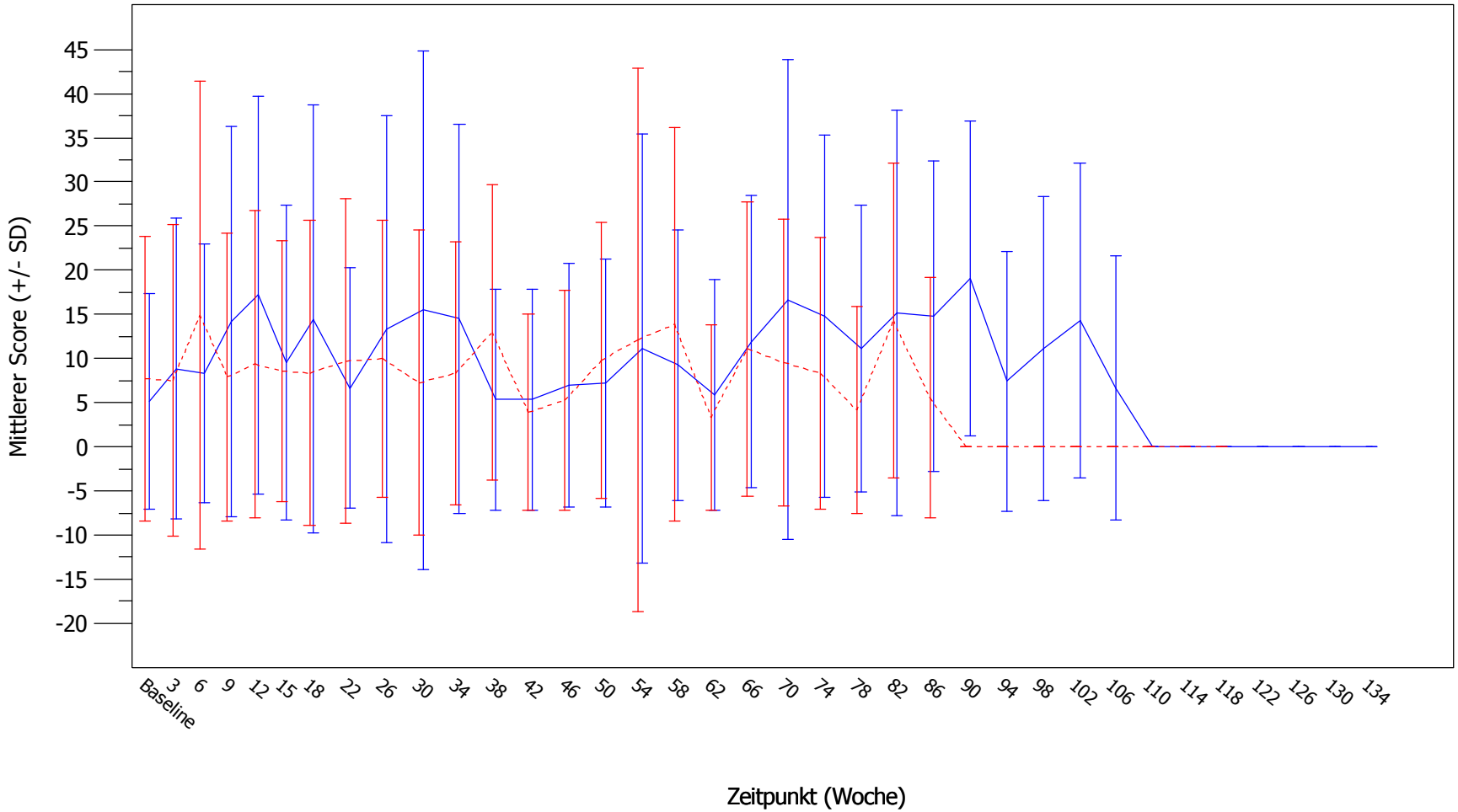


Anzahl Patienten:

39	34	36	33	31	28	30	25	30	28	23	25	25	24	23	21	18	17	14	16	18	15	11	9	7	9	6	7	5	4	2	3	2	2	2	2	CTx+Dur.
39	40	38	38	32	35	28	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Figure 2.5.1.1.14 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Diarrhö across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



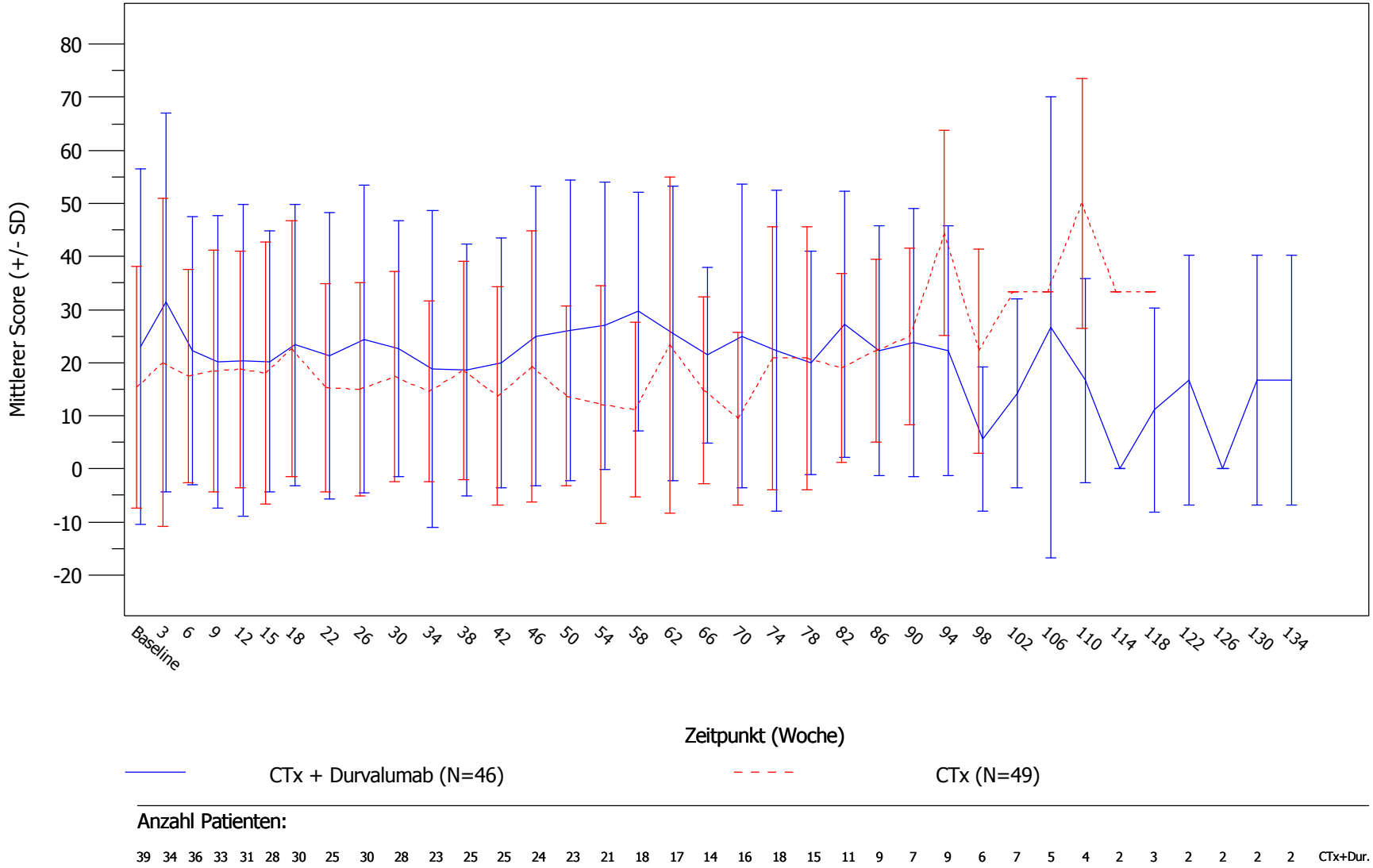
Anzahl Patienten:

39	34	36	33	31	28	30	25	30	28	23	25	25	24	23	21	18	17	14	16	18	15	11	9	7	9	6	7	5	4	2	3	2	2	2	2	CTx+Dur.
39	40	38	38	32	35	28	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.1.1.15 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-C30 Finanzielle Schwierigkeiten across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023

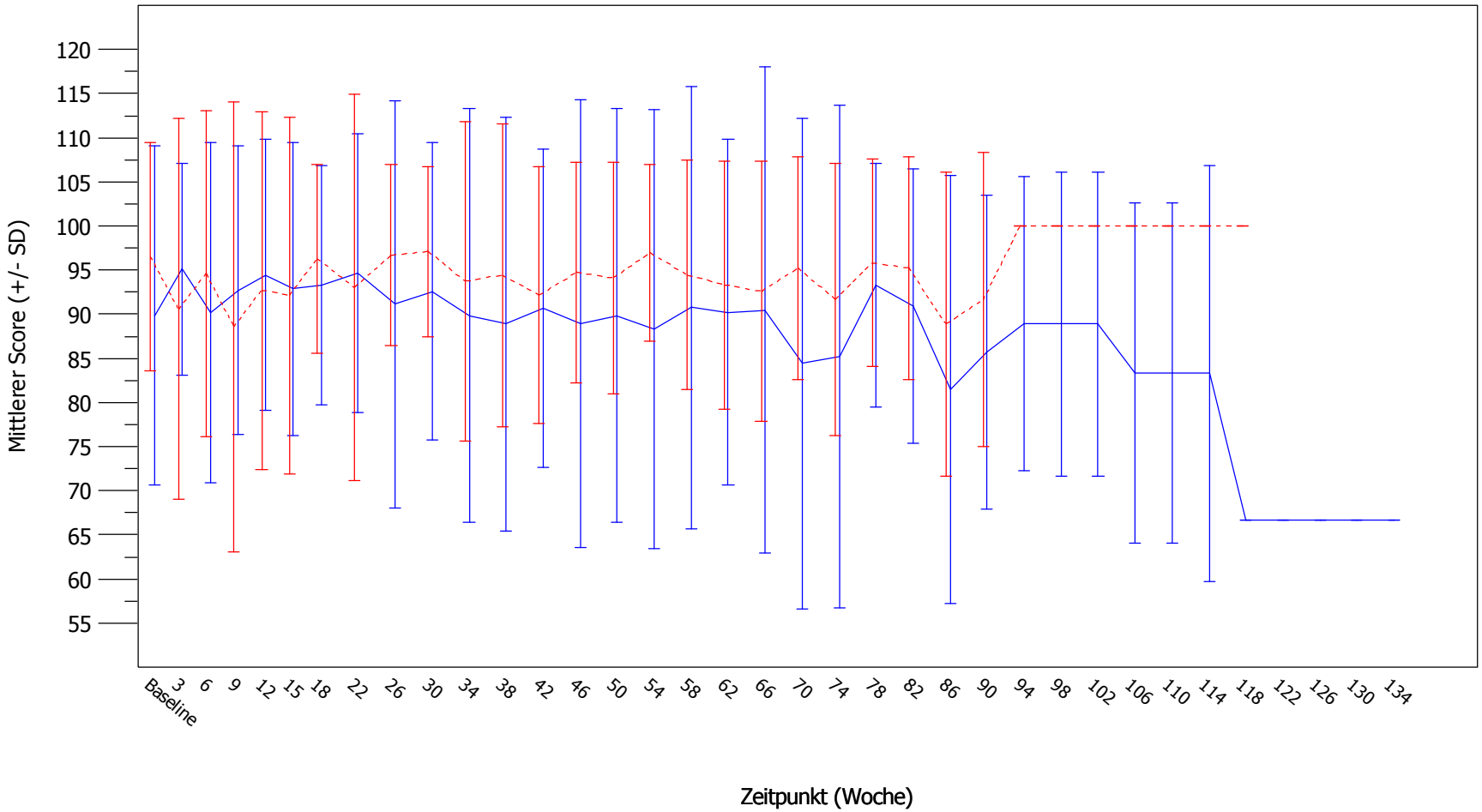


CTx = Carboplatin + Paclitaxel.

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

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.1.1 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Sexuelles Interesse across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

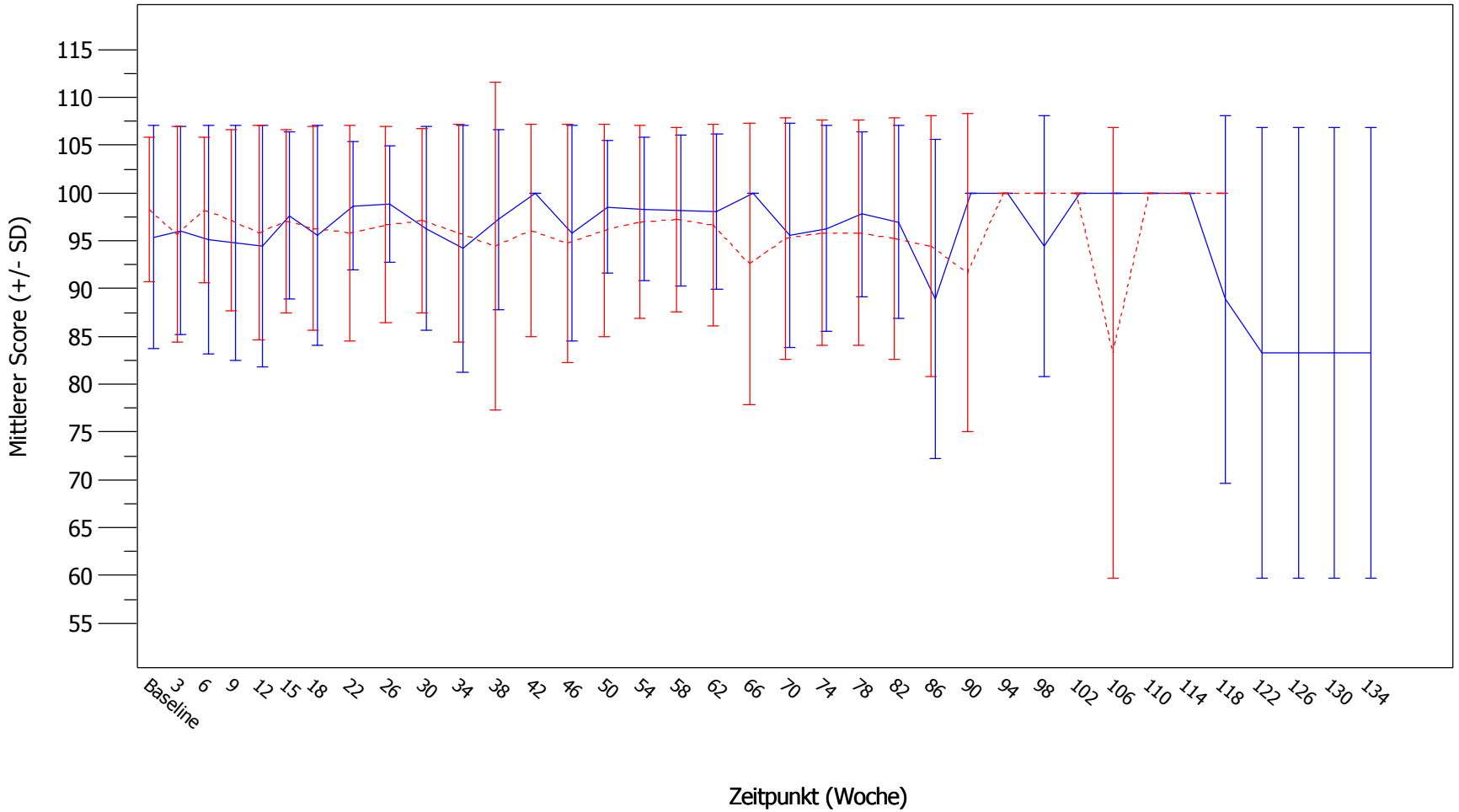
36	34	34	32	30	28	30	25	30	27	23	24	25	24	23	20	18	17	14	15	18	15	11	9	7	9	6	6	4	4	2	3	2	2	2	2	CTx+Dur.
38	39	37	35	32	34	27	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.1.2 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Sexuelle Aktivität across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023

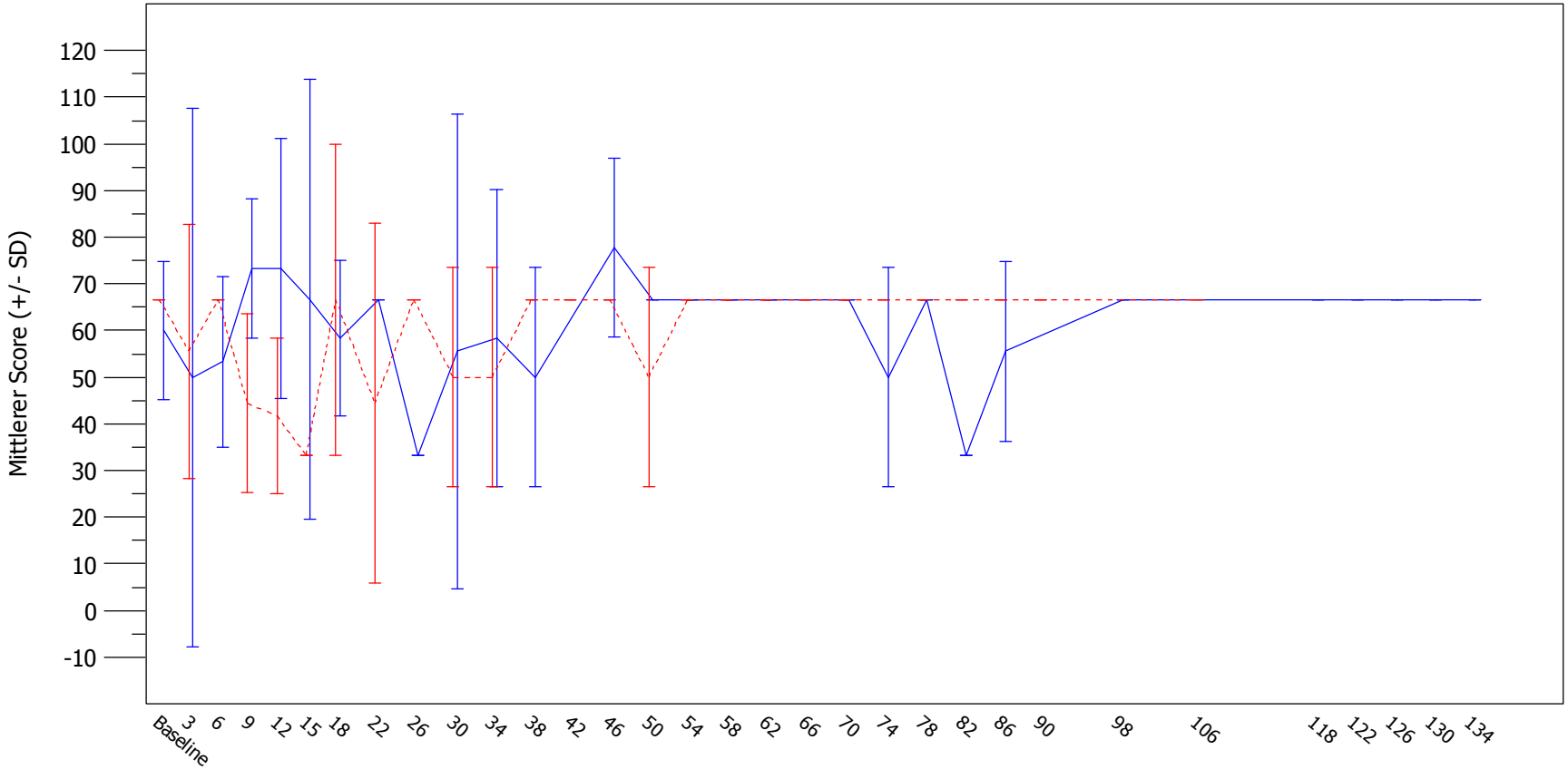


CTx = Carboplatin + Paclitaxel.

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

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 2.5.2.1.3 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Sexuelles Vergnügen across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023

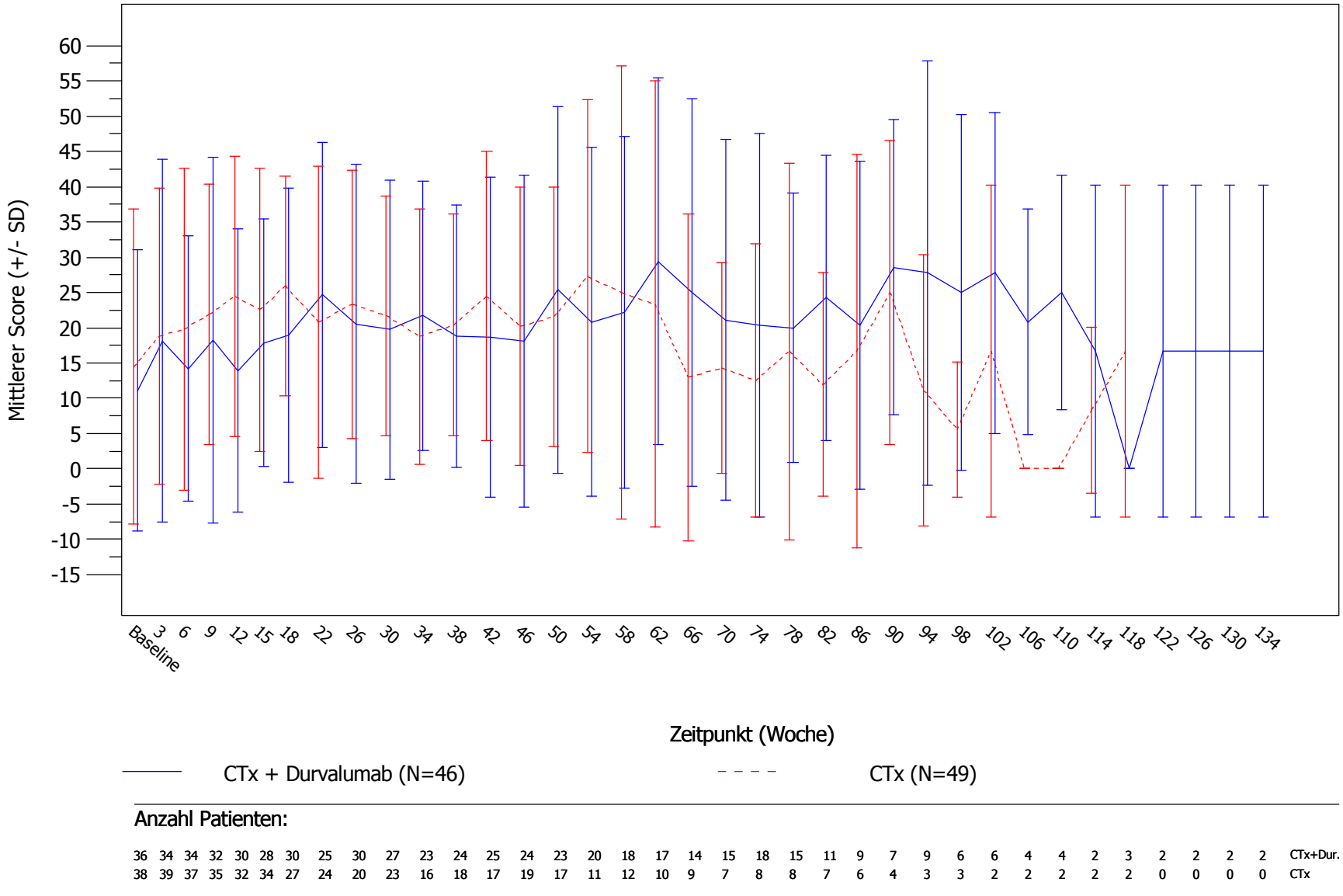


Anzahl Patienten:

5	4	5	5	5	2	4	1	1	3	4	2	0	3	1	1	1	1	0	2	2	1	1	3	0	1	0	1	1	1	1	CTx+Dur.
2	6	2	3	4	3	3	3	2	2	2	2	2	3	2	1	1	1	2	1	1	1	1	1	1	0	1	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Figure 2.5.2.1.4 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Lymphödem across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

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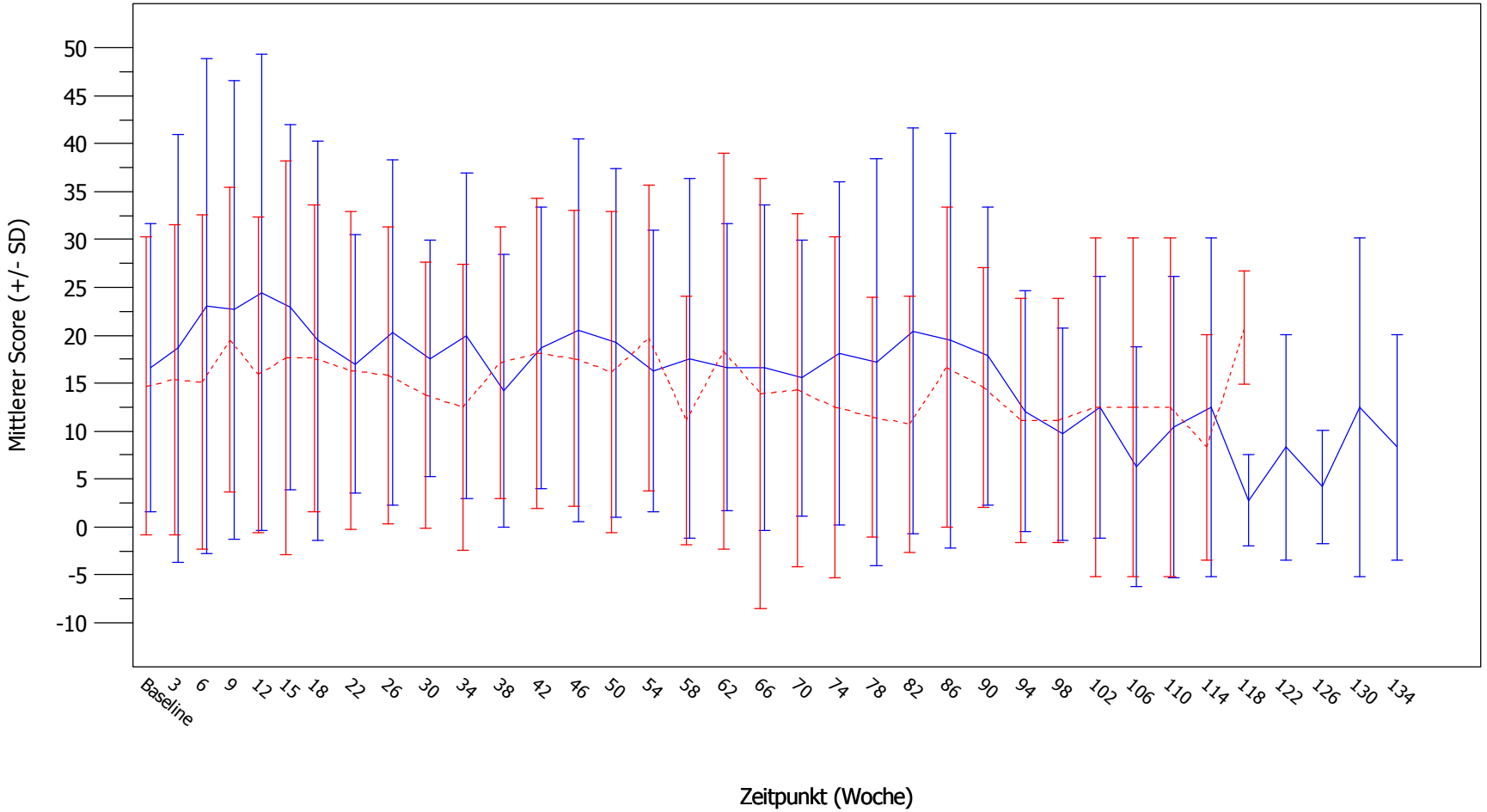
Figure 2.5.2.1.5 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Urologische Symptome across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

36	34	34	32	30	28	30	25	30	27	23	24	25	24	23	20	18	17	14	15	18	15	11	9	7	9	6	6	4	4	2	3	2	2	2	2	CTx+Dur.
38	39	37	35	32	34	27	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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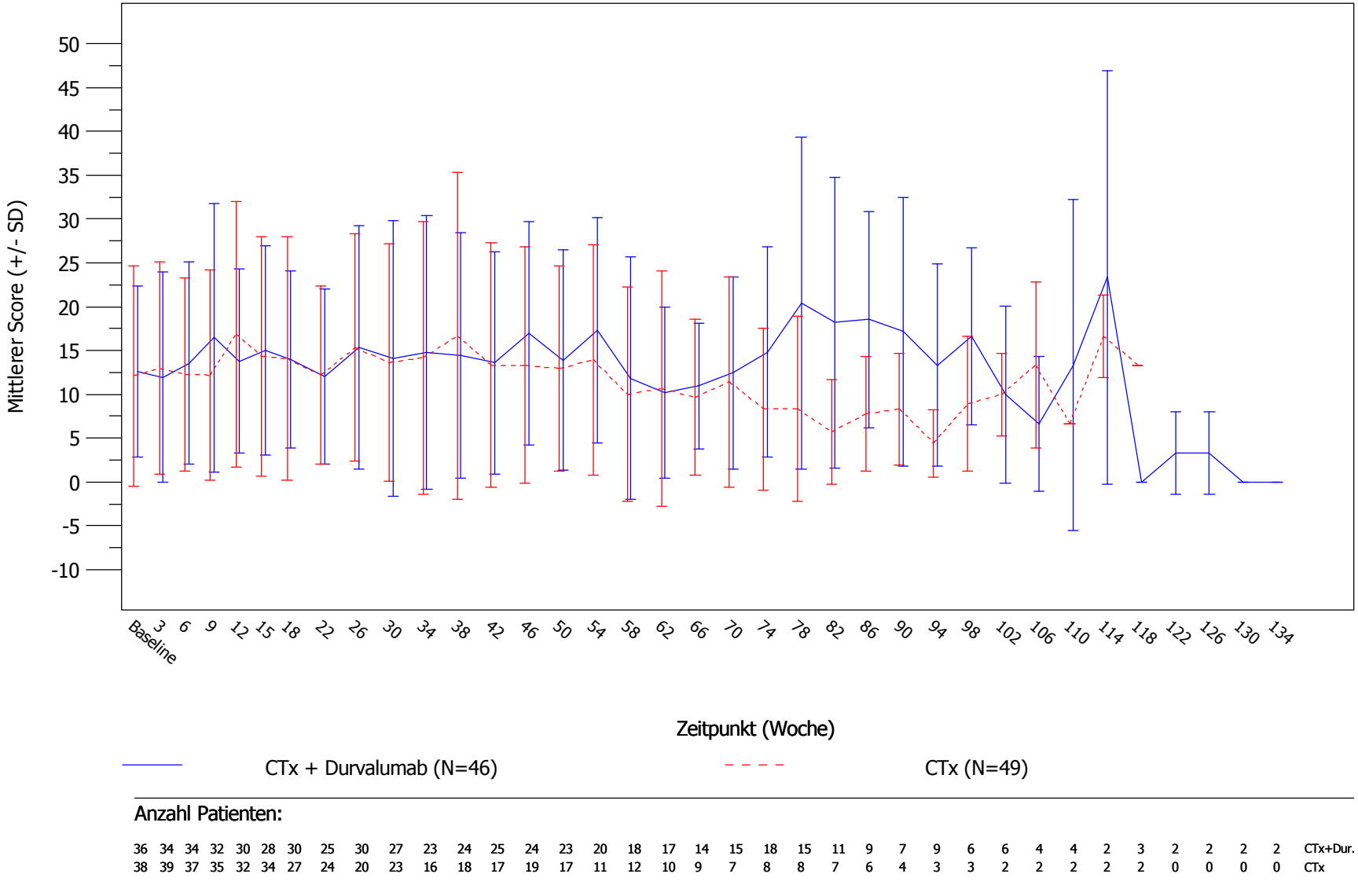
Figure 2.5.2.1.6 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Gastrointestinale Symptome across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

36	34	34	32	30	28	30	25	30	27	23	24	25	24	23	20	18	17	14	15	18	15	11	9	7	9	6	6	4	4	2	3	2	2	2	2	CTx+Dur.
38	39	37	35	32	34	27	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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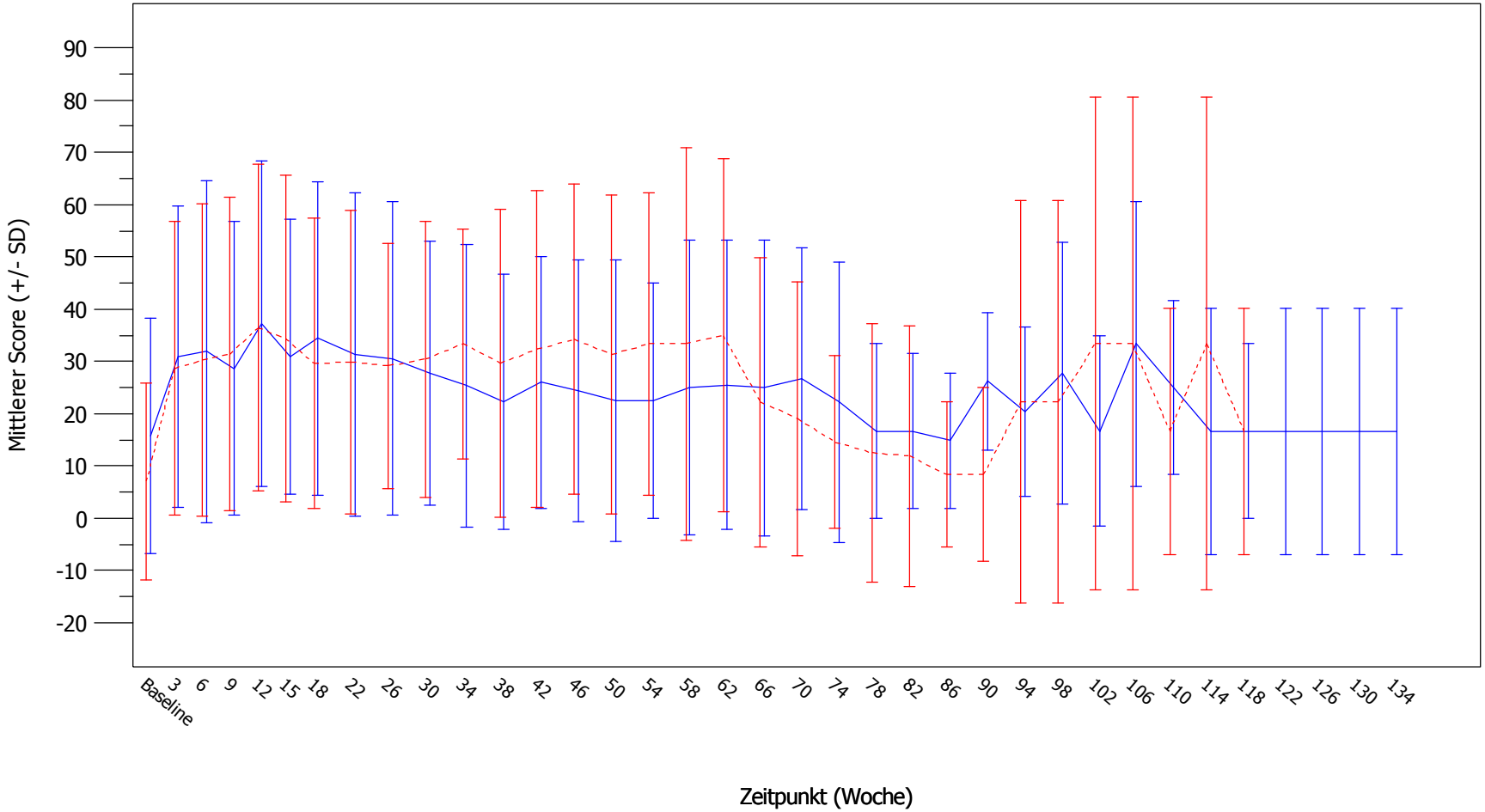
Figure 2.5.2.1.7 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

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

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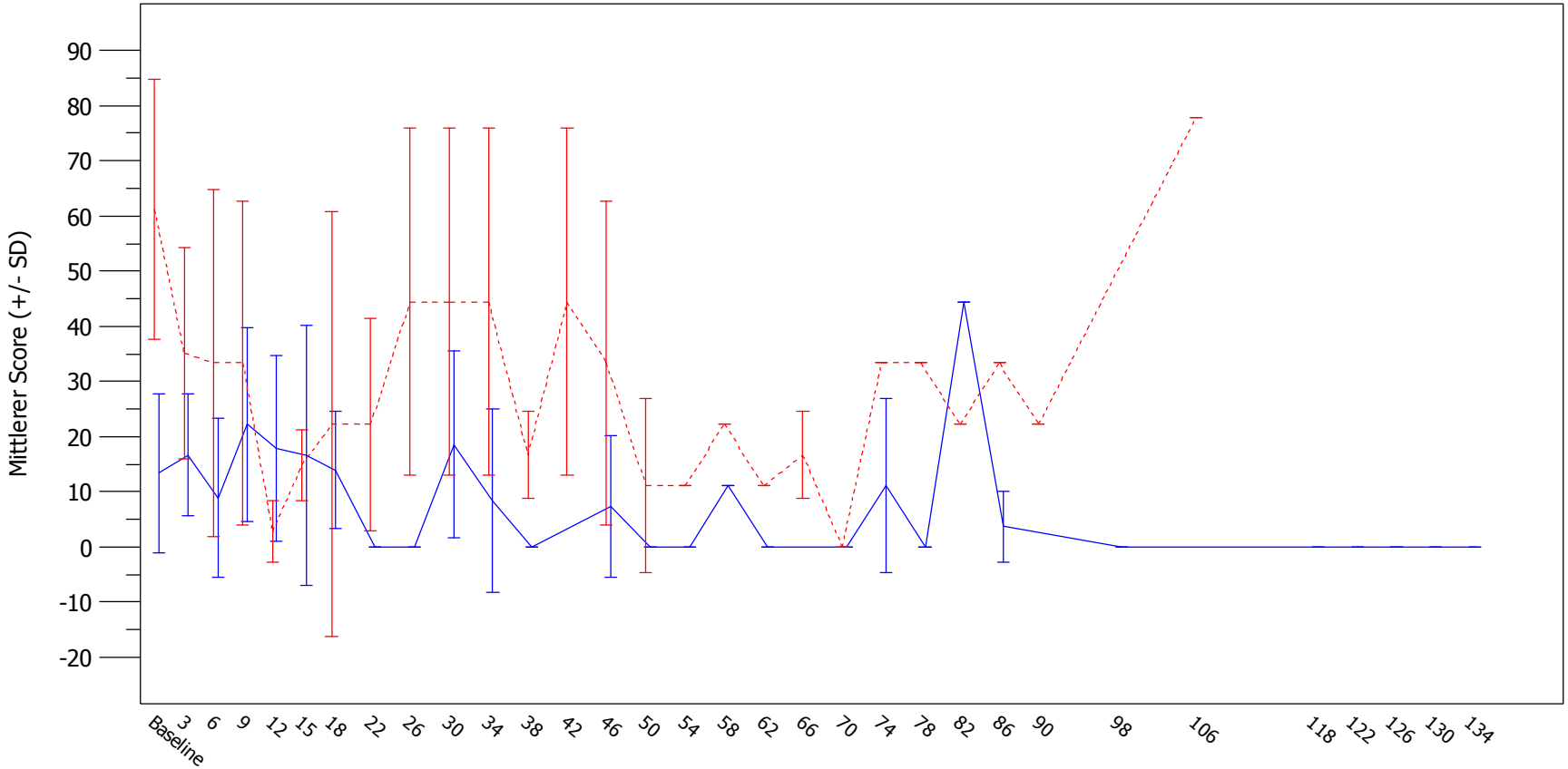
Figure 2.5.2.1.8 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Sexuelle/vaginale Probleme across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

5	4	5	5	5	2	4	1	1	3	4	2	0	3	1	1	1	1	0	2	2	1	1	3	0	1	0	1	1	1	1	1	CTx+Dur.
2	6	2	3	4	3	3	3	2	2	2	2	2	3	2	1	1	1	2	1	1	1	1	1	1	0	1	0	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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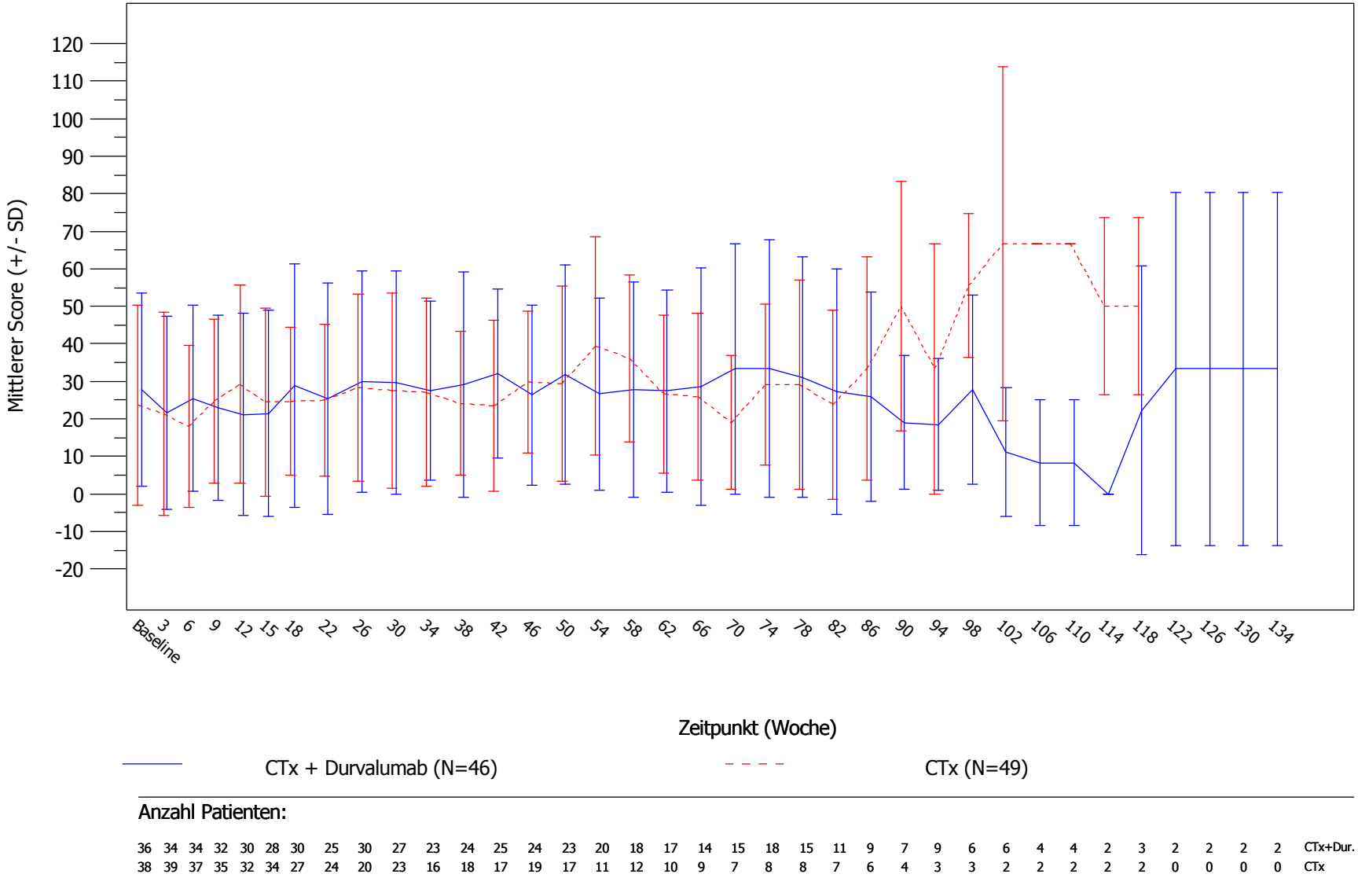
Figure 2.5.2.1.9 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Rücken- und Beckenschmerzen across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

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

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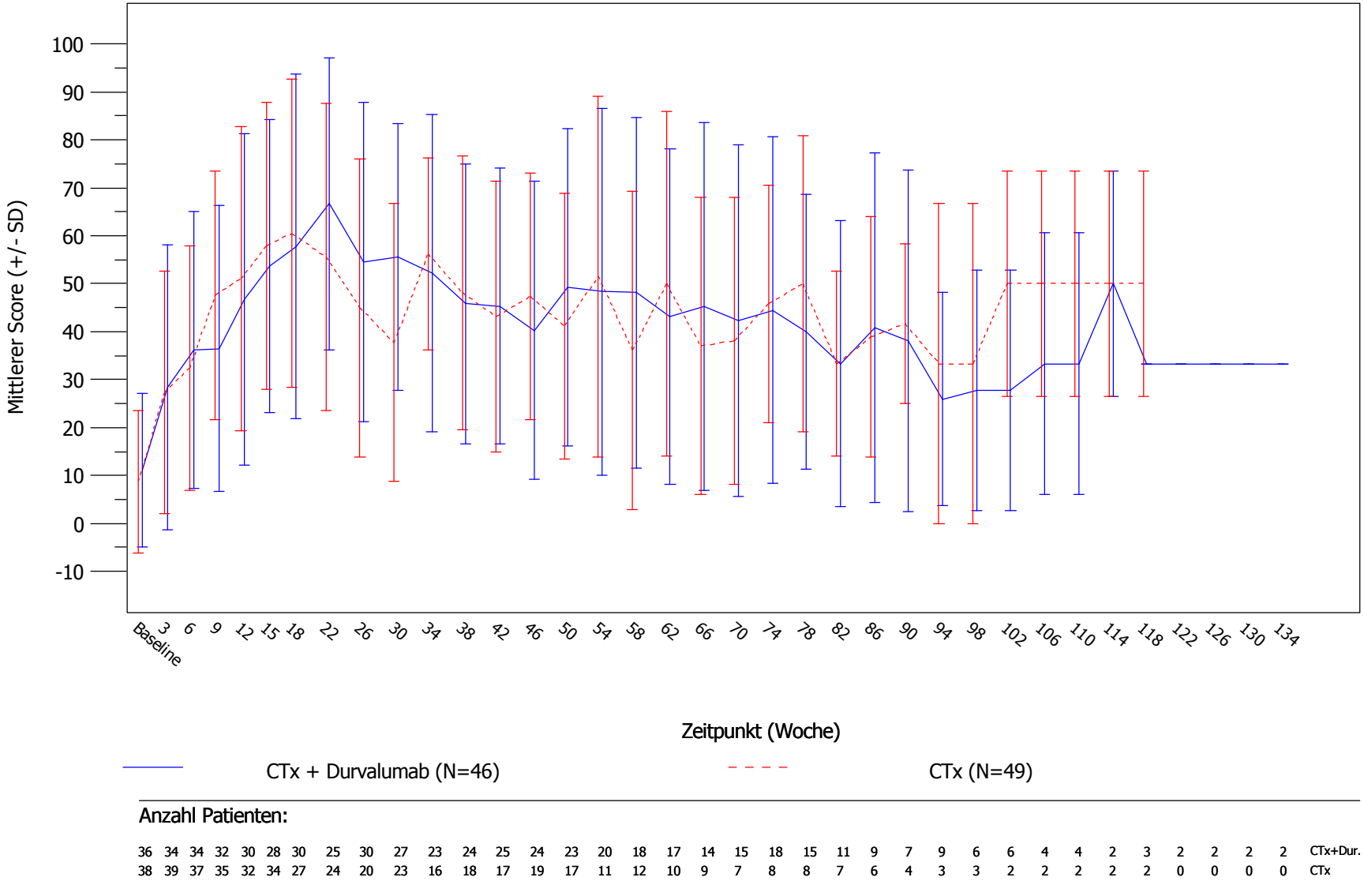
Figure 2.5.2.1.10 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

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

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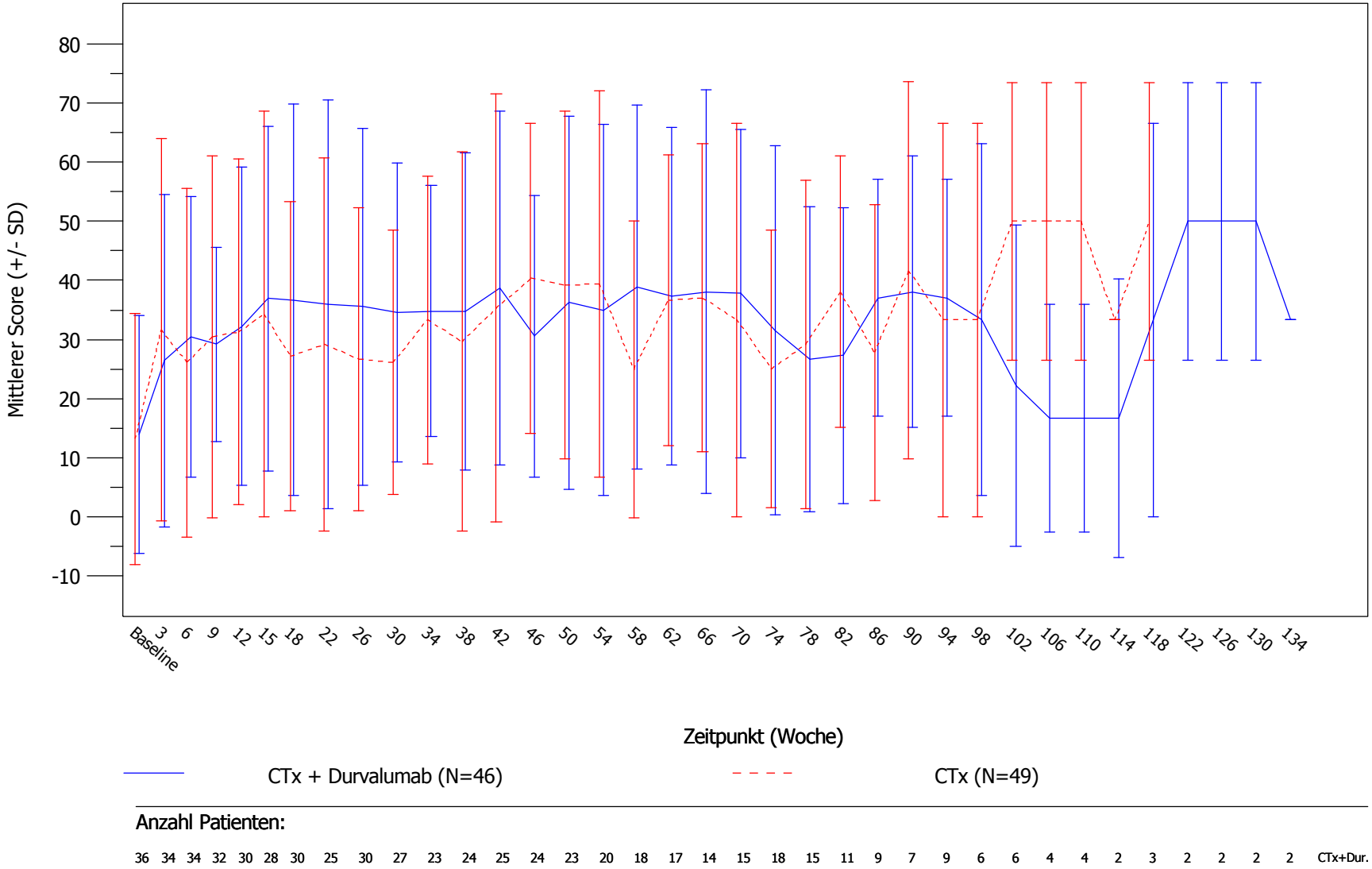
Figure 2.5.2.1.11 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Muskulärer Schmerz across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

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

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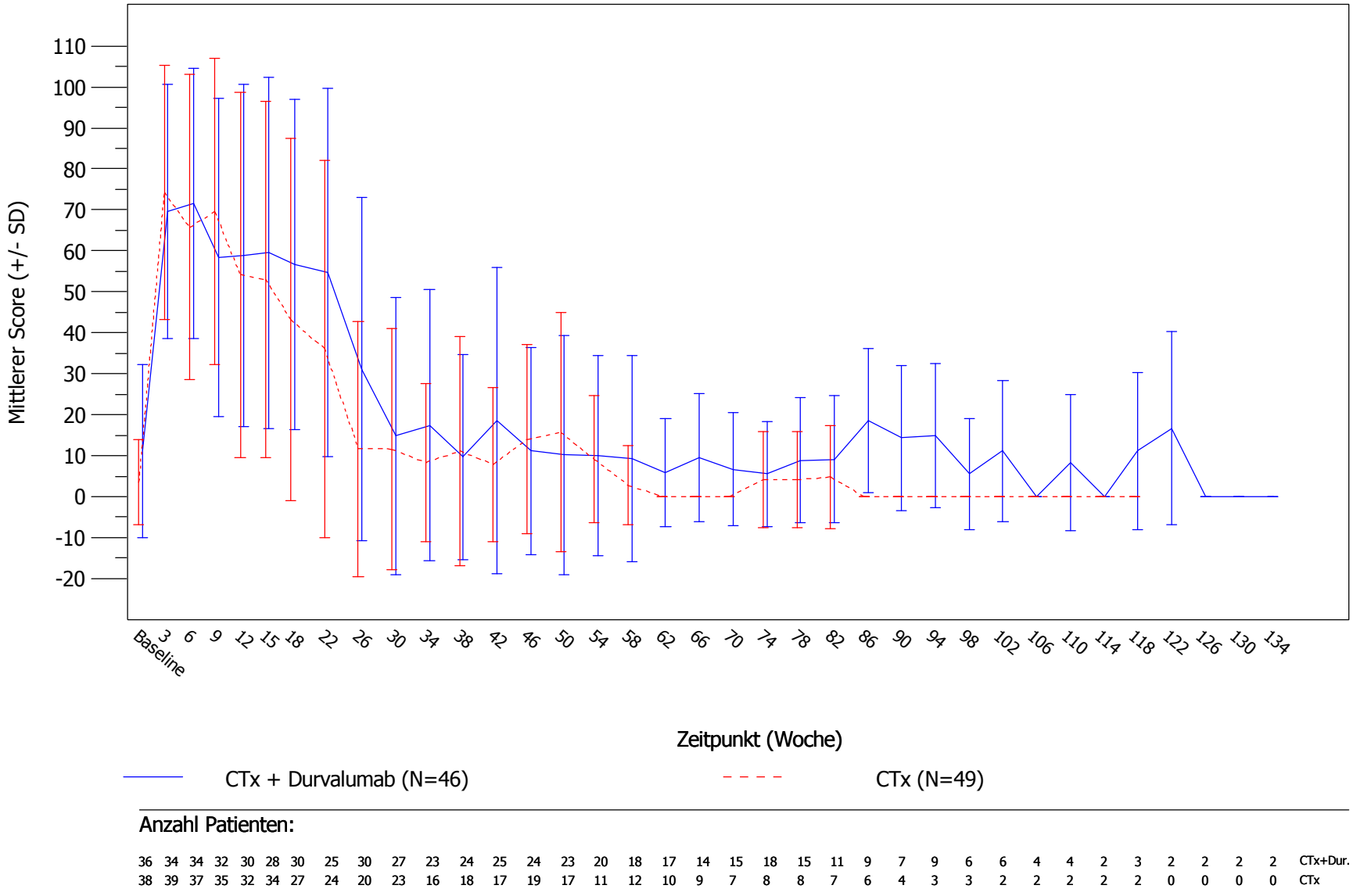
Figure 2.5.2.1.12 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Haarausfall across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

36	34	34	32	30	28	30	25	30	27	23	24	25	24	23	20	18	17	14	15	18	15	11	9	7	9	6	6	4	4	2	3	2	2	2	2	CTx+Dur.
38	39	37	35	32	34	27	24	20	23	16	18	17	19	17	11	12	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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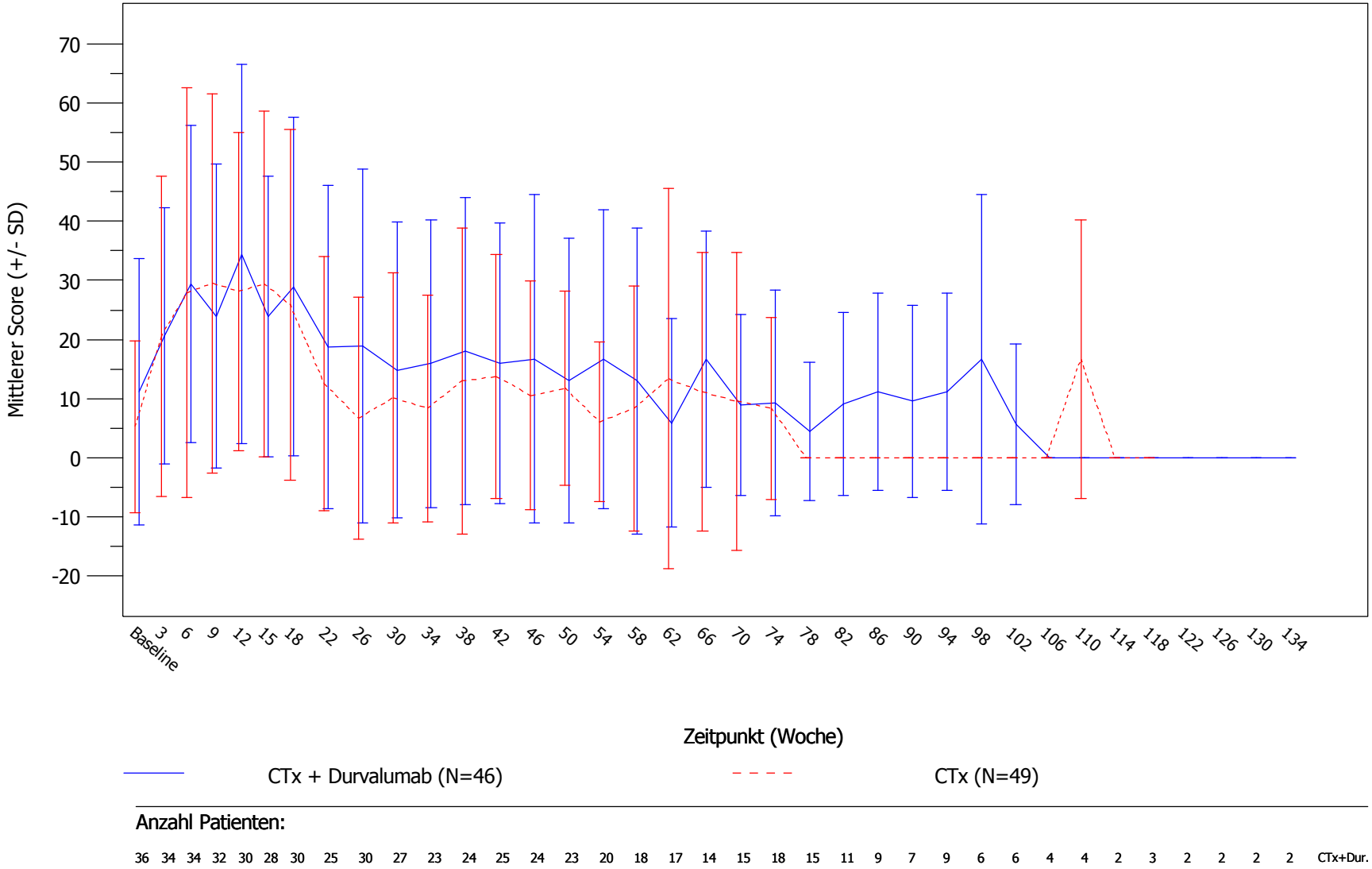
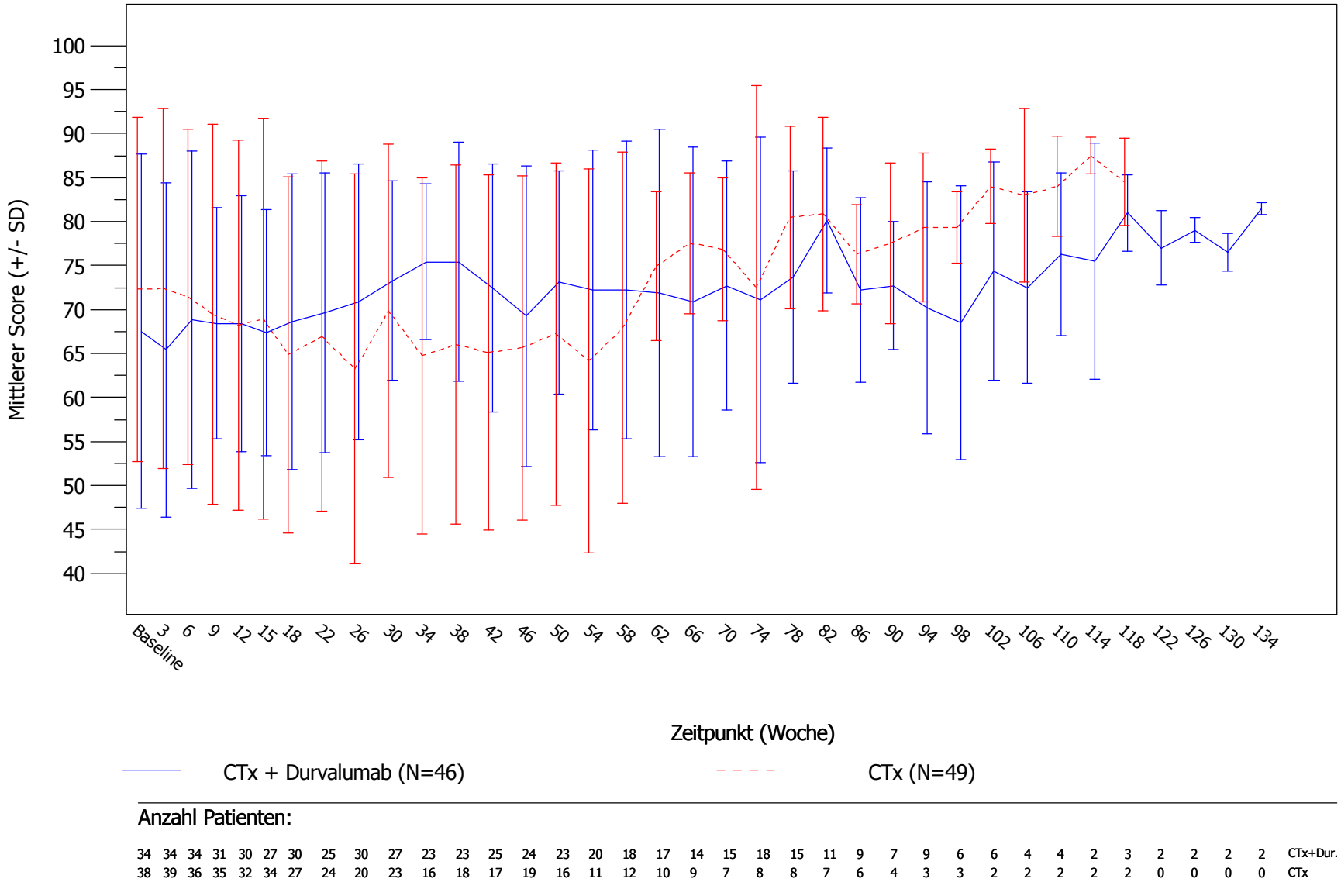
Figure 2.5.2.1.13 DUO-E (dMMR Durva): Mean (+/- SD) plot of EORTC QLQ-EN24 Geschmacksveränderung across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

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

Figure 2.5.3.1.1 DUO-E (dMMR Durva): Mean (+/- SD) plot of EQ-5D-5L Visuelle Analogskala across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



CTx = Carboplatin + Paclitaxel.

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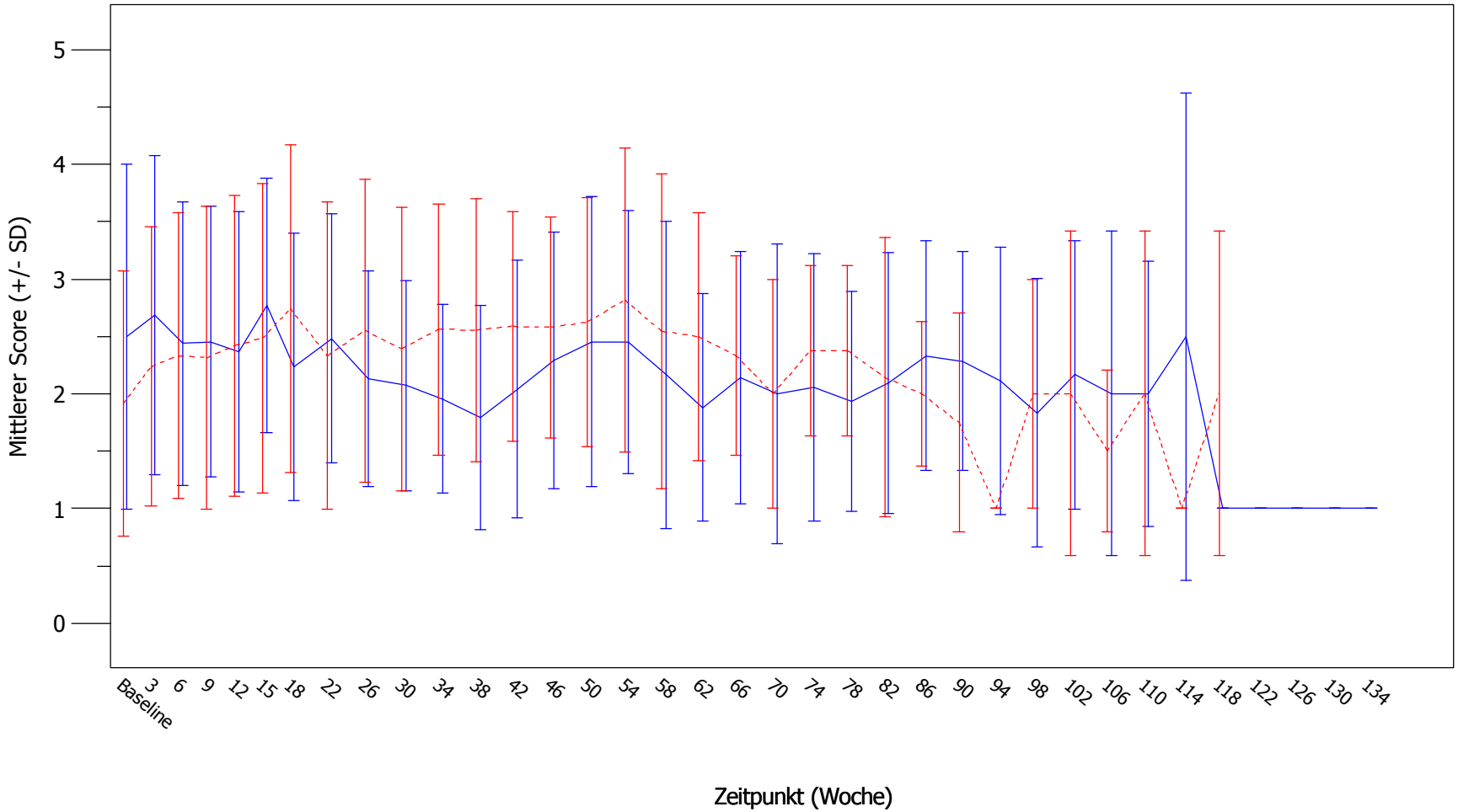
Figure 2.5.4.1.1 DUO-E (dMMR Durva): Mean (+/- SD) plot of PGIS across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

32	35	34	31	30	26	30	25	30	27	23	24	24	24	22	20	18	17	14	15	18	15	11	9	7	9	6	6	4	4	2	3	2	2	2	2	CTx+Dur.
36	38	36	35	31	33	27	24	20	23	16	18	17	19	16	11	11	10	9	7	8	8	7	6	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

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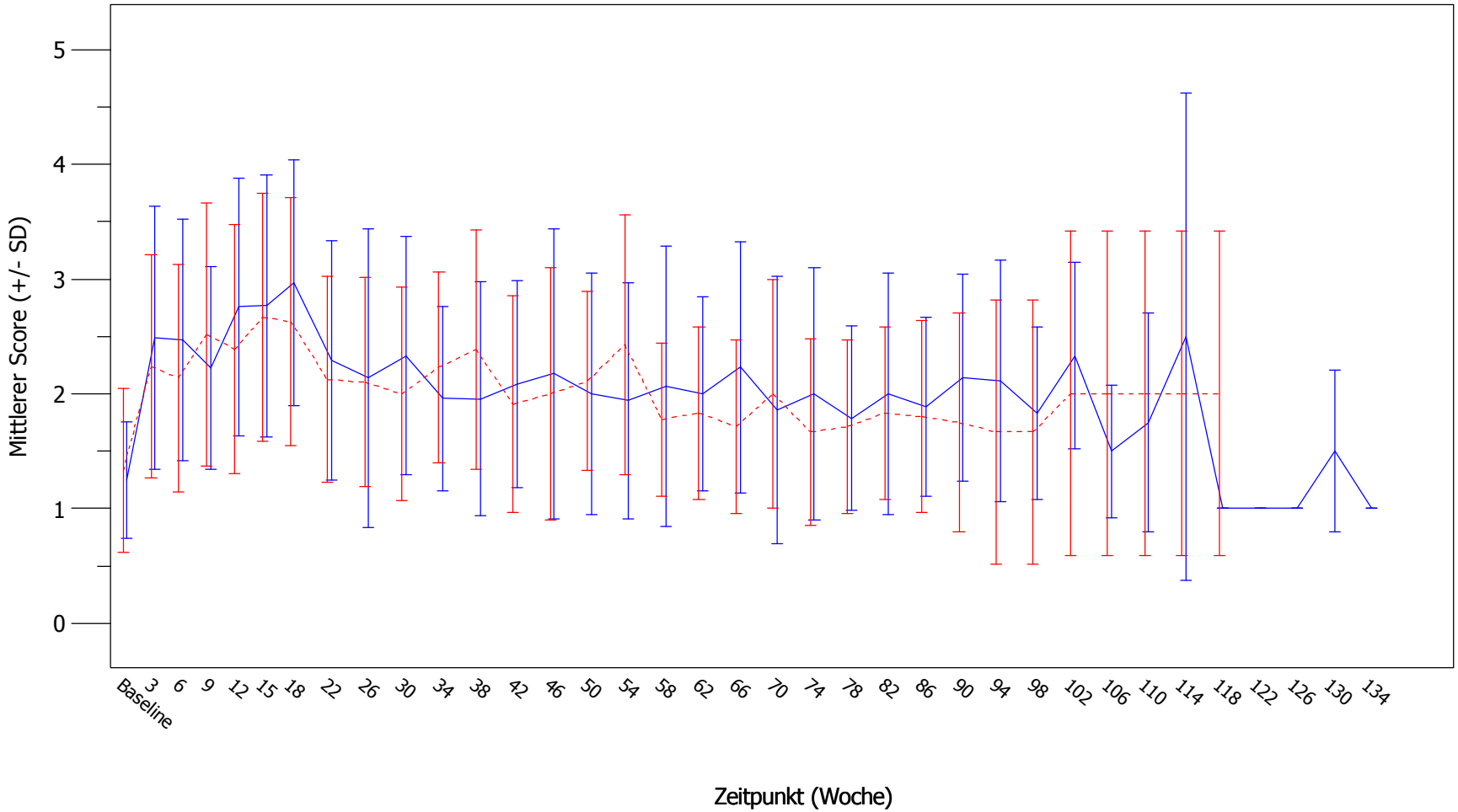
Figure 2.5.5.1.1 DUO-E (dMMR Durva): Mean (+/- SD) plot of PGI-TT across timepoints, by treatment group
Patients with dMMR tumour status, DCO 12APR2023



Anzahl Patienten:

32	35	34	31	29	26	28	24	29	27	24	23	23	23	19	17	15	15	13	14	16	14	10	9	7	9	6	6	4	4	2	3	2	2	2	2	CTx+Dur.
36	38	36	35	31	33	27	24	20	24	13	13	11	11	9	7	9	6	7	5	6	7	6	5	4	3	3	2	2	2	2	2	0	0	0	0	CTx

CTx = Carboplatin + Paclitaxel.

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Allgemeine Lebensqualität/ Gesundheitsszustand	CTx + Durvalumab (N=46)	Baseline	39	65,81	20,394	0,0	66,67	100,0
		Tag 22 (Woche 3)	34	59,80	21,757	0,0	66,67	91,7
		Tag 43 (Woche 6)	36	63,89	17,928	16,7	66,67	100,0
		Tag 64 (Woche 9)	33	64,65	16,006	33,3	66,67	100,0
		Tag 85 (Woche 12)	31	62,10	15,788	33,3	66,67	91,7
		Tag 106 (Woche 15)	28	58,63	16,115	16,7	58,33	83,3
		Tag 127 (Woche 18)	30	58,89	19,930	16,7	62,50	91,7
		Tag 155 (Woche 22)	25	65,00	12,729	50,0	66,67	91,7
		Tag 183 (Woche 26)	30	68,61	13,959	33,3	66,67	91,7
		Tag 211 (Woche 30)	28	68,75	11,255	50,0	66,67	91,7
		Tag 239 (Woche 34)	23	69,57	11,680	33,3	66,67	91,7
		Tag 267 (Woche 38)	25	69,00	13,718	33,3	66,67	91,7
		Tag 295 (Woche 42)	25	70,00	16,492	16,7	66,67	100,0
		Tag 323 (Woche 46)	24	65,63	19,859	16,7	66,67	91,7
		Tag 351 (Woche 50)	23	68,84	13,581	41,7	66,67	91,7
		Tag 379 (Woche 54)	21	69,84	15,916	33,3	66,67	100,0
		Tag 407 (Woche 58)	18	66,20	14,706	33,3	66,67	83,3
		Tag 435 (Woche 62)	17	68,14	16,201	25,0	66,67	91,7
		Tag 463 (Woche 66)	14	67,26	17,439	33,3	66,67	100,0
		Tag 491 (Woche 70)	16	66,15	17,070	33,3	66,67	83,3
		Tag 519 (Woche 74)	18	68,06	14,921	33,3	66,67	83,3
		Tag 547 (Woche 78)	15	73,33	10,541	50,0	75,00	83,3
		Tag 575 (Woche 82)	11	73,48	11,677	58,3	66,67	91,7
		Tag 603 (Woche 86)	9	68,52	11,620	50,0	66,67	83,3
		Tag 631 (Woche 90)	7	69,05	11,501	50,0	66,67	83,3
		Tag 659 (Woche 94)	9	70,37	13,249	50,0	66,67	83,3
		Tag 687 (Woche 98)	6	65,28	20,012	33,3	70,83	83,3
		Tag 715 (Woche 102)	7	72,62	17,156	50,0	66,67	100,0
		Tag 743 (Woche 106)	5	71,67	16,245	50,0	66,67	91,7
		Tag 771 (Woche 110)	4	66,67	13,608	50,0	66,67	83,3
		Tag 799 (Woche 114)	2	75,00	11,785	66,7	75,00	83,3

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Allgemeine Lebensqualität/ Gesundheitsszustand	CTx + Durvalumab (N=46)	Tag 827 (Woche 118)	3	72,22	9,623	66,7	66,67	83,3
		Tag 855 (Woche 122)	2	70,83	5,893	66,7	70,83	75,0
		Tag 883 (Woche 126)	2	70,83	5,893	66,7	70,83	75,0
		Tag 911 (Woche 130)	2	70,83	5,893	66,7	70,83	75,0
		Tag 939 (Woche 134)	2	70,83	5,893	66,7	70,83	75,0
	CTx (N=49)	Baseline	39	72,65	20,586	33,3	66,67	100,0
		Tag 22 (Woche 3)	40	67,08	20,668	16,7	66,67	100,0
		Tag 43 (Woche 6)	38	66,67	21,748	0,0	66,67	100,0
		Tag 64 (Woche 9)	38	66,23	19,370	16,7	66,67	100,0
		Tag 85 (Woche 12)	32	61,72	21,778	8,3	66,67	100,0
		Tag 106 (Woche 15)	35	62,86	23,426	0,0	66,67	100,0
		Tag 127 (Woche 18)	28	62,20	19,041	33,3	66,67	100,0
		Tag 155 (Woche 22)	24	64,58	17,245	33,3	66,67	100,0
		Tag 183 (Woche 26)	20	59,58	18,590	33,3	66,67	100,0
		Tag 211 (Woche 30)	23	65,58	18,685	33,3	66,67	100,0
		Tag 239 (Woche 34)	16	61,98	20,177	16,7	66,67	83,3
		Tag 267 (Woche 38)	18	64,81	21,305	33,3	66,67	100,0
		Tag 295 (Woche 42)	17	56,37	19,439	16,7	66,67	83,3
		Tag 323 (Woche 46)	19	61,40	19,287	16,7	66,67	83,3
		Tag 351 (Woche 50)	17	61,76	18,648	16,7	66,67	83,3
		Tag 379 (Woche 54)	11	59,09	21,231	33,3	66,67	83,3
		Tag 407 (Woche 58)	12	67,36	23,425	16,7	66,67	100,0
		Tag 435 (Woche 62)	10	66,67	11,785	50,0	66,67	83,3
		Tag 463 (Woche 66)	9	74,07	12,805	66,7	66,67	100,0
		Tag 491 (Woche 70)	7	72,62	7,927	66,7	66,67	83,3
		Tag 519 (Woche 74)	8	75,00	13,363	66,7	66,67	100,0
		Tag 547 (Woche 78)	8	72,92	15,269	50,0	66,67	100,0
		Tag 575 (Woche 82)	7	78,57	13,486	66,7	75,00	100,0
		Tag 603 (Woche 86)	6	72,22	6,804	66,7	70,83	83,3
		Tag 631 (Woche 90)	4	62,50	8,333	50,0	66,67	66,7
		Tag 659 (Woche 94)	3	72,22	9,623	66,7	66,67	83,3

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Allgemeine Lebensqualität/ Gesundheitsszustand	CTx (N=49)	Tag 687 (Woche 98)	3	66,67	0,000	66,7	66,67	66,7
		Tag 715 (Woche 102)	2	87,50	5,893	83,3	87,50	91,7
		Tag 743 (Woche 106)	2	75,00	11,785	66,7	75,00	83,3
		Tag 771 (Woche 110)	2	75,00	11,785	66,7	75,00	83,3
		Tag 799 (Woche 114)	2	83,33	0,000	83,3	83,33	83,3
		Tag 827 (Woche 118)	2	75,00	11,785	66,7	75,00	83,3
EORTC QLQ-C30 Funktionsskala: Körper	CTx + Durvalumab (N=46)	Baseline	39	75,90	15,568	33,3	73,33	100,0
		Tag 22 (Woche 3)	34	74,71	21,573	0,0	80,00	100,0
		Tag 43 (Woche 6)	36	77,04	17,490	20,0	80,00	100,0
		Tag 64 (Woche 9)	33	75,35	18,142	33,3	80,00	100,0
		Tag 85 (Woche 12)	31	73,12	19,738	33,3	80,00	100,0
		Tag 106 (Woche 15)	28	69,76	21,734	26,7	70,00	100,0
		Tag 127 (Woche 18)	30	72,89	16,230	33,3	76,67	100,0
		Tag 155 (Woche 22)	25	74,67	15,753	40,0	73,33	100,0
		Tag 183 (Woche 26)	30	71,56	21,792	26,7	73,33	100,0
		Tag 211 (Woche 30)	28	77,62	14,540	40,0	76,67	100,0
		Tag 239 (Woche 34)	23	77,97	13,697	46,7	80,00	100,0
		Tag 267 (Woche 38)	25	82,67	14,272	46,7	86,67	100,0
		Tag 295 (Woche 42)	25	76,53	18,770	40,0	80,00	100,0
		Tag 323 (Woche 46)	24	77,50	20,507	13,3	80,00	100,0
		Tag 351 (Woche 50)	23	79,71	19,225	26,7	80,00	100,0
		Tag 379 (Woche 54)	21	77,78	15,251	46,7	80,00	100,0
		Tag 407 (Woche 58)	18	78,52	18,514	40,0	80,00	100,0
		Tag 435 (Woche 62)	17	79,61	20,203	33,3	86,67	100,0
		Tag 463 (Woche 66)	14	79,52	21,636	33,3	93,33	100,0
		Tag 491 (Woche 70)	16	76,67	23,727	20,0	86,67	100,0
		Tag 519 (Woche 74)	18	80,00	20,195	33,3	83,33	100,0
		Tag 547 (Woche 78)	15	81,33	18,890	33,3	86,67	100,0
		Tag 575 (Woche 82)	11	73,94	24,121	40,0	66,67	100,0
		Tag 603 (Woche 86)	9	74,07	19,277	40,0	73,33	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Körper	CTx + Durvalumab (N=46)	Tag 631 (Woche 90)	7	76,19	24,603	33,3	80,00	100,0
		Tag 659 (Woche 94)	9	80,00	20,548	46,7	86,67	100,0
		Tag 687 (Woche 98)	6	85,56	14,857	66,7	93,33	100,0
		Tag 715 (Woche 102)	7	82,86	22,724	40,0	93,33	100,0
		Tag 743 (Woche 106)	5	81,33	24,676	40,0	86,67	100,0
		Tag 771 (Woche 110)	4	78,33	39,016	20,0	96,67	100,0
		Tag 799 (Woche 114)	2	76,67	32,998	53,3	76,67	100,0
		Tag 827 (Woche 118)	3	97,78	3,849	93,3	100,00	100,0
		Tag 855 (Woche 122)	2	96,67	4,714	93,3	96,67	100,0
		Tag 883 (Woche 126)	2	96,67	4,714	93,3	96,67	100,0
		Tag 911 (Woche 130)	2	96,67	4,714	93,3	96,67	100,0
		Tag 939 (Woche 134)	2	96,67	4,714	93,3	96,67	100,0
	CTx (N=49)	Baseline	39	84,96	14,406	53,3	86,67	100,0
		Tag 22 (Woche 3)	40	78,67	20,711	20,0	86,67	100,0
		Tag 43 (Woche 6)	38	77,02	20,251	26,7	86,67	100,0
		Tag 64 (Woche 9)	38	73,16	23,275	6,7	80,00	100,0
		Tag 85 (Woche 12)	32	71,25	24,093	6,7	76,67	100,0
		Tag 106 (Woche 15)	35	69,71	24,218	13,3	80,00	100,0
		Tag 127 (Woche 18)	28	68,81	23,451	13,3	73,33	100,0
		Tag 155 (Woche 22)	24	77,50	15,704	46,7	80,00	100,0
		Tag 183 (Woche 26)	20	71,67	21,398	26,7	73,33	100,0
		Tag 211 (Woche 30)	23	76,81	18,408	33,3	80,00	100,0
		Tag 239 (Woche 34)	16	75,42	19,584	26,7	73,33	100,0
		Tag 267 (Woche 38)	18	75,19	19,377	33,3	73,33	100,0
		Tag 295 (Woche 42)	17	75,29	17,914	33,3	73,33	100,0
		Tag 323 (Woche 46)	19	77,89	16,033	46,7	80,00	100,0
		Tag 351 (Woche 50)	17	74,90	15,189	53,3	73,33	100,0
		Tag 379 (Woche 54)	11	73,94	16,721	40,0	73,33	100,0
		Tag 407 (Woche 58)	12	81,67	16,606	46,7	80,00	100,0
		Tag 435 (Woche 62)	10	79,33	15,854	60,0	76,67	100,0
		Tag 463 (Woche 66)	9	83,70	16,025	66,7	80,00	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Körper	CTx (N=49)	Tag 491 (Woche 70)	7	86,67	13,878	66,7	86,67	100,0
		Tag 519 (Woche 74)	8	84,17	13,773	60,0	83,33	100,0
		Tag 547 (Woche 78)	8	90,00	11,269	73,3	93,33	100,0
		Tag 575 (Woche 82)	7	88,57	12,599	66,7	86,67	100,0
		Tag 603 (Woche 86)	6	87,78	11,483	73,3	86,67	100,0
		Tag 631 (Woche 90)	4	83,33	11,547	73,3	80,00	100,0
		Tag 659 (Woche 94)	3	86,67	13,333	73,3	86,67	100,0
		Tag 687 (Woche 98)	3	84,44	16,777	66,7	86,67	100,0
		Tag 715 (Woche 102)	2	86,67	18,856	73,3	86,67	100,0
		Tag 743 (Woche 106)	2	86,67	18,856	73,3	86,67	100,0
		Tag 771 (Woche 110)	2	86,67	18,856	73,3	86,67	100,0
		Tag 799 (Woche 114)	2	86,67	18,856	73,3	86,67	100,0
		Tag 827 (Woche 118)	2	86,67	18,856	73,3	86,67	100,0
EORTC QLQ-C30 Funktionsskala: Rolle	CTx + Durvalumab (N=46)	Baseline	39	74,36	22,571	16,7	83,33	100,0
		Tag 22 (Woche 3)	34	75,49	26,665	0,0	75,00	100,0
		Tag 43 (Woche 6)	36	73,61	23,696	0,0	75,00	100,0
		Tag 64 (Woche 9)	33	71,72	21,034	33,3	66,67	100,0
		Tag 85 (Woche 12)	31	70,43	21,391	33,3	66,67	100,0
		Tag 106 (Woche 15)	28	64,29	29,991	0,0	66,67	100,0
		Tag 127 (Woche 18)	30	67,78	25,496	0,0	66,67	100,0
		Tag 155 (Woche 22)	25	68,00	25,874	0,0	66,67	100,0
		Tag 183 (Woche 26)	30	67,78	29,664	0,0	66,67	100,0
		Tag 211 (Woche 30)	28	75,00	23,787	33,3	75,00	100,0
		Tag 239 (Woche 34)	23	78,99	23,147	33,3	83,33	100,0
		Tag 267 (Woche 38)	25	78,67	25,694	0,0	83,33	100,0
		Tag 295 (Woche 42)	25	77,33	25,404	0,0	83,33	100,0
		Tag 323 (Woche 46)	24	78,47	24,316	16,7	83,33	100,0
		Tag 351 (Woche 50)	23	80,43	23,917	16,7	83,33	100,0
		Tag 379 (Woche 54)	21	74,60	21,486	33,3	66,67	100,0
		Tag 407 (Woche 58)	18	79,63	23,952	33,3	91,67	100,0
		Tag 435 (Woche 62)	17	79,41	27,969	0,0	83,33	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Rolle	CTx + Durvalumab (N=46)	Tag 463 (Woche 66)	14	79,76	27,872	0,0	91,67	100,0
		Tag 491 (Woche 70)	16	83,33	26,527	0,0	100,00	100,0
		Tag 519 (Woche 74)	18	79,63	23,952	16,7	83,33	100,0
		Tag 547 (Woche 78)	15	83,33	20,893	33,3	100,00	100,0
		Tag 575 (Woche 82)	11	80,30	24,516	33,3	100,00	100,0
		Tag 603 (Woche 86)	9	77,78	22,048	33,3	83,33	100,0
		Tag 631 (Woche 90)	7	83,33	25,459	33,3	100,00	100,0
		Tag 659 (Woche 94)	9	79,63	23,241	33,3	83,33	100,0
		Tag 687 (Woche 98)	6	91,67	13,944	66,7	100,00	100,0
		Tag 715 (Woche 102)	7	85,71	26,227	33,3	100,00	100,0
		Tag 743 (Woche 106)	5	86,67	29,814	33,3	100,00	100,0
		Tag 771 (Woche 110)	4	83,33	33,333	33,3	100,00	100,0
		Tag 799 (Woche 114)	2	66,67	47,140	33,3	66,67	100,0
		Tag 827 (Woche 118)	3	100,00	0,000	100,0	100,00	100,0
		Tag 855 (Woche 122)	2	100,00	0,000	100,0	100,00	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
	CTx (N=49)	Baseline	39	81,62	24,120	0,0	83,33	100,0
		Tag 22 (Woche 3)	40	71,25	27,987	0,0	66,67	100,0
		Tag 43 (Woche 6)	38	75,88	26,761	0,0	83,33	100,0
		Tag 64 (Woche 9)	38	71,05	30,923	0,0	66,67	100,0
		Tag 85 (Woche 12)	32	69,79	28,220	0,0	66,67	100,0
		Tag 106 (Woche 15)	35	69,52	28,147	0,0	66,67	100,0
		Tag 127 (Woche 18)	28	61,31	30,447	0,0	66,67	100,0
		Tag 155 (Woche 22)	24	76,39	23,008	0,0	66,67	100,0
		Tag 183 (Woche 26)	20	65,83	29,357	0,0	66,67	100,0
		Tag 211 (Woche 30)	23	75,36	27,920	0,0	66,67	100,0
		Tag 239 (Woche 34)	16	70,83	29,502	0,0	66,67	100,0
		Tag 267 (Woche 38)	18	70,37	29,459	0,0	66,67	100,0
		Tag 295 (Woche 42)	17	69,61	27,154	16,7	66,67	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Rolle	CTx (N=49)	Tag 323 (Woche 46)	19	72,81	20,943	33,3	66,67	100,0
		Tag 351 (Woche 50)	17	66,67	19,543	33,3	66,67	100,0
		Tag 379 (Woche 54)	11	65,15	21,672	33,3	66,67	100,0
		Tag 407 (Woche 58)	12	79,17	29,409	33,3	100,00	100,0
		Tag 435 (Woche 62)	10	75,00	21,155	33,3	66,67	100,0
		Tag 463 (Woche 66)	9	79,63	20,031	50,0	66,67	100,0
		Tag 491 (Woche 70)	7	85,71	26,227	33,3	100,00	100,0
		Tag 519 (Woche 74)	8	83,33	25,198	33,3	100,00	100,0
		Tag 547 (Woche 78)	8	81,25	24,296	33,3	91,67	100,0
		Tag 575 (Woche 82)	7	92,86	13,113	66,7	100,00	100,0
		Tag 603 (Woche 86)	6	83,33	18,257	66,7	83,33	100,0
		Tag 631 (Woche 90)	4	79,17	25,000	50,0	83,33	100,0
		Tag 659 (Woche 94)	3	77,78	38,490	33,3	100,00	100,0
		Tag 687 (Woche 98)	3	77,78	38,490	33,3	100,00	100,0
		Tag 715 (Woche 102)	2	83,33	23,570	66,7	83,33	100,0
		Tag 743 (Woche 106)	2	83,33	23,570	66,7	83,33	100,0
		Tag 771 (Woche 110)	2	66,67	47,140	33,3	66,67	100,0
		Tag 799 (Woche 114)	2	75,00	35,355	50,0	75,00	100,0
		Tag 827 (Woche 118)	2	66,67	47,140	33,3	66,67	100,0
EORTC QLQ-C30 Funktionsskala: Emotionalität	CTx + Durvalumab (N=46)	Baseline	39	70,30	18,515	25,0	75,00	100,0
		Tag 22 (Woche 3)	34	71,57	21,528	16,7	75,00	100,0
		Tag 43 (Woche 6)	36	76,16	21,561	16,7	75,00	100,0
		Tag 64 (Woche 9)	33	77,78	21,109	8,3	83,33	100,0
		Tag 85 (Woche 12)	31	78,49	15,332	41,7	83,33	100,0
		Tag 106 (Woche 15)	28	72,62	21,016	25,0	75,00	100,0
		Tag 127 (Woche 18)	30	77,78	18,222	41,7	79,17	100,0
		Tag 155 (Woche 22)	25	78,33	18,002	50,0	83,33	100,0
		Tag 183 (Woche 26)	30	74,44	25,327	25,0	83,33	100,0
		Tag 211 (Woche 30)	28	75,89	21,196	33,3	79,17	100,0
		Tag 239 (Woche 34)	23	79,35	18,096	41,7	83,33	100,0
		Tag 267 (Woche 38)	25	78,00	19,526	50,0	83,33	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Emotionalität	CTx + Durvalumab (N=46)	Tag 295 (Woche 42)	25	70,67	24,664	33,3	83,33	100,0
		Tag 323 (Woche 46)	24	69,79	26,559	25,0	79,17	100,0
		Tag 351 (Woche 50)	23	71,38	24,208	16,7	66,67	100,0
		Tag 379 (Woche 54)	21	67,06	21,807	8,3	75,00	100,0
		Tag 407 (Woche 58)	18	69,91	26,374	8,3	79,17	100,0
		Tag 435 (Woche 62)	17	78,92	19,121	33,3	83,33	100,0
		Tag 463 (Woche 66)	14	75,00	24,460	8,3	79,17	100,0
		Tag 491 (Woche 70)	16	72,40	25,408	16,7	79,17	100,0
		Tag 519 (Woche 74)	18	77,31	23,010	25,0	79,17	100,0
		Tag 547 (Woche 78)	15	78,33	14,365	58,3	75,00	100,0
		Tag 575 (Woche 82)	11	77,27	15,851	58,3	66,67	100,0
		Tag 603 (Woche 86)	9	76,85	19,886	50,0	75,00	100,0
		Tag 631 (Woche 90)	7	75,00	18,002	58,3	66,67	100,0
		Tag 659 (Woche 94)	9	77,78	16,137	50,0	83,33	100,0
		Tag 687 (Woche 98)	6	79,17	20,917	50,0	79,17	100,0
		Tag 715 (Woche 102)	7	85,71	14,996	66,7	83,33	100,0
		Tag 743 (Woche 106)	5	78,33	20,069	58,3	66,67	100,0
		Tag 771 (Woche 110)	4	83,33	19,245	66,7	83,33	100,0
		Tag 799 (Woche 114)	2	100,00	0,000	100,0	100,00	100,0
		Tag 827 (Woche 118)	3	91,67	14,434	75,0	100,00	100,0
		Tag 855 (Woche 122)	2	83,33	23,570	66,7	83,33	100,0
		Tag 883 (Woche 126)	2	87,50	17,678	75,0	87,50	100,0
		Tag 911 (Woche 130)	2	79,17	29,463	58,3	79,17	100,0
		Tag 939 (Woche 134)	2	83,33	23,570	66,7	83,33	100,0
	CTx (N=49)	Baseline	39	77,78	17,452	33,3	83,33	100,0
		Tag 22 (Woche 3)	40	81,87	17,489	25,0	83,33	100,0
		Tag 43 (Woche 6)	38	79,82	16,283	25,0	83,33	100,0
		Tag 64 (Woche 9)	38	79,82	24,708	0,0	83,33	100,0
		Tag 85 (Woche 12)	32	81,51	21,454	8,3	83,33	100,0
		Tag 106 (Woche 15)	35	78,33	21,409	16,7	75,00	100,0
		Tag 127 (Woche 18)	28	78,57	21,687	25,0	83,33	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Emotionalität	CTx (N=49)	Tag 155 (Woche 22)	24	80,56	17,663	41,7	83,33	100,0
		Tag 183 (Woche 26)	20	75,00	21,116	16,7	75,00	100,0
		Tag 211 (Woche 30)	23	78,62	19,916	33,3	75,00	100,0
		Tag 239 (Woche 34)	16	77,60	22,917	25,0	79,17	100,0
		Tag 267 (Woche 38)	18	75,93	19,780	25,0	75,00	100,0
		Tag 295 (Woche 42)	17	78,92	17,460	33,3	75,00	100,0
		Tag 323 (Woche 46)	19	73,68	18,894	33,3	75,00	100,0
		Tag 351 (Woche 50)	17	78,92	18,427	41,7	75,00	100,0
		Tag 379 (Woche 54)	11	76,52	15,284	58,3	75,00	100,0
		Tag 407 (Woche 58)	12	84,72	17,707	58,3	95,83	100,0
		Tag 435 (Woche 62)	10	79,17	18,530	41,7	79,17	100,0
		Tag 463 (Woche 66)	9	80,56	23,570	33,3	83,33	100,0
		Tag 491 (Woche 70)	7	80,95	24,398	50,0	100,00	100,0
		Tag 519 (Woche 74)	8	87,50	17,252	66,7	100,00	100,0
		Tag 547 (Woche 78)	8	89,58	13,176	66,7	95,83	100,0
		Tag 575 (Woche 82)	7	90,48	12,199	66,7	91,67	100,0
		Tag 603 (Woche 86)	6	88,89	16,387	58,3	95,83	100,0
		Tag 631 (Woche 90)	4	83,33	19,245	66,7	83,33	100,0
		Tag 659 (Woche 94)	3	88,89	19,245	66,7	100,00	100,0
		Tag 687 (Woche 98)	3	88,89	19,245	66,7	100,00	100,0
		Tag 715 (Woche 102)	2	83,33	23,570	66,7	83,33	100,0
		Tag 743 (Woche 106)	2	66,67	47,140	33,3	66,67	100,0
		Tag 771 (Woche 110)	2	83,33	23,570	66,7	83,33	100,0
		Tag 799 (Woche 114)	2	83,33	23,570	66,7	83,33	100,0
		Tag 827 (Woche 118)	2	83,33	23,570	66,7	83,33	100,0
EORTC QLQ-C30 Funktionsskala: Kognition	CTx + Durvalumab (N=46)	Baseline	39	85,90	15,550	50,0	83,33	100,0
		Tag 22 (Woche 3)	34	80,88	16,983	33,3	83,33	100,0
		Tag 43 (Woche 6)	36	80,09	17,737	16,7	83,33	100,0
		Tag 64 (Woche 9)	33	80,81	18,690	33,3	83,33	100,0
		Tag 85 (Woche 12)	31	80,11	17,437	33,3	83,33	100,0
		Tag 106 (Woche 15)	28	73,81	22,420	33,3	83,33	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Kognition	CTx + Durvalumab (N=46)	Tag 127 (Woche 18)	30	77,78	20,684	16,7	83,33	100,0
		Tag 155 (Woche 22)	25	75,33	18,708	33,3	66,67	100,0
		Tag 183 (Woche 26)	30	72,22	23,298	0,0	83,33	100,0
		Tag 211 (Woche 30)	28	76,19	19,473	33,3	66,67	100,0
		Tag 239 (Woche 34)	23	75,36	17,313	50,0	66,67	100,0
		Tag 267 (Woche 38)	25	76,67	19,245	33,3	83,33	100,0
		Tag 295 (Woche 42)	25	78,00	18,459	33,3	83,33	100,0
		Tag 323 (Woche 46)	24	73,61	23,008	16,7	66,67	100,0
		Tag 351 (Woche 50)	23	71,01	20,237	16,7	66,67	100,0
		Tag 379 (Woche 54)	21	69,05	24,316	0,0	66,67	100,0
		Tag 407 (Woche 58)	18	72,22	18,078	33,3	66,67	100,0
		Tag 435 (Woche 62)	17	75,49	16,789	50,0	66,67	100,0
		Tag 463 (Woche 66)	14	84,52	13,812	66,7	83,33	100,0
		Tag 491 (Woche 70)	16	79,17	17,743	50,0	83,33	100,0
		Tag 519 (Woche 74)	18	74,07	21,559	33,3	66,67	100,0
		Tag 547 (Woche 78)	15	78,89	14,729	50,0	83,33	100,0
		Tag 575 (Woche 82)	11	83,33	16,667	66,7	83,33	100,0
		Tag 603 (Woche 86)	9	79,63	18,215	50,0	83,33	100,0
		Tag 631 (Woche 90)	7	78,57	12,599	66,7	83,33	100,0
		Tag 659 (Woche 94)	9	85,19	15,466	66,7	83,33	100,0
		Tag 687 (Woche 98)	6	83,33	14,907	66,7	83,33	100,0
		Tag 715 (Woche 102)	7	90,48	13,113	66,7	100,00	100,0
		Tag 743 (Woche 106)	5	93,33	9,129	83,3	100,00	100,0
		Tag 771 (Woche 110)	4	95,83	8,333	83,3	100,00	100,0
		Tag 799 (Woche 114)	2	83,33	23,570	66,7	83,33	100,0
		Tag 827 (Woche 118)	3	88,89	19,245	66,7	100,00	100,0
		Tag 855 (Woche 122)	2	83,33	23,570	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	75,00	11,785	66,7	75,00	83,3
		Tag 939 (Woche 134)	2	83,33	23,570	66,7	83,33	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Kognition	CTx (N=49)	Baseline	39	86,32	15,706	50,0	83,33	100,0
		Tag 22 (Woche 3)	40	87,92	19,607	16,7	100,00	100,0
		Tag 43 (Woche 6)	38	85,09	16,343	33,3	83,33	100,0
		Tag 64 (Woche 9)	38	79,82	20,562	0,0	83,33	100,0
		Tag 85 (Woche 12)	32	82,29	17,929	33,3	83,33	100,0
		Tag 106 (Woche 15)	35	81,43	16,554	33,3	83,33	100,0
		Tag 127 (Woche 18)	28	77,38	15,853	33,3	75,00	100,0
		Tag 155 (Woche 22)	24	85,42	12,348	66,7	83,33	100,0
		Tag 183 (Woche 26)	20	81,67	17,853	50,0	83,33	100,0
		Tag 211 (Woche 30)	23	83,33	15,891	50,0	83,33	100,0
		Tag 239 (Woche 34)	16	83,33	14,907	50,0	83,33	100,0
		Tag 267 (Woche 38)	18	75,93	17,360	50,0	75,00	100,0
		Tag 295 (Woche 42)	17	79,41	15,057	50,0	83,33	100,0
		Tag 323 (Woche 46)	19	82,46	15,188	50,0	83,33	100,0
		Tag 351 (Woche 50)	17	82,35	13,782	66,7	83,33	100,0
		Tag 379 (Woche 54)	11	78,79	19,848	33,3	83,33	100,0
		Tag 407 (Woche 58)	12	88,89	16,412	50,0	100,00	100,0
		Tag 435 (Woche 62)	10	80,00	17,213	50,0	83,33	100,0
		Tag 463 (Woche 66)	9	88,89	16,667	50,0	100,00	100,0
		Tag 491 (Woche 70)	7	88,10	18,545	50,0	100,00	100,0
		Tag 519 (Woche 74)	8	85,42	16,517	50,0	83,33	100,0
		Tag 547 (Woche 78)	8	87,50	17,252	50,0	91,67	100,0
		Tag 575 (Woche 82)	7	90,48	13,113	66,7	100,00	100,0
		Tag 603 (Woche 86)	6	86,11	12,546	66,7	83,33	100,0
		Tag 631 (Woche 90)	4	87,50	15,957	66,7	91,67	100,0
		Tag 659 (Woche 94)	3	88,89	9,623	83,3	83,33	100,0
		Tag 687 (Woche 98)	3	94,44	9,623	83,3	100,00	100,0
		Tag 715 (Woche 102)	2	91,67	11,785	83,3	91,67	100,0
		Tag 743 (Woche 106)	2	91,67	11,785	83,3	91,67	100,0
		Tag 771 (Woche 110)	2	91,67	11,785	83,3	91,67	100,0
		Tag 799 (Woche 114)	2	83,33	0,000	83,3	83,33	83,3

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Kognition	CTx (N=49)	Tag 827 (Woche 118)	2	100,00	0,000	100,0	100,00	100,0
EORTC QLQ-C30 Funktionsskala: Sozial	CTx + Durvalumab (N=46)	Baseline	39	71,79	21,681	33,3	66,67	100,0
		Tag 22 (Woche 3)	34	69,12	29,908	0,0	66,67	100,0
		Tag 43 (Woche 6)	36	74,07	23,719	16,7	83,33	100,0
		Tag 64 (Woche 9)	33	77,78	22,695	0,0	83,33	100,0
		Tag 85 (Woche 12)	31	73,12	21,806	33,3	66,67	100,0
		Tag 106 (Woche 15)	28	67,86	27,190	0,0	66,67	100,0
		Tag 127 (Woche 18)	30	66,11	27,152	0,0	66,67	100,0
		Tag 155 (Woche 22)	25	74,00	25,945	16,7	83,33	100,0
		Tag 183 (Woche 26)	30	74,44	21,323	33,3	66,67	100,0
		Tag 211 (Woche 30)	28	78,57	19,698	50,0	83,33	100,0
		Tag 239 (Woche 34)	23	78,26	21,576	16,7	83,33	100,0
		Tag 267 (Woche 38)	25	82,00	23,034	16,7	83,33	100,0
		Tag 295 (Woche 42)	25	82,00	18,584	50,0	83,33	100,0
		Tag 323 (Woche 46)	24	74,31	29,067	0,0	75,00	100,0
		Tag 351 (Woche 50)	23	79,71	21,879	33,3	83,33	100,0
		Tag 379 (Woche 54)	21	78,57	21,822	33,3	83,33	100,0
		Tag 407 (Woche 58)	18	78,70	21,241	33,3	83,33	100,0
		Tag 435 (Woche 62)	17	82,35	23,177	33,3	100,00	100,0
		Tag 463 (Woche 66)	14	78,57	26,497	0,0	83,33	100,0
		Tag 491 (Woche 70)	16	81,25	25,730	0,0	83,33	100,0
		Tag 519 (Woche 74)	18	78,70	25,441	0,0	83,33	100,0
		Tag 547 (Woche 78)	15	82,22	14,729	66,7	83,33	100,0
		Tag 575 (Woche 82)	11	77,27	18,668	50,0	83,33	100,0
		Tag 603 (Woche 86)	9	75,93	18,840	50,0	66,67	100,0
		Tag 631 (Woche 90)	7	76,19	13,113	66,7	66,67	100,0
		Tag 659 (Woche 94)	9	83,33	18,634	50,0	83,33	100,0
		Tag 687 (Woche 98)	6	86,11	16,387	66,7	91,67	100,0
		Tag 715 (Woche 102)	7	85,71	14,996	66,7	83,33	100,0
		Tag 743 (Woche 106)	5	80,00	18,257	66,7	66,67	100,0
		Tag 771 (Woche 110)	4	79,17	15,957	66,7	75,00	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Sozial	CTx + Durvalumab (N=46)	Tag 799 (Woche 114)	2	83,33	23,570	66,7	83,33	100,0
		Tag 827 (Woche 118)	3	100,00	0,000	100,0	100,00	100,0
		Tag 855 (Woche 122)	2	91,67	11,785	83,3	91,67	100,0
		Tag 883 (Woche 126)	2	91,67	11,785	83,3	91,67	100,0
		Tag 911 (Woche 130)	2	91,67	11,785	83,3	91,67	100,0
		Tag 939 (Woche 134)	2	83,33	23,570	66,7	83,33	100,0
	CTx (N=49)	Baseline	39	80,77	20,781	16,7	83,33	100,0
		Tag 22 (Woche 3)	40	76,67	24,979	0,0	83,33	100,0
		Tag 43 (Woche 6)	38	80,70	22,437	16,7	83,33	100,0
		Tag 64 (Woche 9)	38	75,00	27,875	0,0	75,00	100,0
		Tag 85 (Woche 12)	32	73,96	24,662	0,0	66,67	100,0
		Tag 106 (Woche 15)	35	73,33	28,354	0,0	83,33	100,0
		Tag 127 (Woche 18)	28	70,24	24,993	0,0	66,67	100,0
		Tag 155 (Woche 22)	24	78,47	22,241	16,7	83,33	100,0
		Tag 183 (Woche 26)	20	78,33	28,150	0,0	83,33	100,0
		Tag 211 (Woche 30)	23	80,43	22,277	33,3	83,33	100,0
		Tag 239 (Woche 34)	16	76,04	24,319	16,7	83,33	100,0
		Tag 267 (Woche 38)	18	73,15	28,662	16,7	66,67	100,0
		Tag 295 (Woche 42)	17	75,49	22,911	33,3	66,67	100,0
		Tag 323 (Woche 46)	19	73,68	24,417	33,3	66,67	100,0
		Tag 351 (Woche 50)	17	76,47	18,689	33,3	66,67	100,0
		Tag 379 (Woche 54)	11	80,30	22,134	33,3	83,33	100,0
		Tag 407 (Woche 58)	12	83,33	21,320	50,0	100,00	100,0
		Tag 435 (Woche 62)	10	76,67	23,831	33,3	75,00	100,0
		Tag 463 (Woche 66)	9	81,48	24,216	33,3	100,00	100,0
		Tag 491 (Woche 70)	7	90,48	16,265	66,7	100,00	100,0
		Tag 519 (Woche 74)	8	83,33	15,430	66,7	83,33	100,0
		Tag 547 (Woche 78)	8	89,58	23,465	33,3	100,00	100,0
		Tag 575 (Woche 82)	7	88,10	15,853	66,7	100,00	100,0
		Tag 603 (Woche 86)	6	80,56	26,701	33,3	91,67	100,0
		Tag 631 (Woche 90)	4	83,33	13,608	66,7	83,33	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Funktionsskala: Sozial	CTx (N=49)	Tag 659 (Woche 94)	3	72,22	34,694	33,3	83,33	100,0
		Tag 687 (Woche 98)	3	83,33	16,667	66,7	83,33	100,0
		Tag 715 (Woche 102)	2	66,67	47,140	33,3	66,67	100,0
		Tag 743 (Woche 106)	2	83,33	23,570	66,7	83,33	100,0
		Tag 771 (Woche 110)	2	66,67	47,140	33,3	66,67	100,0
		Tag 799 (Woche 114)	2	66,67	23,570	50,0	66,67	83,3
		Tag 827 (Woche 118)	2	66,67	47,140	33,3	66,67	100,0
EORTC QLQ-C30 Fatigue	CTx + Durvalumab (N=46)	Baseline	39	33,90	18,548	0,0	33,33	88,9
		Tag 22 (Woche 3)	34	39,54	20,321	0,0	33,33	100,0
		Tag 43 (Woche 6)	36	35,19	19,608	0,0	33,33	100,0
		Tag 64 (Woche 9)	33	34,34	17,648	0,0	33,33	66,7
		Tag 85 (Woche 12)	31	39,07	20,662	0,0	33,33	100,0
		Tag 106 (Woche 15)	28	46,03	24,514	0,0	44,44	100,0
		Tag 127 (Woche 18)	30	46,67	21,122	0,0	44,44	88,9
		Tag 155 (Woche 22)	25	34,67	22,978	0,0	33,33	88,9
		Tag 183 (Woche 26)	30	35,19	20,233	0,0	33,33	77,8
		Tag 211 (Woche 30)	28	29,37	19,414	0,0	33,33	66,7
		Tag 239 (Woche 34)	23	31,40	17,295	0,0	33,33	66,7
		Tag 267 (Woche 38)	25	27,11	19,532	0,0	33,33	100,0
		Tag 295 (Woche 42)	25	33,33	25,256	0,0	33,33	100,0
		Tag 323 (Woche 46)	24	28,70	20,958	0,0	33,33	88,9
		Tag 351 (Woche 50)	23	34,78	20,462	0,0	33,33	77,8
		Tag 379 (Woche 54)	21	35,45	19,443	0,0	33,33	66,7
		Tag 407 (Woche 58)	18	33,95	22,376	0,0	27,78	77,8
		Tag 435 (Woche 62)	17	35,29	24,918	0,0	33,33	100,0
		Tag 463 (Woche 66)	14	30,16	20,640	0,0	33,33	77,8
		Tag 491 (Woche 70)	16	34,03	24,501	0,0	33,33	100,0
		Tag 519 (Woche 74)	18	30,86	23,042	0,0	33,33	88,9
		Tag 547 (Woche 78)	15	31,11	16,903	0,0	33,33	66,7
		Tag 575 (Woche 82)	11	24,24	17,082	0,0	22,22	55,6
		Tag 603 (Woche 86)	9	30,86	19,859	0,0	33,33	66,7

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Fatigue	CTx + Durvalumab (N=46)	Tag 631 (Woche 90)	7	25,40	19,994	0,0	33,33	55,6
		Tag 659 (Woche 94)	9	28,40	22,981	0,0	33,33	55,6
		Tag 687 (Woche 98)	6	24,07	24,762	0,0	22,22	66,7
		Tag 715 (Woche 102)	7	23,81	23,508	0,0	22,22	66,7
		Tag 743 (Woche 106)	5	26,67	25,580	0,0	22,22	66,7
		Tag 771 (Woche 110)	4	27,78	29,397	0,0	22,22	66,7
		Tag 799 (Woche 114)	2	33,33	47,140	0,0	33,33	66,7
		Tag 827 (Woche 118)	3	11,11	11,111	0,0	11,11	22,2
		Tag 855 (Woche 122)	2	27,78	7,857	22,2	27,78	33,3
		Tag 883 (Woche 126)	2	22,22	0,000	22,2	22,22	22,2
		Tag 911 (Woche 130)	2	22,22	15,713	11,1	22,22	33,3
		Tag 939 (Woche 134)	2	22,22	0,000	22,2	22,22	22,2
	CTx (N=49)	Baseline	39	27,07	18,167	0,0	22,22	66,7
		Tag 22 (Woche 3)	40	33,89	24,259	0,0	33,33	100,0
		Tag 43 (Woche 6)	38	35,67	23,839	0,0	33,33	100,0
		Tag 64 (Woche 9)	38	38,30	25,271	0,0	33,33	100,0
		Tag 85 (Woche 12)	32	37,15	21,972	0,0	33,33	100,0
		Tag 106 (Woche 15)	35	38,41	28,690	0,0	33,33	100,0
		Tag 127 (Woche 18)	28	41,27	25,456	0,0	38,89	100,0
		Tag 155 (Woche 22)	24	32,87	20,059	0,0	33,33	66,7
		Tag 183 (Woche 26)	20	37,22	19,835	0,0	33,33	66,7
		Tag 211 (Woche 30)	23	31,88	22,797	0,0	33,33	88,9
		Tag 239 (Woche 34)	16	37,50	21,802	0,0	33,33	77,8
		Tag 267 (Woche 38)	18	35,19	24,477	0,0	33,33	77,8
		Tag 295 (Woche 42)	17	38,56	25,795	0,0	44,44	77,8
		Tag 323 (Woche 46)	19	36,84	19,963	0,0	33,33	77,8
		Tag 351 (Woche 50)	17	37,25	20,008	0,0	33,33	77,8
		Tag 379 (Woche 54)	11	27,27	16,751	0,0	33,33	55,6
		Tag 407 (Woche 58)	12	26,85	21,429	0,0	27,78	77,8
		Tag 435 (Woche 62)	10	26,67	25,767	0,0	22,22	66,7
		Tag 463 (Woche 66)	9	23,46	15,158	0,0	22,22	44,4
		Tag 491 (Woche 70)	7	22,22	14,344	0,0	22,22	44,4

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Fatigue	CTx (N=49)	Tag 519 (Woche 74)	8	23,61	15,069	0,0	27,78	44,4
		Tag 547 (Woche 78)	8	15,28	14,472	0,0	16,67	33,3
		Tag 575 (Woche 82)	7	19,05	13,929	0,0	22,22	33,3
		Tag 603 (Woche 86)	6	25,93	16,728	0,0	33,33	44,4
		Tag 631 (Woche 90)	4	22,22	15,713	0,0	27,78	33,3
		Tag 659 (Woche 94)	3	11,11	19,245	0,0	0,00	33,3
		Tag 687 (Woche 98)	3	14,81	16,973	0,0	11,11	33,3
		Tag 715 (Woche 102)	2	11,11	15,713	0,0	11,11	22,2
		Tag 743 (Woche 106)	2	16,67	7,857	11,1	16,67	22,2
		Tag 771 (Woche 110)	2	22,22	15,713	11,1	22,22	33,3
		Tag 799 (Woche 114)	2	16,67	7,857	11,1	16,67	22,2
		Tag 827 (Woche 118)	2	22,22	15,713	11,1	22,22	33,3
EORTC QLQ-C30 Übelkeit und Erbrechen	CTx + Durvalumab (N=46)	Baseline	39	6,41	11,223	0,0	0,00	33,3
		Tag 22 (Woche 3)	34	8,33	17,041	0,0	0,00	66,7
		Tag 43 (Woche 6)	36	12,50	20,461	0,0	0,00	83,3
		Tag 64 (Woche 9)	33	10,10	15,556	0,0	0,00	50,0
		Tag 85 (Woche 12)	31	10,75	16,414	0,0	0,00	66,7
		Tag 106 (Woche 15)	28	10,71	17,102	0,0	0,00	66,7
		Tag 127 (Woche 18)	30	11,67	16,464	0,0	0,00	66,7
		Tag 155 (Woche 22)	25	6,00	10,628	0,0	0,00	33,3
		Tag 183 (Woche 26)	30	8,33	12,947	0,0	0,00	50,0
		Tag 211 (Woche 30)	28	4,17	9,755	0,0	0,00	33,3
		Tag 239 (Woche 34)	23	4,35	9,014	0,0	0,00	33,3
		Tag 267 (Woche 38)	25	4,00	7,265	0,0	0,00	16,7
		Tag 295 (Woche 42)	25	6,00	9,477	0,0	0,00	33,3
		Tag 323 (Woche 46)	24	4,86	9,167	0,0	0,00	33,3
		Tag 351 (Woche 50)	23	2,90	6,459	0,0	0,00	16,7
		Tag 379 (Woche 54)	21	8,73	13,560	0,0	0,00	50,0
		Tag 407 (Woche 58)	18	2,78	6,391	0,0	0,00	16,7
		Tag 435 (Woche 62)	17	2,94	6,549	0,0	0,00	16,7
		Tag 463 (Woche 66)	14	2,38	6,052	0,0	0,00	16,7

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Übelkeit und Erbrechen	CTx + Durvalumab (N=46)	Tag 491 (Woche 70)	16	7,29	12,124	0,0	0,00	33,3
		Tag 519 (Woche 74)	18	8,33	14,292	0,0	0,00	50,0
		Tag 547 (Woche 78)	15	6,67	12,280	0,0	0,00	33,3
		Tag 575 (Woche 82)	11	3,03	6,742	0,0	0,00	16,7
		Tag 603 (Woche 86)	9	12,96	16,197	0,0	16,67	50,0
		Tag 631 (Woche 90)	7	4,76	8,133	0,0	0,00	16,7
		Tag 659 (Woche 94)	9	3,70	7,349	0,0	0,00	16,7
		Tag 687 (Woche 98)	6	0,00	0,000	0,0	0,00	0,0
		Tag 715 (Woche 102)	7	0,00	0,000	0,0	0,00	0,0
		Tag 743 (Woche 106)	5	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	4	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	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)	2	0,00	0,000	0,0	0,00	0,0
		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	8,33	11,785	0,0	8,33	16,7
	CTx (N=49)	Baseline	39	3,85	8,936	0,0	0,00	33,3
		Tag 22 (Woche 3)	40	9,17	14,593	0,0	0,00	50,0
		Tag 43 (Woche 6)	38	8,33	13,836	0,0	0,00	50,0
		Tag 64 (Woche 9)	38	10,53	16,173	0,0	0,00	66,7
		Tag 85 (Woche 12)	32	8,85	16,387	0,0	0,00	66,7
		Tag 106 (Woche 15)	35	9,52	14,169	0,0	0,00	50,0
		Tag 127 (Woche 18)	28	8,33	14,699	0,0	0,00	50,0
		Tag 155 (Woche 22)	24	4,17	8,860	0,0	0,00	33,3
		Tag 183 (Woche 26)	20	5,00	7,836	0,0	0,00	16,7
		Tag 211 (Woche 30)	23	7,25	11,040	0,0	0,00	33,3
		Tag 239 (Woche 34)	16	6,25	10,319	0,0	0,00	33,3
		Tag 267 (Woche 38)	18	10,19	14,164	0,0	0,00	33,3
		Tag 295 (Woche 42)	17	6,86	10,306	0,0	0,00	33,3
		Tag 323 (Woche 46)	19	6,14	12,681	0,0	0,00	50,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Übelkeit und Erbrechen	CTx (N=49)	Tag 351 (Woche 50)	17	5,88	10,106	0,0	0,00	33,3
		Tag 379 (Woche 54)	11	4,55	7,785	0,0	0,00	16,7
		Tag 407 (Woche 58)	12	4,17	10,360	0,0	0,00	33,3
		Tag 435 (Woche 62)	10	5,00	11,249	0,0	0,00	33,3
		Tag 463 (Woche 66)	9	1,85	5,556	0,0	0,00	16,7
		Tag 491 (Woche 70)	7	7,14	13,113	0,0	0,00	33,3
		Tag 519 (Woche 74)	8	6,25	8,626	0,0	0,00	16,7
		Tag 547 (Woche 78)	8	4,17	11,785	0,0	0,00	33,3
		Tag 575 (Woche 82)	7	2,38	6,299	0,0	0,00	16,7
		Tag 603 (Woche 86)	6	2,78	6,804	0,0	0,00	16,7
		Tag 631 (Woche 90)	4	4,17	8,333	0,0	0,00	16,7
		Tag 659 (Woche 94)	3	0,00	0,000	0,0	0,00	0,0
		Tag 687 (Woche 98)	3	0,00	0,000	0,0	0,00	0,0
		Tag 715 (Woche 102)	2	8,33	11,785	0,0	8,33	16,7
		Tag 743 (Woche 106)	2	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	2	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	2	0,00	0,000	0,0	0,00	0,0
EORTC QLQ-C30 Schmerzen	CTx + Durvalumab (N=46)	Baseline	39	27,35	26,070	0,0	16,67	100,0
		Tag 22 (Woche 3)	34	27,94	23,470	0,0	33,33	100,0
		Tag 43 (Woche 6)	36	26,39	20,461	0,0	33,33	100,0
		Tag 64 (Woche 9)	33	18,18	16,332	0,0	16,67	50,0
		Tag 85 (Woche 12)	31	20,97	24,709	0,0	16,67	100,0
		Tag 106 (Woche 15)	28	25,60	25,452	0,0	25,00	100,0
		Tag 127 (Woche 18)	30	31,11	25,795	0,0	33,33	100,0
		Tag 155 (Woche 22)	25	28,67	25,240	0,0	33,33	100,0
		Tag 183 (Woche 26)	30	28,33	23,222	0,0	25,00	83,3
		Tag 211 (Woche 30)	28	22,62	20,893	0,0	16,67	66,7
		Tag 239 (Woche 34)	23	18,84	15,328	0,0	16,67	50,0
		Tag 267 (Woche 38)	25	23,33	16,667	0,0	33,33	50,0
		Tag 295 (Woche 42)	25	24,67	23,629	0,0	16,67	83,3

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Schmerzen	CTx + Durvalumab (N=46)	Tag 323 (Woche 46)	24	21,53	19,951	0,0	16,67	66,7
		Tag 351 (Woche 50)	23	23,91	23,477	0,0	16,67	83,3
		Tag 379 (Woche 54)	21	21,43	21,822	0,0	16,67	66,7
		Tag 407 (Woche 58)	18	27,78	24,254	0,0	33,33	83,3
		Tag 435 (Woche 62)	17	22,55	20,362	0,0	33,33	66,7
		Tag 463 (Woche 66)	14	19,05	22,510	0,0	16,67	83,3
		Tag 491 (Woche 70)	16	19,79	25,253	0,0	16,67	100,0
		Tag 519 (Woche 74)	18	22,22	24,918	0,0	16,67	100,0
		Tag 547 (Woche 78)	15	16,67	14,086	0,0	16,67	33,3
		Tag 575 (Woche 82)	11	16,67	12,910	0,0	16,67	33,3
		Tag 603 (Woche 86)	9	18,52	17,568	0,0	16,67	50,0
		Tag 631 (Woche 90)	7	21,43	12,599	0,0	16,67	33,3
		Tag 659 (Woche 94)	9	18,52	21,155	0,0	16,67	66,7
		Tag 687 (Woche 98)	6	16,67	21,082	0,0	8,33	50,0
		Tag 715 (Woche 102)	7	11,90	15,853	0,0	0,00	33,3
		Tag 743 (Woche 106)	5	10,00	14,907	0,0	0,00	33,3
		Tag 771 (Woche 110)	4	12,50	15,957	0,0	8,33	33,3
		Tag 799 (Woche 114)	2	16,67	23,570	0,0	16,67	33,3
		Tag 827 (Woche 118)	3	22,22	25,459	0,0	16,67	50,0
		Tag 855 (Woche 122)	2	8,33	11,785	0,0	8,33	16,7
		Tag 883 (Woche 126)	2	8,33	11,785	0,0	8,33	16,7
		Tag 911 (Woche 130)	2	25,00	11,785	16,7	25,00	33,3
		Tag 939 (Woche 134)	2	16,67	0,000	16,7	16,67	16,7
	CTx (N=49)	Baseline	39	21,37	24,167	0,0	16,67	83,3
		Tag 22 (Woche 3)	40	27,92	25,146	0,0	33,33	100,0
		Tag 43 (Woche 6)	38	21,05	21,811	0,0	16,67	66,7
		Tag 64 (Woche 9)	38	26,75	29,900	0,0	16,67	100,0
		Tag 85 (Woche 12)	32	27,08	29,558	0,0	16,67	100,0
		Tag 106 (Woche 15)	35	28,10	28,803	0,0	16,67	100,0
		Tag 127 (Woche 18)	28	27,98	25,278	0,0	33,33	100,0
		Tag 155 (Woche 22)	24	23,61	23,008	0,0	16,67	66,7
		Tag 183 (Woche 26)	20	27,50	26,642	0,0	25,00	66,7

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Schmerzen	CTx (N=49)	Tag 211 (Woche 30)	23	23,91	20,613	0,0	33,33	66,7
		Tag 239 (Woche 34)	16	27,08	22,669	0,0	25,00	66,7
		Tag 267 (Woche 38)	18	28,70	23,435	0,0	33,33	66,7
		Tag 295 (Woche 42)	17	31,37	26,927	0,0	33,33	83,3
		Tag 323 (Woche 46)	19	28,95	25,964	0,0	16,67	66,7
		Tag 351 (Woche 50)	17	25,49	23,657	0,0	33,33	66,7
		Tag 379 (Woche 54)	11	37,88	24,823	0,0	50,00	66,7
		Tag 407 (Woche 58)	12	20,83	28,538	0,0	0,00	66,7
		Tag 435 (Woche 62)	10	26,67	26,294	0,0	25,00	66,7
		Tag 463 (Woche 66)	9	20,37	18,215	0,0	16,67	50,0
		Tag 491 (Woche 70)	7	26,19	25,198	0,0	16,67	66,7
		Tag 519 (Woche 74)	8	20,83	17,252	0,0	33,33	33,3
		Tag 547 (Woche 78)	8	16,67	19,920	0,0	8,33	50,0
		Tag 575 (Woche 82)	7	21,43	12,599	0,0	16,67	33,3
		Tag 603 (Woche 86)	6	27,78	25,092	0,0	33,33	66,7
		Tag 631 (Woche 90)	4	37,50	8,333	33,3	33,33	50,0
		Tag 659 (Woche 94)	3	16,67	16,667	0,0	16,67	33,3
		Tag 687 (Woche 98)	3	33,33	28,868	16,7	16,67	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)	2	41,67	35,355	16,7	41,67	66,7
		Tag 799 (Woche 114)	2	25,00	11,785	16,7	25,00	33,3
		Tag 827 (Woche 118)	2	33,33	0,000	33,3	33,33	33,3
EORTC QLQ-C30 Dyspnoe	CTx + Durvalumab (N=46)	Baseline	39	17,09	18,531	0,0	0,00	66,7
		Tag 22 (Woche 3)	34	16,67	20,515	0,0	0,00	66,7
		Tag 43 (Woche 6)	36	17,59	21,802	0,0	0,00	66,7
		Tag 64 (Woche 9)	33	20,20	23,481	0,0	0,00	66,7
		Tag 85 (Woche 12)	31	19,35	20,681	0,0	33,33	66,7
		Tag 106 (Woche 15)	28	29,76	29,171	0,0	33,33	100,0
		Tag 127 (Woche 18)	30	23,33	26,479	0,0	16,67	66,7
		Tag 155 (Woche 22)	25	20,00	19,245	0,0	33,33	66,7
		Tag 183 (Woche 26)	30	20,00	25,671	0,0	0,00	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Dyspnoe	CTx + Durvalumab (N=46)	Tag 211 (Woche 30)	28	16,67	24,845	0,0	0,00	66,7
		Tag 239 (Woche 34)	23	15,94	19,770	0,0	0,00	66,7
		Tag 267 (Woche 38)	25	20,00	28,868	0,0	0,00	100,0
		Tag 295 (Woche 42)	25	17,33	30,611	0,0	0,00	100,0
		Tag 323 (Woche 46)	24	20,83	25,656	0,0	16,67	100,0
		Tag 351 (Woche 50)	23	26,09	28,349	0,0	33,33	100,0
		Tag 379 (Woche 54)	21	19,05	22,537	0,0	0,00	66,7
		Tag 407 (Woche 58)	18	24,07	25,063	0,0	33,33	66,7
		Tag 435 (Woche 62)	17	17,65	26,661	0,0	0,00	100,0
		Tag 463 (Woche 66)	14	21,43	28,063	0,0	16,67	100,0
		Tag 491 (Woche 70)	16	14,58	27,131	0,0	0,00	100,0
		Tag 519 (Woche 74)	18	16,67	23,570	0,0	0,00	66,7
		Tag 547 (Woche 78)	15	17,78	17,213	0,0	33,33	33,3
		Tag 575 (Woche 82)	11	18,18	22,918	0,0	0,00	66,7
		Tag 603 (Woche 86)	9	18,52	17,568	0,0	33,33	33,3
		Tag 631 (Woche 90)	7	14,29	17,817	0,0	0,00	33,3
		Tag 659 (Woche 94)	9	18,52	17,568	0,0	33,33	33,3
		Tag 687 (Woche 98)	6	22,22	27,217	0,0	16,67	66,7
		Tag 715 (Woche 102)	7	19,05	17,817	0,0	33,33	33,3
		Tag 743 (Woche 106)	5	6,67	14,907	0,0	0,00	33,3
		Tag 771 (Woche 110)	4	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	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)	2	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	0,00	0,000	0,0	0,00	0,0
	CTx (N=49)	Baseline	39	10,26	17,361	0,0	0,00	66,7
		Tag 22 (Woche 3)	40	14,17	19,810	0,0	0,00	66,7
		Tag 43 (Woche 6)	38	14,04	19,957	0,0	0,00	66,7
		Tag 64 (Woche 9)	38	19,30	19,957	0,0	33,33	66,7
		Tag 85 (Woche 12)	32	18,75	25,312	0,0	0,00	66,7

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Dyspnoe	CTx (N=49)	Tag 106 (Woche 15)	35	21,90	22,785	0,0	33,33	66,7
		Tag 127 (Woche 18)	28	25,00	21,517	0,0	33,33	66,7
		Tag 155 (Woche 22)	24	19,44	21,795	0,0	16,67	66,7
		Tag 183 (Woche 26)	20	16,67	22,942	0,0	0,00	66,7
		Tag 211 (Woche 30)	23	18,84	16,896	0,0	33,33	33,3
		Tag 239 (Woche 34)	16	20,83	23,960	0,0	16,67	66,7
		Tag 267 (Woche 38)	18	24,07	25,063	0,0	33,33	66,7
		Tag 295 (Woche 42)	17	27,45	26,965	0,0	33,33	66,7
		Tag 323 (Woche 46)	19	21,05	22,800	0,0	33,33	66,7
		Tag 351 (Woche 50)	17	19,61	23,743	0,0	0,00	66,7
		Tag 379 (Woche 54)	11	12,12	22,473	0,0	0,00	66,7
		Tag 407 (Woche 58)	12	13,89	22,285	0,0	0,00	66,7
		Tag 435 (Woche 62)	10	13,33	17,213	0,0	0,00	33,3
		Tag 463 (Woche 66)	9	11,11	16,667	0,0	0,00	33,3
		Tag 491 (Woche 70)	7	9,52	25,198	0,0	0,00	66,7
		Tag 519 (Woche 74)	8	4,17	11,785	0,0	0,00	33,3
		Tag 547 (Woche 78)	8	4,17	11,785	0,0	0,00	33,3
		Tag 575 (Woche 82)	7	4,76	12,599	0,0	0,00	33,3
		Tag 603 (Woche 86)	6	16,67	27,889	0,0	0,00	66,7
		Tag 631 (Woche 90)	4	16,67	19,245	0,0	16,67	33,3
		Tag 659 (Woche 94)	3	11,11	19,245	0,0	0,00	33,3
		Tag 687 (Woche 98)	3	0,00	0,000	0,0	0,00	0,0
		Tag 715 (Woche 102)	2	0,00	0,000	0,0	0,00	0,0
		Tag 743 (Woche 106)	2	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	2	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	2	0,00	0,000	0,0	0,00	0,0
EORTC QLQ-C30 Schlaflosigkeit	CTx + Durvalumab (N=46)	Baseline	39	35,90	27,977	0,0	33,33	100,0
		Tag 22 (Woche 3)	34	37,25	30,445	0,0	33,33	100,0
		Tag 43 (Woche 6)	36	36,11	31,244	0,0	33,33	100,0
		Tag 64 (Woche 9)	33	27,27	28,204	0,0	33,33	100,0
		Tag 85 (Woche 12)	31	30,11	31,452	0,0	33,33	100,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Schlaflosigkeit	CTx + Durvalumab (N=46)	Tag 106 (Woche 15)	28	40,48	29,197	0,0	33,33	100,0
		Tag 127 (Woche 18)	30	33,33	26,261	0,0	33,33	100,0
		Tag 155 (Woche 22)	25	36,00	31,798	0,0	33,33	100,0
		Tag 183 (Woche 26)	30	35,56	30,240	0,0	33,33	100,0
		Tag 211 (Woche 30)	28	33,33	30,089	0,0	33,33	100,0
		Tag 239 (Woche 34)	23	28,99	25,235	0,0	33,33	100,0
		Tag 267 (Woche 38)	25	25,33	24,114	0,0	33,33	66,7
		Tag 295 (Woche 42)	25	30,67	30,307	0,0	33,33	100,0
		Tag 323 (Woche 46)	24	30,56	30,954	0,0	33,33	100,0
		Tag 351 (Woche 50)	23	40,58	36,177	0,0	33,33	100,0
		Tag 379 (Woche 54)	21	39,68	32,692	0,0	33,33	100,0
		Tag 407 (Woche 58)	18	35,19	29,087	0,0	33,33	100,0
		Tag 435 (Woche 62)	17	29,41	30,917	0,0	33,33	100,0
		Tag 463 (Woche 66)	14	21,43	21,111	0,0	33,33	66,7
		Tag 491 (Woche 70)	16	27,08	30,353	0,0	33,33	100,0
		Tag 519 (Woche 74)	18	29,63	34,087	0,0	33,33	100,0
		Tag 547 (Woche 78)	15	35,56	36,659	0,0	33,33	100,0
		Tag 575 (Woche 82)	11	33,33	36,515	0,0	33,33	100,0
		Tag 603 (Woche 86)	9	40,74	32,394	0,0	33,33	100,0
		Tag 631 (Woche 90)	7	42,86	37,090	0,0	33,33	100,0
		Tag 659 (Woche 94)	9	33,33	33,333	0,0	33,33	100,0
		Tag 687 (Woche 98)	6	27,78	25,092	0,0	33,33	66,7
		Tag 715 (Woche 102)	7	33,33	33,333	0,0	33,33	100,0
		Tag 743 (Woche 106)	5	33,33	40,825	0,0	33,33	100,0
		Tag 771 (Woche 110)	4	41,67	41,944	0,0	33,33	100,0
		Tag 799 (Woche 114)	2	50,00	70,711	0,0	50,00	100,0
		Tag 827 (Woche 118)	3	33,33	33,333	0,0	33,33	66,7
		Tag 855 (Woche 122)	2	50,00	23,570	33,3	50,00	66,7
		Tag 883 (Woche 126)	2	33,33	0,000	33,3	33,33	33,3
		Tag 911 (Woche 130)	2	66,67	0,000	66,7	66,67	66,7
		Tag 939 (Woche 134)	2	33,33	0,000	33,3	33,33	33,3

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Schlaflosigkeit	CTx (N=49)	Baseline	39	26,50	25,569	0,0	33,33	66,7
		Tag 22 (Woche 3)	40	24,17	26,135	0,0	33,33	100,0
		Tag 43 (Woche 6)	38	21,93	23,604	0,0	33,33	66,7
		Tag 64 (Woche 9)	38	26,32	30,173	0,0	33,33	100,0
		Tag 85 (Woche 12)	32	25,00	29,329	0,0	16,67	100,0
		Tag 106 (Woche 15)	35	25,71	25,675	0,0	33,33	66,7
		Tag 127 (Woche 18)	28	29,76	26,198	0,0	33,33	100,0
		Tag 155 (Woche 22)	24	23,61	20,803	0,0	33,33	66,7
		Tag 183 (Woche 26)	20	23,33	21,898	0,0	33,33	66,7
		Tag 211 (Woche 30)	23	26,09	24,529	0,0	33,33	66,7
		Tag 239 (Woche 34)	16	29,17	20,638	0,0	33,33	66,7
		Tag 267 (Woche 38)	18	29,63	19,433	0,0	33,33	66,7
		Tag 295 (Woche 42)	17	25,49	30,114	0,0	33,33	100,0
		Tag 323 (Woche 46)	19	29,82	24,582	0,0	33,33	66,7
		Tag 351 (Woche 50)	17	31,37	24,918	0,0	33,33	66,7
		Tag 379 (Woche 54)	11	21,21	22,473	0,0	33,33	66,7
		Tag 407 (Woche 58)	12	22,22	25,950	0,0	16,67	66,7
		Tag 435 (Woche 62)	10	16,67	23,570	0,0	0,00	66,7
		Tag 463 (Woche 66)	9	22,22	23,570	0,0	33,33	66,7
		Tag 491 (Woche 70)	7	19,05	17,817	0,0	33,33	33,3
		Tag 519 (Woche 74)	8	20,83	24,801	0,0	16,67	66,7
		Tag 547 (Woche 78)	8	16,67	25,198	0,0	0,00	66,7
		Tag 575 (Woche 82)	7	19,05	26,227	0,0	0,00	66,7
		Tag 603 (Woche 86)	6	22,22	27,217	0,0	16,67	66,7
		Tag 631 (Woche 90)	4	16,67	19,245	0,0	16,67	33,3
		Tag 659 (Woche 94)	3	0,00	0,000	0,0	0,00	0,0
		Tag 687 (Woche 98)	3	0,00	0,000	0,0	0,00	0,0
		Tag 715 (Woche 102)	2	0,00	0,000	0,0	0,00	0,0
		Tag 743 (Woche 106)	2	16,67	23,570	0,0	16,67	33,3
		Tag 771 (Woche 110)	2	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	2	0,00	0,000	0,0	0,00	0,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Appetitverlust	CTx + Durvalumab (N=46)	Baseline	39	26,50	26,688	0,0	33,33	100,0
		Tag 22 (Woche 3)	34	25,49	29,654	0,0	33,33	100,0
		Tag 43 (Woche 6)	36	23,15	27,394	0,0	16,67	100,0
		Tag 64 (Woche 9)	33	18,18	23,704	0,0	0,00	100,0
		Tag 85 (Woche 12)	31	20,43	23,847	0,0	33,33	100,0
		Tag 106 (Woche 15)	28	25,00	29,572	0,0	33,33	100,0
		Tag 127 (Woche 18)	30	25,56	24,264	0,0	33,33	100,0
		Tag 155 (Woche 22)	25	14,67	19,437	0,0	0,00	66,7
		Tag 183 (Woche 26)	30	14,44	18,944	0,0	0,00	66,7
		Tag 211 (Woche 30)	28	9,52	17,817	0,0	0,00	66,7
		Tag 239 (Woche 34)	23	8,70	14,966	0,0	0,00	33,3
		Tag 267 (Woche 38)	25	10,67	23,014	0,0	0,00	100,0
		Tag 295 (Woche 42)	25	14,67	23,727	0,0	0,00	100,0
		Tag 323 (Woche 46)	24	16,67	26,006	0,0	0,00	100,0
		Tag 351 (Woche 50)	23	10,14	18,627	0,0	0,00	66,7
		Tag 379 (Woche 54)	21	12,70	16,587	0,0	0,00	33,3
		Tag 407 (Woche 58)	18	5,56	12,783	0,0	0,00	33,3
		Tag 435 (Woche 62)	17	5,88	13,098	0,0	0,00	33,3
		Tag 463 (Woche 66)	14	11,90	16,575	0,0	0,00	33,3
		Tag 491 (Woche 70)	16	6,25	13,437	0,0	0,00	33,3
		Tag 519 (Woche 74)	18	11,11	16,169	0,0	0,00	33,3
		Tag 547 (Woche 78)	15	8,89	15,258	0,0	0,00	33,3
		Tag 575 (Woche 82)	11	12,12	22,473	0,0	0,00	66,7
		Tag 603 (Woche 86)	9	11,11	16,667	0,0	0,00	33,3
		Tag 631 (Woche 90)	7	19,05	17,817	0,0	33,33	33,3
		Tag 659 (Woche 94)	9	11,11	16,667	0,0	0,00	33,3
		Tag 687 (Woche 98)	6	5,56	13,608	0,0	0,00	33,3
		Tag 715 (Woche 102)	7	4,76	12,599	0,0	0,00	33,3
		Tag 743 (Woche 106)	5	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	4	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	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

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Appetitverlust	CTx + Durvalumab (N=46)	Tag 855 (Woche 122)	2	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
	CTx (N=49)	Baseline	39	13,68	21,245	0,0	0,00	66,7
		Tag 22 (Woche 3)	40	16,67	22,646	0,0	0,00	100,0
		Tag 43 (Woche 6)	38	20,18	22,647	0,0	16,67	66,7
		Tag 64 (Woche 9)	38	22,81	25,826	0,0	16,67	66,7
		Tag 85 (Woche 12)	32	23,96	30,801	0,0	0,00	100,0
		Tag 106 (Woche 15)	35	25,71	25,675	0,0	33,33	100,0
		Tag 127 (Woche 18)	28	22,62	25,746	0,0	16,67	66,7
		Tag 155 (Woche 22)	24	13,89	19,453	0,0	0,00	66,7
		Tag 183 (Woche 26)	20	21,67	27,091	0,0	0,00	66,7
		Tag 211 (Woche 30)	23	21,74	27,723	0,0	0,00	66,7
		Tag 239 (Woche 34)	16	18,75	20,972	0,0	16,67	66,7
		Tag 267 (Woche 38)	18	16,67	20,612	0,0	0,00	66,7
		Tag 295 (Woche 42)	17	19,61	23,743	0,0	0,00	66,7
		Tag 323 (Woche 46)	19	15,79	23,223	0,0	0,00	66,7
		Tag 351 (Woche 50)	17	15,69	26,661	0,0	0,00	66,7
		Tag 379 (Woche 54)	11	6,06	13,484	0,0	0,00	33,3
		Tag 407 (Woche 58)	12	5,56	19,245	0,0	0,00	66,7
		Tag 435 (Woche 62)	10	13,33	32,203	0,0	0,00	100,0
		Tag 463 (Woche 66)	9	11,11	16,667	0,0	0,00	33,3
		Tag 491 (Woche 70)	7	9,52	25,198	0,0	0,00	66,7
		Tag 519 (Woche 74)	8	12,50	24,801	0,0	0,00	66,7
		Tag 547 (Woche 78)	8	0,00	0,000	0,0	0,00	0,0
		Tag 575 (Woche 82)	7	4,76	12,599	0,0	0,00	33,3
		Tag 603 (Woche 86)	6	0,00	0,000	0,0	0,00	0,0
		Tag 631 (Woche 90)	4	0,00	0,000	0,0	0,00	0,0
		Tag 659 (Woche 94)	3	0,00	0,000	0,0	0,00	0,0
		Tag 687 (Woche 98)	3	0,00	0,000	0,0	0,00	0,0
		Tag 715 (Woche 102)	2	0,00	0,000	0,0	0,00	0,0

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Appetitverlust	CTx (N=49)	Tag 743 (Woche 106)	2	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	2	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	2	0,00	0,000	0,0	0,00	0,0
EORTC QLQ-C30 Verstopfung	CTx + Durvalumab (N=46)	Baseline	39	20,51	27,161	0,0	0,00	100,0
		Tag 22 (Woche 3)	34	23,53	31,280	0,0	0,00	100,0
		Tag 43 (Woche 6)	36	23,15	26,210	0,0	33,33	100,0
		Tag 64 (Woche 9)	33	22,22	27,217	0,0	0,00	100,0
		Tag 85 (Woche 12)	31	21,51	29,248	0,0	0,00	100,0
		Tag 106 (Woche 15)	28	20,24	22,842	0,0	16,67	66,7
		Tag 127 (Woche 18)	30	22,22	23,705	0,0	33,33	66,7
		Tag 155 (Woche 22)	25	10,67	18,559	0,0	0,00	66,7
		Tag 183 (Woche 26)	30	21,11	25,496	0,0	16,67	100,0
		Tag 211 (Woche 30)	28	14,29	21,138	0,0	0,00	66,7
		Tag 239 (Woche 34)	23	15,94	19,770	0,0	0,00	66,7
		Tag 267 (Woche 38)	25	17,33	16,997	0,0	33,33	33,3
		Tag 295 (Woche 42)	25	17,33	16,997	0,0	33,33	33,3
		Tag 323 (Woche 46)	24	22,22	25,380	0,0	33,33	100,0
		Tag 351 (Woche 50)	23	17,39	24,349	0,0	0,00	66,7
		Tag 379 (Woche 54)	21	7,94	14,548	0,0	0,00	33,3
		Tag 407 (Woche 58)	18	16,67	20,612	0,0	0,00	66,7
		Tag 435 (Woche 62)	17	19,61	26,507	0,0	0,00	100,0
		Tag 463 (Woche 66)	14	14,29	17,118	0,0	0,00	33,3
		Tag 491 (Woche 70)	16	18,75	27,131	0,0	0,00	100,0
		Tag 519 (Woche 74)	18	18,52	23,493	0,0	0,00	66,7
		Tag 547 (Woche 78)	15	20,00	24,560	0,0	0,00	66,7
		Tag 575 (Woche 82)	11	15,15	17,408	0,0	0,00	33,3
		Tag 603 (Woche 86)	9	22,22	23,570	0,0	33,33	66,7
		Tag 631 (Woche 90)	7	23,81	25,198	0,0	33,33	66,7
		Tag 659 (Woche 94)	9	11,11	16,667	0,0	0,00	33,3
		Tag 687 (Woche 98)	6	16,67	18,257	0,0	16,67	33,3
		Tag 715 (Woche 102)	7	14,29	17,817	0,0	0,00	33,3

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Verstopfung	CTx + Durvalumab (N=46)	Tag 743 (Woche 106)	5	6,67	14,907	0,0	0,00	33,3
		Tag 771 (Woche 110)	4	8,33	16,667	0,0	0,00	33,3
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	3	11,11	19,245	0,0	0,00	33,3
		Tag 855 (Woche 122)	2	16,67	23,570	0,0	16,67	33,3
		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
	CTx (N=49)	Baseline	39	17,09	22,778	0,0	0,00	66,7
		Tag 22 (Woche 3)	40	20,00	27,006	0,0	0,00	100,0
		Tag 43 (Woche 6)	38	29,82	28,778	0,0	33,33	100,0
		Tag 64 (Woche 9)	38	28,07	28,502	0,0	33,33	100,0
		Tag 85 (Woche 12)	32	28,13	32,911	0,0	33,33	100,0
		Tag 106 (Woche 15)	35	34,29	33,806	0,0	33,33	100,0
		Tag 127 (Woche 18)	28	33,33	30,089	0,0	33,33	100,0
		Tag 155 (Woche 22)	24	23,61	26,882	0,0	33,33	100,0
		Tag 183 (Woche 26)	20	25,00	26,213	0,0	33,33	66,7
		Tag 211 (Woche 30)	23	26,09	31,713	0,0	33,33	100,0
		Tag 239 (Woche 34)	16	22,92	29,107	0,0	16,67	100,0
		Tag 267 (Woche 38)	18	25,93	24,403	0,0	33,33	66,7
		Tag 295 (Woche 42)	17	23,53	25,725	0,0	33,33	66,7
		Tag 323 (Woche 46)	19	28,07	27,807	0,0	33,33	66,7
		Tag 351 (Woche 50)	17	27,45	31,700	0,0	33,33	100,0
		Tag 379 (Woche 54)	11	21,21	22,473	0,0	33,33	66,7
		Tag 407 (Woche 58)	12	16,67	22,473	0,0	0,00	66,7
		Tag 435 (Woche 62)	10	10,00	16,102	0,0	0,00	33,3
		Tag 463 (Woche 66)	9	14,81	24,216	0,0	0,00	66,7
		Tag 491 (Woche 70)	7	9,52	16,265	0,0	0,00	33,3
		Tag 519 (Woche 74)	8	8,33	15,430	0,0	0,00	33,3
		Tag 547 (Woche 78)	8	12,50	24,801	0,0	0,00	66,7
		Tag 575 (Woche 82)	7	4,76	12,599	0,0	0,00	33,3
		Tag 603 (Woche 86)	6	16,67	27,889	0,0	0,00	66,7

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Verstopfung	CTx (N=49)	Tag 631 (Woche 90)	4	8,33	16,667	0,0	0,00	33,3
		Tag 659 (Woche 94)	3	0,00	0,000	0,0	0,00	0,0
		Tag 687 (Woche 98)	3	11,11	19,245	0,0	0,00	33,3
		Tag 715 (Woche 102)	2	0,00	0,000	0,0	0,00	0,0
		Tag 743 (Woche 106)	2	16,67	23,570	0,0	16,67	33,3
		Tag 771 (Woche 110)	2	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	16,67	23,570	0,0	16,67	33,3
		Tag 827 (Woche 118)	2	16,67	23,570	0,0	16,67	33,3
EORTC QLQ-C30 Diarrhö	CTx + Durvalumab (N=46)	Baseline	39	5,13	12,184	0,0	0,00	33,3
		Tag 22 (Woche 3)	34	8,82	17,034	0,0	0,00	66,7
		Tag 43 (Woche 6)	36	8,33	14,639	0,0	0,00	33,3
		Tag 64 (Woche 9)	33	14,14	22,096	0,0	0,00	100,0
		Tag 85 (Woche 12)	31	17,20	22,560	0,0	0,00	66,7
		Tag 106 (Woche 15)	28	9,52	17,817	0,0	0,00	66,7
		Tag 127 (Woche 18)	30	14,44	24,264	0,0	0,00	66,7
		Tag 155 (Woche 22)	25	6,67	13,608	0,0	0,00	33,3
		Tag 183 (Woche 26)	30	13,33	24,132	0,0	0,00	100,0
		Tag 211 (Woche 30)	28	15,48	29,372	0,0	0,00	100,0
		Tag 239 (Woche 34)	23	14,49	22,079	0,0	0,00	66,7
		Tag 267 (Woche 38)	25	5,33	12,472	0,0	0,00	33,3
		Tag 295 (Woche 42)	25	5,33	12,472	0,0	0,00	33,3
		Tag 323 (Woche 46)	24	6,94	13,828	0,0	0,00	33,3
		Tag 351 (Woche 50)	23	7,25	14,058	0,0	0,00	33,3
		Tag 379 (Woche 54)	21	11,11	24,343	0,0	0,00	100,0
		Tag 407 (Woche 58)	18	9,26	15,363	0,0	0,00	33,3
		Tag 435 (Woche 62)	17	5,88	13,098	0,0	0,00	33,3
		Tag 463 (Woche 66)	14	11,90	16,575	0,0	0,00	33,3
		Tag 491 (Woche 70)	16	16,67	27,217	0,0	0,00	100,0
		Tag 519 (Woche 74)	18	14,81	20,523	0,0	0,00	66,7
		Tag 547 (Woche 78)	15	11,11	16,265	0,0	0,00	33,3
		Tag 575 (Woche 82)	11	15,15	22,918	0,0	0,00	66,7
		Tag 603 (Woche 86)	9	14,81	17,568	0,0	0,00	33,3

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Diarrhö	CTx + Durvalumab (N=46)	Tag 631 (Woche 90)	7	19,05	17,817	0,0	33,33	33,3
		Tag 659 (Woche 94)	9	7,41	14,699	0,0	0,00	33,3
		Tag 687 (Woche 98)	6	11,11	17,213	0,0	0,00	33,3
		Tag 715 (Woche 102)	7	14,29	17,817	0,0	0,00	33,3
		Tag 743 (Woche 106)	5	6,67	14,907	0,0	0,00	33,3
		Tag 771 (Woche 110)	4	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	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)	2	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
	CTx (N=49)	Baseline	39	7,69	16,153	0,0	0,00	66,7
		Tag 22 (Woche 3)	40	7,50	17,683	0,0	0,00	66,7
		Tag 43 (Woche 6)	38	14,91	26,506	0,0	0,00	100,0
		Tag 64 (Woche 9)	38	7,89	16,319	0,0	0,00	66,7
		Tag 85 (Woche 12)	32	9,37	17,422	0,0	0,00	66,7
		Tag 106 (Woche 15)	35	8,57	14,781	0,0	0,00	33,3
		Tag 127 (Woche 18)	28	8,33	17,273	0,0	0,00	66,7
		Tag 155 (Woche 22)	24	9,72	18,334	0,0	0,00	66,7
		Tag 183 (Woche 26)	20	10,00	15,672	0,0	0,00	33,3
		Tag 211 (Woche 30)	23	7,25	17,281	0,0	0,00	66,7
		Tag 239 (Woche 34)	16	8,33	14,907	0,0	0,00	33,3
		Tag 267 (Woche 38)	18	12,96	16,721	0,0	0,00	33,3
		Tag 295 (Woche 42)	17	3,92	11,070	0,0	0,00	33,3
		Tag 323 (Woche 46)	19	5,26	12,488	0,0	0,00	33,3
		Tag 351 (Woche 50)	17	9,80	15,656	0,0	0,00	33,3
		Tag 379 (Woche 54)	11	12,12	30,814	0,0	0,00	100,0
		Tag 407 (Woche 58)	12	13,89	22,285	0,0	0,00	66,7
		Tag 435 (Woche 62)	10	3,33	10,541	0,0	0,00	33,3
		Tag 463 (Woche 66)	9	11,11	16,667	0,0	0,00	33,3
		Tag 491 (Woche 70)	7	9,52	16,265	0,0	0,00	33,3

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Diarrhö	CTx (N=49)	Tag 519 (Woche 74)	8	8,33	15,430	0,0	0,00	33,3
		Tag 547 (Woche 78)	8	4,17	11,785	0,0	0,00	33,3
		Tag 575 (Woche 82)	7	14,29	17,817	0,0	0,00	33,3
		Tag 603 (Woche 86)	6	5,56	13,608	0,0	0,00	33,3
		Tag 631 (Woche 90)	4	0,00	0,000	0,0	0,00	0,0
		Tag 659 (Woche 94)	3	0,00	0,000	0,0	0,00	0,0
		Tag 687 (Woche 98)	3	0,00	0,000	0,0	0,00	0,0
		Tag 715 (Woche 102)	2	0,00	0,000	0,0	0,00	0,0
		Tag 743 (Woche 106)	2	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	2	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	2	0,00	0,000	0,0	0,00	0,0
EORTC QLQ-C30 Finanzielle Schwierigkeiten	CTx + Durvalumab (N=46)	Baseline	39	23,08	33,468	0,0	0,00	100,0
		Tag 22 (Woche 3)	34	31,37	35,714	0,0	33,33	100,0
		Tag 43 (Woche 6)	36	22,22	25,198	0,0	16,67	66,7
		Tag 64 (Woche 9)	33	20,20	27,562	0,0	0,00	100,0
		Tag 85 (Woche 12)	31	20,43	29,411	0,0	0,00	100,0
		Tag 106 (Woche 15)	28	20,24	24,578	0,0	16,67	100,0
		Tag 127 (Woche 18)	30	23,33	26,479	0,0	33,33	100,0
		Tag 155 (Woche 22)	25	21,33	27,012	0,0	0,00	100,0
		Tag 183 (Woche 26)	30	24,44	28,945	0,0	16,67	100,0
		Tag 211 (Woche 30)	28	22,62	24,094	0,0	33,33	66,7
		Tag 239 (Woche 34)	23	18,84	29,858	0,0	0,00	100,0
		Tag 267 (Woche 38)	25	18,67	23,727	0,0	0,00	66,7
		Tag 295 (Woche 42)	25	20,00	23,570	0,0	0,00	66,7
		Tag 323 (Woche 46)	24	25,00	28,233	0,0	33,33	100,0
		Tag 351 (Woche 50)	23	26,09	28,349	0,0	33,33	66,7
		Tag 379 (Woche 54)	21	26,98	27,119	0,0	33,33	100,0
		Tag 407 (Woche 58)	18	29,63	22,547	0,0	33,33	66,7
		Tag 435 (Woche 62)	17	25,49	27,712	0,0	33,33	66,7
		Tag 463 (Woche 66)	14	21,43	16,575	0,0	33,33	33,3

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Finanzielle Schwierigkeiten	CTx + Durvalumab (N=46)	Tag 491 (Woche 70)	16	25,00	28,545	0,0	33,33	100,0
		Tag 519 (Woche 74)	18	22,22	30,250	0,0	0,00	100,0
		Tag 547 (Woche 78)	15	20,00	21,082	0,0	33,33	66,7
		Tag 575 (Woche 82)	11	27,27	25,025	0,0	33,33	66,7
		Tag 603 (Woche 86)	9	22,22	23,570	0,0	33,33	66,7
		Tag 631 (Woche 90)	7	23,81	25,198	0,0	33,33	66,7
		Tag 659 (Woche 94)	9	22,22	23,570	0,0	33,33	66,7
		Tag 687 (Woche 98)	6	5,56	13,608	0,0	0,00	33,3
		Tag 715 (Woche 102)	7	14,29	17,817	0,0	0,00	33,3
		Tag 743 (Woche 106)	5	26,67	43,461	0,0	0,00	100,0
		Tag 771 (Woche 110)	4	16,67	19,245	0,0	16,67	33,3
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	3	11,11	19,245	0,0	0,00	33,3
		Tag 855 (Woche 122)	2	16,67	23,570	0,0	16,67	33,3
		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
	CTx (N=49)	Baseline	39	15,38	22,745	0,0	0,00	100,0
		Tag 22 (Woche 3)	40	20,00	30,940	0,0	0,00	100,0
		Tag 43 (Woche 6)	38	17,54	20,115	0,0	0,00	66,7
		Tag 64 (Woche 9)	38	18,42	22,855	0,0	0,00	66,7
		Tag 85 (Woche 12)	32	18,75	22,300	0,0	0,00	66,7
		Tag 106 (Woche 15)	35	18,10	24,711	0,0	0,00	100,0
		Tag 127 (Woche 18)	28	22,62	24,094	0,0	33,33	66,7
		Tag 155 (Woche 22)	24	15,28	19,608	0,0	0,00	66,7
		Tag 183 (Woche 26)	20	15,00	20,160	0,0	0,00	66,7
		Tag 211 (Woche 30)	23	17,39	19,770	0,0	0,00	66,7
		Tag 239 (Woche 34)	16	14,58	17,078	0,0	0,00	33,3
		Tag 267 (Woche 38)	18	18,52	20,523	0,0	16,67	66,7
		Tag 295 (Woche 42)	17	13,73	20,612	0,0	0,00	66,7
		Tag 323 (Woche 46)	19	19,30	25,618	0,0	0,00	66,7

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

Table 2.6.1.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-C30 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-C30 Finanzielle Schwierigkeiten	CTx (N=49)	Tag 351 (Woche 50)	17	13,73	16,910	0,0	0,00	33,3
		Tag 379 (Woche 54)	11	12,12	22,473	0,0	0,00	66,7
		Tag 407 (Woche 58)	12	11,11	16,412	0,0	0,00	33,3
		Tag 435 (Woche 62)	10	23,33	31,623	0,0	0,00	66,7
		Tag 463 (Woche 66)	9	14,81	17,568	0,0	0,00	33,3
		Tag 491 (Woche 70)	7	9,52	16,265	0,0	0,00	33,3
		Tag 519 (Woche 74)	8	20,83	24,801	0,0	16,67	66,7
		Tag 547 (Woche 78)	8	20,83	24,801	0,0	16,67	66,7
		Tag 575 (Woche 82)	7	19,05	17,817	0,0	33,33	33,3
		Tag 603 (Woche 86)	6	22,22	17,213	0,0	33,33	33,3
		Tag 631 (Woche 90)	4	25,00	16,667	0,0	33,33	33,3
		Tag 659 (Woche 94)	3	44,44	19,245	33,3	33,33	66,7
		Tag 687 (Woche 98)	3	22,22	19,245	0,0	33,33	33,3
		Tag 715 (Woche 102)	2	33,33	0,000	33,3	33,33	33,3
		Tag 743 (Woche 106)	2	33,33	0,000	33,3	33,33	33,3
		Tag 771 (Woche 110)	2	50,00	23,570	33,3	50,00	66,7
		Tag 799 (Woche 114)	2	33,33	0,000	33,3	33,33	33,3
		Tag 827 (Woche 118)	2	33,33	0,000	33,3	33,33	33,3

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelles Interesse	CTx + Durvalumab (N=46)	Baseline	36	89,81	19,222	33,3	100,00	100,0
		Tag 22 (Woche 3)	34	95,10	11,983	66,7	100,00	100,0
		Tag 43 (Woche 6)	34	90,20	19,296	33,3	100,00	100,0
		Tag 64 (Woche 9)	32	92,71	16,361	33,3	100,00	100,0
		Tag 85 (Woche 12)	30	94,44	15,371	33,3	100,00	100,0
		Tag 106 (Woche 15)	28	92,86	16,623	33,3	100,00	100,0
		Tag 127 (Woche 18)	30	93,33	13,561	66,7	100,00	100,0
		Tag 155 (Woche 22)	25	94,67	15,753	33,3	100,00	100,0
		Tag 183 (Woche 26)	30	91,11	23,050	0,0	100,00	100,0
		Tag 211 (Woche 30)	27	92,59	16,879	33,3	100,00	100,0
		Tag 239 (Woche 34)	23	89,86	23,430	0,0	100,00	100,0
		Tag 267 (Woche 38)	24	88,89	23,399	0,0	100,00	100,0
		Tag 295 (Woche 42)	25	90,67	18,053	33,3	100,00	100,0
		Tag 323 (Woche 46)	24	88,89	25,380	0,0	100,00	100,0
		Tag 351 (Woche 50)	23	89,86	23,430	0,0	100,00	100,0
		Tag 379 (Woche 54)	20	88,33	24,839	0,0	100,00	100,0
		Tag 407 (Woche 58)	18	90,74	25,063	0,0	100,00	100,0
		Tag 435 (Woche 62)	17	90,20	19,596	33,3	100,00	100,0
		Tag 463 (Woche 66)	14	90,48	27,514	0,0	100,00	100,0
		Tag 491 (Woche 70)	15	84,44	27,794	0,0	100,00	100,0
		Tag 519 (Woche 74)	18	85,19	28,520	0,0	100,00	100,0
		Tag 547 (Woche 78)	15	93,33	13,801	66,7	100,00	100,0
		Tag 575 (Woche 82)	11	90,91	15,570	66,7	100,00	100,0
		Tag 603 (Woche 86)	9	81,48	24,216	33,3	100,00	100,0
		Tag 631 (Woche 90)	7	85,71	17,817	66,7	100,00	100,0
		Tag 659 (Woche 94)	9	88,89	16,667	66,7	100,00	100,0
		Tag 687 (Woche 98)	6	88,89	17,213	66,7	100,00	100,0
		Tag 715 (Woche 102)	6	88,89	17,213	66,7	100,00	100,0
		Tag 743 (Woche 106)	4	83,33	19,245	66,7	83,33	100,0
		Tag 771 (Woche 110)	4	83,33	19,245	66,7	83,33	100,0
		Tag 799 (Woche 114)	2	83,33	23,570	66,7	83,33	100,0

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelles Interesse	CTx + Durvalumab (N=46)	Tag 827 (Woche 118)	3	66,67	0,000	66,7	66,67	66,7
		Tag 855 (Woche 122)	2	66,67	0,000	66,7	66,67	66,7
		Tag 883 (Woche 126)	2	66,67	0,000	66,7	66,67	66,7
		Tag 911 (Woche 130)	2	66,67	0,000	66,7	66,67	66,7
		Tag 939 (Woche 134)	2	66,67	0,000	66,7	66,67	66,7
	CTx (N=49)	Baseline	38	96,49	12,944	33,3	100,00	100,0
		Tag 22 (Woche 3)	39	90,60	21,560	0,0	100,00	100,0
		Tag 43 (Woche 6)	37	94,59	18,448	0,0	100,00	100,0
		Tag 64 (Woche 9)	35	88,57	25,492	0,0	100,00	100,0
		Tag 85 (Woche 12)	32	92,71	20,275	0,0	100,00	100,0
		Tag 106 (Woche 15)	34	92,16	20,199	0,0	100,00	100,0
		Tag 127 (Woche 18)	27	96,30	10,675	66,7	100,00	100,0
		Tag 155 (Woche 22)	24	93,06	21,934	0,0	100,00	100,0
		Tag 183 (Woche 26)	20	96,67	10,260	66,7	100,00	100,0
		Tag 211 (Woche 30)	23	97,10	9,603	66,7	100,00	100,0
		Tag 239 (Woche 34)	16	93,75	18,130	33,3	100,00	100,0
		Tag 267 (Woche 38)	18	94,44	17,150	33,3	100,00	100,0
		Tag 295 (Woche 42)	17	92,16	14,575	66,7	100,00	100,0
		Tag 323 (Woche 46)	19	94,74	12,488	66,7	100,00	100,0
		Tag 351 (Woche 50)	17	94,12	13,098	66,7	100,00	100,0
		Tag 379 (Woche 54)	11	96,97	10,050	66,7	100,00	100,0
		Tag 407 (Woche 58)	12	94,44	12,975	66,7	100,00	100,0
		Tag 435 (Woche 62)	10	93,33	14,055	66,7	100,00	100,0
		Tag 463 (Woche 66)	9	92,59	14,699	66,7	100,00	100,0
		Tag 491 (Woche 70)	7	95,24	12,599	66,7	100,00	100,0
		Tag 519 (Woche 74)	8	91,67	15,430	66,7	100,00	100,0
		Tag 547 (Woche 78)	8	95,83	11,785	66,7	100,00	100,0
		Tag 575 (Woche 82)	7	95,24	12,599	66,7	100,00	100,0
		Tag 603 (Woche 86)	6	88,89	17,213	66,7	100,00	100,0
		Tag 631 (Woche 90)	4	91,67	16,667	66,7	100,00	100,0
		Tag 659 (Woche 94)	3	100,00	0,000	100,0	100,00	100,0

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelles Interesse	CTx (N=49)	Tag 687 (Woche 98)	3	100,00	0,000	100,0	100,00	100,0
		Tag 715 (Woche 102)	2	100,00	0,000	100,0	100,00	100,0
		Tag 743 (Woche 106)	2	100,00	0,000	100,0	100,00	100,0
		Tag 771 (Woche 110)	2	100,00	0,000	100,0	100,00	100,0
		Tag 799 (Woche 114)	2	100,00	0,000	100,0	100,00	100,0
		Tag 827 (Woche 118)	2	100,00	0,000	100,0	100,00	100,0
EORTC QLQ-EN24 Sexuelle Aktivität	CTx + Durvalumab (N=46)	Baseline	36	95,37	11,691	66,7	100,00	100,0
		Tag 22 (Woche 3)	34	96,08	10,901	66,7	100,00	100,0
		Tag 43 (Woche 6)	34	95,10	11,983	66,7	100,00	100,0
		Tag 64 (Woche 9)	32	94,79	12,297	66,7	100,00	100,0
		Tag 85 (Woche 12)	30	94,44	12,635	66,7	100,00	100,0
		Tag 106 (Woche 15)	28	97,62	8,742	66,7	100,00	100,0
		Tag 127 (Woche 18)	30	95,56	11,525	66,7	100,00	100,0
		Tag 155 (Woche 22)	25	98,67	6,667	66,7	100,00	100,0
		Tag 183 (Woche 26)	30	98,89	6,086	66,7	100,00	100,0
		Tag 211 (Woche 30)	27	96,30	10,675	66,7	100,00	100,0
		Tag 239 (Woche 34)	23	94,20	12,918	66,7	100,00	100,0
		Tag 267 (Woche 38)	24	97,22	9,411	66,7	100,00	100,0
		Tag 295 (Woche 42)	25	100,00	0,000	100,0	100,00	100,0
		Tag 323 (Woche 46)	24	95,83	11,261	66,7	100,00	100,0
		Tag 351 (Woche 50)	23	98,55	6,950	66,7	100,00	100,0
		Tag 379 (Woche 54)	20	98,33	7,454	66,7	100,00	100,0
		Tag 407 (Woche 58)	18	98,15	7,857	66,7	100,00	100,0
		Tag 435 (Woche 62)	17	98,04	8,085	66,7	100,00	100,0
		Tag 463 (Woche 66)	14	100,00	0,000	100,0	100,00	100,0
		Tag 491 (Woche 70)	15	95,56	11,729	66,7	100,00	100,0
		Tag 519 (Woche 74)	18	96,30	10,779	66,7	100,00	100,0
		Tag 547 (Woche 78)	15	97,78	8,607	66,7	100,00	100,0
		Tag 575 (Woche 82)	11	96,97	10,050	66,7	100,00	100,0
		Tag 603 (Woche 86)	9	88,89	16,667	66,7	100,00	100,0
		Tag 631 (Woche 90)	7	100,00	0,000	100,0	100,00	100,0

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelle Aktivität	CTx + Durvalumab (N=46)	Tag 659 (Woche 94)	9	100,00	0,000	100,0	100,00	100,0
		Tag 687 (Woche 98)	6	94,44	13,608	66,7	100,00	100,0
		Tag 715 (Woche 102)	6	100,00	0,000	100,0	100,00	100,0
		Tag 743 (Woche 106)	4	100,00	0,000	100,0	100,00	100,0
		Tag 771 (Woche 110)	4	100,00	0,000	100,0	100,00	100,0
		Tag 799 (Woche 114)	2	100,00	0,000	100,0	100,00	100,0
		Tag 827 (Woche 118)	3	88,89	19,245	66,7	100,00	100,0
		Tag 855 (Woche 122)	2	83,33	23,570	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	83,33	23,570	66,7	83,33	100,0
		Tag 939 (Woche 134)	2	83,33	23,570	66,7	83,33	100,0
	CTx (N=49)	Baseline	38	98,25	7,543	66,7	100,00	100,0
		Tag 22 (Woche 3)	39	95,73	11,290	66,7	100,00	100,0
		Tag 43 (Woche 6)	37	98,20	7,641	66,7	100,00	100,0
		Tag 64 (Woche 9)	35	97,14	9,468	66,7	100,00	100,0
		Tag 85 (Woche 12)	32	95,83	11,200	66,7	100,00	100,0
		Tag 106 (Woche 15)	34	97,06	9,597	66,7	100,00	100,0
		Tag 127 (Woche 18)	27	96,30	10,675	66,7	100,00	100,0
		Tag 155 (Woche 22)	24	95,83	11,261	66,7	100,00	100,0
		Tag 183 (Woche 26)	20	96,67	10,260	66,7	100,00	100,0
		Tag 211 (Woche 30)	23	97,10	9,603	66,7	100,00	100,0
		Tag 239 (Woche 34)	16	95,83	11,386	66,7	100,00	100,0
		Tag 267 (Woche 38)	18	94,44	17,150	33,3	100,00	100,0
		Tag 295 (Woche 42)	17	96,08	11,070	66,7	100,00	100,0
		Tag 323 (Woche 46)	19	94,74	12,488	66,7	100,00	100,0
		Tag 351 (Woche 50)	17	96,08	11,070	66,7	100,00	100,0
		Tag 379 (Woche 54)	11	96,97	10,050	66,7	100,00	100,0
		Tag 407 (Woche 58)	12	97,22	9,623	66,7	100,00	100,0
		Tag 435 (Woche 62)	10	96,67	10,541	66,7	100,00	100,0
		Tag 463 (Woche 66)	9	92,59	14,699	66,7	100,00	100,0
		Tag 491 (Woche 70)	7	95,24	12,599	66,7	100,00	100,0
		Tag 519 (Woche 74)	8	95,83	11,785	66,7	100,00	100,0

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelle Aktivität	CTx (N=49)	Tag 547 (Woche 78)	8	95,83	11,785	66,7	100,00	100,0
		Tag 575 (Woche 82)	7	95,24	12,599	66,7	100,00	100,0
		Tag 603 (Woche 86)	6	94,44	13,608	66,7	100,00	100,0
		Tag 631 (Woche 90)	4	91,67	16,667	66,7	100,00	100,0
		Tag 659 (Woche 94)	3	100,00	0,000	100,0	100,00	100,0
		Tag 687 (Woche 98)	3	100,00	0,000	100,0	100,00	100,0
		Tag 715 (Woche 102)	2	100,00	0,000	100,0	100,00	100,0
		Tag 743 (Woche 106)	2	83,33	23,570	66,7	83,33	100,0
		Tag 771 (Woche 110)	2	100,00	0,000	100,0	100,00	100,0
		Tag 799 (Woche 114)	2	100,00	0,000	100,0	100,00	100,0
		Tag 827 (Woche 118)	2	100,00	0,000	100,0	100,00	100,0
EORTC QLQ-EN24 Sexuelles Vergnügen	CTx + Durvalumab (N=46)	Baseline	5	60,00	14,907	33,3	66,67	66,7
		Tag 22 (Woche 3)	4	50,00	57,735	0,0	50,00	100,0
		Tag 43 (Woche 6)	5	53,33	18,257	33,3	66,67	66,7
		Tag 64 (Woche 9)	5	73,33	14,907	66,7	66,67	100,0
		Tag 85 (Woche 12)	5	73,33	27,889	33,3	66,67	100,0
		Tag 106 (Woche 15)	2	66,67	47,140	33,3	66,67	100,0
		Tag 127 (Woche 18)	4	58,33	16,667	33,3	66,67	66,7
		Tag 155 (Woche 22)	1	66,67	NC	66,7	66,67	66,7
		Tag 183 (Woche 26)	1	33,33	NC	33,3	33,33	33,3
		Tag 211 (Woche 30)	3	55,56	50,918	0,0	66,67	100,0
		Tag 239 (Woche 34)	4	58,33	31,914	33,3	50,00	100,0
		Tag 267 (Woche 38)	2	50,00	23,570	33,3	50,00	66,7
		Tag 323 (Woche 46)	3	77,78	19,245	66,7	66,67	100,0
		Tag 351 (Woche 50)	1	66,67	NC	66,7	66,67	66,7
		Tag 379 (Woche 54)	1	66,67	NC	66,7	66,67	66,7
		Tag 407 (Woche 58)	1	66,67	NC	66,7	66,67	66,7
		Tag 435 (Woche 62)	1	66,67	NC	66,7	66,67	66,7
		Tag 491 (Woche 70)	2	66,67	0,000	66,7	66,67	66,7
		Tag 519 (Woche 74)	2	50,00	23,570	33,3	50,00	66,7
		Tag 547 (Woche 78)	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 gsmeanprab 13MAR2024:16:01

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelles Vergnügen	CTx + Durvalumab (N=46)	Tag 575 (Woche 82)	1	33,33	NC	33,3	33,33	33,3
		Tag 603 (Woche 86)	3	55,56	19,245	33,3	66,67	66,7
		Tag 687 (Woche 98)	1	66,67	NC	66,7	66,67	66,7
		Tag 827 (Woche 118)	1	66,67	NC	66,7	66,67	66,7
		Tag 855 (Woche 122)	1	66,67	NC	66,7	66,67	66,7
		Tag 883 (Woche 126)	1	66,67	NC	66,7	66,67	66,7
		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
	CTx (N=49)	Baseline	2	66,67	0,000	66,7	66,67	66,7
		Tag 22 (Woche 3)	6	55,56	27,217	0,0	66,67	66,7
		Tag 43 (Woche 6)	2	66,67	0,000	66,7	66,67	66,7
		Tag 64 (Woche 9)	3	44,44	19,245	33,3	33,33	66,7
		Tag 85 (Woche 12)	4	41,67	16,667	33,3	33,33	66,7
		Tag 106 (Woche 15)	3	33,33	0,000	33,3	33,33	33,3
		Tag 127 (Woche 18)	3	66,67	33,333	33,3	66,67	100,0
		Tag 155 (Woche 22)	3	44,44	38,490	0,0	66,67	66,7
		Tag 183 (Woche 26)	2	66,67	0,000	66,7	66,67	66,7
		Tag 211 (Woche 30)	2	50,00	23,570	33,3	50,00	66,7
		Tag 239 (Woche 34)	2	50,00	23,570	33,3	50,00	66,7
		Tag 267 (Woche 38)	2	66,67	0,000	66,7	66,67	66,7
		Tag 295 (Woche 42)	2	66,67	0,000	66,7	66,67	66,7
		Tag 323 (Woche 46)	3	66,67	0,000	66,7	66,67	66,7
		Tag 351 (Woche 50)	2	50,00	23,570	33,3	50,00	66,7
		Tag 379 (Woche 54)	1	66,67	NC	66,7	66,67	66,7
		Tag 407 (Woche 58)	1	66,67	NC	66,7	66,67	66,7
		Tag 435 (Woche 62)	1	66,67	NC	66,7	66,67	66,7
		Tag 463 (Woche 66)	2	66,67	0,000	66,7	66,67	66,7
		Tag 491 (Woche 70)	1	66,67	NC	66,7	66,67	66,7
		Tag 519 (Woche 74)	1	66,67	NC	66,7	66,67	66,7
		Tag 547 (Woche 78)	1	66,67	NC	66,7	66,67	66,7
		Tag 575 (Woche 82)	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 gsmeanprab 13MAR2024:16:01

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelles Vergnügen	CTx (N=49)	Tag 603 (Woche 86)	1	66,67	NC	66,7	66,67	66,7
		Tag 631 (Woche 90)	1	66,67	NC	66,7	66,67	66,7
		Tag 743 (Woche 106)	1	66,67	NC	66,7	66,67	66,7
EORTC QLQ-EN24 Lymphödem	CTx + Durvalumab (N=46)	Baseline	36	11,11	19,920	0,0	0,00	83,3
		Tag 22 (Woche 3)	34	18,14	25,744	0,0	8,33	100,0
		Tag 43 (Woche 6)	34	14,22	18,862	0,0	8,33	66,7
		Tag 64 (Woche 9)	32	18,23	25,875	0,0	8,33	100,0
		Tag 85 (Woche 12)	30	13,89	20,097	0,0	8,33	83,3
		Tag 106 (Woche 15)	28	17,86	17,526	0,0	16,67	66,7
		Tag 127 (Woche 18)	30	18,89	20,869	0,0	16,67	83,3
		Tag 155 (Woche 22)	25	24,67	21,581	0,0	16,67	66,7
		Tag 183 (Woche 26)	30	20,56	22,609	0,0	16,67	83,3
		Tag 211 (Woche 30)	27	19,75	21,202	0,0	16,67	83,3
		Tag 239 (Woche 34)	23	21,74	19,092	0,0	16,67	66,7
		Tag 267 (Woche 38)	24	18,75	18,593	0,0	16,67	66,7
		Tag 295 (Woche 42)	25	18,67	22,730	0,0	16,67	83,3
		Tag 323 (Woche 46)	24	18,06	23,527	0,0	8,33	66,7
		Tag 351 (Woche 50)	23	25,36	26,049	0,0	33,33	83,3
		Tag 379 (Woche 54)	20	20,83	24,706	0,0	16,67	100,0
		Tag 407 (Woche 58)	18	22,22	24,918	0,0	16,67	83,3
		Tag 435 (Woche 62)	17	29,41	26,040	0,0	16,67	100,0
		Tag 463 (Woche 66)	14	25,00	27,542	0,0	25,00	100,0
		Tag 491 (Woche 70)	15	21,11	25,562	0,0	16,67	100,0
		Tag 519 (Woche 74)	18	20,37	27,150	0,0	16,67	100,0
		Tag 547 (Woche 78)	15	20,00	19,107	0,0	16,67	66,7
		Tag 575 (Woche 82)	11	24,24	20,226	0,0	33,33	66,7
		Tag 603 (Woche 86)	9	20,37	23,241	0,0	16,67	66,7
		Tag 631 (Woche 90)	7	28,57	20,893	0,0	33,33	66,7
		Tag 659 (Woche 94)	9	27,78	30,046	0,0	16,67	83,3
		Tag 687 (Woche 98)	6	25,00	25,276	0,0	25,00	66,7
		Tag 715 (Woche 102)	6	27,78	22,771	0,0	25,00	66,7

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Lymphödem	CTx + Durvalumab (N=46)	Tag 743 (Woche 106)	4	20,83	15,957	0,0	25,00	33,3
		Tag 771 (Woche 110)	4	25,00	16,667	0,0	33,33	33,3
		Tag 799 (Woche 114)	2	16,67	23,570	0,0	16,67	33,3
		Tag 827 (Woche 118)	3	0,00	0,000	0,0	0,00	0,0
		Tag 855 (Woche 122)	2	16,67	23,570	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
	CTx (N=49)	Baseline	38	14,47	22,317	0,0	0,00	100,0
		Tag 22 (Woche 3)	39	18,80	21,005	0,0	16,67	100,0
		Tag 43 (Woche 6)	37	19,82	22,851	0,0	16,67	83,3
		Tag 64 (Woche 9)	35	21,90	18,423	0,0	16,67	66,7
		Tag 85 (Woche 12)	32	24,48	19,849	0,0	33,33	66,7
		Tag 106 (Woche 15)	34	22,55	20,051	0,0	16,67	83,3
		Tag 127 (Woche 18)	27	25,93	15,562	0,0	16,67	66,7
		Tag 155 (Woche 22)	24	20,83	22,116	0,0	16,67	83,3
		Tag 183 (Woche 26)	20	23,33	19,041	0,0	25,00	50,0
		Tag 211 (Woche 30)	23	21,74	16,993	0,0	16,67	50,0
		Tag 239 (Woche 34)	16	18,75	18,130	0,0	16,67	50,0
		Tag 267 (Woche 38)	18	20,37	15,713	0,0	16,67	50,0
		Tag 295 (Woche 42)	17	24,51	20,512	0,0	33,33	66,7
		Tag 323 (Woche 46)	19	20,18	19,704	0,0	16,67	66,7
		Tag 351 (Woche 50)	17	21,57	18,413	0,0	33,33	50,0
		Tag 379 (Woche 54)	11	27,27	25,025	0,0	33,33	66,7
		Tag 407 (Woche 58)	12	25,00	32,177	0,0	16,67	100,0
		Tag 435 (Woche 62)	10	23,33	31,623	0,0	16,67	100,0
		Tag 463 (Woche 66)	9	12,96	23,241	0,0	0,00	66,7
		Tag 491 (Woche 70)	7	14,29	14,996	0,0	16,67	33,3
		Tag 519 (Woche 74)	8	12,50	19,416	0,0	0,00	50,0
		Tag 547 (Woche 78)	8	16,67	26,726	0,0	0,00	66,7
		Tag 575 (Woche 82)	7	11,90	15,853	0,0	0,00	33,3
		Tag 603 (Woche 86)	6	16,67	27,889	0,0	0,00	66,7

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Lymphödem	CTx (N=49)	Tag 631 (Woche 90)	4	25,00	21,517	0,0	25,00	50,0
		Tag 659 (Woche 94)	3	11,11	19,245	0,0	0,00	33,3
		Tag 687 (Woche 98)	3	5,56	9,623	0,0	0,00	16,7
		Tag 715 (Woche 102)	2	16,67	23,570	0,0	16,67	33,3
		Tag 743 (Woche 106)	2	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	2	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	8,33	11,785	0,0	8,33	16,7
		Tag 827 (Woche 118)	2	16,67	23,570	0,0	16,67	33,3
EORTC QLQ-EN24 Urologische Symptome	CTx + Durvalumab (N=46)	Baseline	36	16,67	15,040	0,0	16,67	50,0
		Tag 22 (Woche 3)	34	18,63	22,291	0,0	12,50	91,7
		Tag 43 (Woche 6)	34	23,04	25,792	0,0	16,67	91,7
		Tag 64 (Woche 9)	32	22,66	23,969	0,0	16,67	100,0
		Tag 85 (Woche 12)	30	24,44	24,849	0,0	16,67	91,7
		Tag 106 (Woche 15)	28	22,92	19,060	0,0	16,67	75,0
		Tag 127 (Woche 18)	30	19,44	20,800	0,0	12,50	75,0
		Tag 155 (Woche 22)	25	17,00	13,497	0,0	16,67	41,7
		Tag 183 (Woche 26)	30	20,28	18,004	0,0	16,67	75,0
		Tag 211 (Woche 30)	27	17,59	12,303	0,0	16,67	41,7
		Tag 239 (Woche 34)	23	19,93	16,993	0,0	16,67	66,7
		Tag 267 (Woche 38)	24	14,24	14,219	0,0	12,50	41,7
		Tag 295 (Woche 42)	25	18,67	14,688	0,0	16,67	41,7
		Tag 323 (Woche 46)	24	20,49	19,961	0,0	16,67	66,7
		Tag 351 (Woche 50)	23	19,20	18,194	0,0	16,67	75,0
		Tag 379 (Woche 54)	20	16,25	14,679	0,0	16,67	58,3
		Tag 407 (Woche 58)	18	17,59	18,719	0,0	16,67	75,0
		Tag 435 (Woche 62)	17	16,67	15,023	0,0	16,67	50,0
		Tag 463 (Woche 66)	14	16,67	16,984	0,0	12,50	41,7
		Tag 491 (Woche 70)	15	15,56	14,388	0,0	16,67	41,7
		Tag 519 (Woche 74)	18	18,06	17,907	0,0	16,67	58,3
		Tag 547 (Woche 78)	15	17,22	21,238	0,0	8,33	75,0
		Tag 575 (Woche 82)	11	20,45	21,201	0,0	25,00	66,7

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Urologische Symptome	CTx + Durvalumab (N=46)	Tag 603 (Woche 86)	9	19,44	21,651	0,0	16,67	66,7
		Tag 631 (Woche 90)	7	17,86	15,537	0,0	8,33	41,7
		Tag 659 (Woche 94)	9	12,04	12,577	0,0	8,33	33,3
		Tag 687 (Woche 98)	6	9,72	11,076	0,0	8,33	25,0
		Tag 715 (Woche 102)	6	12,50	13,693	0,0	8,33	33,3
		Tag 743 (Woche 106)	4	6,25	12,500	0,0	0,00	25,0
		Tag 771 (Woche 110)	4	10,42	15,775	0,0	4,17	33,3
		Tag 799 (Woche 114)	2	12,50	17,678	0,0	12,50	25,0
		Tag 827 (Woche 118)	3	2,78	4,811	0,0	0,00	8,3
		Tag 855 (Woche 122)	2	8,33	11,785	0,0	8,33	16,7
		Tag 883 (Woche 126)	2	4,17	5,893	0,0	4,17	8,3
		Tag 911 (Woche 130)	2	12,50	17,678	0,0	12,50	25,0
		Tag 939 (Woche 134)	2	8,33	11,785	0,0	8,33	16,7
	CTx (N=49)	Baseline	38	14,69	15,552	0,0	8,33	58,3
		Tag 22 (Woche 3)	39	15,38	16,170	0,0	8,33	58,3
		Tag 43 (Woche 6)	37	15,09	17,440	0,0	8,33	66,7
		Tag 64 (Woche 9)	35	19,52	15,907	0,0	16,67	58,3
		Tag 85 (Woche 12)	32	15,89	16,445	0,0	12,50	66,7
		Tag 106 (Woche 15)	34	17,65	20,594	0,0	8,33	75,0
		Tag 127 (Woche 18)	27	17,59	16,068	0,0	16,67	58,3
		Tag 155 (Woche 22)	24	16,32	16,572	0,0	12,50	58,3
		Tag 183 (Woche 26)	20	15,83	15,508	0,0	8,33	50,0
		Tag 211 (Woche 30)	23	13,77	13,901	0,0	8,33	50,0
		Tag 239 (Woche 34)	16	12,50	14,907	0,0	8,33	50,0
		Tag 267 (Woche 38)	18	17,13	14,140	0,0	16,67	50,0
		Tag 295 (Woche 42)	17	18,14	16,201	0,0	16,67	58,3
		Tag 323 (Woche 46)	19	17,54	15,440	0,0	16,67	50,0
		Tag 351 (Woche 50)	17	16,18	16,789	0,0	8,33	58,3
		Tag 379 (Woche 54)	11	19,70	15,931	0,0	16,67	41,7
		Tag 407 (Woche 58)	12	11,11	12,975	0,0	8,33	41,7
		Tag 435 (Woche 62)	10	18,33	20,713	0,0	12,50	66,7

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Urologische Symptome	CTx (N=49)	Tag 463 (Woche 66)	9	13,89	22,438	0,0	8,33	66,7
		Tag 491 (Woche 70)	7	14,29	18,456	0,0	8,33	50,0
		Tag 519 (Woche 74)	8	12,50	17,817	0,0	0,00	41,7
		Tag 547 (Woche 78)	8	11,46	12,550	0,0	8,33	33,3
		Tag 575 (Woche 82)	7	10,71	13,363	0,0	8,33	33,3
		Tag 603 (Woche 86)	6	16,67	16,667	0,0	16,67	41,7
		Tag 631 (Woche 90)	4	14,58	12,500	0,0	16,67	25,0
		Tag 659 (Woche 94)	3	11,11	12,729	0,0	8,33	25,0
		Tag 687 (Woche 98)	3	11,11	12,729	0,0	8,33	25,0
		Tag 715 (Woche 102)	2	12,50	17,678	0,0	12,50	25,0
		Tag 743 (Woche 106)	2	12,50	17,678	0,0	12,50	25,0
		Tag 771 (Woche 110)	2	12,50	17,678	0,0	12,50	25,0
		Tag 799 (Woche 114)	2	8,33	11,785	0,0	8,33	16,7
		Tag 827 (Woche 118)	2	20,83	5,893	16,7	20,83	25,0
EORTC QLQ-EN24 Gastrointestinale Symptome	CTx + Durvalumab (N=46)	Baseline	36	12,59	9,795	0,0	13,33	33,3
		Tag 22 (Woche 3)	34	11,96	12,036	0,0	6,67	53,3
		Tag 43 (Woche 6)	34	13,53	11,545	0,0	13,33	33,3
		Tag 64 (Woche 9)	32	16,46	15,332	0,0	13,33	53,3
		Tag 85 (Woche 12)	30	13,78	10,495	0,0	13,33	40,0
		Tag 106 (Woche 15)	28	15,00	11,984	0,0	13,33	40,0
		Tag 127 (Woche 18)	30	14,00	10,111	0,0	13,33	46,7
		Tag 155 (Woche 22)	25	12,00	10,000	0,0	13,33	46,7
		Tag 183 (Woche 26)	30	15,33	13,913	0,0	13,33	53,3
		Tag 211 (Woche 30)	27	14,07	15,726	0,0	13,33	66,7
		Tag 239 (Woche 34)	23	14,78	15,564	0,0	6,67	60,0
		Tag 267 (Woche 38)	24	14,44	13,993	0,0	13,33	53,3
		Tag 295 (Woche 42)	25	13,60	12,690	0,0	13,33	46,7
		Tag 323 (Woche 46)	24	16,94	12,737	0,0	13,33	46,7
		Tag 351 (Woche 50)	23	13,91	12,539	0,0	13,33	46,7
		Tag 379 (Woche 54)	20	17,33	12,869	0,0	16,67	46,7
		Tag 407 (Woche 58)	18	11,85	13,825	0,0	6,67	53,3

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Gastrointestinale Symptome	CTx + Durvalumab (N=46)	Tag 435 (Woche 62)	17	10,20	9,752	0,0	6,67	26,7
		Tag 463 (Woche 66)	14	10,95	7,212	0,0	13,33	26,7
		Tag 491 (Woche 70)	15	12,44	10,945	0,0	13,33	40,0
		Tag 519 (Woche 74)	18	14,81	12,003	0,0	13,33	40,0
		Tag 547 (Woche 78)	15	20,44	18,935	0,0	13,33	73,3
		Tag 575 (Woche 82)	11	18,18	16,624	0,0	13,33	46,7
		Tag 603 (Woche 86)	9	18,52	12,373	0,0	20,00	40,0
		Tag 631 (Woche 90)	7	17,14	15,327	0,0	20,00	40,0
		Tag 659 (Woche 94)	9	13,33	11,547	0,0	20,00	26,7
		Tag 687 (Woche 98)	6	16,67	10,111	0,0	16,67	26,7
		Tag 715 (Woche 102)	6	10,00	10,111	0,0	10,00	26,7
		Tag 743 (Woche 106)	4	6,67	7,698	0,0	6,67	13,3
		Tag 771 (Woche 110)	4	13,33	18,856	0,0	6,67	40,0
		Tag 799 (Woche 114)	2	23,33	23,570	6,7	23,33	40,0
		Tag 827 (Woche 118)	3	0,00	0,000	0,0	0,00	0,0
		Tag 855 (Woche 122)	2	3,33	4,714	0,0	3,33	6,7
		Tag 883 (Woche 126)	2	3,33	4,714	0,0	3,33	6,7
		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
	CTx (N=49)	Baseline	38	12,11	12,578	0,0	6,67	46,7
		Tag 22 (Woche 3)	39	12,99	12,135	0,0	13,33	40,0
		Tag 43 (Woche 6)	37	12,25	11,057	0,0	13,33	53,3
		Tag 64 (Woche 9)	35	12,19	12,044	0,0	6,67	60,0
		Tag 85 (Woche 12)	32	16,88	15,144	0,0	13,33	66,7
		Tag 106 (Woche 15)	34	14,31	13,646	0,0	13,33	53,3
		Tag 127 (Woche 18)	27	14,07	13,878	0,0	13,33	60,0
		Tag 155 (Woche 22)	24	12,22	10,152	0,0	13,33	33,3
		Tag 183 (Woche 26)	20	15,33	12,996	0,0	13,33	46,7
		Tag 211 (Woche 30)	23	13,62	13,555	0,0	6,67	53,3
		Tag 239 (Woche 34)	16	14,17	15,563	0,0	10,00	53,3
		Tag 267 (Woche 38)	18	16,67	18,612	0,0	13,33	66,7

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Gastrointestinale Symptome	CTx (N=49)	Tag 295 (Woche 42)	17	13,33	13,944	0,0	13,33	53,3
		Tag 323 (Woche 46)	19	13,33	13,517	0,0	6,67	53,3
		Tag 351 (Woche 50)	17	12,94	11,660	0,0	13,33	46,7
		Tag 379 (Woche 54)	11	13,94	13,150	0,0	13,33	40,0
		Tag 407 (Woche 58)	12	10,00	12,227	0,0	6,67	33,3
		Tag 435 (Woche 62)	10	10,67	13,407	0,0	6,67	40,0
		Tag 463 (Woche 66)	9	9,63	8,889	0,0	6,67	26,7
		Tag 491 (Woche 70)	7	11,43	11,996	0,0	6,67	33,3
		Tag 519 (Woche 74)	8	8,33	9,258	0,0	6,67	26,7
		Tag 547 (Woche 78)	8	8,33	10,541	0,0	3,33	26,7
		Tag 575 (Woche 82)	7	5,71	5,998	0,0	6,67	13,3
		Tag 603 (Woche 86)	6	7,78	6,555	0,0	10,00	13,3
		Tag 631 (Woche 90)	4	8,33	6,383	0,0	10,00	13,3
		Tag 659 (Woche 94)	3	4,44	3,849	0,0	6,67	6,7
		Tag 687 (Woche 98)	3	8,89	7,698	0,0	13,33	13,3
		Tag 715 (Woche 102)	2	10,00	4,714	6,7	10,00	13,3
		Tag 743 (Woche 106)	2	13,33	9,428	6,7	13,33	20,0
		Tag 771 (Woche 110)	2	6,67	0,000	6,7	6,67	6,7
		Tag 799 (Woche 114)	2	16,67	4,714	13,3	16,67	20,0
		Tag 827 (Woche 118)	2	13,33	0,000	13,3	13,33	13,3
EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung	CTx + Durvalumab (N=46)	Baseline	36	15,74	22,518	0,0	0,00	83,3
		Tag 22 (Woche 3)	34	30,88	28,760	0,0	25,00	100,0
		Tag 43 (Woche 6)	34	31,86	32,662	0,0	33,33	100,0
		Tag 64 (Woche 9)	32	28,65	28,155	0,0	25,00	100,0
		Tag 85 (Woche 12)	30	37,22	31,160	0,0	33,33	100,0
		Tag 106 (Woche 15)	28	30,95	26,338	0,0	33,33	83,3
		Tag 127 (Woche 18)	30	34,44	29,985	0,0	33,33	100,0
		Tag 155 (Woche 22)	25	31,33	30,927	0,0	33,33	100,0
		Tag 183 (Woche 26)	30	30,56	30,033	0,0	33,33	100,0
		Tag 211 (Woche 30)	27	27,78	25,318	0,0	33,33	83,3
		Tag 239 (Woche 34)	23	25,36	27,001	0,0	33,33	100,0

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung	CTx + Durvalumab (N=46)	Tag 267 (Woche 38)	24	22,22	24,409	0,0	16,67	83,3
		Tag 295 (Woche 42)	25	26,00	24,095	0,0	33,33	83,3
		Tag 323 (Woche 46)	24	24,31	25,050	0,0	16,67	83,3
		Tag 351 (Woche 50)	23	22,46	26,878	0,0	16,67	100,0
		Tag 379 (Woche 54)	20	22,50	22,475	0,0	25,00	66,7
		Tag 407 (Woche 58)	18	25,00	28,151	0,0	33,33	100,0
		Tag 435 (Woche 62)	17	25,49	27,712	0,0	16,67	100,0
		Tag 463 (Woche 66)	14	25,00	28,307	0,0	16,67	100,0
		Tag 491 (Woche 70)	15	26,67	25,040	0,0	33,33	100,0
		Tag 519 (Woche 74)	18	22,22	26,813	0,0	16,67	100,0
		Tag 547 (Woche 78)	15	16,67	16,667	0,0	16,67	50,0
		Tag 575 (Woche 82)	11	16,67	14,907	0,0	16,67	33,3
		Tag 603 (Woche 86)	9	14,81	13,029	0,0	16,67	33,3
		Tag 631 (Woche 90)	7	26,19	13,113	0,0	33,33	33,3
		Tag 659 (Woche 94)	9	20,37	16,197	0,0	33,33	33,3
		Tag 687 (Woche 98)	6	27,78	25,092	0,0	33,33	66,7
		Tag 715 (Woche 102)	6	16,67	18,257	0,0	16,67	33,3
		Tag 743 (Woche 106)	4	33,33	27,217	0,0	33,33	66,7
		Tag 771 (Woche 110)	4	25,00	16,667	0,0	33,33	33,3
		Tag 799 (Woche 114)	2	16,67	23,570	0,0	16,67	33,3
		Tag 827 (Woche 118)	3	16,67	16,667	0,0	16,67	33,3
		Tag 855 (Woche 122)	2	16,67	23,570	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
	CTx (N=49)	Baseline	38	7,02	18,837	0,0	0,00	100,0
		Tag 22 (Woche 3)	39	28,63	28,084	0,0	33,33	100,0
		Tag 43 (Woche 6)	37	30,18	29,876	0,0	33,33	100,0
		Tag 64 (Woche 9)	35	31,43	29,916	0,0	33,33	100,0
		Tag 85 (Woche 12)	32	36,46	31,234	0,0	33,33	100,0
		Tag 106 (Woche 15)	34	34,31	31,232	0,0	33,33	100,0

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Eingeschränkte Körperwahrnehmung	CTx (N=49)	Tag 127 (Woche 18)	27	29,63	27,863	0,0	33,33	83,3
		Tag 155 (Woche 22)	24	29,86	29,067	0,0	33,33	100,0
		Tag 183 (Woche 26)	20	29,17	23,493	0,0	33,33	66,7
		Tag 211 (Woche 30)	23	30,43	26,425	0,0	33,33	66,7
		Tag 239 (Woche 34)	16	33,33	21,943	0,0	33,33	66,7
		Tag 267 (Woche 38)	18	29,63	29,459	0,0	33,33	100,0
		Tag 295 (Woche 42)	17	32,35	30,317	0,0	33,33	100,0
		Tag 323 (Woche 46)	19	34,21	29,645	0,0	33,33	100,0
		Tag 351 (Woche 50)	17	31,37	30,552	0,0	33,33	100,0
		Tag 379 (Woche 54)	11	33,33	28,868	0,0	33,33	100,0
		Tag 407 (Woche 58)	12	33,33	37,605	0,0	33,33	100,0
		Tag 435 (Woche 62)	10	35,00	33,747	0,0	33,33	100,0
		Tag 463 (Woche 66)	9	22,22	27,639	0,0	16,67	66,7
		Tag 491 (Woche 70)	7	19,05	26,227	0,0	0,00	66,7
		Tag 519 (Woche 74)	8	14,58	16,517	0,0	8,33	33,3
		Tag 547 (Woche 78)	8	12,50	24,801	0,0	0,00	66,7
		Tag 575 (Woche 82)	7	11,90	24,934	0,0	0,00	66,7
		Tag 603 (Woche 86)	6	8,33	13,944	0,0	0,00	33,3
		Tag 631 (Woche 90)	4	8,33	16,667	0,0	0,00	33,3
		Tag 659 (Woche 94)	3	22,22	38,490	0,0	0,00	66,7
		Tag 687 (Woche 98)	3	22,22	38,490	0,0	0,00	66,7
		Tag 715 (Woche 102)	2	33,33	47,140	0,0	33,33	66,7
		Tag 743 (Woche 106)	2	33,33	47,140	0,0	33,33	66,7
		Tag 771 (Woche 110)	2	16,67	23,570	0,0	16,67	33,3
		Tag 799 (Woche 114)	2	33,33	47,140	0,0	33,33	66,7
		Tag 827 (Woche 118)	2	16,67	23,570	0,0	16,67	33,3
EORTC QLQ-EN24 Sexuelle/vaginale Probleme	CTx + Durvalumab (N=46)	Baseline	5	13,33	14,487	0,0	11,11	33,3
		Tag 22 (Woche 3)	4	16,67	11,111	11,1	11,11	33,3
		Tag 43 (Woche 6)	5	8,89	14,487	0,0	0,00	33,3
		Tag 64 (Woche 9)	5	22,22	17,568	0,0	22,22	44,4
		Tag 85 (Woche 12)	5	17,78	16,851	0,0	11,11	44,4

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelle/vaginale Probleme	CTx + Durvalumab (N=46)	Tag 106 (Woche 15)	2	16,67	23,570	0,0	16,67	33,3
		Tag 127 (Woche 18)	4	13,89	10,638	0,0	16,67	22,2
		Tag 155 (Woche 22)	1	0,00	NC	0,0	0,00	0,0
		Tag 183 (Woche 26)	1	0,00	NC	0,0	0,00	0,0
		Tag 211 (Woche 30)	3	18,52	16,973	0,0	22,22	33,3
		Tag 239 (Woche 34)	4	8,33	16,667	0,0	0,00	33,3
		Tag 267 (Woche 38)	2	0,00	0,000	0,0	0,00	0,0
		Tag 323 (Woche 46)	3	7,41	12,830	0,0	0,00	22,2
		Tag 351 (Woche 50)	1	0,00	NC	0,0	0,00	0,0
		Tag 379 (Woche 54)	1	0,00	NC	0,0	0,00	0,0
		Tag 407 (Woche 58)	1	11,11	NC	11,1	11,11	11,1
		Tag 435 (Woche 62)	1	0,00	NC	0,0	0,00	0,0
		Tag 491 (Woche 70)	2	0,00	0,000	0,0	0,00	0,0
		Tag 519 (Woche 74)	2	11,11	15,713	0,0	11,11	22,2
		Tag 547 (Woche 78)	1	0,00	NC	0,0	0,00	0,0
		Tag 575 (Woche 82)	1	44,44	NC	44,4	44,44	44,4
		Tag 603 (Woche 86)	3	3,70	6,415	0,0	0,00	11,1
		Tag 687 (Woche 98)	1	0,00	NC	0,0	0,00	0,0
		Tag 827 (Woche 118)	1	0,00	NC	0,0	0,00	0,0
		Tag 855 (Woche 122)	1	0,00	NC	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
	CTx (N=49)	Baseline	2	61,11	23,570	44,4	61,11	77,8
		Tag 22 (Woche 3)	6	35,19	19,138	11,1	33,33	55,6
		Tag 43 (Woche 6)	2	33,33	31,427	11,1	33,33	55,6
		Tag 64 (Woche 9)	3	33,33	29,397	11,1	22,22	66,7
		Tag 85 (Woche 12)	4	2,78	5,556	0,0	0,00	11,1
		Tag 106 (Woche 15)	3	14,81	6,415	11,1	11,11	22,2
		Tag 127 (Woche 18)	3	22,22	38,490	0,0	0,00	66,7
		Tag 155 (Woche 22)	3	22,22	19,245	0,0	33,33	33,3

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Sexuelle/vaginale Probleme	CTx (N=49)	Tag 183 (Woche 26)	2	44,44	31,427	22,2	44,44	66,7
		Tag 211 (Woche 30)	2	44,44	31,427	22,2	44,44	66,7
		Tag 239 (Woche 34)	2	44,44	31,427	22,2	44,44	66,7
		Tag 267 (Woche 38)	2	16,67	7,857	11,1	16,67	22,2
		Tag 295 (Woche 42)	2	44,44	31,427	22,2	44,44	66,7
		Tag 323 (Woche 46)	3	33,33	29,397	11,1	22,22	66,7
		Tag 351 (Woche 50)	2	11,11	15,713	0,0	11,11	22,2
		Tag 379 (Woche 54)	1	11,11	NC	11,1	11,11	11,1
		Tag 407 (Woche 58)	1	22,22	NC	22,2	22,22	22,2
		Tag 435 (Woche 62)	1	11,11	NC	11,1	11,11	11,1
		Tag 463 (Woche 66)	2	16,67	7,857	11,1	16,67	22,2
		Tag 491 (Woche 70)	1	0,00	NC	0,0	0,00	0,0
		Tag 519 (Woche 74)	1	33,33	NC	33,3	33,33	33,3
		Tag 547 (Woche 78)	1	33,33	NC	33,3	33,33	33,3
		Tag 575 (Woche 82)	1	22,22	NC	22,2	22,22	22,2
		Tag 603 (Woche 86)	1	33,33	NC	33,3	33,33	33,3
		Tag 631 (Woche 90)	1	22,22	NC	22,2	22,22	22,2
		Tag 743 (Woche 106)	1	77,78	NC	77,8	77,78	77,8
EORTC QLQ-EN24 Rücken- und Beckenschmerzen	CTx + Durvalumab (N=46)	Baseline	36	27,78	25,820	0,0	33,33	100,0
		Tag 22 (Woche 3)	34	21,57	25,797	0,0	16,67	100,0
		Tag 43 (Woche 6)	34	25,49	24,699	0,0	33,33	66,7
		Tag 64 (Woche 9)	32	22,92	24,593	0,0	33,33	66,7
		Tag 85 (Woche 12)	30	21,11	26,957	0,0	0,00	66,7
		Tag 106 (Woche 15)	28	21,43	27,539	0,0	16,67	100,0
		Tag 127 (Woche 18)	30	28,89	32,440	0,0	33,33	100,0
		Tag 155 (Woche 22)	25	25,33	30,852	0,0	33,33	100,0
		Tag 183 (Woche 26)	30	30,00	29,491	0,0	33,33	100,0
		Tag 211 (Woche 30)	27	29,63	29,719	0,0	33,33	100,0
		Tag 239 (Woche 34)	23	27,54	23,894	0,0	33,33	66,7
		Tag 267 (Woche 38)	24	29,17	29,996	0,0	33,33	100,0
		Tag 295 (Woche 42)	25	32,00	22,526	0,0	33,33	66,7

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Rücken- und Beckenschmerzen	CTx + Durvalumab (N=46)	Tag 323 (Woche 46)	24	26,39	24,035	0,0	33,33	66,7
		Tag 351 (Woche 50)	23	31,88	29,264	0,0	33,33	100,0
		Tag 379 (Woche 54)	20	26,67	25,592	0,0	33,33	66,7
		Tag 407 (Woche 58)	18	27,78	28,583	0,0	33,33	100,0
		Tag 435 (Woche 62)	17	27,45	26,965	0,0	33,33	100,0
		Tag 463 (Woche 66)	14	28,57	31,642	0,0	33,33	100,0
		Tag 491 (Woche 70)	15	33,33	33,333	0,0	33,33	100,0
		Tag 519 (Woche 74)	18	33,33	34,300	0,0	33,33	100,0
		Tag 547 (Woche 78)	15	31,11	32,038	0,0	33,33	100,0
		Tag 575 (Woche 82)	11	27,27	32,722	0,0	33,33	100,0
		Tag 603 (Woche 86)	9	25,93	27,778	0,0	33,33	66,7
		Tag 631 (Woche 90)	7	19,05	17,817	0,0	33,33	33,3
		Tag 659 (Woche 94)	9	18,52	17,568	0,0	33,33	33,3
		Tag 687 (Woche 98)	6	27,78	25,092	0,0	33,33	66,7
		Tag 715 (Woche 102)	6	11,11	17,213	0,0	0,00	33,3
		Tag 743 (Woche 106)	4	8,33	16,667	0,0	0,00	33,3
		Tag 771 (Woche 110)	4	8,33	16,667	0,0	0,00	33,3
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	3	22,22	38,490	0,0	0,00	66,7
		Tag 855 (Woche 122)	2	33,33	47,140	0,0	33,33	66,7
		Tag 883 (Woche 126)	2	33,33	47,140	0,0	33,33	66,7
		Tag 911 (Woche 130)	2	33,33	47,140	0,0	33,33	66,7
		Tag 939 (Woche 134)	2	33,33	47,140	0,0	33,33	66,7
	CTx (N=49)	Baseline	38	23,68	26,743	0,0	33,33	100,0
		Tag 22 (Woche 3)	39	21,37	27,023	0,0	0,00	100,0
		Tag 43 (Woche 6)	37	18,02	21,652	0,0	0,00	66,7
		Tag 64 (Woche 9)	35	24,76	21,907	0,0	33,33	66,7
		Tag 85 (Woche 12)	32	29,17	26,437	0,0	33,33	100,0
		Tag 106 (Woche 15)	34	24,51	25,037	0,0	33,33	100,0
		Tag 127 (Woche 18)	27	24,69	19,812	0,0	33,33	66,7
		Tag 155 (Woche 22)	24	25,00	20,264	0,0	33,33	66,7

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Rücken- und Beckenschmerzen	CTx (N=49)	Tag 183 (Woche 26)	20	28,33	24,839	0,0	33,33	66,7
		Tag 211 (Woche 30)	23	27,54	25,922	0,0	33,33	66,7
		Tag 239 (Woche 34)	16	27,08	25,000	0,0	33,33	66,7
		Tag 267 (Woche 38)	18	24,07	19,150	0,0	33,33	66,7
		Tag 295 (Woche 42)	17	23,53	22,866	0,0	33,33	66,7
		Tag 323 (Woche 46)	19	29,82	18,904	0,0	33,33	66,7
		Tag 351 (Woche 50)	17	29,41	26,040	0,0	33,33	66,7
		Tag 379 (Woche 54)	11	39,39	29,129	0,0	33,33	100,0
		Tag 407 (Woche 58)	12	36,11	22,285	0,0	33,33	66,7
		Tag 435 (Woche 62)	10	26,67	21,082	0,0	33,33	66,7
		Tag 463 (Woche 66)	9	25,93	22,222	0,0	33,33	66,7
		Tag 491 (Woche 70)	7	19,05	17,817	0,0	33,33	33,3
		Tag 519 (Woche 74)	8	29,17	21,362	0,0	33,33	66,7
		Tag 547 (Woche 78)	8	29,17	27,817	0,0	33,33	66,7
		Tag 575 (Woche 82)	7	23,81	25,198	0,0	33,33	66,7
		Tag 603 (Woche 86)	6	33,33	29,814	0,0	33,33	66,7
		Tag 631 (Woche 90)	4	50,00	33,333	33,3	33,33	100,0
		Tag 659 (Woche 94)	3	33,33	33,333	0,0	33,33	66,7
		Tag 687 (Woche 98)	3	55,56	19,245	33,3	66,67	66,7
		Tag 715 (Woche 102)	2	66,67	47,140	33,3	66,67	100,0
		Tag 743 (Woche 106)	2	66,67	0,000	66,7	66,67	66,7
		Tag 771 (Woche 110)	2	66,67	0,000	66,7	66,67	66,7
		Tag 799 (Woche 114)	2	50,00	23,570	33,3	50,00	66,7
		Tag 827 (Woche 118)	2	50,00	23,570	33,3	50,00	66,7
EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl	CTx + Durvalumab (N=46)	Baseline	36	11,11	15,936	0,0	0,00	33,3
		Tag 22 (Woche 3)	34	28,43	29,738	0,0	33,33	100,0
		Tag 43 (Woche 6)	34	36,27	28,859	0,0	33,33	100,0
		Tag 64 (Woche 9)	32	36,46	29,765	0,0	33,33	100,0
		Tag 85 (Woche 12)	30	46,67	34,575	0,0	33,33	100,0
		Tag 106 (Woche 15)	28	53,57	30,550	0,0	33,33	100,0
		Tag 127 (Woche 18)	30	57,78	36,022	0,0	66,67	100,0

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl	CTx + Durvalumab (N=46)	Tag 155 (Woche 22)	25	66,67	30,429	33,3	66,67	100,0
		Tag 183 (Woche 26)	30	54,44	33,314	0,0	66,67	100,0
		Tag 211 (Woche 30)	27	55,56	27,735	0,0	66,67	100,0
		Tag 239 (Woche 34)	23	52,17	33,069	0,0	33,33	100,0
		Tag 267 (Woche 38)	24	45,83	29,180	0,0	33,33	100,0
		Tag 295 (Woche 42)	25	45,33	28,674	0,0	33,33	100,0
		Tag 323 (Woche 46)	24	40,28	31,051	0,0	33,33	100,0
		Tag 351 (Woche 50)	23	49,28	33,135	0,0	33,33	100,0
		Tag 379 (Woche 54)	20	48,33	38,198	0,0	33,33	100,0
		Tag 407 (Woche 58)	18	48,15	36,555	0,0	33,33	100,0
		Tag 435 (Woche 62)	17	43,14	34,890	0,0	33,33	100,0
		Tag 463 (Woche 66)	14	45,24	38,358	0,0	33,33	100,0
		Tag 491 (Woche 70)	15	42,22	36,659	0,0	33,33	100,0
		Tag 519 (Woche 74)	18	44,44	36,155	0,0	33,33	100,0
		Tag 547 (Woche 78)	15	40,00	28,730	0,0	33,33	66,7
		Tag 575 (Woche 82)	11	33,33	29,814	0,0	33,33	66,7
		Tag 603 (Woche 86)	9	40,74	36,430	0,0	33,33	100,0
		Tag 631 (Woche 90)	7	38,10	35,635	0,0	33,33	100,0
		Tag 659 (Woche 94)	9	25,93	22,222	0,0	33,33	66,7
		Tag 687 (Woche 98)	6	27,78	25,092	0,0	33,33	66,7
		Tag 715 (Woche 102)	6	27,78	25,092	0,0	33,33	66,7
		Tag 743 (Woche 106)	4	33,33	27,217	0,0	33,33	66,7
		Tag 771 (Woche 110)	4	33,33	27,217	0,0	33,33	66,7
		Tag 799 (Woche 114)	2	50,00	23,570	33,3	50,00	66,7
		Tag 827 (Woche 118)	3	33,33	0,000	33,3	33,33	33,3
		Tag 855 (Woche 122)	2	33,33	0,000	33,3	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	33,33	0,000	33,3	33,33	33,3

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl	CTx (N=49)	Baseline	38	8,77	14,875	0,0	0,00	33,3
		Tag 22 (Woche 3)	39	27,35	25,215	0,0	33,33	66,7
		Tag 43 (Woche 6)	37	32,43	25,442	0,0	33,33	66,7
		Tag 64 (Woche 9)	35	47,62	25,928	0,0	33,33	100,0
		Tag 85 (Woche 12)	32	51,04	31,662	0,0	66,67	100,0
		Tag 106 (Woche 15)	34	57,84	29,937	0,0	66,67	100,0
		Tag 127 (Woche 18)	27	60,49	32,075	0,0	66,67	100,0
		Tag 155 (Woche 22)	24	55,56	32,103	0,0	50,00	100,0
		Tag 183 (Woche 26)	20	45,00	31,110	0,0	33,33	100,0
		Tag 211 (Woche 30)	23	37,68	28,962	0,0	33,33	100,0
		Tag 239 (Woche 34)	16	56,25	20,069	33,3	66,67	100,0
		Tag 267 (Woche 38)	18	48,15	28,520	0,0	66,67	100,0
		Tag 295 (Woche 42)	17	43,14	28,296	0,0	33,33	100,0
		Tag 323 (Woche 46)	19	47,37	25,618	0,0	33,33	100,0
		Tag 351 (Woche 50)	17	41,18	27,712	0,0	33,33	100,0
		Tag 379 (Woche 54)	11	51,52	37,605	0,0	66,67	100,0
		Tag 407 (Woche 58)	12	36,11	33,207	0,0	33,33	100,0
		Tag 435 (Woche 62)	10	50,00	36,004	0,0	50,00	100,0
		Tag 463 (Woche 66)	9	37,04	30,932	0,0	33,33	100,0
		Tag 491 (Woche 70)	7	38,10	29,991	0,0	33,33	66,7
		Tag 519 (Woche 74)	8	45,83	24,801	0,0	50,00	66,7
		Tag 547 (Woche 78)	8	50,00	30,861	0,0	50,00	100,0
		Tag 575 (Woche 82)	7	33,33	19,245	0,0	33,33	66,7
		Tag 603 (Woche 86)	6	38,89	25,092	0,0	33,33	66,7
		Tag 631 (Woche 90)	4	41,67	16,667	33,3	33,33	66,7
		Tag 659 (Woche 94)	3	33,33	33,333	0,0	33,33	66,7
		Tag 687 (Woche 98)	3	33,33	33,333	0,0	33,33	66,7
		Tag 715 (Woche 102)	2	50,00	23,570	33,3	50,00	66,7
		Tag 743 (Woche 106)	2	50,00	23,570	33,3	50,00	66,7
		Tag 771 (Woche 110)	2	50,00	23,570	33,3	50,00	66,7
		Tag 799 (Woche 114)	2	50,00	23,570	33,3	50,00	66,7

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl	CTx (N=49)	Tag 827 (Woche 118)	2	50,00	23,570	33,3	50,00	66,7
EORTC QLQ-EN24 Muskulärer Schmerz	CTx + Durvalumab (N=46)	Baseline	36	13,89	20,119	0,0	0,00	66,7
		Tag 22 (Woche 3)	34	26,47	28,164	0,0	33,33	100,0
		Tag 43 (Woche 6)	34	30,39	23,738	0,0	33,33	100,0
		Tag 64 (Woche 9)	32	29,17	16,396	0,0	33,33	66,7
		Tag 85 (Woche 12)	30	32,22	26,957	0,0	33,33	100,0
		Tag 106 (Woche 15)	28	36,90	29,171	0,0	33,33	100,0
		Tag 127 (Woche 18)	30	36,67	33,160	0,0	33,33	100,0
		Tag 155 (Woche 22)	25	36,00	34,588	0,0	33,33	100,0
		Tag 183 (Woche 26)	30	35,56	30,240	0,0	33,33	100,0
		Tag 211 (Woche 30)	27	34,57	25,287	0,0	33,33	100,0
		Tag 239 (Woche 34)	23	34,78	21,269	0,0	33,33	66,7
		Tag 267 (Woche 38)	24	34,72	26,882	0,0	33,33	100,0
		Tag 295 (Woche 42)	25	38,67	29,938	0,0	33,33	100,0
		Tag 323 (Woche 46)	24	30,56	23,909	0,0	33,33	66,7
		Tag 351 (Woche 50)	23	36,23	31,644	0,0	33,33	100,0
		Tag 379 (Woche 54)	20	35,00	31,484	0,0	33,33	100,0
		Tag 407 (Woche 58)	18	38,89	30,785	0,0	33,33	100,0
		Tag 435 (Woche 62)	17	37,25	28,583	0,0	33,33	100,0
		Tag 463 (Woche 66)	14	38,10	34,237	0,0	33,33	100,0
		Tag 491 (Woche 70)	15	37,78	27,794	0,0	33,33	100,0
		Tag 519 (Woche 74)	18	31,48	31,253	0,0	33,33	100,0
		Tag 547 (Woche 78)	15	26,67	25,820	0,0	33,33	66,7
		Tag 575 (Woche 82)	11	27,27	25,025	0,0	33,33	66,7
		Tag 603 (Woche 86)	9	37,04	20,031	0,0	33,33	66,7
		Tag 631 (Woche 90)	7	38,10	23,002	0,0	33,33	66,7
		Tag 659 (Woche 94)	9	37,04	20,031	0,0	33,33	66,7
		Tag 687 (Woche 98)	6	33,33	29,814	0,0	33,33	66,7
		Tag 715 (Woche 102)	6	22,22	27,217	0,0	16,67	66,7
		Tag 743 (Woche 106)	4	16,67	19,245	0,0	16,67	33,3
		Tag 771 (Woche 110)	4	16,67	19,245	0,0	16,67	33,3

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Muskulärer Schmerz	CTx + Durvalumab (N=46)	Tag 799 (Woche 114)	2	16,67	23,570	0,0	16,67	33,3
		Tag 827 (Woche 118)	3	33,33	33,333	0,0	33,33	66,7
		Tag 855 (Woche 122)	2	50,00	23,570	33,3	50,00	66,7
		Tag 883 (Woche 126)	2	50,00	23,570	33,3	50,00	66,7
		Tag 911 (Woche 130)	2	50,00	23,570	33,3	50,00	66,7
		Tag 939 (Woche 134)	2	33,33	0,000	33,3	33,33	33,3
	CTx (N=49)	Baseline	38	13,16	21,280	0,0	0,00	66,7
		Tag 22 (Woche 3)	39	31,62	32,398	0,0	33,33	100,0
		Tag 43 (Woche 6)	37	26,13	29,539	0,0	33,33	100,0
		Tag 64 (Woche 9)	35	30,48	30,648	0,0	33,33	100,0
		Tag 85 (Woche 12)	32	31,25	29,253	0,0	33,33	100,0
		Tag 106 (Woche 15)	34	34,31	34,314	0,0	33,33	100,0
		Tag 127 (Woche 18)	27	27,16	26,209	0,0	33,33	66,7
		Tag 155 (Woche 22)	24	29,17	31,565	0,0	33,33	100,0
		Tag 183 (Woche 26)	20	26,67	25,592	0,0	33,33	66,7
		Tag 211 (Woche 30)	23	26,09	22,375	0,0	33,33	66,7
		Tag 239 (Woche 34)	16	33,33	24,343	0,0	33,33	66,7
		Tag 267 (Woche 38)	18	29,63	32,113	0,0	33,33	100,0
		Tag 295 (Woche 42)	17	35,29	36,268	0,0	33,33	100,0
		Tag 323 (Woche 46)	19	40,35	26,244	0,0	33,33	100,0
		Tag 351 (Woche 50)	17	39,22	29,428	0,0	33,33	100,0
		Tag 379 (Woche 54)	11	39,39	32,722	0,0	33,33	100,0
		Tag 407 (Woche 58)	12	25,00	25,126	0,0	33,33	66,7
		Tag 435 (Woche 62)	10	36,67	24,595	0,0	33,33	66,7
		Tag 463 (Woche 66)	9	37,04	26,058	0,0	33,33	66,7
		Tag 491 (Woche 70)	7	33,33	33,333	0,0	33,33	66,7
		Tag 519 (Woche 74)	8	25,00	23,570	0,0	33,33	66,7
		Tag 547 (Woche 78)	8	29,17	27,817	0,0	33,33	66,7
		Tag 575 (Woche 82)	7	38,10	23,002	0,0	33,33	66,7
		Tag 603 (Woche 86)	6	27,78	25,092	0,0	33,33	66,7
		Tag 631 (Woche 90)	4	41,67	31,914	0,0	50,00	66,7
		Tag 659 (Woche 94)	3	33,33	33,333	0,0	33,33	66,7

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Muskulärer Schmerz	CTx (N=49)	Tag 687 (Woche 98)	3	33,33	33,333	0,0	33,33	66,7
		Tag 715 (Woche 102)	2	50,00	23,570	33,3	50,00	66,7
		Tag 743 (Woche 106)	2	50,00	23,570	33,3	50,00	66,7
		Tag 771 (Woche 110)	2	50,00	23,570	33,3	50,00	66,7
		Tag 799 (Woche 114)	2	33,33	0,000	33,3	33,33	33,3
		Tag 827 (Woche 118)	2	50,00	23,570	33,3	50,00	66,7
EORTC QLQ-EN24 Haarausfall	CTx + Durvalumab (N=46)	Baseline	36	11,11	21,082	0,0	0,00	66,7
		Tag 22 (Woche 3)	34	69,61	31,105	0,0	66,67	100,0
		Tag 43 (Woche 6)	34	71,57	32,960	0,0	66,67	100,0
		Tag 64 (Woche 9)	32	58,33	38,799	0,0	66,67	100,0
		Tag 85 (Woche 12)	30	58,89	41,692	0,0	66,67	100,0
		Tag 106 (Woche 15)	28	59,52	42,896	0,0	66,67	100,0
		Tag 127 (Woche 18)	30	56,67	40,258	0,0	66,67	100,0
		Tag 155 (Woche 22)	25	54,67	45,010	0,0	66,67	100,0
		Tag 183 (Woche 26)	30	31,11	41,921	0,0	0,00	100,0
		Tag 211 (Woche 30)	27	14,81	33,758	0,0	0,00	100,0
		Tag 239 (Woche 34)	23	17,39	33,135	0,0	0,00	100,0
		Tag 267 (Woche 38)	24	9,72	25,020	0,0	0,00	100,0
		Tag 295 (Woche 42)	25	18,67	37,367	0,0	0,00	100,0
		Tag 323 (Woche 46)	24	11,11	25,380	0,0	0,00	100,0
		Tag 351 (Woche 50)	23	10,14	29,189	0,0	0,00	100,0
		Tag 379 (Woche 54)	20	10,00	24,423	0,0	0,00	100,0
		Tag 407 (Woche 58)	18	9,26	25,063	0,0	0,00	100,0
		Tag 435 (Woche 62)	17	5,88	13,098	0,0	0,00	33,3
		Tag 463 (Woche 66)	14	9,52	15,627	0,0	0,00	33,3
		Tag 491 (Woche 70)	15	6,67	13,801	0,0	0,00	33,3
		Tag 519 (Woche 74)	18	5,56	12,783	0,0	0,00	33,3
		Tag 547 (Woche 78)	15	8,89	15,258	0,0	0,00	33,3
		Tag 575 (Woche 82)	11	9,09	15,570	0,0	0,00	33,3
		Tag 603 (Woche 86)	9	18,52	17,568	0,0	33,33	33,3
		Tag 631 (Woche 90)	7	14,29	17,817	0,0	0,00	33,3
		Tag 659 (Woche 94)	9	14,81	17,568	0,0	0,00	33,3

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Haarausfall	CTx + Durvalumab (N=46)	Tag 687 (Woche 98)	6	5,56	13,608	0,0	0,00	33,3
		Tag 715 (Woche 102)	6	11,11	17,213	0,0	0,00	33,3
		Tag 743 (Woche 106)	4	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	4	8,33	16,667	0,0	0,00	33,3
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	3	11,11	19,245	0,0	0,00	33,3
		Tag 855 (Woche 122)	2	16,67	23,570	0,0	16,67	33,3
		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
	CTx (N=49)	Baseline	38	3,51	10,367	0,0	0,00	33,3
		Tag 22 (Woche 3)	39	74,36	31,027	0,0	100,00	100,0
		Tag 43 (Woche 6)	37	65,77	37,257	0,0	100,00	100,0
		Tag 64 (Woche 9)	35	69,52	37,374	0,0	100,00	100,0
		Tag 85 (Woche 12)	32	54,17	44,601	0,0	50,00	100,0
		Tag 106 (Woche 15)	34	52,94	43,514	0,0	33,33	100,0
		Tag 127 (Woche 18)	27	43,21	44,159	0,0	33,33	100,0
		Tag 155 (Woche 22)	24	36,11	46,017	0,0	0,00	100,0
		Tag 183 (Woche 26)	20	11,67	31,110	0,0	0,00	100,0
		Tag 211 (Woche 30)	23	11,59	29,488	0,0	0,00	100,0
		Tag 239 (Woche 34)	16	8,33	19,245	0,0	0,00	66,7
		Tag 267 (Woche 38)	18	11,11	28,006	0,0	0,00	100,0
		Tag 295 (Woche 42)	17	7,84	18,743	0,0	0,00	66,7
		Tag 323 (Woche 46)	19	14,04	23,083	0,0	0,00	66,7
		Tag 351 (Woche 50)	17	15,69	29,149	0,0	0,00	100,0
		Tag 379 (Woche 54)	11	9,09	15,570	0,0	0,00	33,3
		Tag 407 (Woche 58)	12	2,78	9,623	0,0	0,00	33,3
		Tag 435 (Woche 62)	10	0,00	0,000	0,0	0,00	0,0
		Tag 463 (Woche 66)	9	0,00	0,000	0,0	0,00	0,0
		Tag 491 (Woche 70)	7	0,00	0,000	0,0	0,00	0,0
		Tag 519 (Woche 74)	8	4,17	11,785	0,0	0,00	33,3
		Tag 547 (Woche 78)	8	4,17	11,785	0,0	0,00	33,3

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Haarausfall	CTx (N=49)	Tag 575 (Woche 82)	7	4,76	12,599	0,0	0,00	33,3
		Tag 603 (Woche 86)	6	0,00	0,000	0,0	0,00	0,0
		Tag 631 (Woche 90)	4	0,00	0,000	0,0	0,00	0,0
		Tag 659 (Woche 94)	3	0,00	0,000	0,0	0,00	0,0
		Tag 687 (Woche 98)	3	0,00	0,000	0,0	0,00	0,0
		Tag 715 (Woche 102)	2	0,00	0,000	0,0	0,00	0,0
		Tag 743 (Woche 106)	2	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	2	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	2	0,00	0,000	0,0	0,00	0,0
EORTC QLQ-EN24 Geschmacksveränderung	CTx + Durvalumab (N=46)	Baseline	36	11,11	22,537	0,0	0,00	100,0
		Tag 22 (Woche 3)	34	20,59	21,734	0,0	33,33	66,7
		Tag 43 (Woche 6)	34	29,41	26,924	0,0	33,33	100,0
		Tag 64 (Woche 9)	32	23,96	25,729	0,0	33,33	100,0
		Tag 85 (Woche 12)	30	34,44	32,144	0,0	33,33	100,0
		Tag 106 (Woche 15)	28	23,81	23,757	0,0	33,33	100,0
		Tag 127 (Woche 18)	30	28,89	28,679	0,0	33,33	100,0
		Tag 155 (Woche 22)	25	18,67	27,352	0,0	0,00	100,0
		Tag 183 (Woche 26)	30	18,89	29,921	0,0	0,00	100,0
		Tag 211 (Woche 30)	27	14,81	25,036	0,0	0,00	100,0
		Tag 239 (Woche 34)	23	15,94	24,349	0,0	0,00	100,0
		Tag 267 (Woche 38)	24	18,06	25,968	0,0	0,00	100,0
		Tag 295 (Woche 42)	25	16,00	23,805	0,0	0,00	100,0
		Tag 323 (Woche 46)	24	16,67	27,802	0,0	0,00	100,0
		Tag 351 (Woche 50)	23	13,04	24,077	0,0	0,00	100,0
		Tag 379 (Woche 54)	20	16,67	25,363	0,0	0,00	100,0
		Tag 407 (Woche 58)	18	12,96	25,918	0,0	0,00	100,0
		Tag 435 (Woche 62)	17	5,88	17,620	0,0	0,00	66,7
		Tag 463 (Woche 66)	14	16,67	21,681	0,0	0,00	66,7
		Tag 491 (Woche 70)	15	8,89	15,258	0,0	0,00	33,3
		Tag 519 (Woche 74)	18	9,26	19,150	0,0	0,00	66,7

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Geschmacksveränderung	CTx + Durvalumab (N=46)	Tag 547 (Woche 78)	15	4,44	11,729	0,0	0,00	33,3
		Tag 575 (Woche 82)	11	9,09	15,570	0,0	0,00	33,3
		Tag 603 (Woche 86)	9	11,11	16,667	0,0	0,00	33,3
		Tag 631 (Woche 90)	7	9,52	16,265	0,0	0,00	33,3
		Tag 659 (Woche 94)	9	11,11	16,667	0,0	0,00	33,3
		Tag 687 (Woche 98)	6	16,67	27,889	0,0	0,00	66,7
		Tag 715 (Woche 102)	6	5,56	13,608	0,0	0,00	33,3
		Tag 743 (Woche 106)	4	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	4	0,00	0,000	0,0	0,00	0,0
		Tag 799 (Woche 114)	2	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)	2	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
	CTx (N=49)	Baseline	38	5,26	14,553	0,0	0,00	66,7
		Tag 22 (Woche 3)	39	20,51	27,161	0,0	0,00	100,0
		Tag 43 (Woche 6)	37	27,93	34,706	0,0	0,00	100,0
		Tag 64 (Woche 9)	35	29,52	32,106	0,0	33,33	100,0
		Tag 85 (Woche 12)	32	28,13	26,920	0,0	33,33	100,0
		Tag 106 (Woche 15)	34	29,41	29,319	0,0	33,33	100,0
		Tag 127 (Woche 18)	27	25,93	29,719	0,0	33,33	100,0
		Tag 155 (Woche 22)	24	12,50	21,563	0,0	0,00	66,7
		Tag 183 (Woche 26)	20	6,67	20,520	0,0	0,00	66,7
		Tag 211 (Woche 30)	23	10,14	21,165	0,0	0,00	66,7
		Tag 239 (Woche 34)	16	8,33	19,245	0,0	0,00	66,7
		Tag 267 (Woche 38)	18	12,96	25,918	0,0	0,00	66,7
		Tag 295 (Woche 42)	17	13,73	20,612	0,0	0,00	66,7
		Tag 323 (Woche 46)	19	10,53	19,413	0,0	0,00	66,7
		Tag 351 (Woche 50)	17	11,76	16,420	0,0	0,00	33,3
		Tag 379 (Woche 54)	11	6,06	13,484	0,0	0,00	33,3

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

Table 2.6.2.1 DUO-E (dMMR Durva): Summary of absolute values of EORTC QLQ-EN24 results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EORTC QLQ-EN24 Geschmacksveränderung	CTx (N=49)	Tag 407 (Woche 58)	12	8,33	20,719	0,0	0,00	66,7
		Tag 435 (Woche 62)	10	13,33	32,203	0,0	0,00	100,0
		Tag 463 (Woche 66)	9	11,11	23,570	0,0	0,00	66,7
		Tag 491 (Woche 70)	7	9,52	25,198	0,0	0,00	66,7
		Tag 519 (Woche 74)	8	8,33	15,430	0,0	0,00	33,3
		Tag 547 (Woche 78)	8	0,00	0,000	0,0	0,00	0,0
		Tag 575 (Woche 82)	7	0,00	0,000	0,0	0,00	0,0
		Tag 603 (Woche 86)	6	0,00	0,000	0,0	0,00	0,0
		Tag 631 (Woche 90)	4	0,00	0,000	0,0	0,00	0,0
		Tag 659 (Woche 94)	3	0,00	0,000	0,0	0,00	0,0
		Tag 687 (Woche 98)	3	0,00	0,000	0,0	0,00	0,0
		Tag 715 (Woche 102)	2	0,00	0,000	0,0	0,00	0,0
		Tag 743 (Woche 106)	2	0,00	0,000	0,0	0,00	0,0
		Tag 771 (Woche 110)	2	16,67	23,570	0,0	16,67	33,3
		Tag 799 (Woche 114)	2	0,00	0,000	0,0	0,00	0,0
		Tag 827 (Woche 118)	2	0,00	0,000	0,0	0,00	0,0

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

Table 2.6.3.1 DUO-E (dMMR Durva): Summary of absolute values of EQ-5D-5L VAS scores over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EQ-5D-5L Visuelle Analogskala	CTx + Durvalumab (N=46)	Baseline	34	67,53	20,139	0,0	70,00	100,0
		Tag 22 (Woche 3)	34	65,41	19,003	7,0	71,50	93,0
		Tag 43 (Woche 6)	34	68,85	19,155	14,0	75,00	96,0
		Tag 64 (Woche 9)	31	68,45	13,097	40,0	75,00	87,0
		Tag 85 (Woche 12)	30	68,37	14,561	30,0	70,00	91,0
		Tag 106 (Woche 15)	27	67,33	13,984	35,0	70,00	87,0
		Tag 127 (Woche 18)	30	68,60	16,835	25,0	74,50	91,0
		Tag 155 (Woche 22)	25	69,64	15,885	31,0	70,00	91,0
		Tag 183 (Woche 26)	30	70,87	15,717	31,0	75,50	93,0
		Tag 211 (Woche 30)	27	73,30	11,367	50,0	77,00	91,0
		Tag 239 (Woche 34)	23	75,43	8,826	51,0	77,00	88,0
		Tag 267 (Woche 38)	23	75,43	13,577	34,0	78,00	100,0
		Tag 295 (Woche 42)	25	72,44	14,086	33,0	75,00	90,0
		Tag 323 (Woche 46)	24	69,29	17,084	22,0	71,00	90,0
		Tag 351 (Woche 50)	23	73,09	12,692	50,0	77,00	91,0
		Tag 379 (Woche 54)	20	72,25	15,930	23,0	75,00	88,0
		Tag 407 (Woche 58)	18	72,22	16,900	20,0	74,00	90,0
		Tag 435 (Woche 62)	17	71,88	18,624	9,0	76,00	90,0
		Tag 463 (Woche 66)	14	70,86	17,597	19,0	71,50	89,0
		Tag 491 (Woche 70)	15	72,73	14,119	31,0	76,00	89,0
		Tag 519 (Woche 74)	18	71,06	18,482	8,0	73,50	90,0
		Tag 547 (Woche 78)	15	73,67	12,087	51,0	76,00	88,0
		Tag 575 (Woche 82)	11	80,09	8,227	66,0	80,00	90,0
		Tag 603 (Woche 86)	9	72,22	10,474	58,0	72,00	86,0
		Tag 631 (Woche 90)	7	72,71	7,251	66,0	71,00	85,0
		Tag 659 (Woche 94)	9	70,22	14,316	49,0	70,00	88,0
		Tag 687 (Woche 98)	6	68,50	15,604	50,0	67,00	88,0
		Tag 715 (Woche 102)	6	74,33	12,420	56,0	77,50	87,0
		Tag 743 (Woche 106)	4	72,50	10,909	60,0	72,00	86,0
		Tag 771 (Woche 110)	4	76,25	9,251	70,0	72,50	90,0
		Tag 799 (Woche 114)	2	75,50	13,435	66,0	75,50	85,0
		Tag 827 (Woche 118)	3	81,00	4,359	78,0	79,00	86,0

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

Table 2.6.3.1 DUO-E (dMMR Durva): Summary of absolute values of EQ-5D-5L VAS scores over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EQ-5D-5L Visuelle Analogskala	CTx + Durvalumab (N=46)	Tag 855 (Woche 122)	2	77,00	4,243	74,0	77,00	80,0
		Tag 883 (Woche 126)	2	79,00	1,414	78,0	79,00	80,0
		Tag 911 (Woche 130)	2	76,50	2,121	75,0	76,50	78,0
		Tag 939 (Woche 134)	2	81,50	0,707	81,0	81,50	82,0
	CTx (N=49)	Baseline	38	72,32	19,548	24,0	80,00	100,0
		Tag 22 (Woche 3)	39	72,41	20,429	20,0	76,00	100,0
		Tag 43 (Woche 6)	36	71,47	19,060	26,0	75,50	100,0
		Tag 64 (Woche 9)	35	69,46	21,620	19,0	77,00	100,0
		Tag 85 (Woche 12)	32	68,22	21,060	22,0	75,50	100,0
		Tag 106 (Woche 15)	34	68,97	22,791	7,0	74,50	100,0
		Tag 127 (Woche 18)	27	64,85	20,255	26,0	68,00	100,0
		Tag 155 (Woche 22)	24	66,96	19,885	30,0	71,00	100,0
		Tag 183 (Woche 26)	20	63,25	22,190	29,0	68,50	98,0
		Tag 211 (Woche 30)	23	69,83	18,934	26,0	71,00	100,0
		Tag 239 (Woche 34)	16	64,75	20,237	30,0	70,50	92,0
		Tag 267 (Woche 38)	18	66,00	20,390	27,0	67,00	100,0
		Tag 295 (Woche 42)	17	65,12	20,186	29,0	71,00	90,0
		Tag 323 (Woche 46)	19	65,68	19,559	20,0	71,00	86,0
		Tag 351 (Woche 50)	16	67,25	19,447	25,0	72,50	91,0
		Tag 379 (Woche 54)	11	64,18	21,821	29,0	75,00	84,0
		Tag 407 (Woche 58)	12	67,92	19,975	20,0	76,00	87,0
		Tag 435 (Woche 62)	10	74,90	8,439	58,0	74,00	88,0
		Tag 463 (Woche 66)	9	77,56	8,033	66,0	78,00	89,0
		Tag 491 (Woche 70)	7	76,86	8,112	67,0	78,00	89,0
		Tag 519 (Woche 74)	8	72,50	22,966	28,0	78,00	100,0
		Tag 547 (Woche 78)	8	80,50	10,379	70,0	78,50	100,0
		Tag 575 (Woche 82)	7	80,86	10,976	67,0	81,00	98,0
		Tag 603 (Woche 86)	6	76,33	5,645	70,0	76,00	85,0
		Tag 631 (Woche 90)	4	77,50	9,110	64,0	81,00	84,0
		Tag 659 (Woche 94)	3	79,33	8,505	71,0	79,00	88,0
		Tag 687 (Woche 98)	3	79,33	4,041	75,0	80,00	83,0
		Tag 715 (Woche 102)	2	84,00	4,243	81,0	84,00	87,0

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

Table 2.6.3.1 DUO-E (dMMR Durva): Summary of absolute values of EQ-5D-5L VAS scores over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
EQ-5D-5L Visuelle Analogskala	CTx (N=49)	Tag 743 (Woche 106)	2	83,00	9,899	76,0	83,00	90,0
		Tag 771 (Woche 110)	2	84,00	5,657	80,0	84,00	88,0
		Tag 799 (Woche 114)	2	87,50	2,121	86,0	87,50	89,0
		Tag 827 (Woche 118)	2	84,50	4,950	81,0	84,50	88,0

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

Table 2.6.4.1 DUO-E (dMMR Durva): Summary of absolute values of PGIS questionnaire results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGIS	CTx + Durvalumab (N=46)	Baseline	32	2,50	1,503	1,0	2,50	6,0
		Tag 22 (Woche 3)	35	2,69	1,388	1,0	2,00	6,0
		Tag 43 (Woche 6)	34	2,44	1,236	1,0	2,00	5,0
		Tag 64 (Woche 9)	31	2,45	1,179	1,0	2,00	5,0
		Tag 85 (Woche 12)	30	2,37	1,217	1,0	2,00	5,0
		Tag 106 (Woche 15)	26	2,77	1,107	1,0	3,00	5,0
		Tag 127 (Woche 18)	30	2,23	1,165	1,0	2,00	5,0
		Tag 155 (Woche 22)	25	2,48	1,085	1,0	3,00	4,0
		Tag 183 (Woche 26)	30	2,13	0,937	1,0	2,00	4,0
		Tag 211 (Woche 30)	27	2,07	0,917	1,0	2,00	4,0
		Tag 239 (Woche 34)	23	1,96	0,825	1,0	2,00	4,0
		Tag 267 (Woche 38)	24	1,79	0,977	1,0	1,50	4,0
		Tag 295 (Woche 42)	24	2,04	1,122	1,0	2,00	4,0
		Tag 323 (Woche 46)	24	2,29	1,122	1,0	2,00	4,0
		Tag 351 (Woche 50)	22	2,45	1,262	1,0	2,00	4,0
		Tag 379 (Woche 54)	20	2,45	1,146	1,0	2,00	4,0
		Tag 407 (Woche 58)	18	2,17	1,339	1,0	2,00	5,0
		Tag 435 (Woche 62)	17	1,88	0,993	1,0	2,00	4,0
		Tag 463 (Woche 66)	14	2,14	1,099	1,0	2,00	4,0
		Tag 491 (Woche 70)	15	2,00	1,309	1,0	1,00	5,0
		Tag 519 (Woche 74)	18	2,06	1,162	1,0	2,00	4,0
		Tag 547 (Woche 78)	15	1,93	0,961	1,0	2,00	4,0
		Tag 575 (Woche 82)	11	2,09	1,136	1,0	2,00	4,0
		Tag 603 (Woche 86)	9	2,33	1,000	1,0	2,00	4,0
		Tag 631 (Woche 90)	7	2,29	0,951	1,0	3,00	3,0
		Tag 659 (Woche 94)	9	2,11	1,167	1,0	2,00	4,0
		Tag 687 (Woche 98)	6	1,83	1,169	1,0	1,50	4,0
		Tag 715 (Woche 102)	6	2,17	1,169	1,0	2,00	4,0
		Tag 743 (Woche 106)	4	2,00	1,414	1,0	1,50	4,0
		Tag 771 (Woche 110)	4	2,00	1,155	1,0	2,00	3,0
		Tag 799 (Woche 114)	2	2,50	2,121	1,0	2,50	4,0
		Tag 827 (Woche 118)	3	1,00	0,000	1,0	1,00	1,0

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

Table 2.6.4.1 DUO-E (dMMR Durva): Summary of absolute values of PGIS questionnaire results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGIS	CTx + Durvalumab (N=46)	Tag 855 (Woche 122)	2	1,00	0,000	1,0	1,00	1,0
		Tag 883 (Woche 126)	2	1,00	0,000	1,0	1,00	1,0
		Tag 911 (Woche 130)	2	1,00	0,000	1,0	1,00	1,0
		Tag 939 (Woche 134)	2	1,00	0,000	1,0	1,00	1,0
	CTx (N=49)	Baseline	36	1,92	1,156	1,0	1,50	5,0
		Tag 22 (Woche 3)	38	2,24	1,218	1,0	2,00	5,0
		Tag 43 (Woche 6)	36	2,33	1,242	1,0	2,00	5,0
		Tag 64 (Woche 9)	35	2,31	1,323	1,0	2,00	5,0
		Tag 85 (Woche 12)	31	2,42	1,311	1,0	2,00	5,0
		Tag 106 (Woche 15)	33	2,48	1,349	1,0	2,00	5,0
		Tag 127 (Woche 18)	27	2,74	1,430	1,0	2,00	5,0
		Tag 155 (Woche 22)	24	2,33	1,341	1,0	2,00	5,0
		Tag 183 (Woche 26)	20	2,55	1,317	1,0	2,00	5,0
		Tag 211 (Woche 30)	23	2,39	1,234	1,0	2,00	5,0
		Tag 239 (Woche 34)	16	2,56	1,094	1,0	2,00	4,0
		Tag 267 (Woche 38)	18	2,56	1,149	1,0	3,00	4,0
		Tag 295 (Woche 42)	17	2,59	1,004	1,0	3,00	4,0
		Tag 323 (Woche 46)	19	2,58	0,961	1,0	3,00	4,0
		Tag 351 (Woche 50)	16	2,63	1,088	1,0	3,00	4,0
		Tag 379 (Woche 54)	11	2,82	1,328	1,0	3,00	5,0
		Tag 407 (Woche 58)	11	2,55	1,368	1,0	2,00	5,0
		Tag 435 (Woche 62)	10	2,50	1,080	1,0	2,50	4,0
		Tag 463 (Woche 66)	9	2,33	0,866	1,0	3,00	3,0
		Tag 491 (Woche 70)	7	2,00	1,000	1,0	2,00	3,0
		Tag 519 (Woche 74)	8	2,38	0,744	1,0	2,50	3,0
		Tag 547 (Woche 78)	8	2,38	0,744	1,0	2,50	3,0
		Tag 575 (Woche 82)	7	2,14	1,215	1,0	2,00	4,0
		Tag 603 (Woche 86)	6	2,00	0,632	1,0	2,00	3,0
		Tag 631 (Woche 90)	4	1,75	0,957	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)	3	2,00	1,000	1,0	2,00	3,0
		Tag 715 (Woche 102)	2	2,00	1,414	1,0	2,00	3,0

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

Table 2.6.4.1 DUO-E (dMMR Durva): Summary of absolute values of PGIS questionnaire results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGIS	CTx (N=49)	Tag 743 (Woche 106)	2	1,50	0,707	1,0	1,50	2,0
		Tag 771 (Woche 110)	2	2,00	1,414	1,0	2,00	3,0
		Tag 799 (Woche 114)	2	1,00	0,000	1,0	1,00	1,0
		Tag 827 (Woche 118)	2	2,00	1,414	1,0	2,00	3,0

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

Table 2.6.5.1 DUO-E (dMMR Durva): Summary of absolute values of PGI-TT questionnaire results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGI-TT	CTx + Durvalumab (N=46)	Baseline	32	1,25	0,508	1,0	1,00	3,0
		Tag 22 (Woche 3)	35	2,49	1,147	1,0	2,00	5,0
		Tag 43 (Woche 6)	34	2,47	1,051	1,0	2,00	4,0
		Tag 64 (Woche 9)	31	2,23	0,884	1,0	2,00	4,0
		Tag 85 (Woche 12)	29	2,76	1,123	1,0	3,00	5,0
		Tag 106 (Woche 15)	26	2,77	1,142	1,0	3,00	5,0
		Tag 127 (Woche 18)	28	2,96	1,071	1,0	3,00	5,0
		Tag 155 (Woche 22)	24	2,29	1,042	1,0	2,00	4,0
		Tag 183 (Woche 26)	29	2,14	1,302	1,0	2,00	5,0
		Tag 211 (Woche 30)	27	2,33	1,038	1,0	2,00	5,0
		Tag 239 (Woche 34)	24	1,96	0,806	1,0	2,00	4,0
		Tag 267 (Woche 38)	23	1,96	1,022	1,0	2,00	4,0
		Tag 295 (Woche 42)	23	2,09	0,900	1,0	2,00	4,0
		Tag 323 (Woche 46)	23	2,17	1,267	1,0	2,00	5,0
		Tag 351 (Woche 50)	19	2,00	1,054	1,0	2,00	4,0
		Tag 379 (Woche 54)	17	1,94	1,029	1,0	2,00	5,0
		Tag 407 (Woche 58)	15	2,07	1,223	1,0	2,00	4,0
		Tag 435 (Woche 62)	15	2,00	0,845	1,0	2,00	4,0
		Tag 463 (Woche 66)	13	2,23	1,092	1,0	2,00	5,0
		Tag 491 (Woche 70)	14	1,86	1,167	1,0	1,50	5,0
		Tag 519 (Woche 74)	16	2,00	1,095	1,0	2,00	5,0
		Tag 547 (Woche 78)	14	1,79	0,802	1,0	2,00	3,0
		Tag 575 (Woche 82)	10	2,00	1,054	1,0	2,00	4,0
		Tag 603 (Woche 86)	9	1,89	0,782	1,0	2,00	3,0
		Tag 631 (Woche 90)	7	2,14	0,900	1,0	2,00	3,0
		Tag 659 (Woche 94)	9	2,11	1,054	1,0	2,00	4,0
		Tag 687 (Woche 98)	6	1,83	0,753	1,0	2,00	3,0
		Tag 715 (Woche 102)	6	2,33	0,816	1,0	2,50	3,0
		Tag 743 (Woche 106)	4	1,50	0,577	1,0	1,50	2,0
		Tag 771 (Woche 110)	4	1,75	0,957	1,0	1,50	3,0
		Tag 799 (Woche 114)	2	2,50	2,121	1,0	2,50	4,0
		Tag 827 (Woche 118)	3	1,00	0,000	1,0	1,00	1,0

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

Table 2.6.5.1 DUO-E (dMMR Durva): Summary of absolute values of PGI-TT questionnaire results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGI-TT	CTx + Durvalumab (N=46)	Tag 855 (Woche 122)	2	1,00	0,000	1,0	1,00	1,0
		Tag 883 (Woche 126)	2	1,00	0,000	1,0	1,00	1,0
		Tag 911 (Woche 130)	2	1,50	0,707	1,0	1,50	2,0
		Tag 939 (Woche 134)	2	1,00	0,000	1,0	1,00	1,0
	CTx (N=49)	Baseline	36	1,33	0,717	1,0	1,00	4,0
		Tag 22 (Woche 3)	38	2,24	0,971	1,0	2,00	5,0
		Tag 43 (Woche 6)	36	2,14	0,990	1,0	2,00	5,0
		Tag 64 (Woche 9)	35	2,51	1,147	1,0	2,00	5,0
		Tag 85 (Woche 12)	31	2,39	1,086	1,0	2,00	5,0
		Tag 106 (Woche 15)	33	2,67	1,080	1,0	3,00	4,0
		Tag 127 (Woche 18)	27	2,63	1,079	1,0	3,00	5,0
		Tag 155 (Woche 22)	24	2,13	0,900	1,0	2,00	5,0
		Tag 183 (Woche 26)	20	2,10	0,912	1,0	2,00	4,0
		Tag 211 (Woche 30)	24	2,00	0,933	1,0	2,00	4,0
		Tag 239 (Woche 34)	13	2,23	0,832	1,0	2,00	4,0
		Tag 267 (Woche 38)	13	2,38	1,044	1,0	2,00	4,0
		Tag 295 (Woche 42)	11	1,91	0,944	1,0	2,00	4,0
		Tag 323 (Woche 46)	11	2,00	1,095	1,0	2,00	4,0
		Tag 351 (Woche 50)	9	2,11	0,782	1,0	2,00	3,0
		Tag 379 (Woche 54)	7	2,43	1,134	1,0	3,00	4,0
		Tag 407 (Woche 58)	9	1,78	0,667	1,0	2,00	3,0
		Tag 435 (Woche 62)	6	1,83	0,753	1,0	2,00	3,0
		Tag 463 (Woche 66)	7	1,71	0,756	1,0	2,00	3,0
		Tag 491 (Woche 70)	5	2,00	1,000	1,0	2,00	3,0
		Tag 519 (Woche 74)	6	1,67	0,816	1,0	1,50	3,0
		Tag 547 (Woche 78)	7	1,71	0,756	1,0	2,00	3,0
		Tag 575 (Woche 82)	6	1,83	0,753	1,0	2,00	3,0
		Tag 603 (Woche 86)	5	1,80	0,837	1,0	2,00	3,0
		Tag 631 (Woche 90)	4	1,75	0,957	1,0	1,50	3,0
		Tag 659 (Woche 94)	3	1,67	1,155	1,0	1,00	3,0
		Tag 687 (Woche 98)	3	1,67	1,155	1,0	1,00	3,0
		Tag 715 (Woche 102)	2	2,00	1,414	1,0	2,00	3,0

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

Table 2.6.5.1 DUO-E (dMMR Durva): Summary of absolute values of PGI-TT questionnaire results over time by treatment group
Patients with dMMR tumour status, DCO 12APR2023

				Absolute Werte				
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Median	Max
PGI-TT	CTx (N=49)	Tag 743 (Woche 106)	2	2,00	1,414	1,0	2,00	3,0
		Tag 771 (Woche 110)	2	2,00	1,414	1,0	2,00	3,0
		Tag 799 (Woche 114)	2	2,00	1,414	1,0	2,00	3,0
		Tag 827 (Woche 118)	2	2,00	1,414	1,0	2,00	3,0

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

Table 3.2.1.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first adverse event (total, and by SOC and PT occurring with frequency >=10% of patients in either treatment arm)
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	44	44 (100)	0,1 [0,1; 0,1]	46	46 (100)	0,1 [0,1; 0,1]	1,14	[0,75; 1,73]	0,5640
SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	44	30 (68,2)	3,4 [0,5; 8,2]	46	35 (76,1)	2,1 [0,7; 3,5]	0,79	[0,48; 1,29]	0,3420
PT: Asthenie	44	4 (9,1)	NE [NE; NE]	46	6 (13,0)	NE [NE; NE]	0,63	[0,16; 2,20]	0,4652
PT: Ermuedung	44	15 (34,1)	NE [NE; NE]	46	21 (45,7)	NE [NE; NE]	0,68	[0,34; 1,30]	0,2439
PT: Fieber	44	3 (6,8)	NE [NE; NE]	46	7 (15,2)	NE [NE; NE]	0,34	[0,07; 1,24]	0,1052
PT: Oedem peripher	44	6 (13,6)	NE [NE; NE]	46	6 (13,0)	NE [NE; NE]	0,89	[0,28; 2,89]	0,8488
SOC: Augenerkrankungen	44	9 (20,5)	NE [NE; NE]	46	6 (13,0)	NE [NE; NE]	1,35	[0,48; 4,07]	0,5702
PT: Sehen verschwommen	44	5 (11,4)	NE [NE; NE]	46	1 (2,2)	NE [NE; NE]	5,33	[0,86;102,23]	0,0871
SOC: Endokrine Erkrankungen	44	5 (11,4)	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	1,29	[0,34; 5,21]	0,7118
PT: Hypothyreose	44	5 (11,4)	NE [NE; NE]	46	2 (4,3)	NE [NE; NE]	2,51	[0,54; 17,63]	0,2575
SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums	44	22 (50,0)	16,3 [6,9; NE]	46	16 (34,8)	12,7 [8,3; NE]	1,21	[0,63; 2,36]	0,5761

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1aa 17APR2024:11:32

Table 3.2.1.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first adverse event (total, and by SOC and PT occurring with frequency >=10% of patients in either treatment arm) Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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: Dyspnoe	44	9 (20,5)	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	2,19	[0,71; 8,10]	0,1824
PT: Husten	44	12 (27,3)	NE [NE; NE]	46	7 (15,2)	NE [NE; NE]	1,35	[0,54; 3,67]	0,5270
SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese	44	4 (9,1)	NE [NE; NE]	46	5 (10,9)	NE [NE; NE]	0,61	[0,15; 2,35]	0,4609
SOC: Erkrankungen der Haut und des Unterhautgewebes	44	32 (72,7)	0,7 [0,3; 1,4]	46	29 (63,0)	1,1 [0,7; 9,5]	1,36	[0,82; 2,26]	0,2340
PT: Alopezie	44	23 (52,3)	1,4 [0,5; NE]	46	19 (41,3)	NE [NE; NE]	1,43	[0,78; 2,65]	0,2475
PT: Ausschlag	44	10 (22,7)	NE [NE; NE]	46	6 (13,0)	NE [NE; NE]	1,93	[0,71; 5,67]	0,1986
PT: Pruritus	44	7 (15,9)	NE [NE; NE]	46	5 (10,9)	NE [NE; NE]	1,12	[0,35; 3,82]	0,8447
SOC: Erkrankungen der Nieren und Harnwege	44	7 (15,9)	NE [NE; NE]	46	13 (28,3)	NE [NE; NE]	0,40	[0,14; 0,99]	0,0485*
SOC: Erkrankungen des Blutes und des Lymphsystems	44	22 (50,0)	5,1 [2,8; NE]	46	28 (60,9)	3,4 [1,9; NE]	0,77	[0,44; 1,35]	0,3655
PT: Anaemie	44	18 (40,9)	NE [NE; NE]	46	25 (54,3)	3,7 [2,1; NE]	0,70	[0,38; 1,28]	0,2479

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1aa 17APR2024:11:32

Table 3.2.1.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first adverse event
(total, and by SOC and PT occurring with frequency >=10% of patients in either treatment arm)
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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: Neutropenie	44	7 (15,9)	NE [NE; NE]	46	8 (17,4)	NE [NE; NE]	0,93	[0,33; 2,60]	0,8929
PT: Thrombozytopenie	44	5 (11,4)	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	1,39	[0,37; 5,63]	0,6190
SOC: Erkrankungen des Gastrointestinaltrakts	44	34 (77,3)	0,6 [0,1; 1,6]	46	33 (71,7)	1,1 [0,1; 2,8]	1,13	[0,70; 1,84]	0,5823
PT: Abdominalschmerz	44	6 (13,6)	NE [NE; NE]	46	7 (15,2)	NE [NE; NE]	0,78	[0,25; 2,38]	0,6633
PT: Diarrhoe	44	12 (27,3)	NE [NE; NE]	46	11 (23,9)	NE [NE; NE]	1,12	[0,49; 2,59]	0,7854
PT: Dyspepsie	44	4 (9,1)	NE [NE; NE]	46	6 (13,0)	NE [NE; NE]	0,65	[0,16; 2,27]	0,4962
PT: Erbrechen	44	12 (27,3)	NE [NE; NE]	46	10 (21,7)	NE [NE; NE]	1,13	[0,49; 2,69]	0,7693
PT: Obstipation	44	16 (36,4)	NE [NE; NE]	46	16 (34,8)	NE [NE; NE]	1,06	[0,52; 2,14]	0,8743
PT: Schmerzen Oberbauch	44	5 (11,4)	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	1,05	[0,27; 4,27]	0,9473
PT: Uebelkeit	44	26 (59,1)	6,2 [1,5; NE]	46	22 (47,8)	NE [NE; NE]	1,10	[0,62; 1,96]	0,7117
SOC: Erkrankungen des Nervensystems	44	31 (70,5)	0,9 [0,7; 1,6]	46	34 (73,9)	1,8 [0,7; 2,9]	1,07	[0,66; 1,75]	0,7758
PT: Dysgeusie	44	6 (13,6)	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	1,69	[0,48; 6,62]	0,4083
PT: Hypoaesthesie	44	5 (11,4)	NE [NE; NE]	46	1 (2,2)	NE [NE; NE]	5,11	[0,82; 98,05]	0,0978

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.1.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first adverse event (total, and by SOC and PT occurring with frequency >=10% of patients in either treatment arm)
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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: Kopfschmerzen	44	10 (22,7)	NE [NE; NE]	46	8 (17,4)	NE [NE; NE]	1,26	[0,49; 3,30]	0,6294
PT: Periphere Neuropathie	44	12 (27,3)	NE [NE; NE]	46	9 (19,6)	NE [NE; NE]	1,49	[0,63; 3,65]	0,3670
PT: Periphere sensorische Neuropathie	44	11 (25,0)	NE [NE; NE]	46	17 (37,0)	NE [NE; NE]	0,67	[0,31; 1,42]	0,3057
PT: Schwindelgefuehl	44	6 (13,6)	NE [NE; NE]	46	5 (10,9)	NE [NE; NE]	1,18	[0,35; 4,12]	0,7877
SOC: Erkrankungen des Ohrs und des Labyrinths	44	3 (6,8)	NE [NE; NE]	46	5 (10,9)	NE [NE; NE]	0,58	[0,12; 2,38]	0,4540
SOC: Gefaesserkrankungen	44	8 (18,2)	NE [NE; NE]	46	9 (19,6)	NE [NE; NE]	0,77	[0,29; 2,04]	0,5961
PT: Hypertonie	44	4 (9,1)	NE [NE; NE]	46	7 (15,2)	NE [NE; NE]	0,51	[0,13; 1,69]	0,2726
SOC: Infektionen und parasitaere Erkrankungen	44	23 (52,3)	9,7 [5,7;20,3]	46	18 (39,1)	14,8 [6,7; NE]	1,27	[0,68; 2,38]	0,4545
PT: COVID-19	44	6 (13,6)	NE [NE; NE]	46	7 (15,2)	NE [NE; NE]	0,58	[0,18; 1,76]	0,3225
PT: Harnwegsinfektion	44	7 (15,9)	NE [NE; NE]	46	5 (10,9)	NE [NE; NE]	1,34	[0,43; 4,56]	0,6133
SOC: Psychiatrische Erkrankungen	44	10 (22,7)	NE [NE; NE]	46	6 (13,0)	NE [NE; NE]	1,87	[0,70; 5,51]	0,2172

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.1.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first adverse event (total, and by SOC and PT occurring with frequency >=10% of patients in either treatment arm)
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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: Schlaflosigkeit	44	6 (13,6)	NE [NE; NE]	46	5 (10,9)	NE [NE; NE]	1,20	[0,36; 4,18]	0,7606
SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen	44	29 (65,9)	2,6 [0,7; 6,0]	46	25 (54,3)	9,4 [0,7; NE]	1,20	[0,70; 2,07]	0,5077
PT: Arthralgie	44	18 (40,9)	21,0 [6,5; NE]	46	13 (28,3)	NE [NE; NE]	1,29	[0,63; 2,70]	0,4870
PT: Muskelspasmen	44	5 (11,4)	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	1,26	[0,30; 6,24]	0,7548
PT: Muskulaere Schwaeche	44	6 (13,6)	NE [NE; NE]	46	2 (4,3)	NE [NE; NE]	3,07	[0,71; 20,94]	0,1489
PT: Myalgie	44	5 (11,4)	NE [NE; NE]	46	9 (19,6)	NE [NE; NE]	0,53	[0,16; 1,55]	0,2554
PT: Schmerz in einer Extremitaet	44	9 (20,5)	NE [NE; NE]	46	8 (17,4)	NE [NE; NE]	1,13	[0,43; 3,03]	0,7974
SOC: Stoffwechsel- und Ernaehrungsstoerungen	44	25 (56,8)	8,7 [2,1; NE]	46	22 (47,8)	17,8 [2,0; NE]	1,10	[0,62; 1,96]	0,7401
PT: Appetit vermindert	44	7 (15,9)	NE [NE; NE]	46	11 (23,9)	NE [NE; NE]	0,64	[0,23; 1,62]	0,3520
PT: Hypokaliaemie	44	7 (15,9)	NE [NE; NE]	46	5 (10,9)	NE [NE; NE]	1,39	[0,44; 4,71]	0,5772
PT: Hypomagnesiaemie	44	12 (27,3)	NE [NE; NE]	46	6 (13,0)	NE [NE; NE]	2,13	[0,82; 6,12]	0,1236
SOC: Untersuchungen	44	23 (52,3)	3,4 [1,4; NE]	46	22 (47,8)	5,7 [2,3; NE]	1,17	[0,65; 2,12]	0,5919

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.1.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first adverse event (total, and by SOC and PT occurring with frequency >=10% of patients in either treatment arm)
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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: Alaninaminotransferase erhoeht	44	5 (11,4)	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	1,35	[0,32; 6,69]	0,6841
PT: Gewicht erniedrigt	44	2 (4,5)	NE [NE; NE]	46	7 (15,2)	NE [NE; NE]	0,28	[0,04; 1,16]	0,0892
PT: Leukozytenzahl erniedrigt	44	7 (15,9)	NE [NE; NE]	46	6 (13,0)	NE [NE; NE]	1,23	[0,41; 3,83]	0,7081
PT: Neutrophilenzahl erniedrigt	44	7 (15,9)	NE [NE; NE]	46	10 (21,7)	NE [NE; NE]	0,71	[0,26; 1,85]	0,4849
PT: Thrombozytenzahl vermindert	44	7 (15,9)	NE [NE; NE]	46	6 (13,0)	NE [NE; NE]	1,26	[0,42; 3,91]	0,6774
SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	44	9 (20,5)	NE [NE; NE]	46	5 (10,9)	NE [NE; NE]	1,43	[0,49; 4,71]	0,5209

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.2.1.1D DUO-E (dMMR Durva): 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 dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	44	13 (29,5)	NE [NE; NE]	46	15 (32,6)	NE [NE; NE]	0,81	[0,38; 1,72]	0,5861
SUE SOC: Erkrankungen der Nieren und Harnwege	44	0	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	NC	NC	0,0401*
SUE SOC: Erkrankungen des Blutes und des Lymphsystems	44	1 (2,3)	NE [NE; NE]	46	5 (10,9)	NE [NE; NE]	0,19	[0,01; 1,21]	0,0965
SUE PT: Anaemie	44	0	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	NC	NC	0,0893
SUE SOC: Erkrankungen des Gastrointestinaltrakts	44	5 (11,4)	NE [NE; NE]	46	2 (4,3)	NE [NE; NE]	2,44	[0,52; 17,11]	0,2725
SUE SOC: Erkrankungen des Nervensystems	44	1 (2,3)	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	0,33	[0,02; 2,62]	0,3198
SUE SOC: Infektionen und parasitaere Erkrankungen	44	3 (6,8)	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	1,01	[0,19; 5,48]	0,9884
SUE SOC: Stoffwechsel- und Ernaehrungsstoerungen	44	1 (2,3)	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	0,35	[0,02; 2,74]	0,3427

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.3.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first adverse event leading to discontinuation of study treatment
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	44	9 (20,5)	NE [NE; NE]	46	7 (15,2)	NE [NE; NE]	1,29	[0,48; 3,61]	0,6186

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.4.1.1D DUO-E (dMMR Durva): 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 dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	44	23 (52,3)	7,2 [1,6; NE]	46	29 (63,0)	1,9 [0,7; NE]	0,69	[0,39; 1,19]	0,1798
G>=3 SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	44	3 (6,8)	NE [NE; NE]	46	7 (15,2)	NE [NE; NE]	0,41	[0,09; 1,48]	0,1823
G>=3 PT: Asthenie	44	1 (2,3)	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	0,32	[0,02; 2,50]	0,2968
G>=3 PT: Ermuedung	44	1 (2,3)	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	0,35	[0,02; 2,72]	0,3398
G>=3 SOC: Erkrankungen der Nieren und Harnwege	44	0	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	NC	NC	0,0401*
G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems	44	8 (18,2)	NE [NE; NE]	46	14 (30,4)	NE [NE; NE]	0,54	[0,22; 1,26]	0,1588
G>=3 PT: Anaemie	44	3 (6,8)	NE [NE; NE]	46	10 (21,7)	NE [NE; NE]	0,29	[0,07; 0,96]	0,0489*
G>=3 PT: Neutropenie	44	4 (9,1)	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	1,02	[0,24; 4,32]	0,9755
G>=3 SOC: Erkrankungen des Gastrointestinaltrakts	44	5 (11,4)	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	1,22	[0,32; 4,94]	0,7722

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.4.1.1D DUO-E (dMMR Durva): 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 dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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: Erkrankungen des Nervensystems	44	3 (6,8)	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	0,76	[0,15; 3,47]	0,7249
G>=3 SOC: Gefaesserkrankungen	44	2 (4,5)	NE [NE; NE]	46	7 (15,2)	NE [NE; NE]	0,28	[0,04; 1,17]	0,0932
G>=3 PT: Hypertonie	44	2 (4,5)	NE [NE; NE]	46	7 (15,2)	NE [NE; NE]	0,28	[0,04; 1,17]	0,0932
G>=3 SOC: Infektionen und parasitaere Erkrankungen	44	2 (4,5)	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	0,65	[0,09; 3,94]	0,6366
G>=3 SOC: Stoffwechsel- und Ernaehrungsstoerungen	44	2 (4,5)	NE [NE; NE]	46	4 (8,7)	NE [NE; NE]	0,47	[0,06; 2,41]	0,3704
G>=3 SOC: Untersuchungen	44	5 (11,4)	NE [NE; NE]	46	11 (23,9)	NE [NE; NE]	0,40	[0,13; 1,12]	0,0850
G>=3 PT: Neutrophilenzahl erniedrigt	44	2 (4,5)	NE [NE; NE]	46	8 (17,4)	NE [NE; NE]	0,25	[0,04; 1,001]	0,0588
G>=3 SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	44	3 (6,8)	NE [NE; NE]	46	0	NE [NE; NE]	NC	NC	0,1421

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.5.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first adverse event of special interest (total and by grouped term)
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	44	26 (59,1)	2,0 [0,7; NE]	46	22 (47,8)	NE [NE; NE]	1,50	[0,85; 2,68]	0,1585
UESI GT: Andere seltene/sonstige Ereignisse	44	1 (2,3)	NE [NE; NE]	46	0	NE [NE; NE]	NC	NC	0,3514
UESI GT: Dermatitis/Hautausschlag	44	16 (36,4)	NE [NE; NE]	46	10 (21,7)	NE [NE; NE]	1,88	[0,86; 4,31]	0,1153
UESI GT: Diarrhö/Kolitis	44	13 (29,5)	NE [NE; NE]	46	11 (23,9)	NE [NE; NE]	1,24	[0,55; 2,84]	0,5939
UESI GT: Hyperthyreose Ereignisse	44	2 (4,5)	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	0,64	[0,08; 3,90]	0,6246
UESI GT: Hypothyreose Ereignisse	44	5 (11,4)	NE [NE; NE]	46	2 (4,3)	NE [NE; NE]	2,51	[0,54; 17,63]	0,2575
UESI GT: Infusions- und Überempfindlichkeitsreaktionen	44	2 (4,5)	NE [NE; NE]	46	3 (6,5)	NE [NE; NE]	0,69	[0,09; 4,13]	0,6875
UESI GT: Myositis	44	1 (2,3)	NE [NE; NE]	46	0	NE [NE; NE]	NC	NC	0,3066
UESI GT: Neue primäre Malignität	44	1 (2,3)	NE [NE; NE]	46	1 (2,2)	NE [NE; NE]	0,91	[0,04; 23,13]	0,9479
UESI GT: Pneumonitis	44	3 (6,8)	NE [NE; NE]	46	0	NE [NE; NE]	NC	NC	0,1366

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.5.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first adverse event of special interest (total and by grouped term)
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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: Thyreoiditis	44	2 (4,5)	NE [NE; NE]	46	0	NE [NE; NE]	NC	NC	0,1408

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.6.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first adverse event of special interest with max. CTCAE grade 3 (total and by grouped term)
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	44	5 (11,4)	NE [NE; NE]	46	2 (4,3)	NE [NE; NE]	2,48	[0,53; 17,31]	0,2620
UESI G>=3 GT: Andere seltene/sonstige Ereignisse	44	1 (2,3)	NE [NE; NE]	46	0	NE [NE; NE]	NC	NC	0,3514
UESI G>=3 GT: Dermatitis/Hautausschlag	44	1 (2,3)	NE [NE; NE]	46	1 (2,2)	NE [NE; NE]	1,05	[0,04; 26,42]	0,9749
UESI G>=3 GT: Diarrhö/Kolitis	44	2 (4,5)	NE [NE; NE]	46	1 (2,2)	NE [NE; NE]	2,15	[0,21; 46,15]	0,5229
UESI G>=3 GT: Neue primäre Malignität	44	0	NE [NE; NE]	46	1 (2,2)	NE [NE; NE]	NC	NC	0,3281
UESI G>=3 GT: Pneumonitis	44	1 (2,3)	NE [NE; NE]	46	0	NE [NE; NE]	NC	NC	0,4516

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.2.7.1.1D DUO-E (dMMR Durva): Summary of analysis of time to first serious adverse event of special interest (total and by grouped term)
Patients with dMMR tumour status, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	44	5 (11,4)	NE [NE; NE]	46	1 (2,2)	NE [NE; NE]	5,12	[0,82; 98,11]	0,0968
SUESI GT: Andere seltene/sonstige Ereignisse	44	1 (2,3)	NE [NE; NE]	46	0	NE [NE; NE]	NC	NC	0,3514
SUESI GT: Dermatitis/Hautausschlag	44	2 (4,5)	NE [NE; NE]	46	0	NE [NE; NE]	NC	NC	0,1458
SUESI GT: Diarrhö/Kolitis	44	1 (2,3)	NE [NE; NE]	46	1 (2,2)	NE [NE; NE]	1,07	[0,04; 27,09]	0,9606
SUESI GT: Pneumonitis	44	1 (2,3)	NE [NE; NE]	46	0	NE [NE; NE]	NC	NC	0,4516

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 3.1.1. 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. * p<0.05. CTx = Carboplatin + Paclitaxel.
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Table 3.5.1.1D DUO-E (dMMR Durva): Summary of adverse events leading to discontinuation of study treatment (total, and by SOC and PT)
Patients with dMMR tumour status, DCO 12APR2023

	Number (%) of patients	
System organ class / MedDRA Preferred term	CTx + Durvalumab (N=44)	CTx (N=46)
Patienten mit Abbruch wegen UE	9 (20,5)	7 (15,2)
Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	2 (4,5)	2 (4,3)
Asthenie	0 (0,0)	1 (2,2)
Ermuedung	2 (4,5)	1 (2,2)
Leistung vermindert	1 (2,3)	0 (0,0)
Erkrankungen der Atemwege, des Brustraums und Mediastinums	2 (4,5)	0 (0,0)
Interstitielle Lungenerkrankung	1 (2,3)	0 (0,0)
Pneumonitis	1 (2,3)	0 (0,0)
Erkrankungen der Haut und des Unterhautgewebes	3 (6,8)	0 (0,0)
Alopezie	1 (2,3)	0 (0,0)
Ausschlag makulo-papuloes	1 (2,3)	0 (0,0)
Symmetrisches arzneimittelbedingtes intertriginoeses und flexurales Exanthem	1 (2,3)	0 (0,0)
Erkrankungen des Blutes und des Lymphsystems	1 (2,3)	2 (4,3)
Anaemie	1 (2,3)	2 (4,3)
Erkrankungen des Gastrointestinaltrakts	1 (2,3)	0 (0,0)
Faekulom	1 (2,3)	0 (0,0)
Erkrankungen des Nervensystems	4 (9,1)	3 (6,5)
Apoplektischer Insult	0 (0,0)	1 (2,2)
Neurotoxizitaet	1 (2,3)	0 (0,0)
Periphere Neuropathie	3 (6,8)	1 (2,2)

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 3.5.1.1D DUO-E (dMMR Durva): Summary of adverse events leading to discontinuation of study treatment (total, and by SOC and PT)
Patients with dMMR tumour status, DCO 12APR2023

System organ class / MedDRA Preferred term	Number (%) of patients: CTx + Durvalumab (N=44)	Number (%) of patients: CTx (N=46)
Periphere sensorische Neuropathie	0 (0,0)	1 (2,2)
Erkrankungen des Ohrs und des Labyrinths	0 (0,0)	1 (2,2)
Tinnitus	0 (0,0)	1 (2,2)
Untersuchungen	1 (2,3)	0 (0,0)
Thrombozytenzahl vermindert	1 (2,3)	0 (0,0)
Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	1 (2,3)	0 (0,0)
Schmerzen waehrend eines Eingriffes	1 (2,3)	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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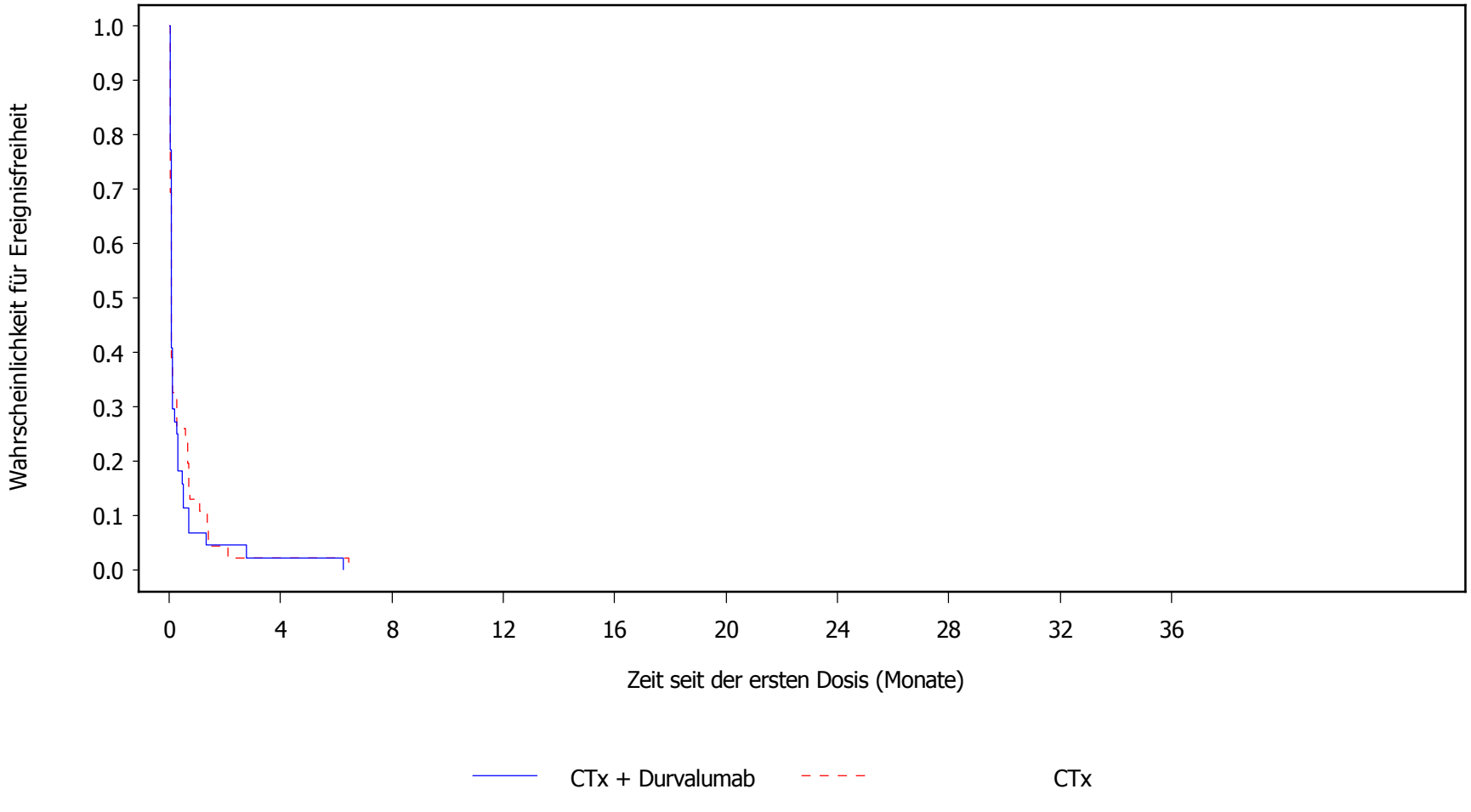
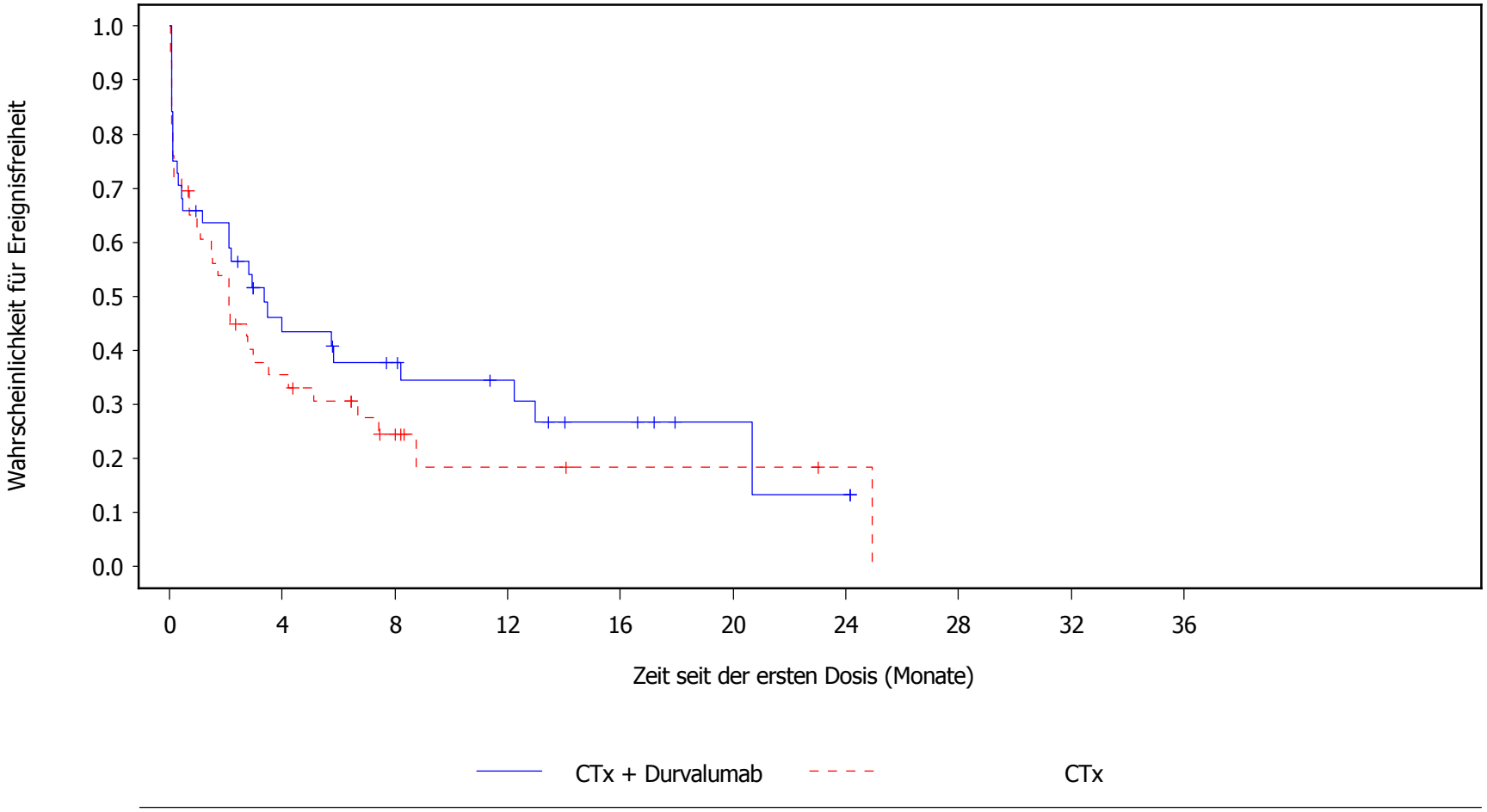
Figure 3.3.1.1D.1 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UE
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	1	0	0	0	0	0	0	0	0	CTx + Durvalumab
46	1	0	0	0	0	0	0	0	0	CTx

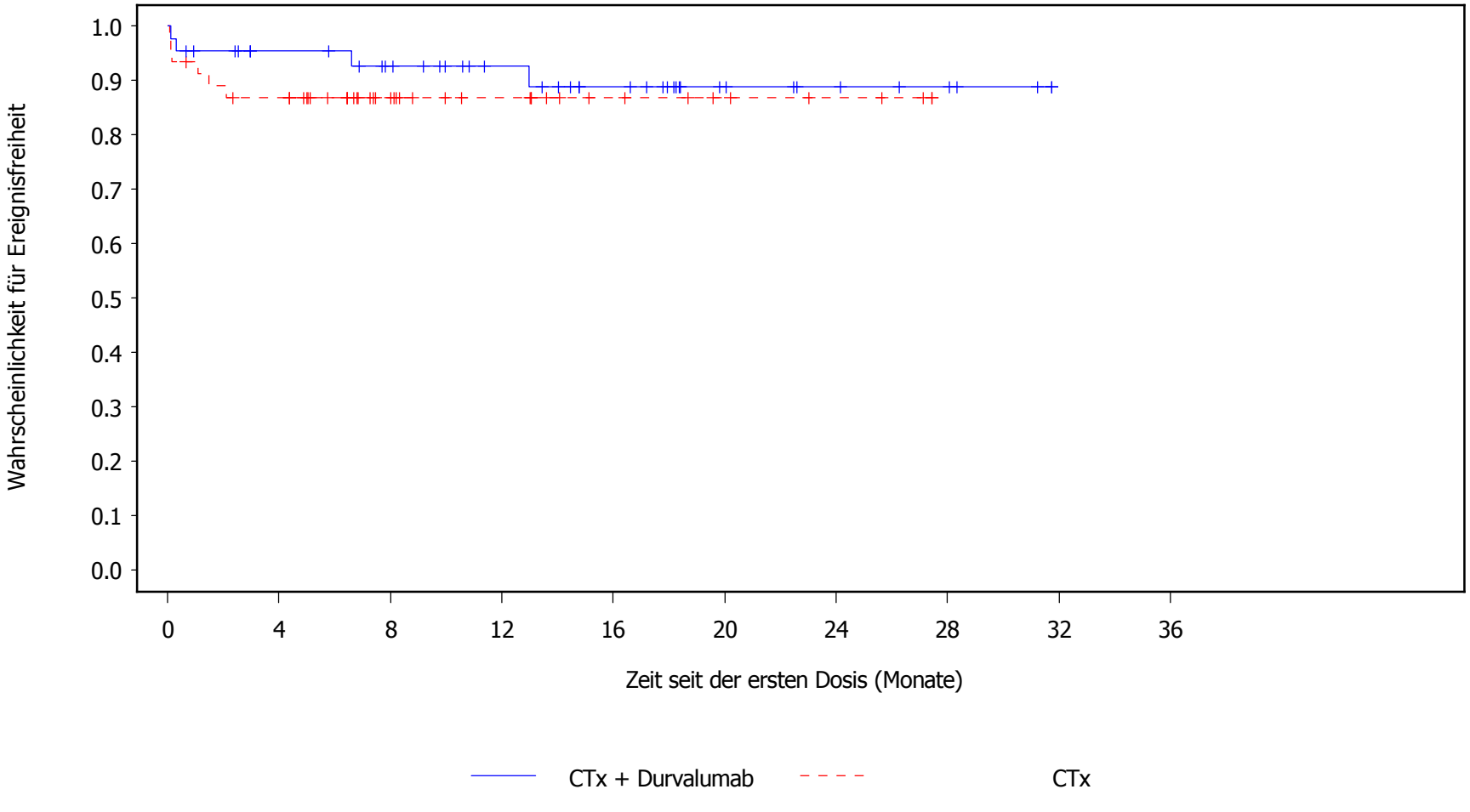
Figure 3.3.1.1D.2 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	17	12	9	5	2	1	0	0	0	CTx + Durvalumab
46	15	7	3	2	2	1	0	0	0	CTx

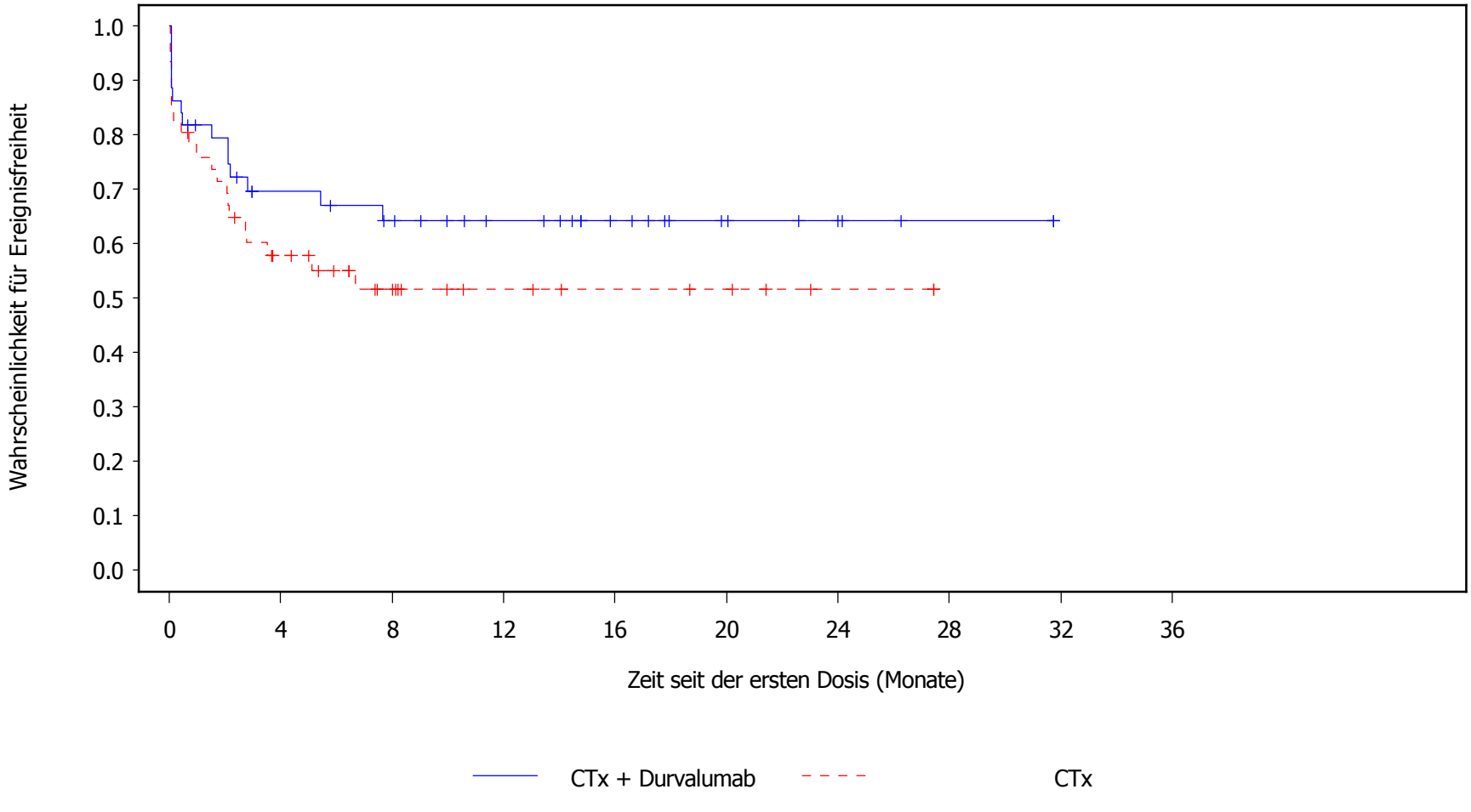
Figure 3.3.1.1D.3 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Asthenie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	31	24	18	9	6	4	0	0	CTx + Durvalumab
46	38	21	14	8	5	3	0	0	0	CTx

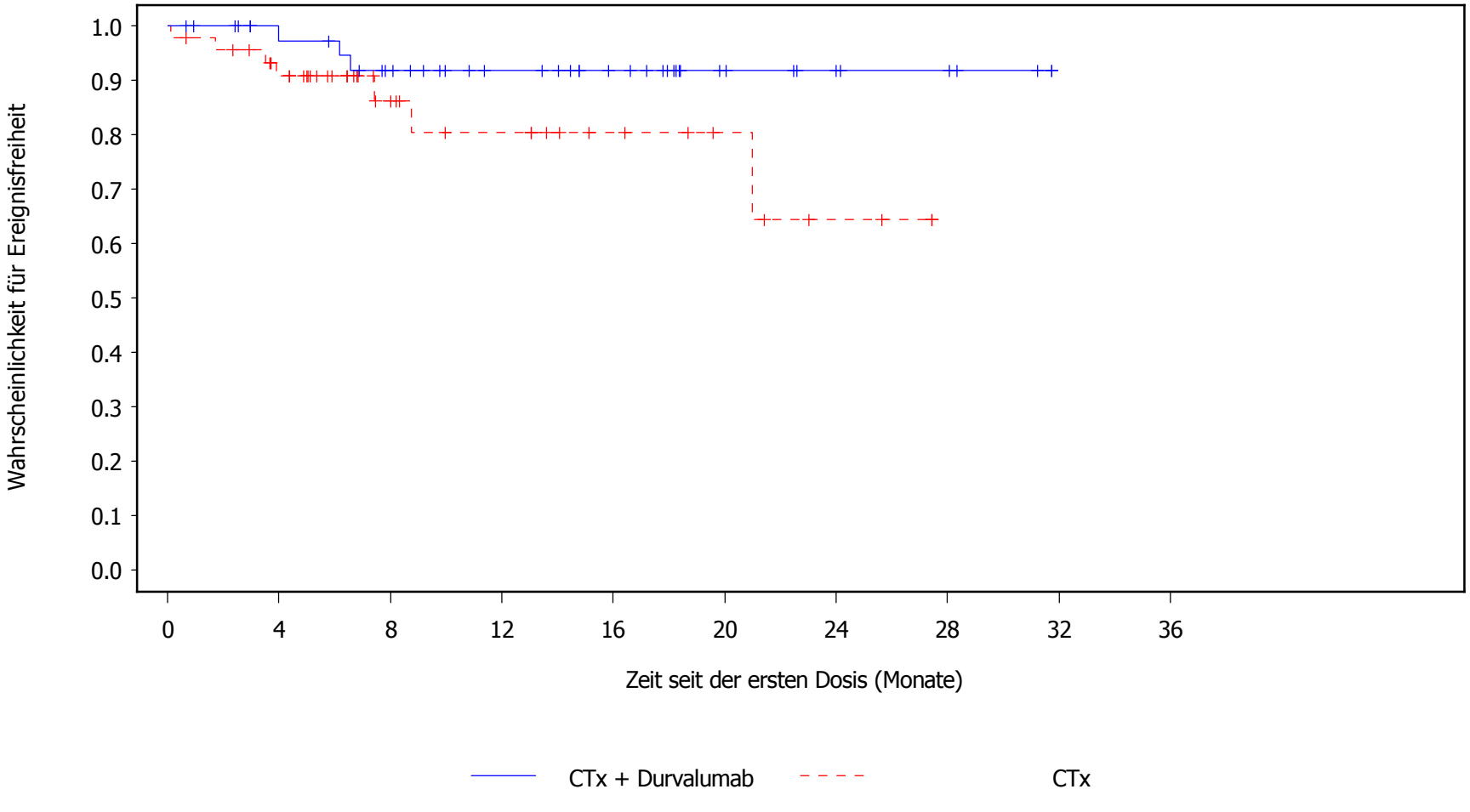
Figure 3.3.1.1D.4 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Ermuedung
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	26	22	17	11	6	4	1	0	0	CTx + Durvalumab
46	23	13	7	5	4	1	0	0	0	CTx

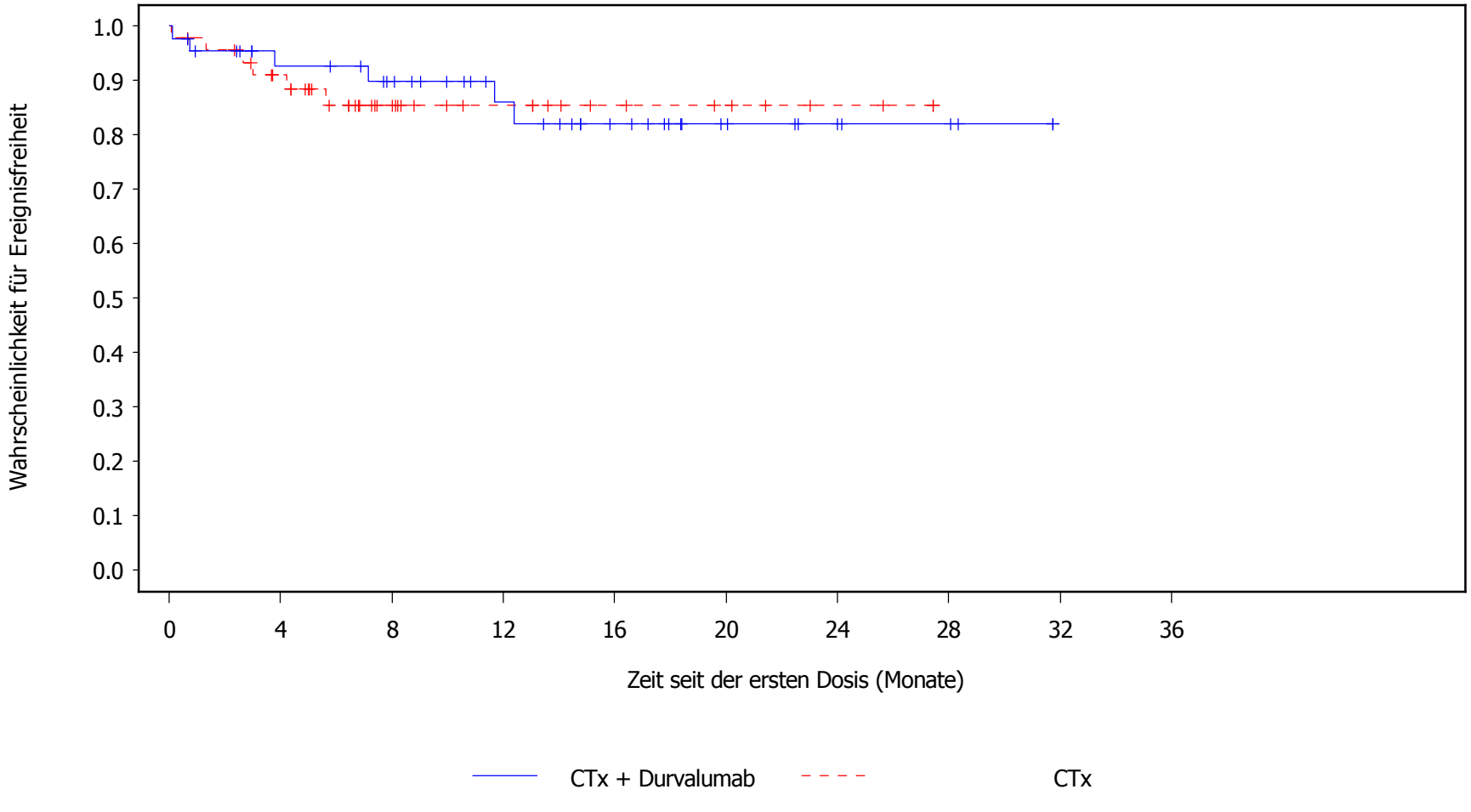
Figure 3.3.1.1D.5 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Fieber
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	37	31	24	18	9	6	4	0	0	CTx + Durvalumab
46	37	18	13	8	5	2	0	0	0	CTx

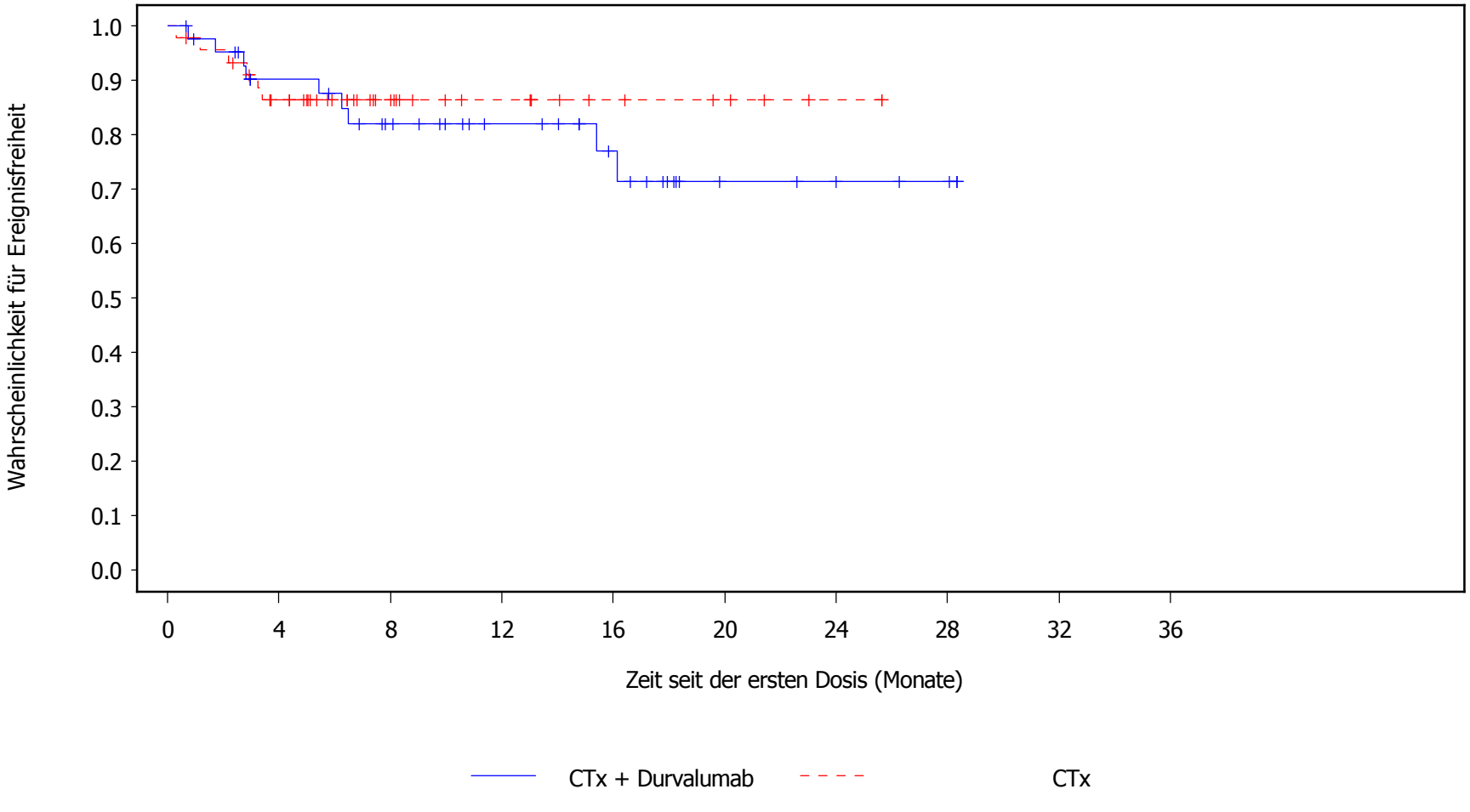
Figure 3.3.1.1D.6 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Oedem peripher
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	35	30	22	15	8	5	3	0	0	CTx + Durvalumab
46	37	19	12	7	5	2	0	0	0	CTx

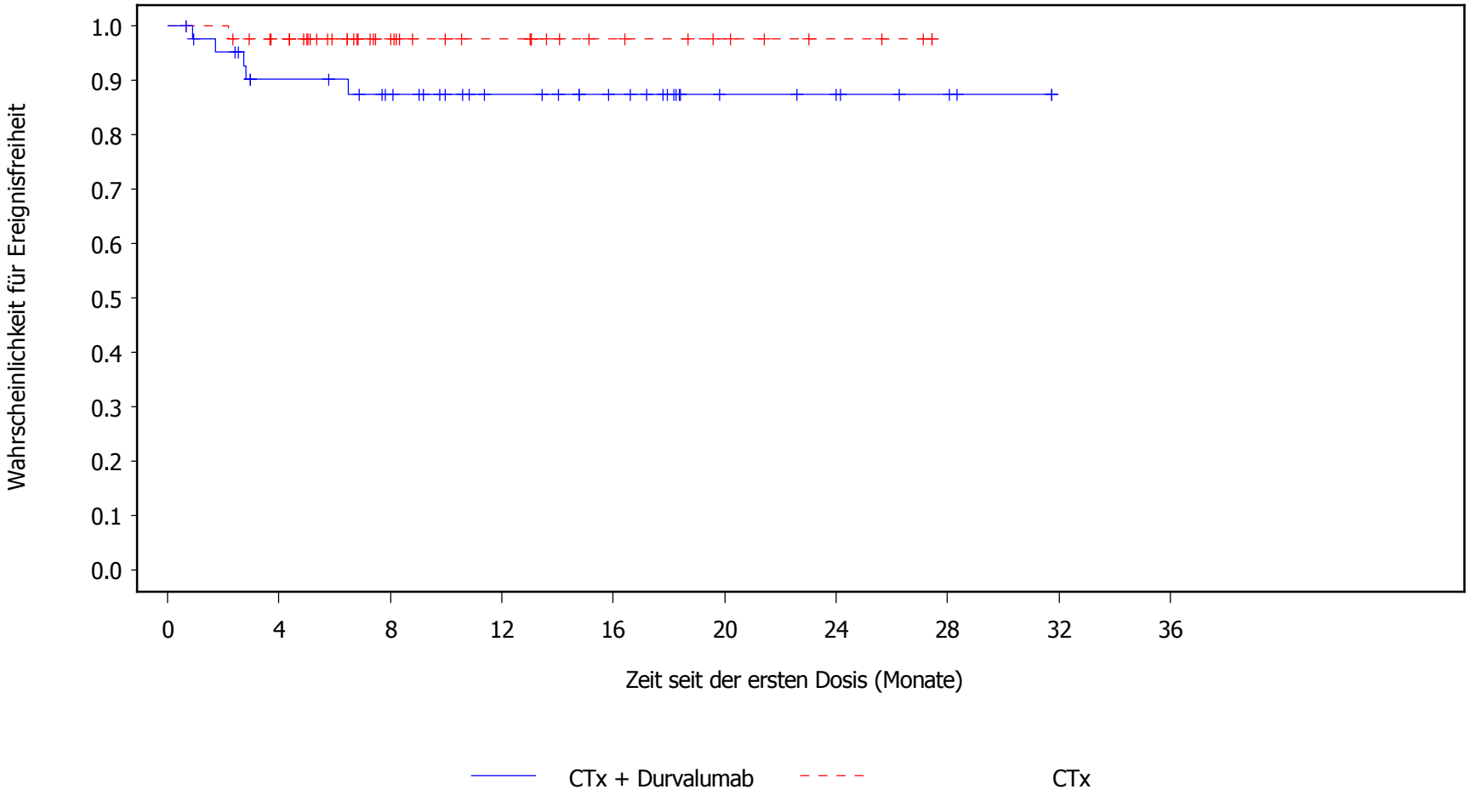
Figure 3.3.1.1D.7 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Augenerkrankungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	27	20	14	5	4	2	0	0	CTx + Durvalumab
46	35	18	11	6	4	1	0	0	0	CTx

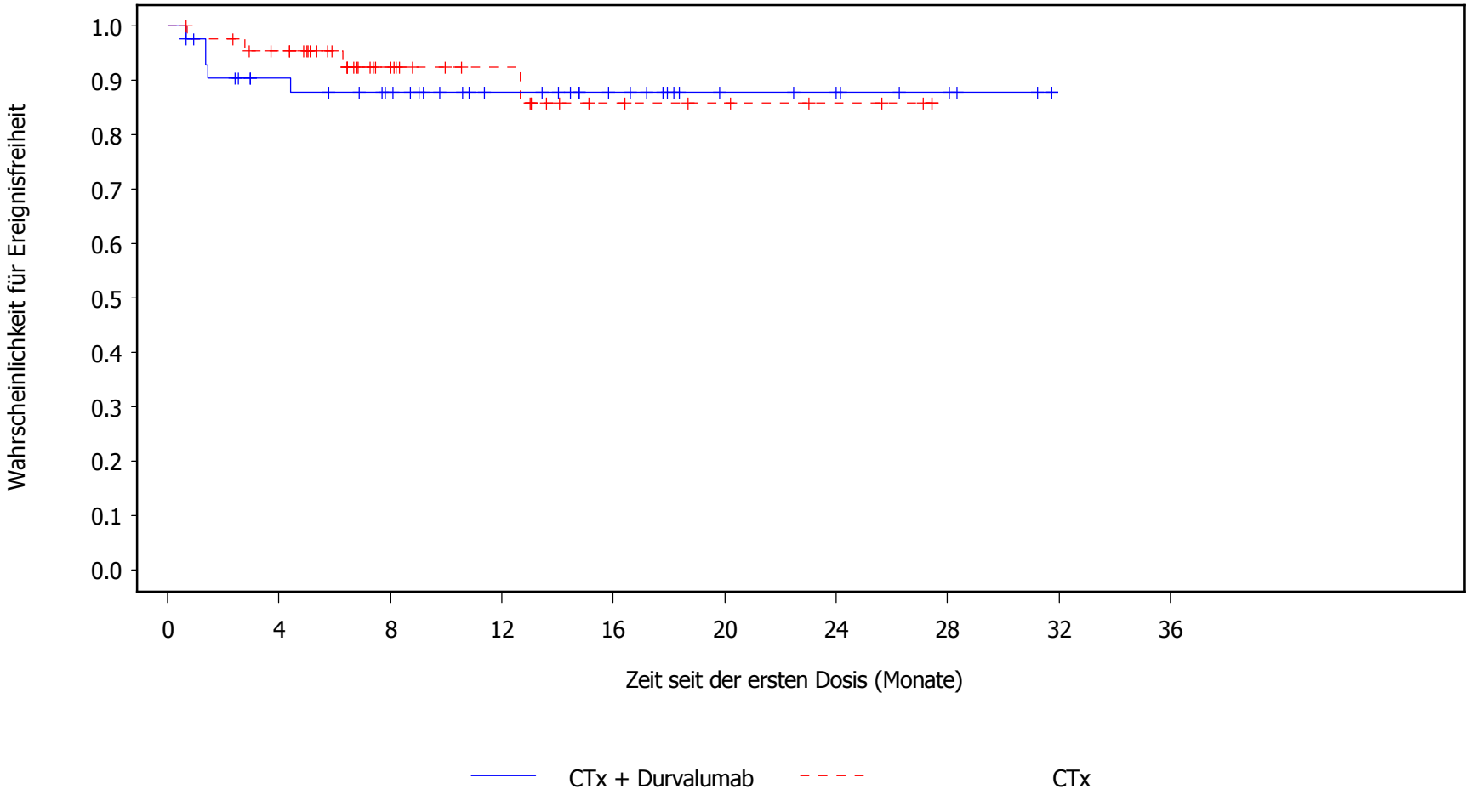
Figure 3.3.1.1D.8 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Sehen verschwommen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	29	21	16	7	6	3	0	0	CTx + Durvalumab
46	40	22	15	9	6	3	0	0	0	CTx

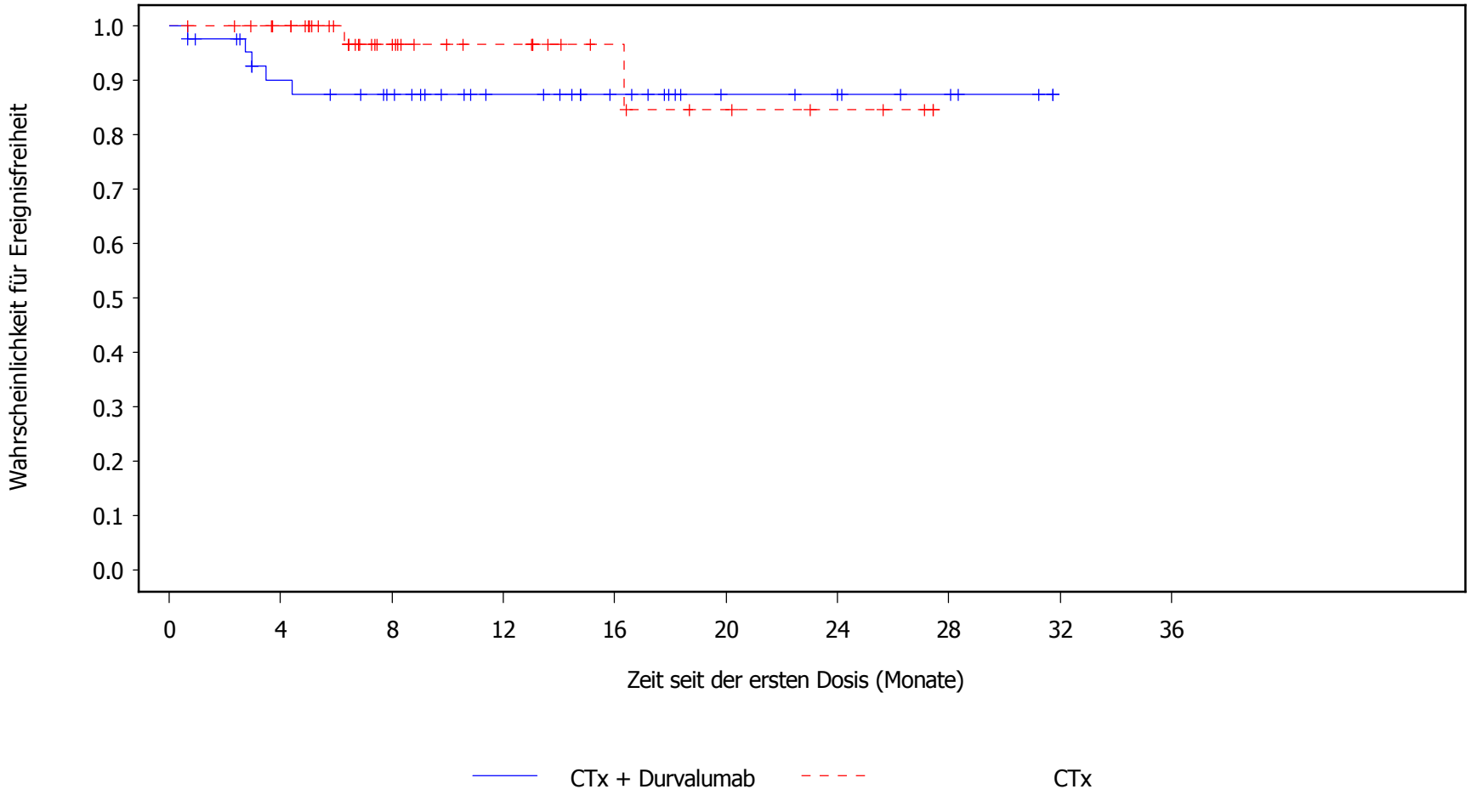
Figure 3.3.1.1D.9 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Endokrine Erkrankungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	29	21	15	8	7	4	0	0	CTx + Durvalumab
46	40	21	14	7	5	3	0	0	0	CTx

Figure 3.3.1.1D.10 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Hypothyreose
Patients with dMMR tumour status, DCO 12APR2023

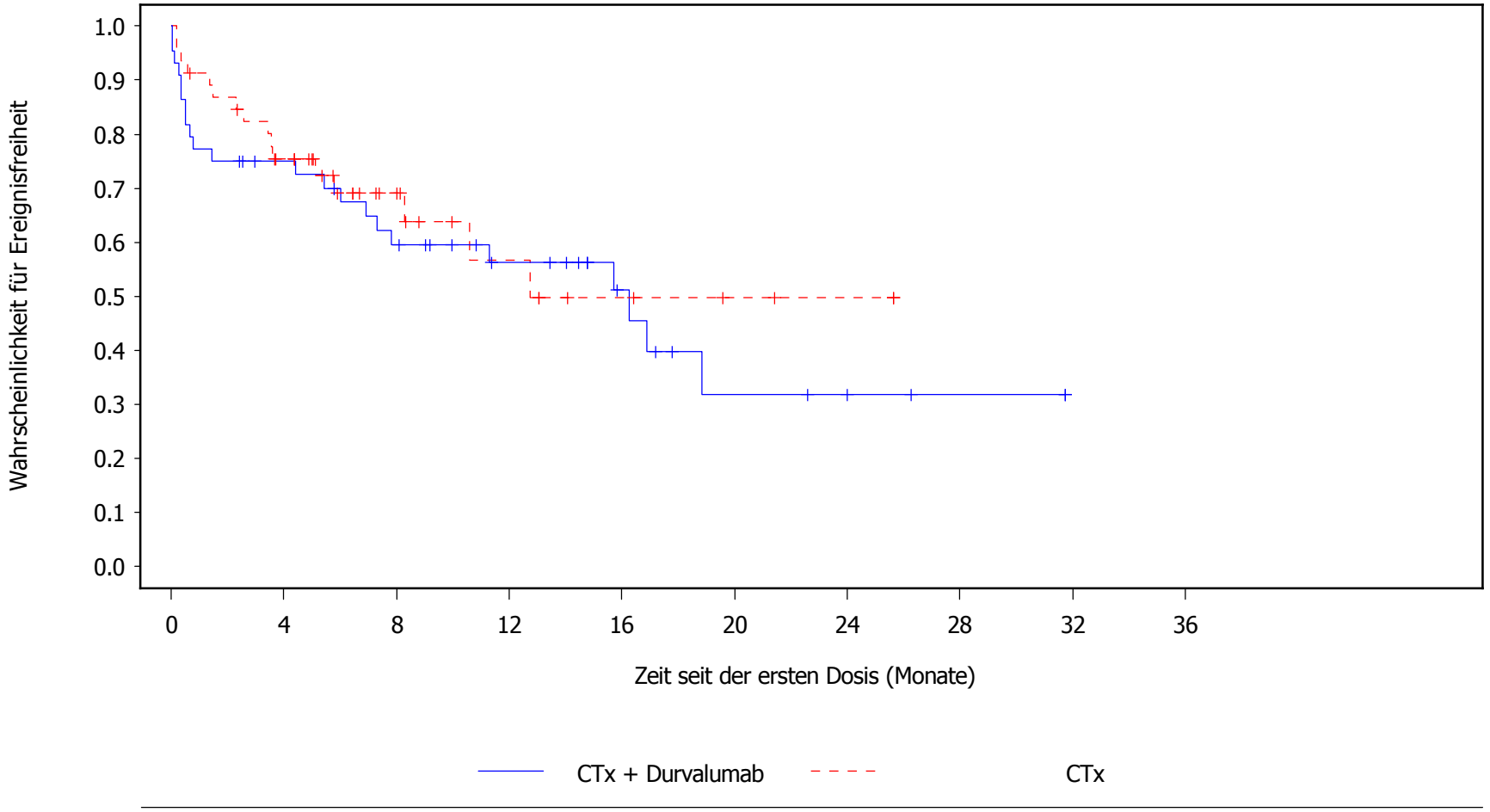


Anzahl an Patienten unter Risiko:

44	34	29	21	15	8	7	4	0	0	CTx + Durvalumab
46	41	21	14	8	5	3	0	0	0	CTx

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.1.1D.11 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	30	23	16	9	4	3	1	0	0	CTx + Durvalumab
46	31	15	8	4	2	1	0	0	0	CTx

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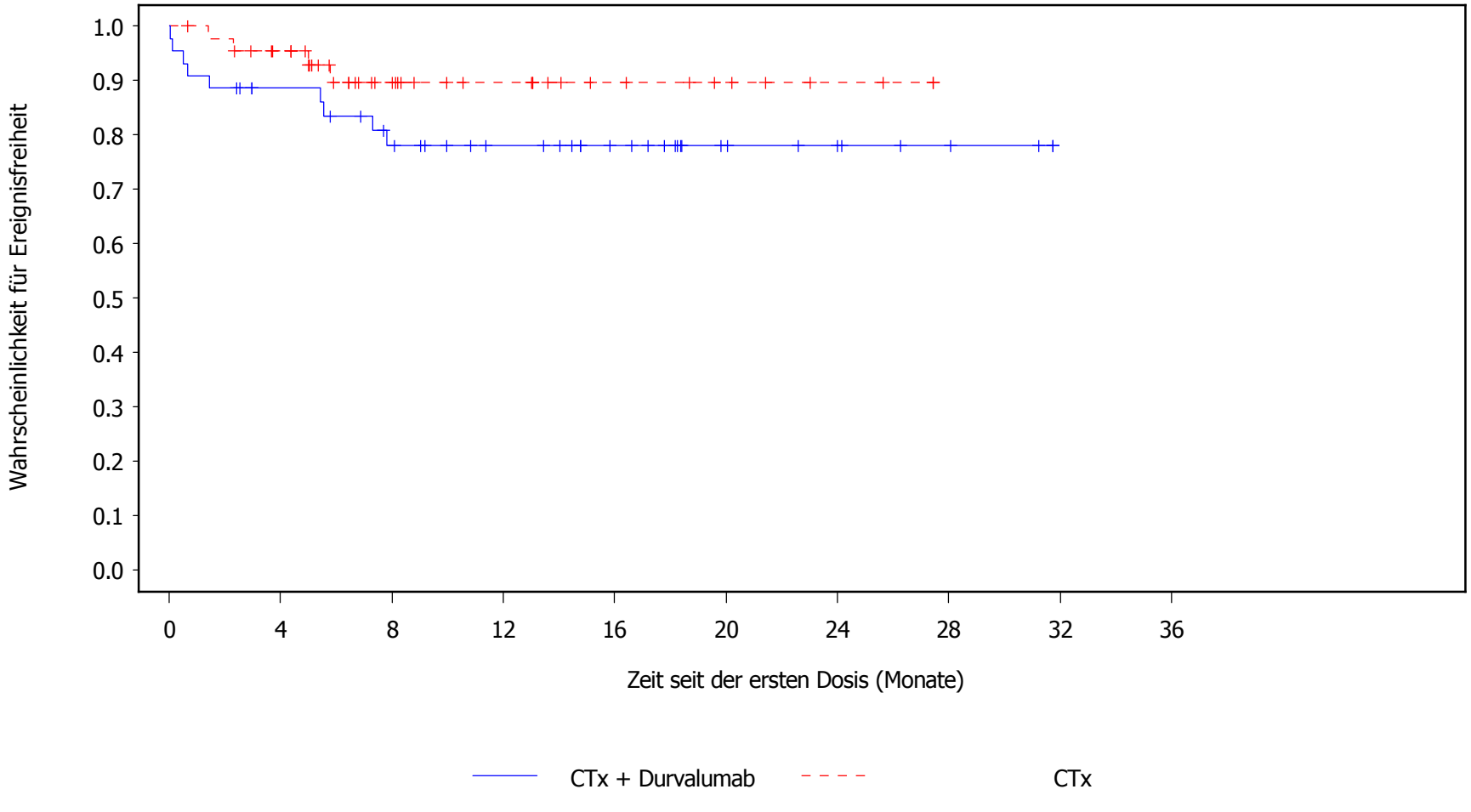
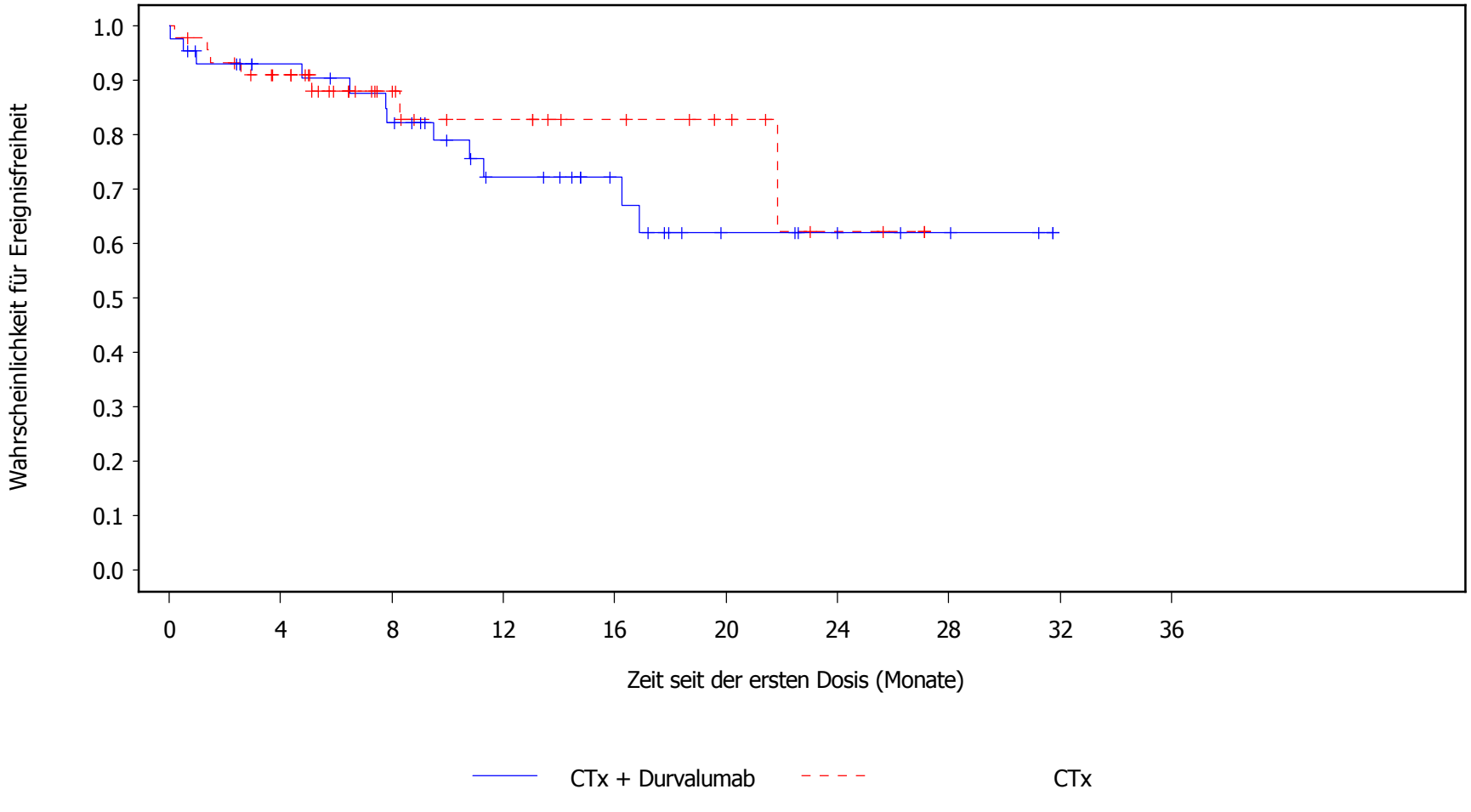
Figure 3.3.1.1D.12 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Dyspnoe
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	35	28	22	16	8	6	3	0	0	CTx + Durvalumab
46	39	21	14	8	5	2	0	0	0	CTx

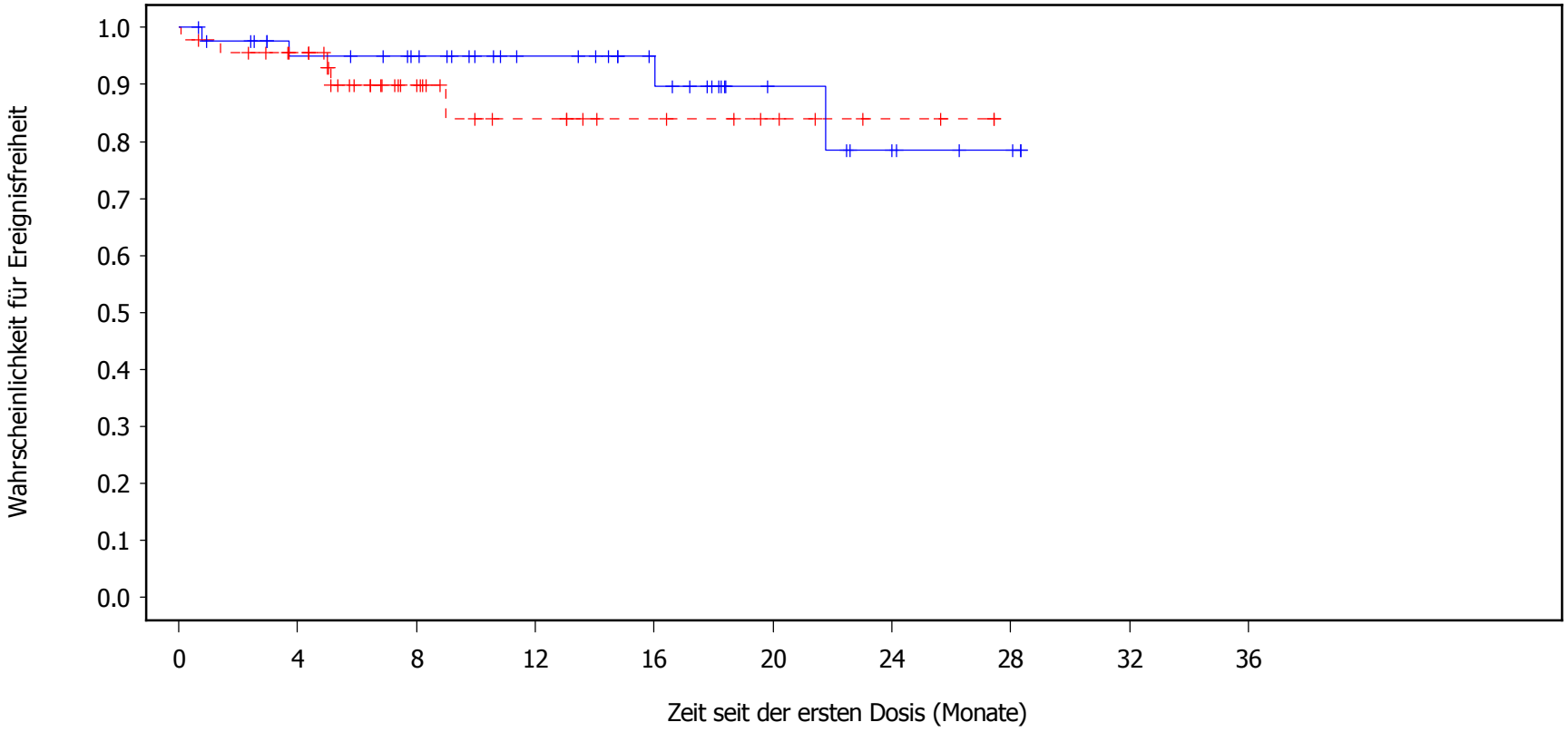
Figure 3.3.1.1D.13 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Husten
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	35	30	20	14	7	5	3	0	0	CTx + Durvalumab
46	37	19	13	9	6	2	0	0	0	CTx

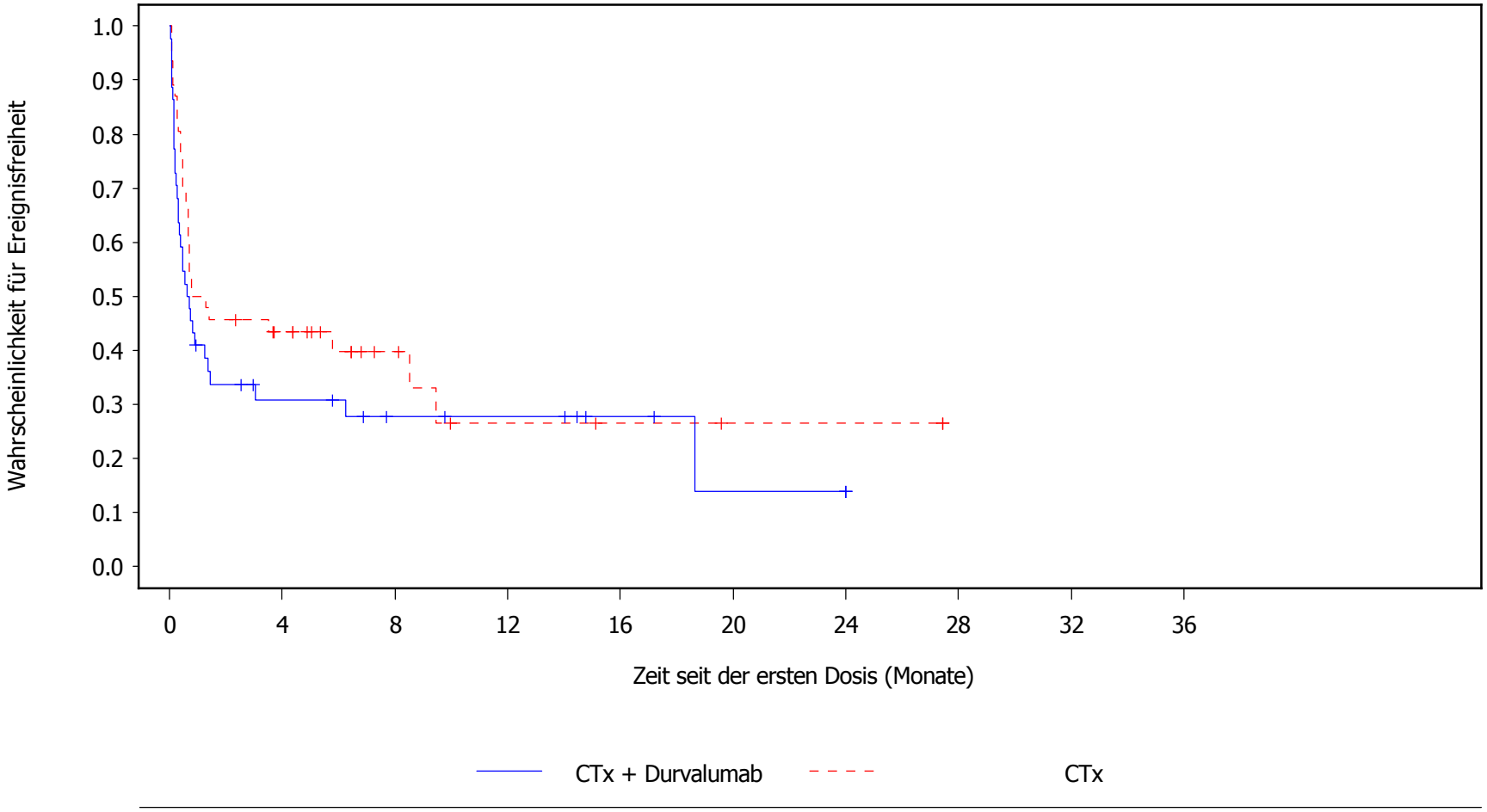
Figure 3.3.1.1D.14 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	32	24	18	8	5	2	0	0	CTx + Durvalumab
46	39	20	12	8	5	2	0	0	0	CTx

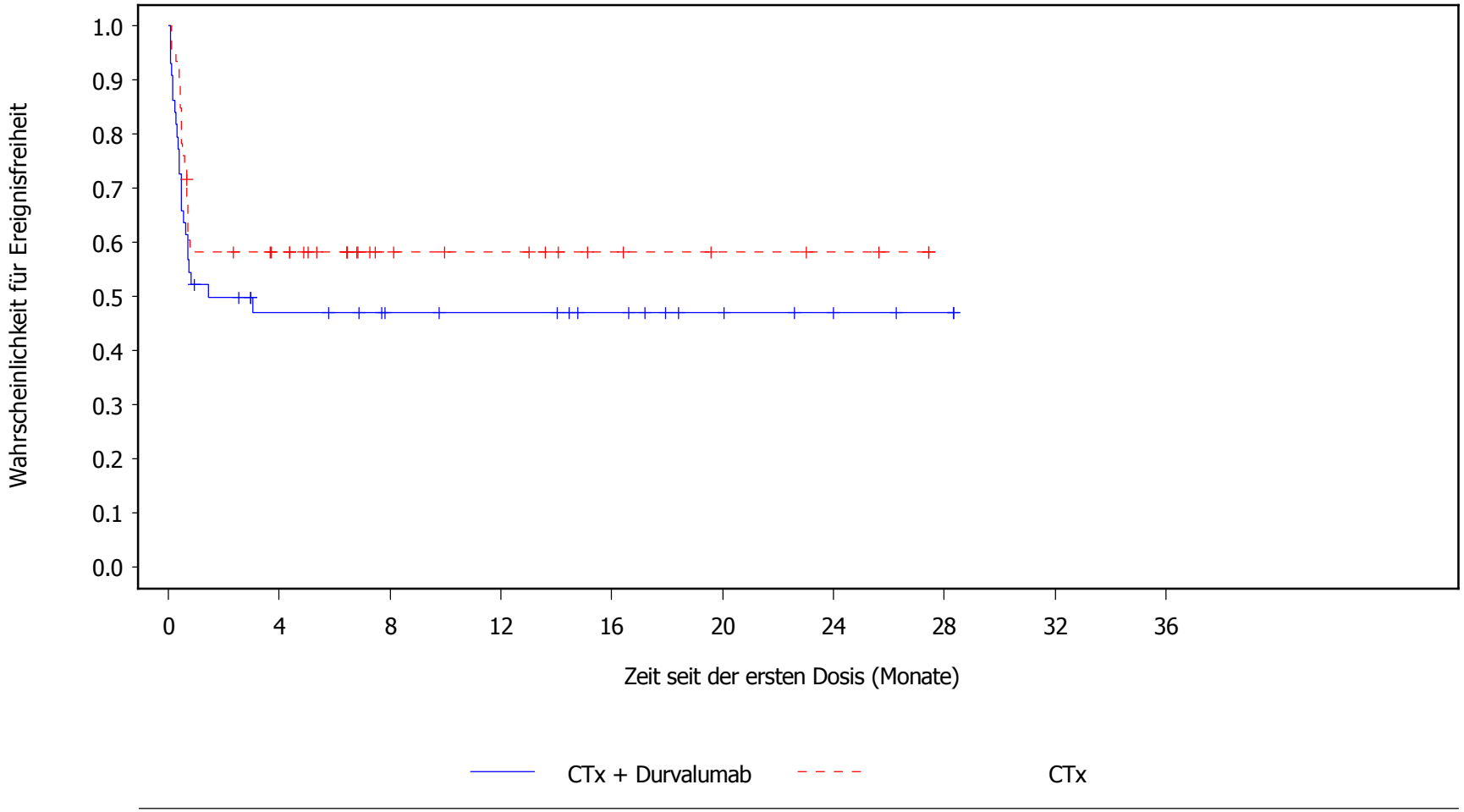
Figure 3.3.1.1D.15 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Haut und des Unterhautgewebes
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	11	7	6	3	1	1	0	0	0	CTx + Durvalumab
46	17	7	3	2	1	1	0	0	0	CTx

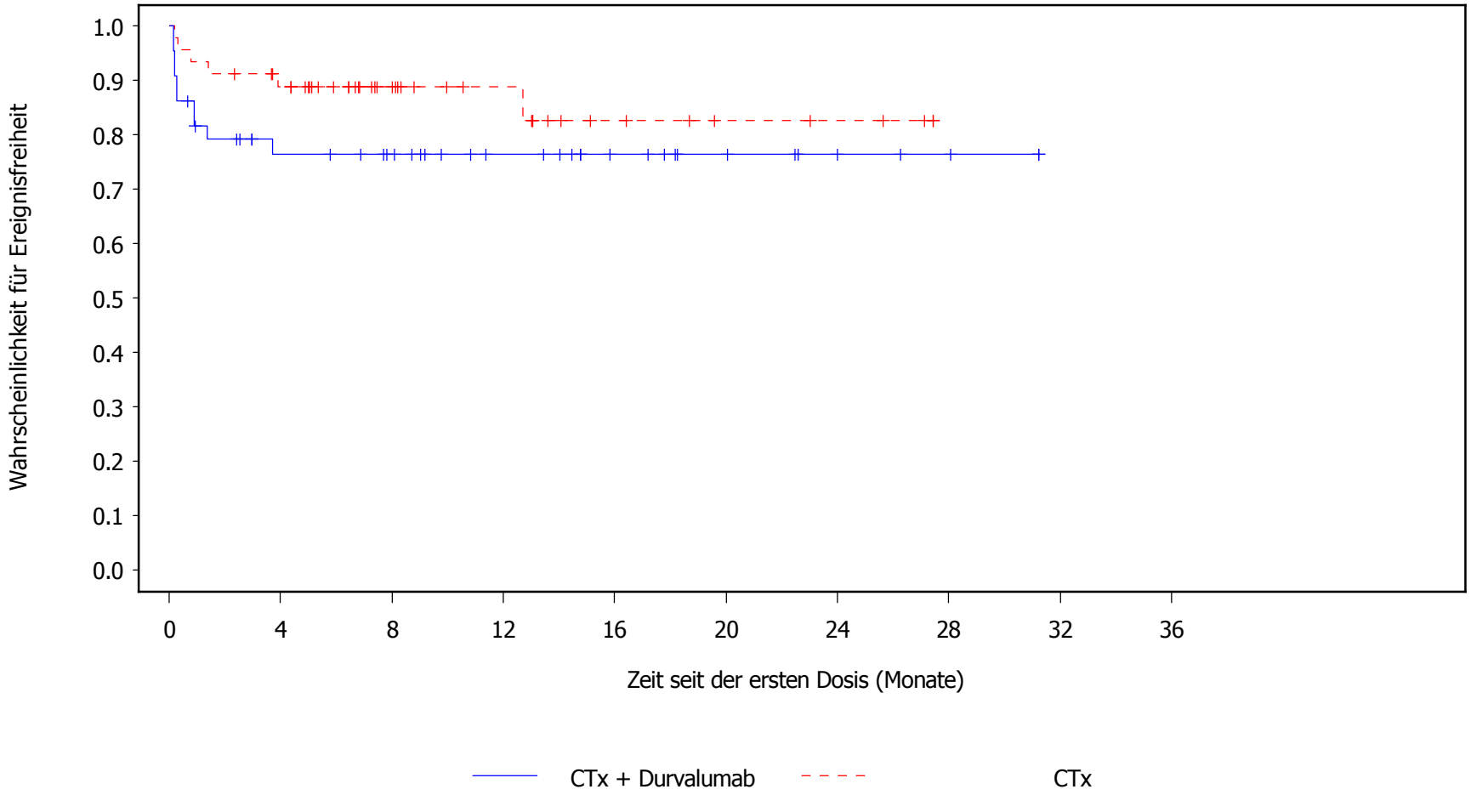
Figure 3.3.1.1D.16 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Alopezie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	17	13	12	9	5	3	1	0	0	CTx + Durvalumab
46	23	11	9	5	3	2	0	0	0	CTx

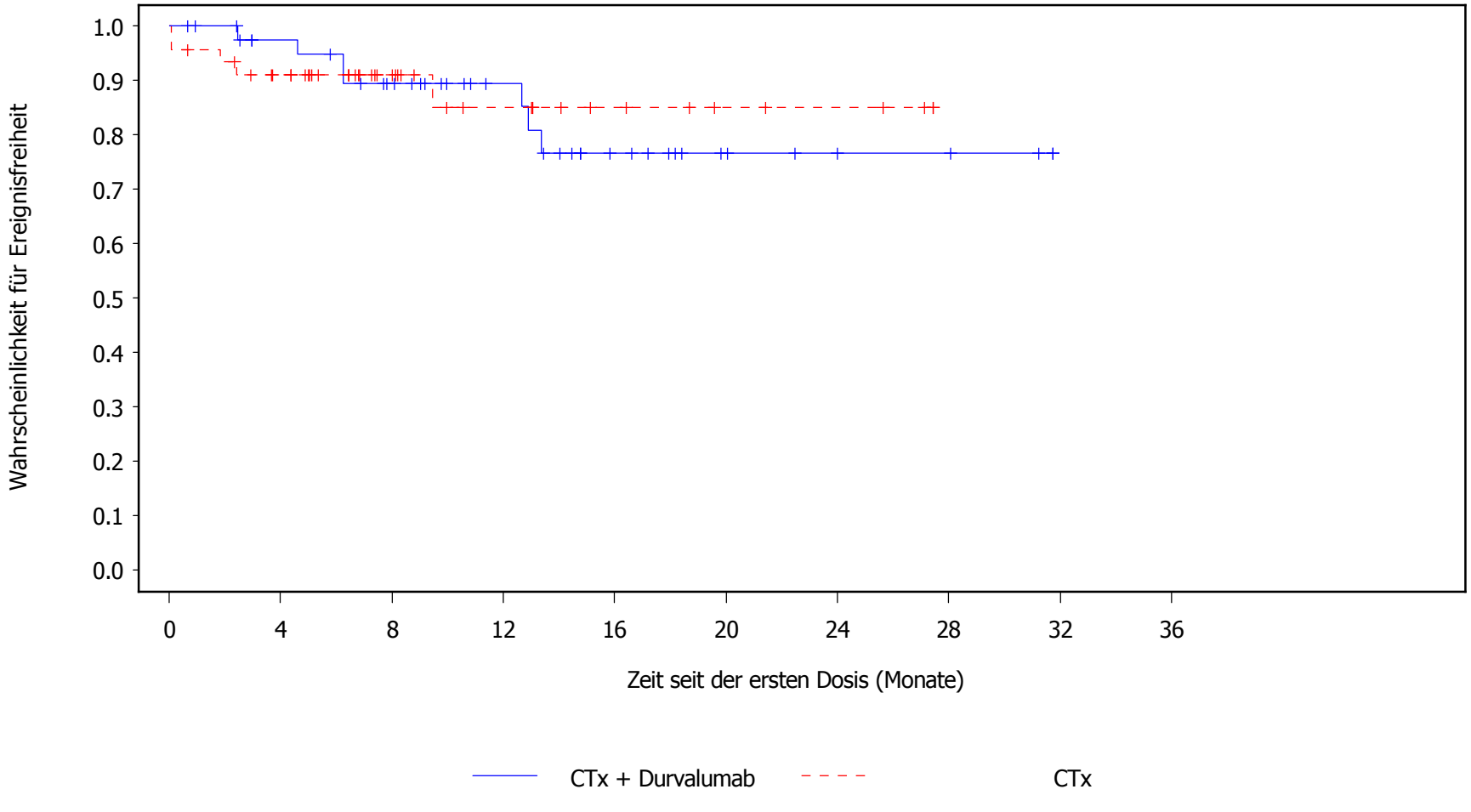
Figure 3.3.1.1D.17 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Ausschlag
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	28	24	17	11	7	4	2	0	0	CTx + Durvalumab
46	38	21	14	7	4	3	0	0	0	CTx

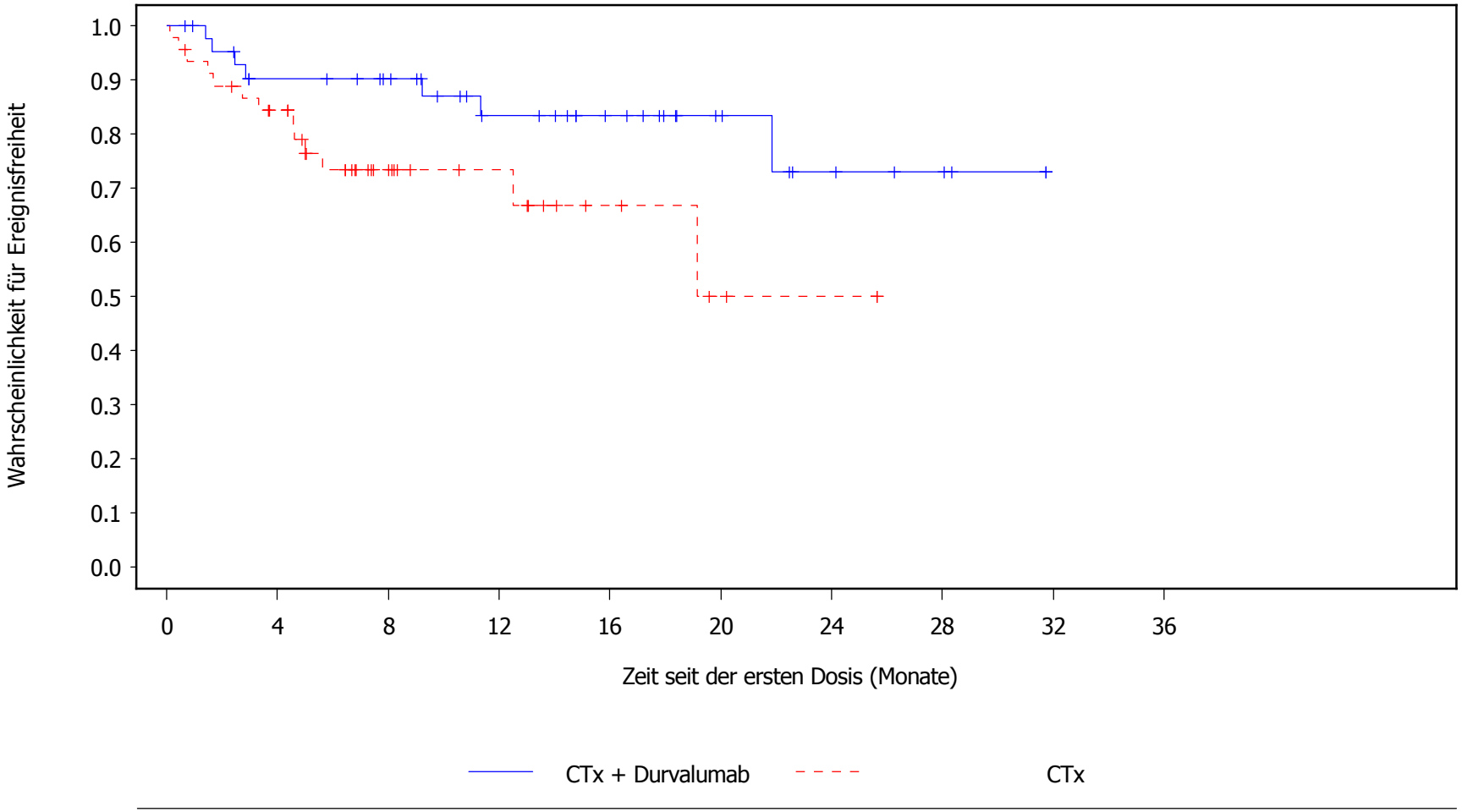
Figure 3.3.1.1D.18 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Pruritus
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	37	30	21	12	6	4	3	0	0	CTx + Durvalumab
46	37	20	12	7	4	3	0	0	0	CTx

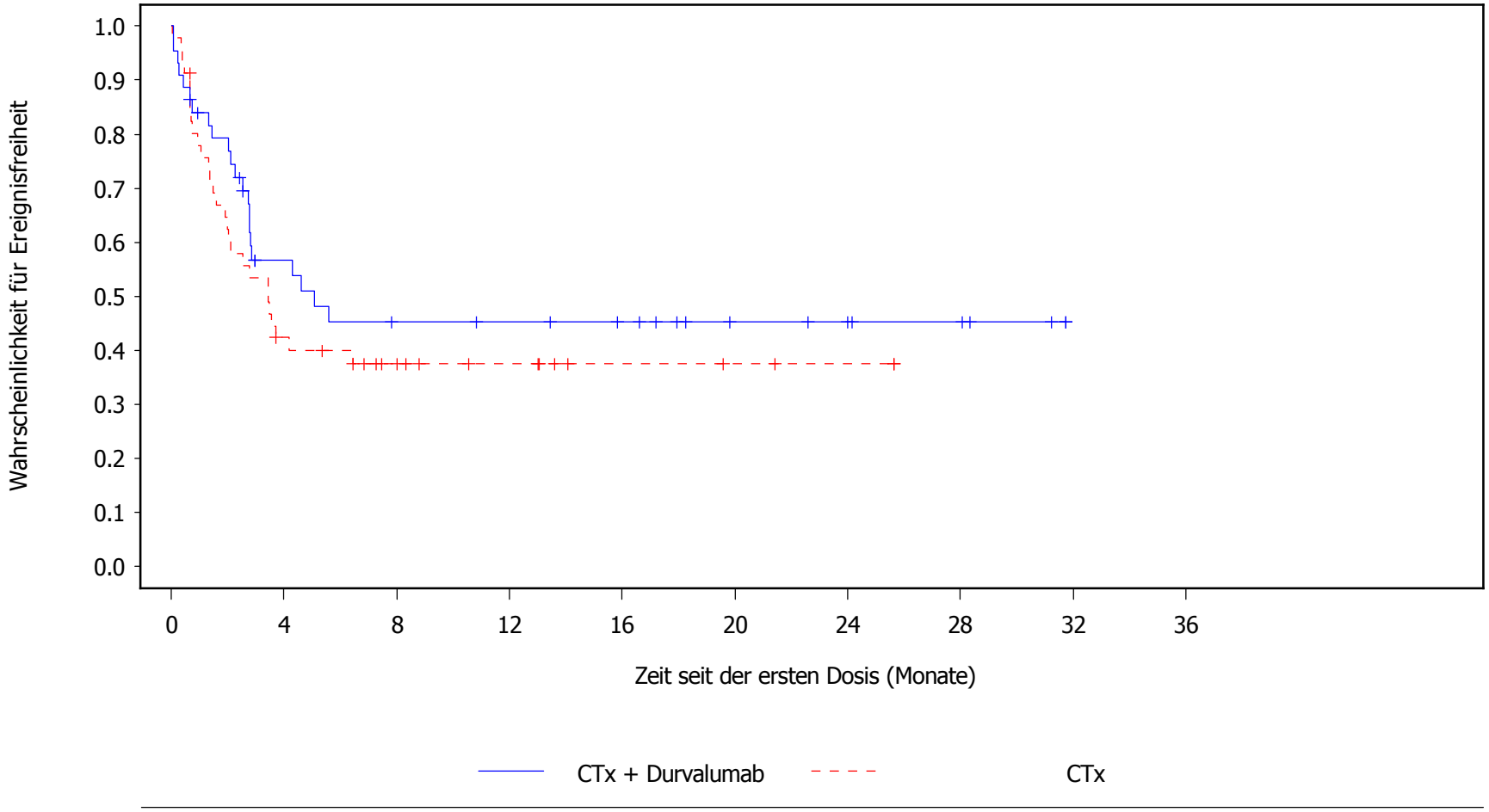
Figure 3.3.1.1D.19 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Nieren und Harnwege
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	35	31	22	16	9	5	3	0	0	CTx + Durvalumab
46	35	17	11	5	2	1	0	0	0	CTx

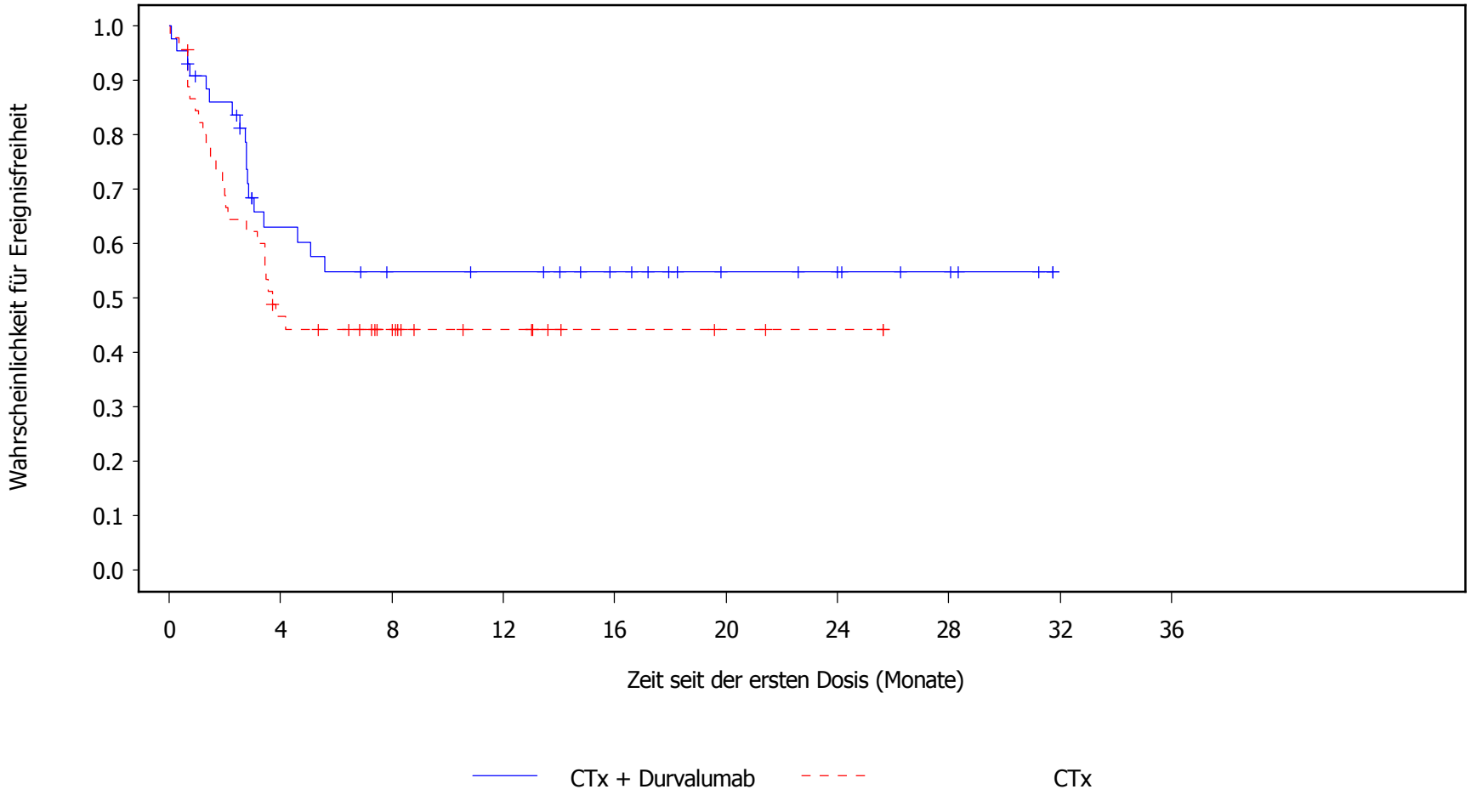
Figure 3.3.1.1D.20 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	20	15	14	12	7	6	4	0	0	CTx + Durvalumab
46	18	11	7	3	2	1	0	0	0	CTx

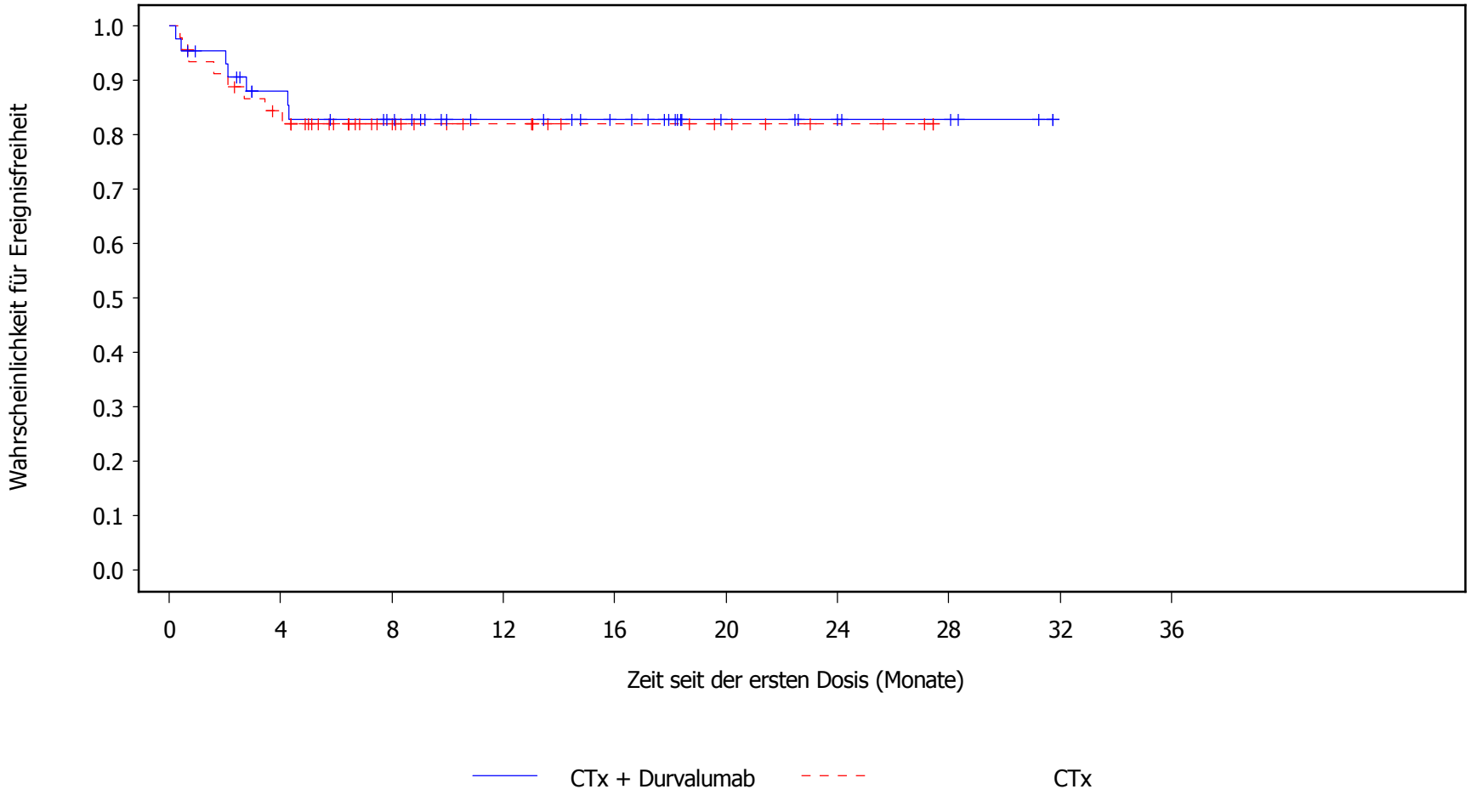
Figure 3.3.1.1D.21 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Anaemie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	23	18	17	13	8	7	4	0	0	CTx + Durvalumab
46	20	13	7	3	2	1	0	0	0	CTx

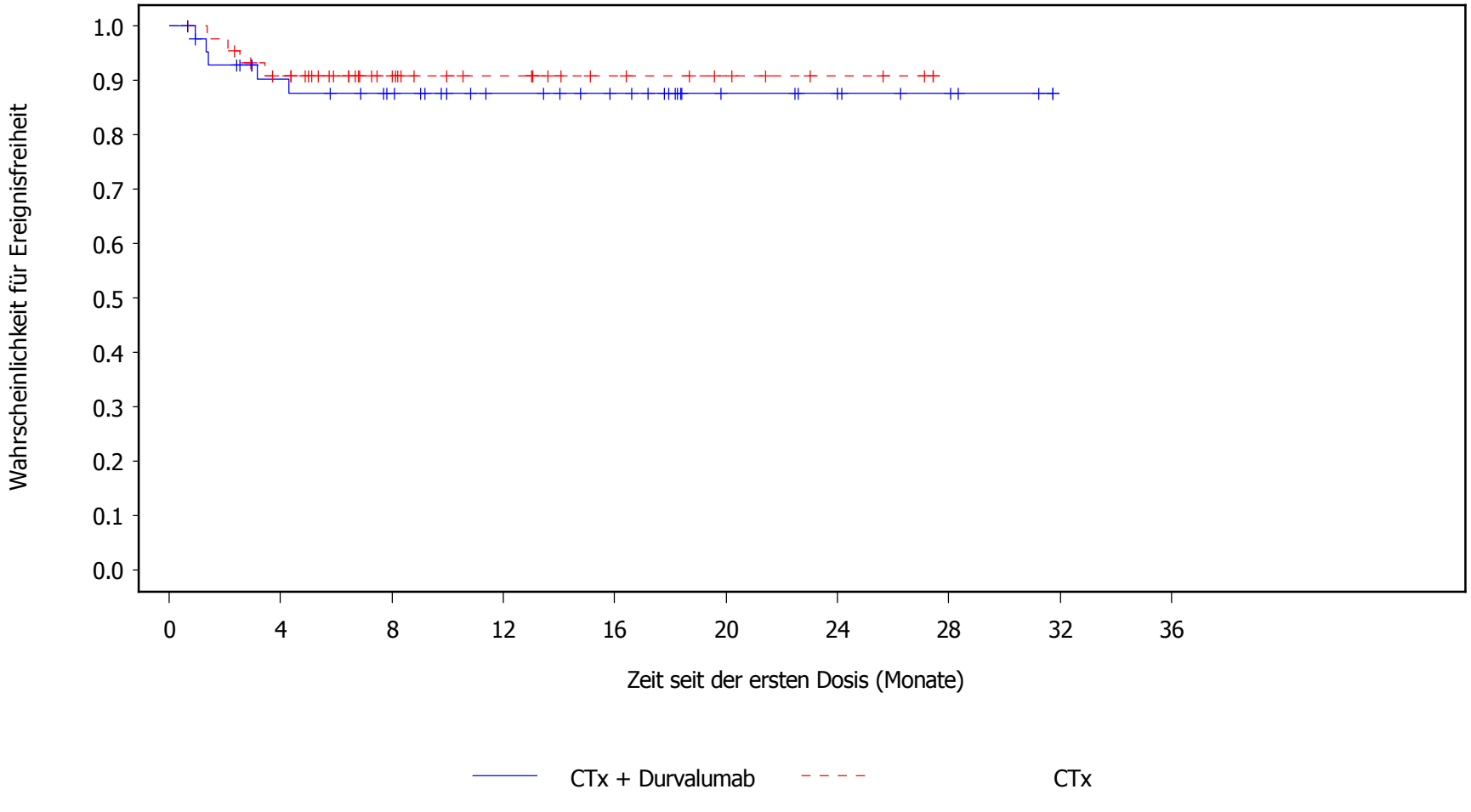
Figure 3.3.1.1D.22 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Neutropenie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	33	28	21	17	8	6	4	0	0	CTx + Durvalumab
46	36	19	13	8	6	3	0	0	0	CTx

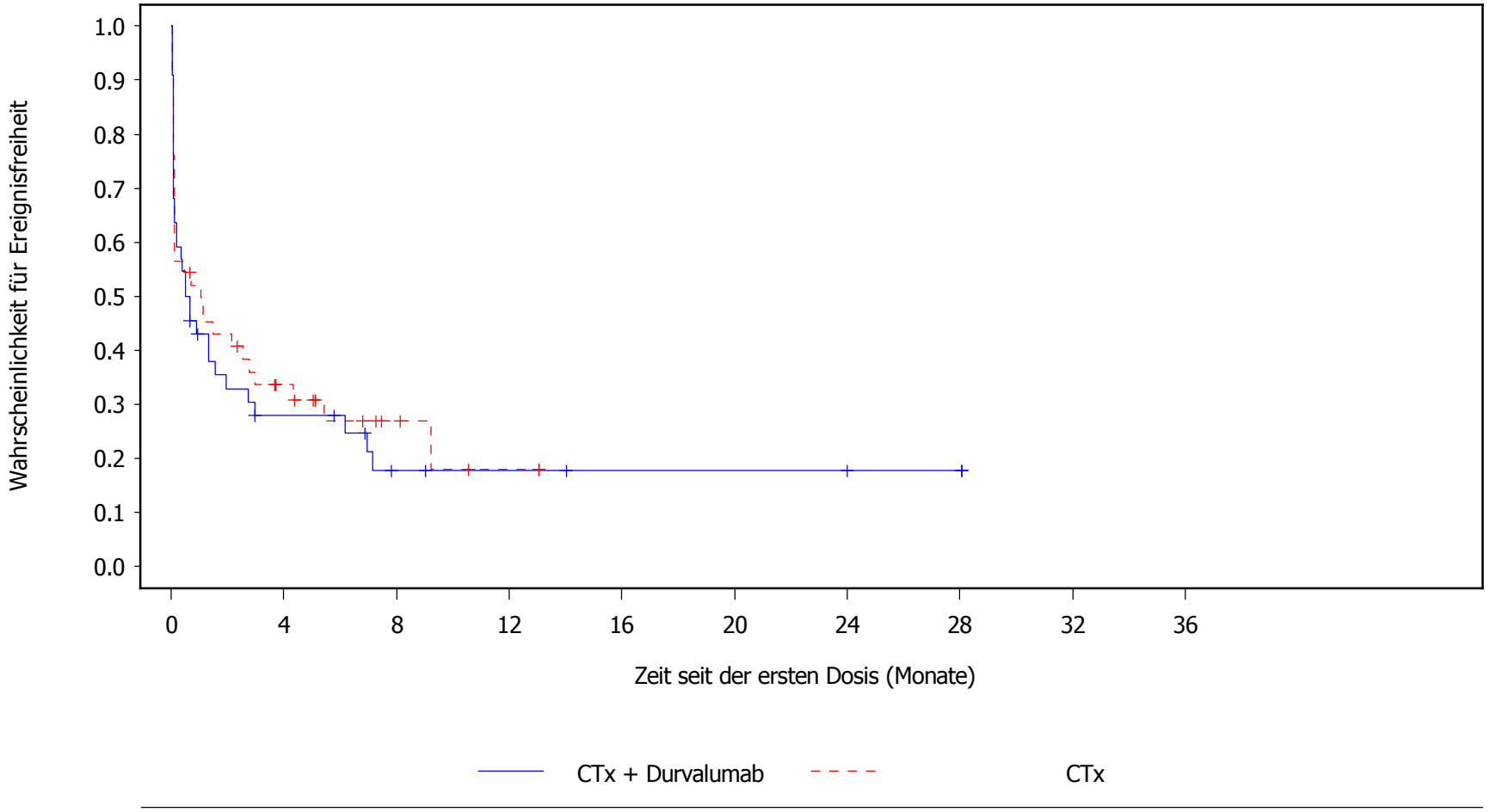
Figure 3.3.1.1D.23 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Thrombozytopenie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	29	22	18	9	7	4	0	0	CTx + Durvalumab
46	38	22	15	9	6	3	0	0	0	CTx

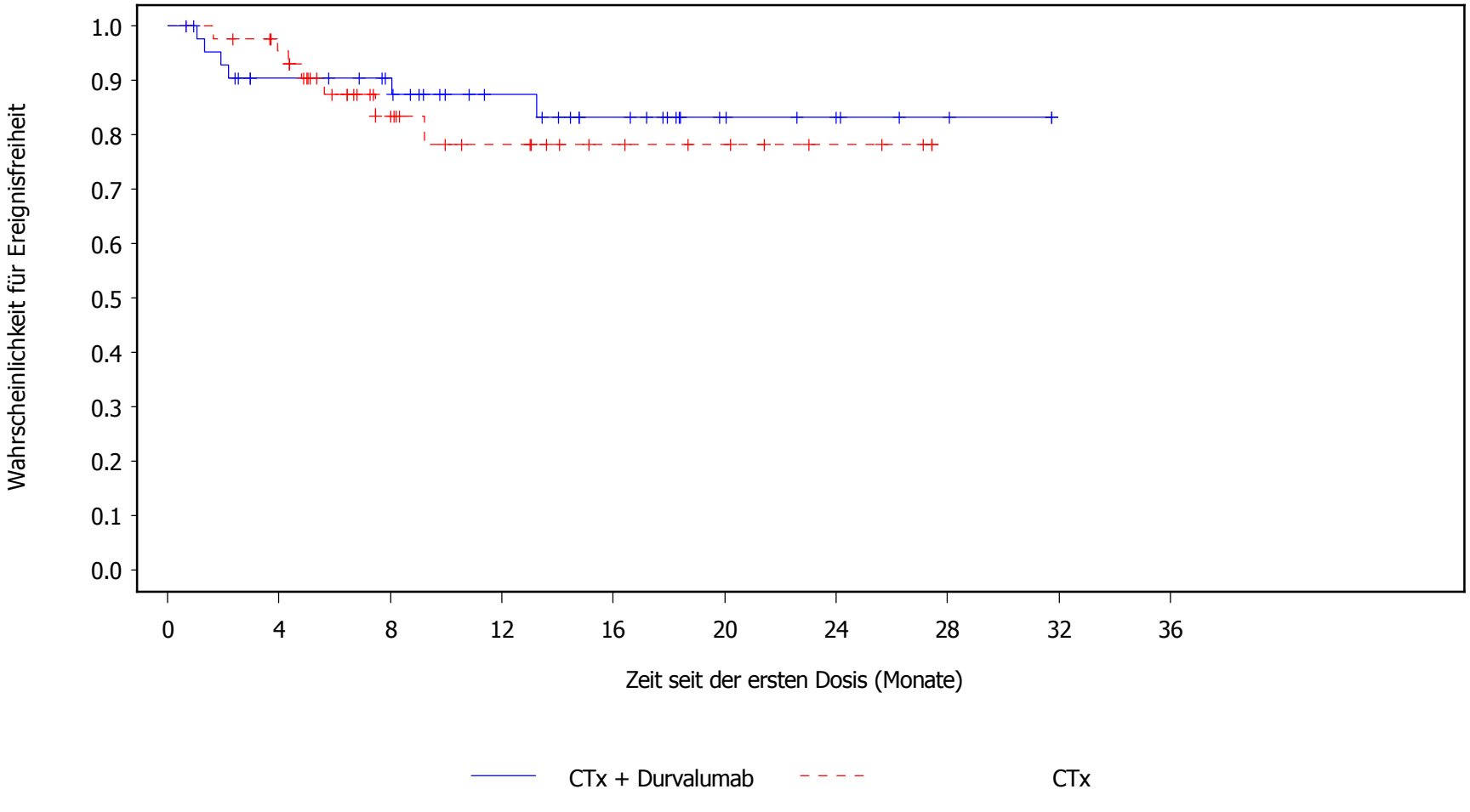
Figure 3.3.1.1D.24 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Gastrointestinaltrakts
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	10	4	3	2	2	2	1	0	0	CTx + Durvalumab
46	12	4	1	0	0	0	0	0	0	CTx

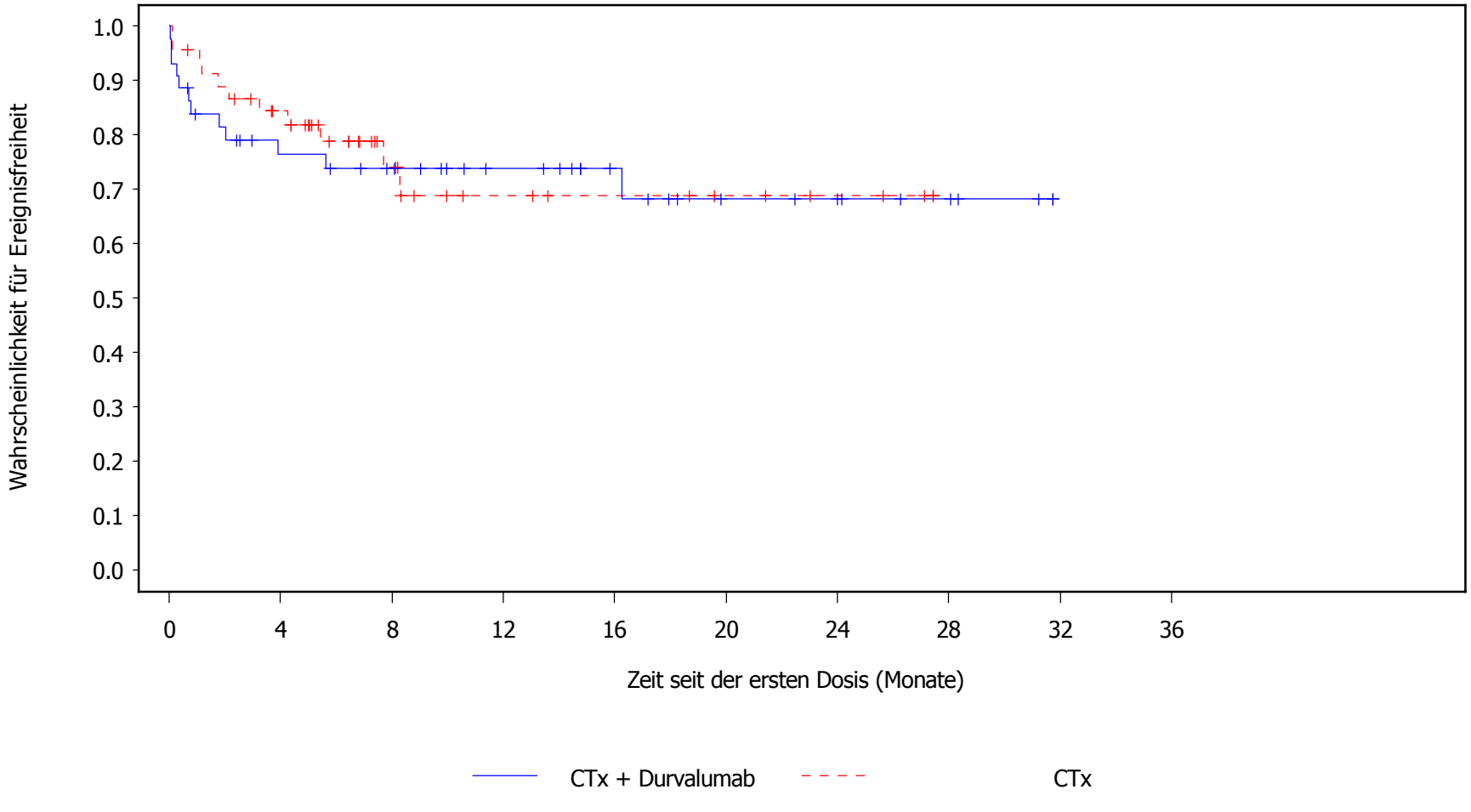
Figure 3.3.1.1D.25 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Abdominalschmerz
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	30	21	15	7	5	2	0	0	CTx + Durvalumab
46	40	20	13	8	6	3	0	0	0	CTx

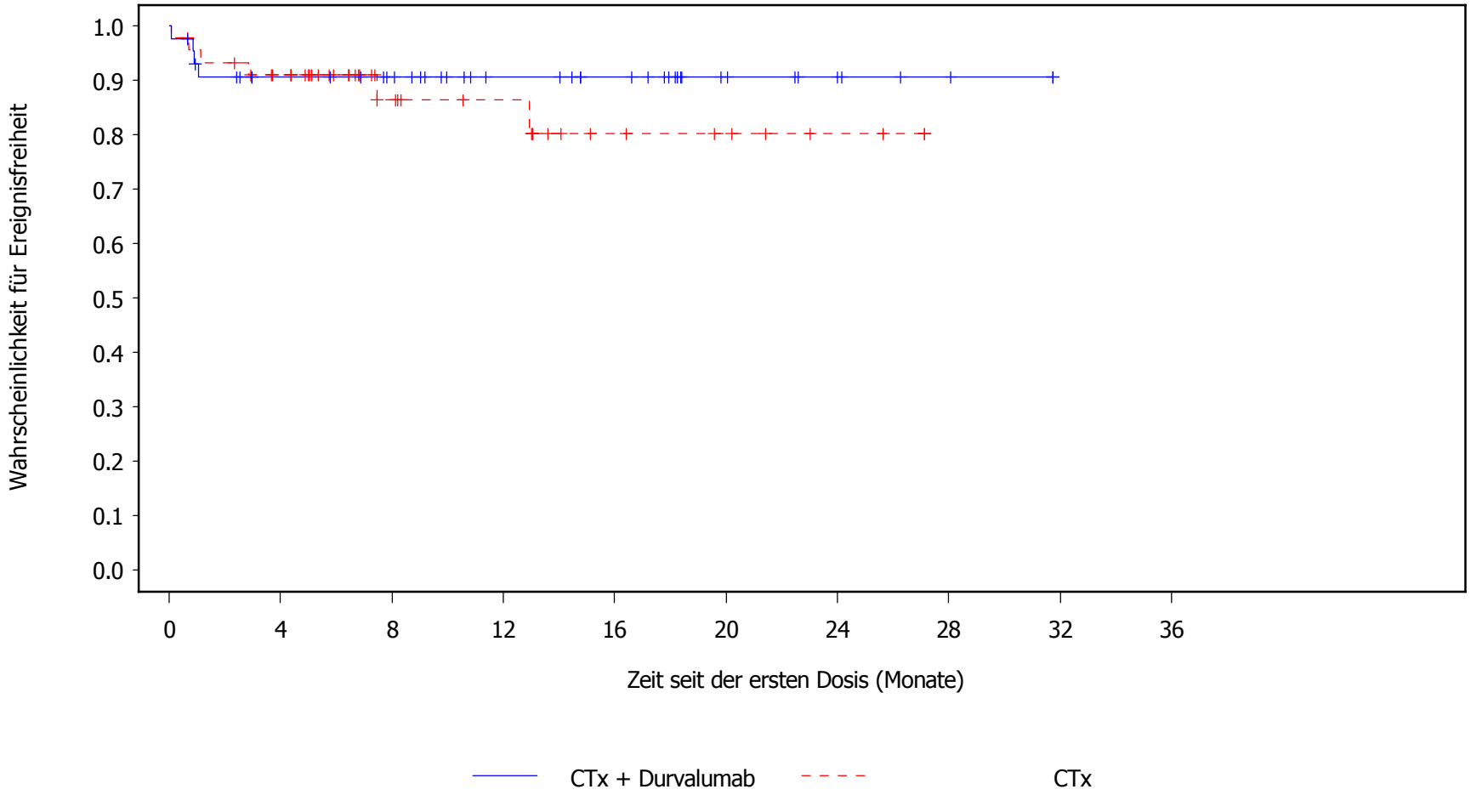
Figure 3.3.1.1D.26 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Diarrhoe
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	29	25	19	13	8	7	4	0	0	CTx + Durvalumab
46	34	16	9	7	5	3	0	0	0	CTx

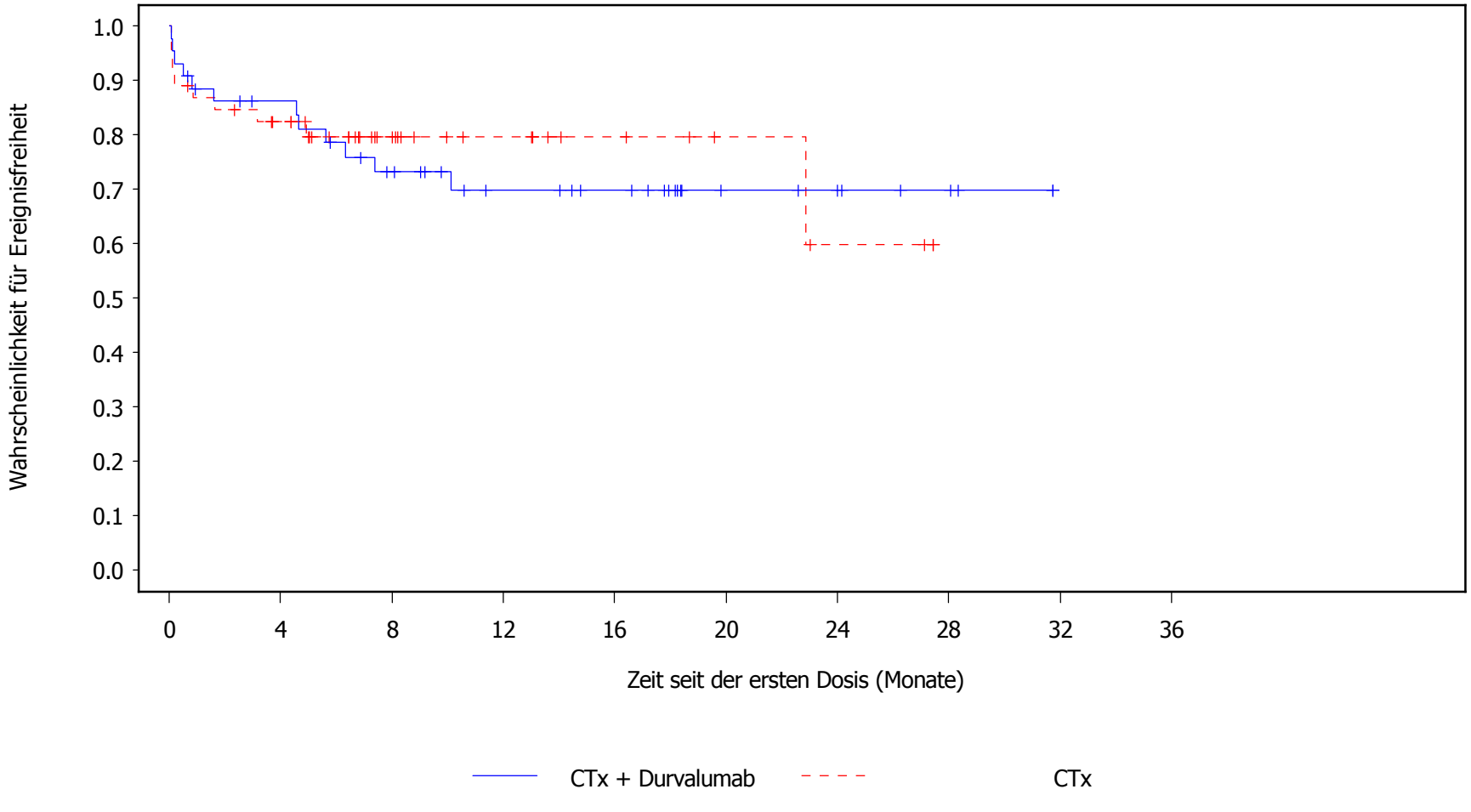
Figure 3.3.1.1D.27 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Dyspepsie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	30	21	17	8	5	2	0	0	CTx + Durvalumab
46	37	18	14	7	5	2	0	0	0	CTx

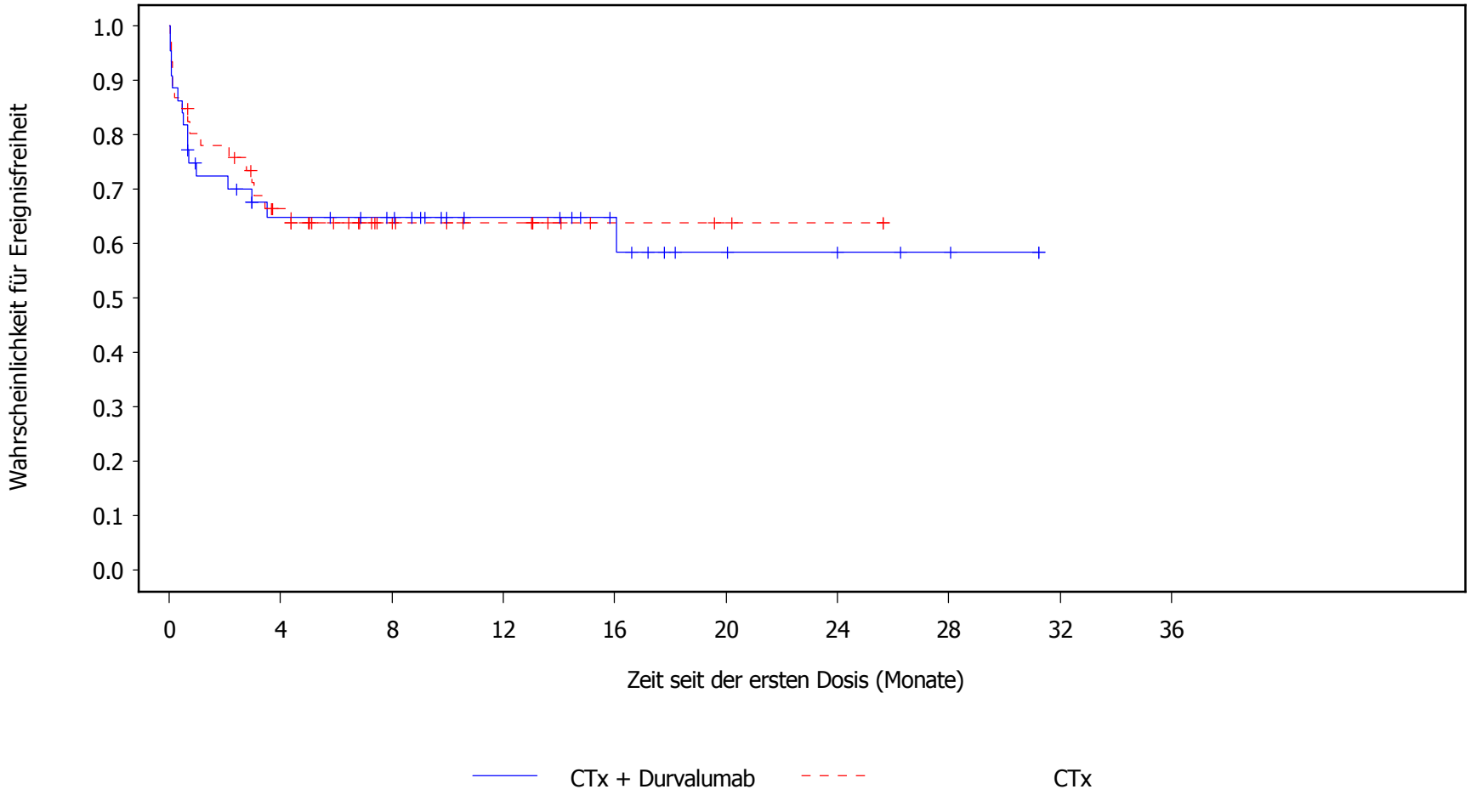
Figure 3.3.1.1D.28 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Erbrechen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	26	19	16	7	6	3	0	0	CTx + Durvalumab
46	34	18	11	7	4	2	0	0	0	CTx

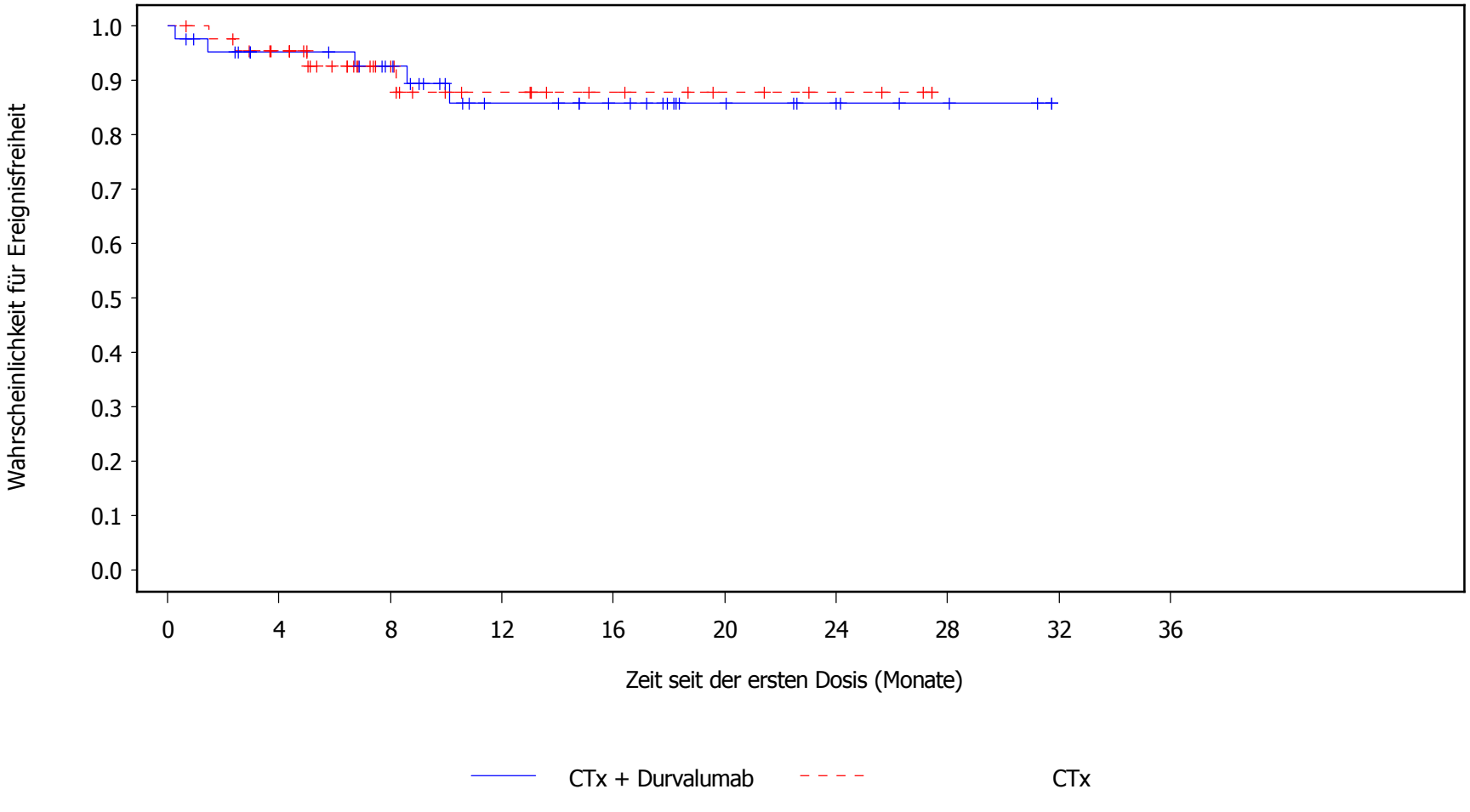
Figure 3.3.1.1D.29 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Obstipation
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	24	21	14	10	5	4	2	0	0	CTx + Durvalumab
46	26	13	9	3	2	1	0	0	0	CTx

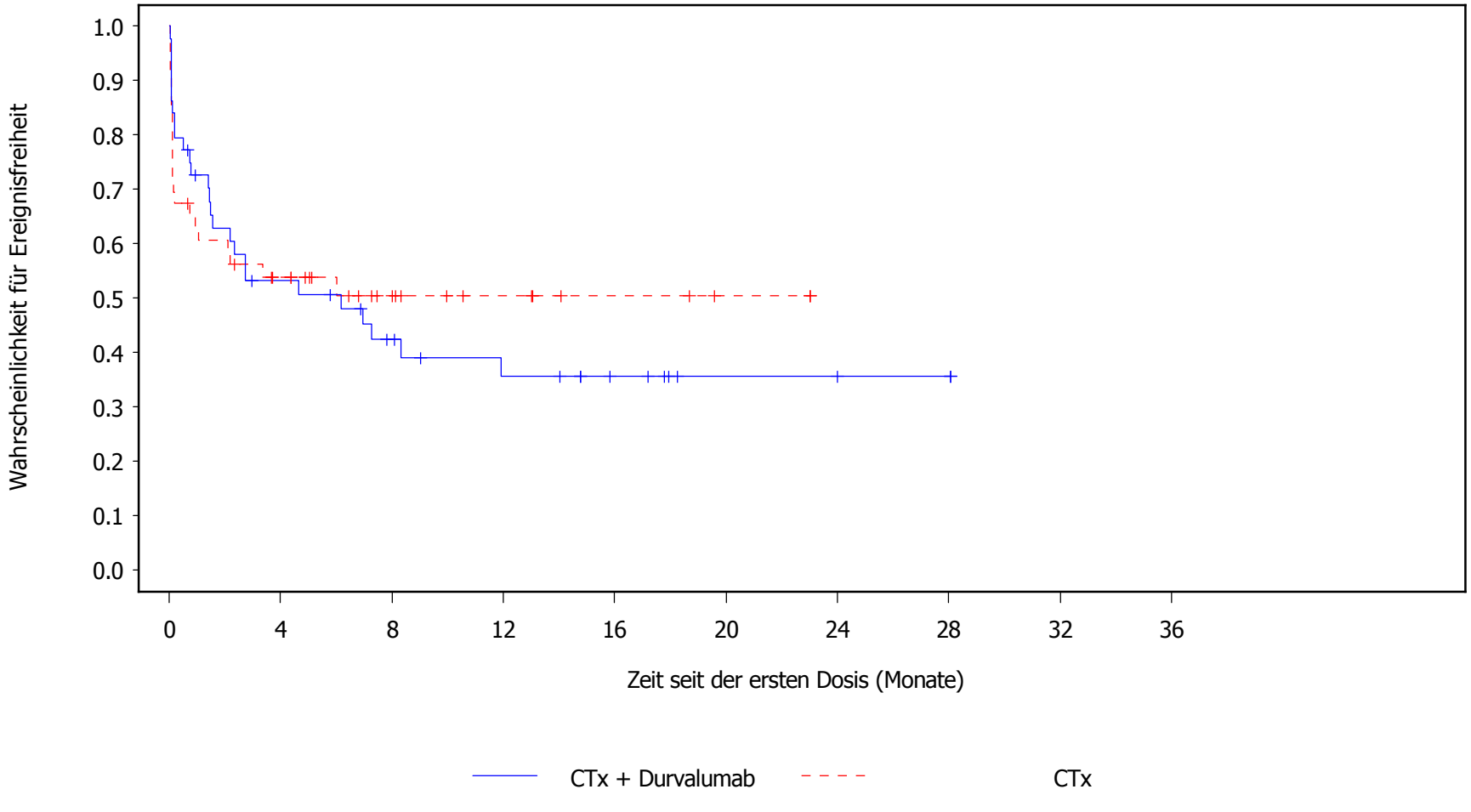
Figure 3.3.1.1D.30 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Schmerzen Oberbauch
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	31	20	16	9	6	3	0	0	CTx + Durvalumab
46	39	21	13	8	5	3	0	0	0	CTx

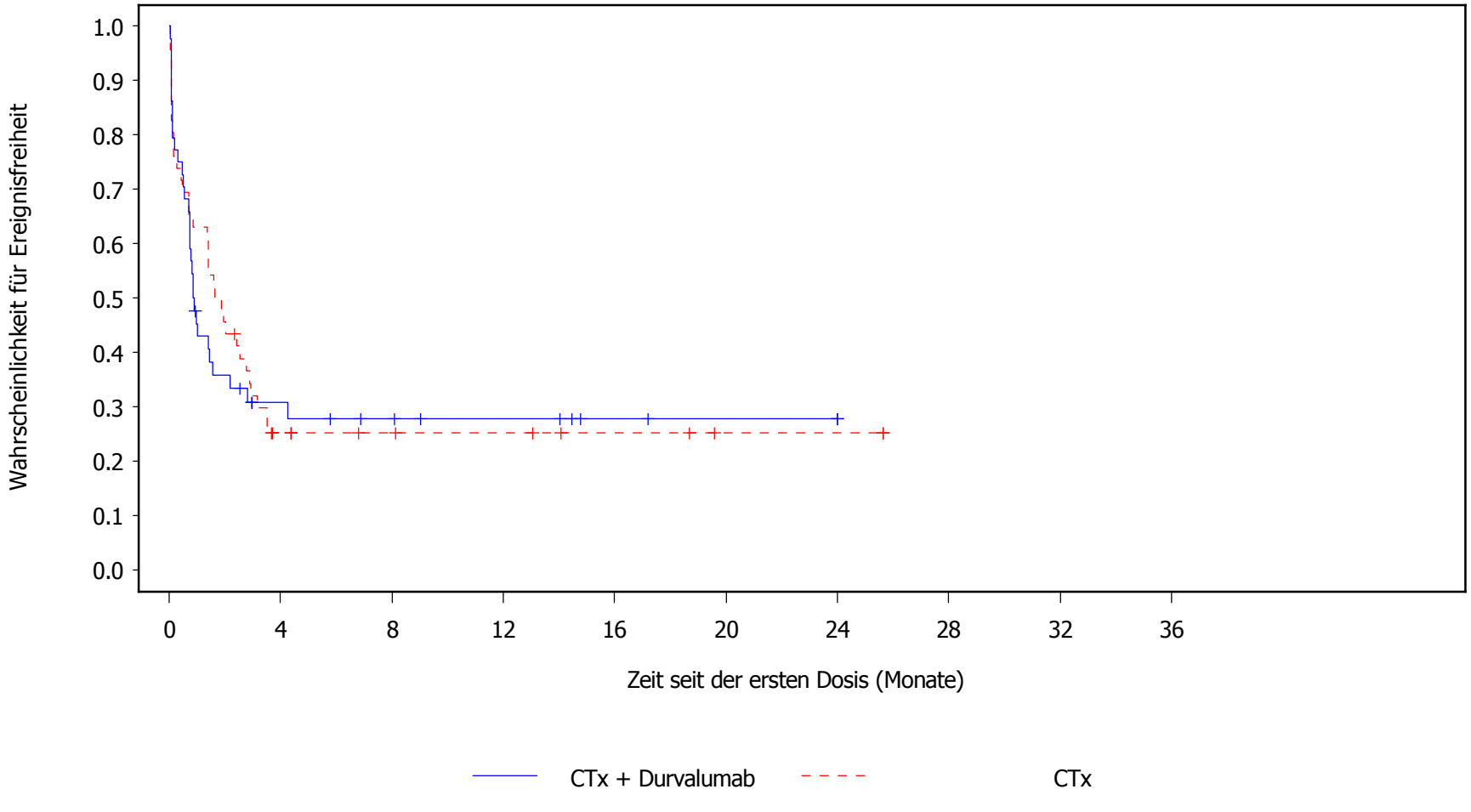
Figure 3.3.1.1D.31 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Uebelkeit
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	21	14	10	6	2	2	1	0	0	CTx + Durvalumab
46	21	11	6	3	1	0	0	0	0	CTx

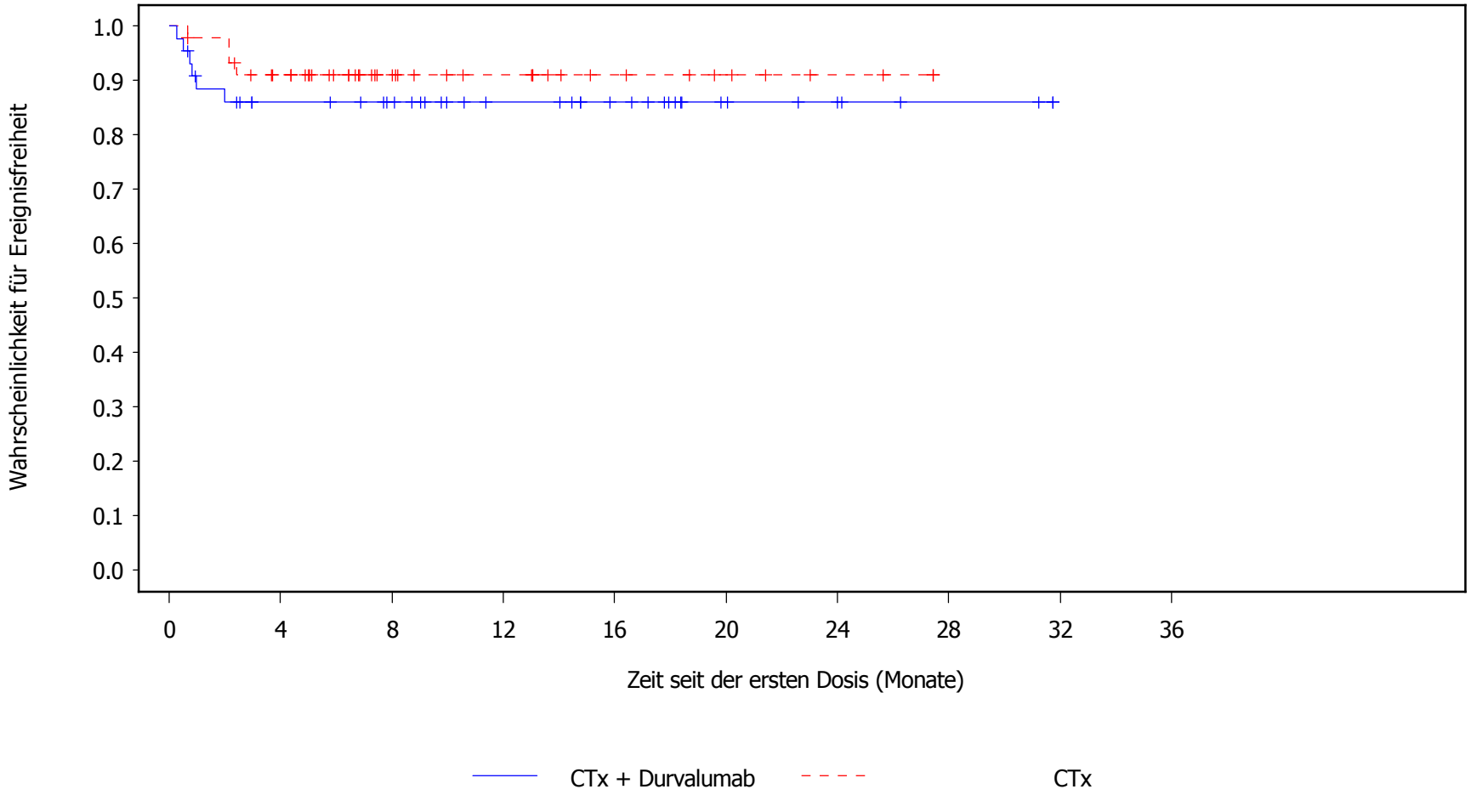
Figure 3.3.1.1D.32 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Nervensystems
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	10	7	5	2	1	1	0	0	0	CTx + Durvalumab
46	9	6	5	3	1	1	0	0	0	CTx

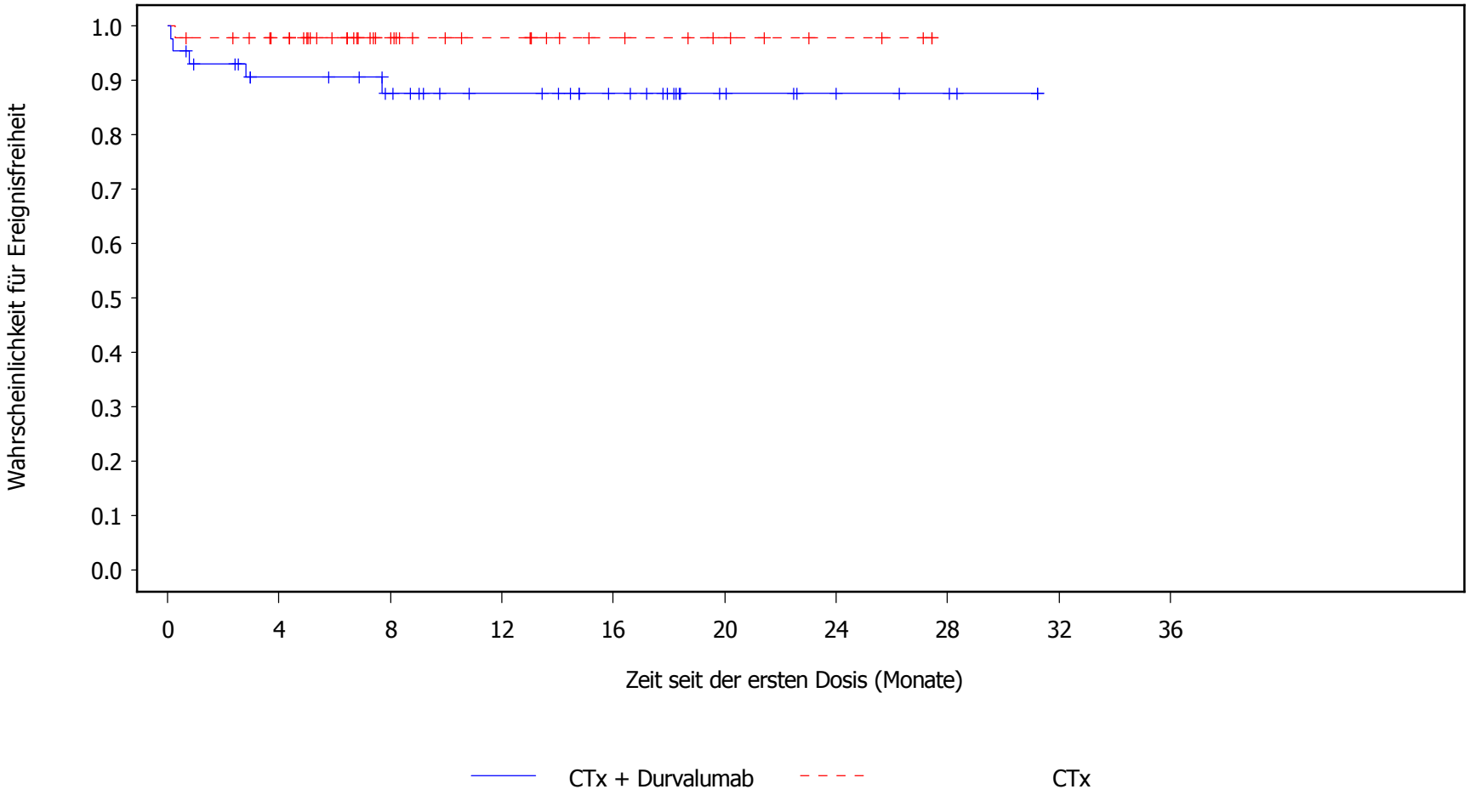
Figure 3.3.1.1D.33 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Dysgeusie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	32	28	20	15	7	5	2	0	0	CTx + Durvalumab
46	37	20	14	8	5	2	0	0	0	CTx

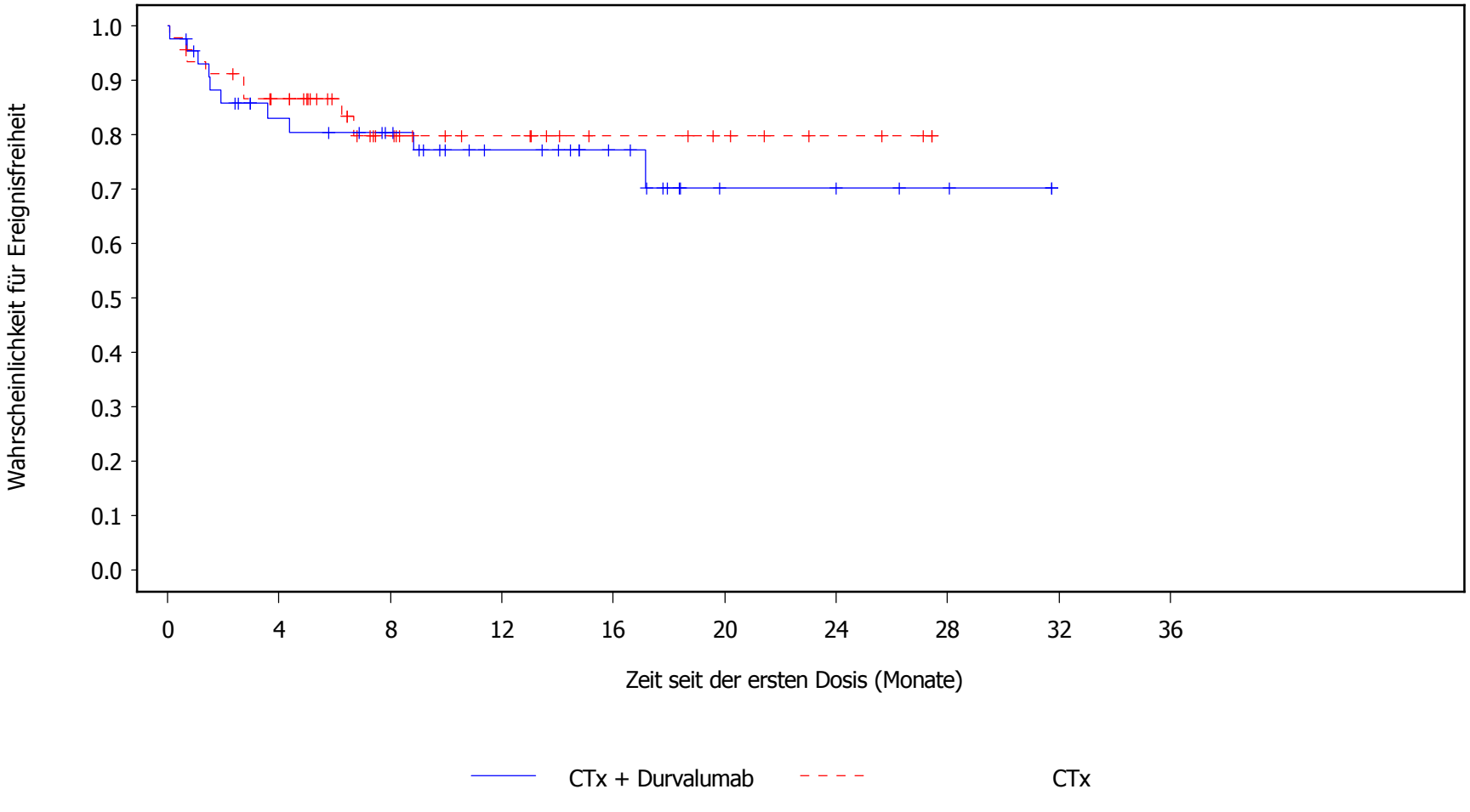
Figure 3.3.1.1D.34 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Hypoaesthesie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	29	23	17	8	5	3	0	0	CTx + Durvalumab
46	40	22	15	9	6	3	0	0	0	CTx

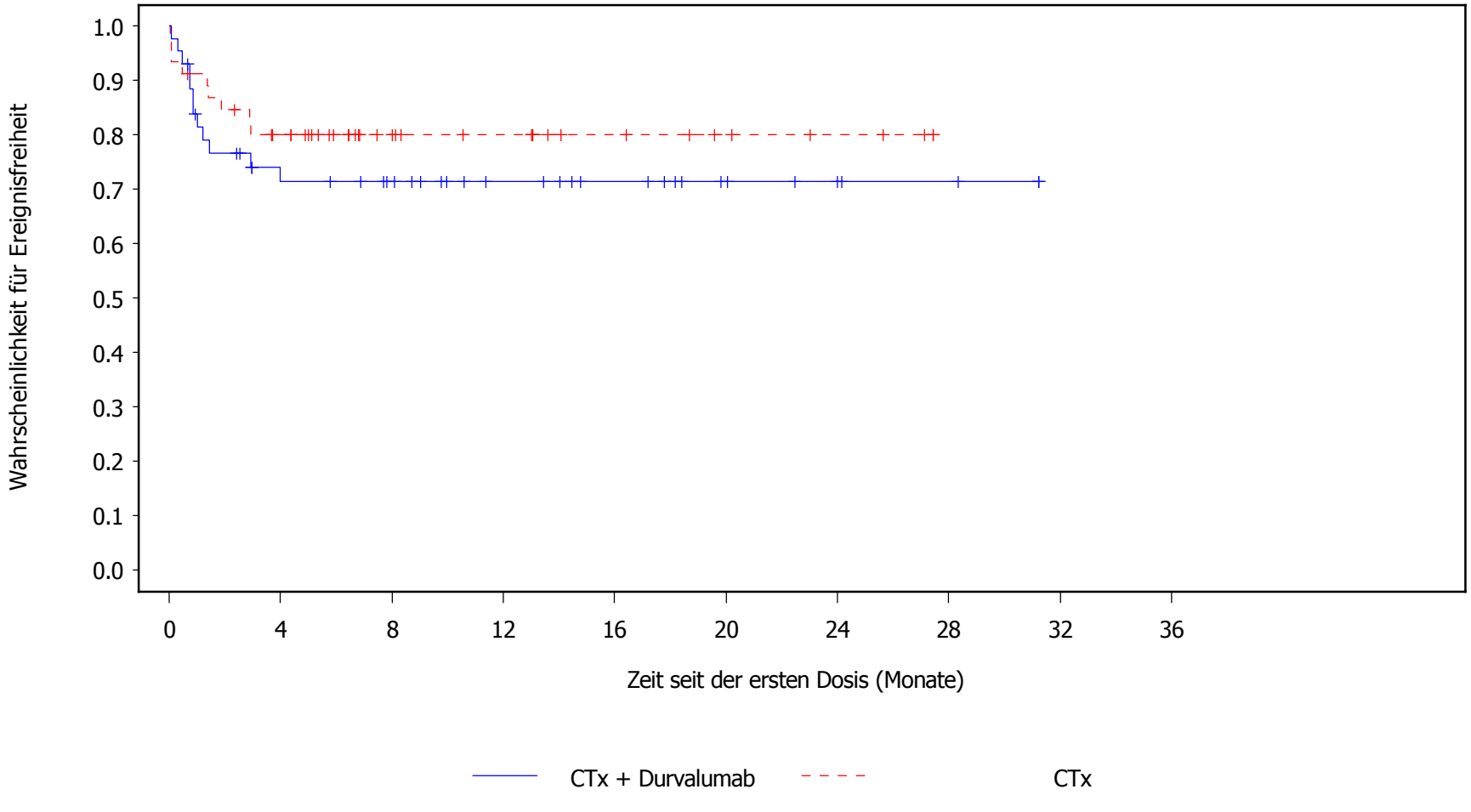
Figure 3.3.1.1D.35 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Kopfschmerzen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	31	26	18	12	4	4	2	0	0	CTx + Durvalumab
46	36	19	13	8	6	3	0	0	0	CTx

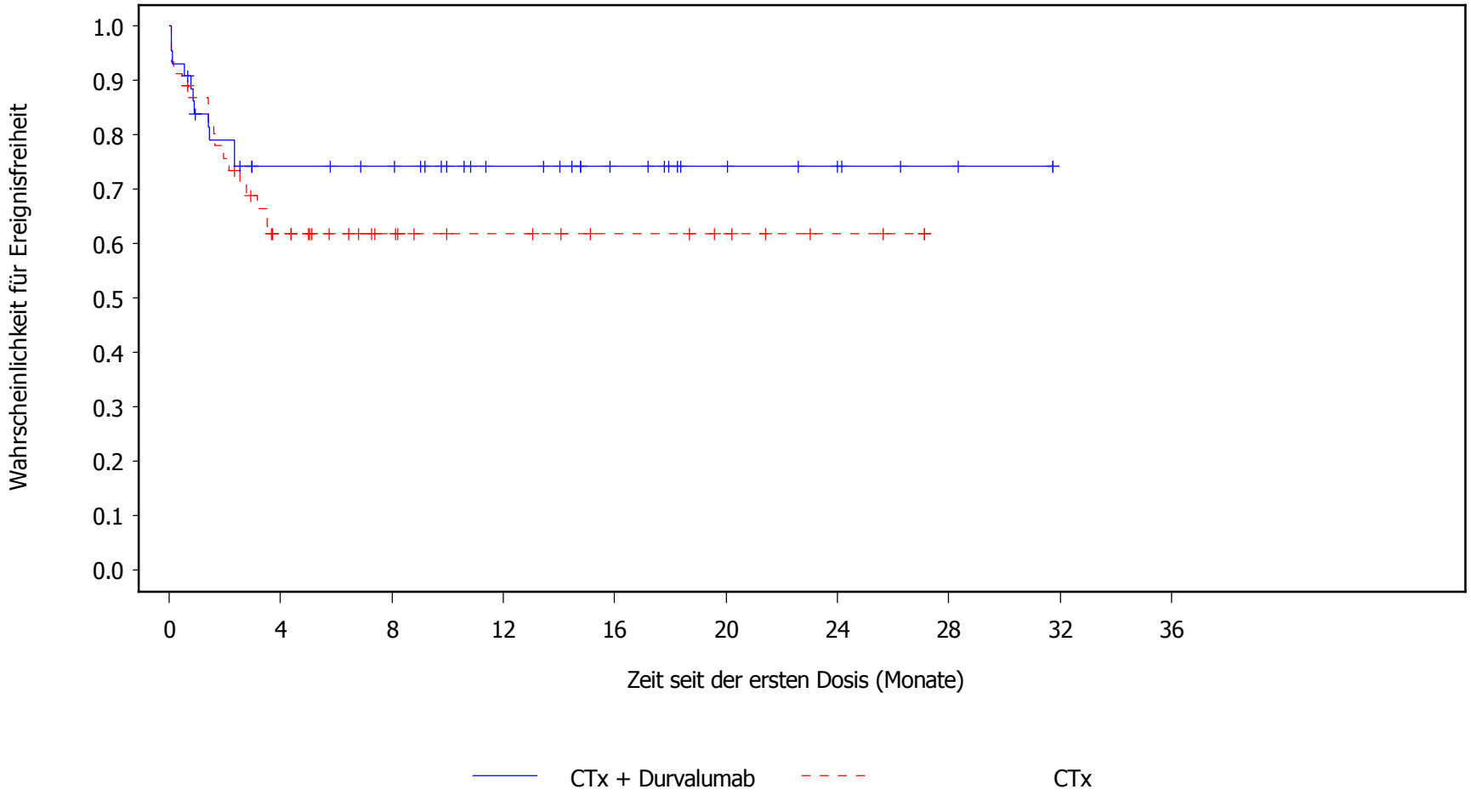
Figure 3.3.1.1D.36 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Periphere Neuropathie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	26	22	15	11	6	4	2	0	0	CTx + Durvalumab
46	33	17	13	8	5	3	0	0	0	CTx

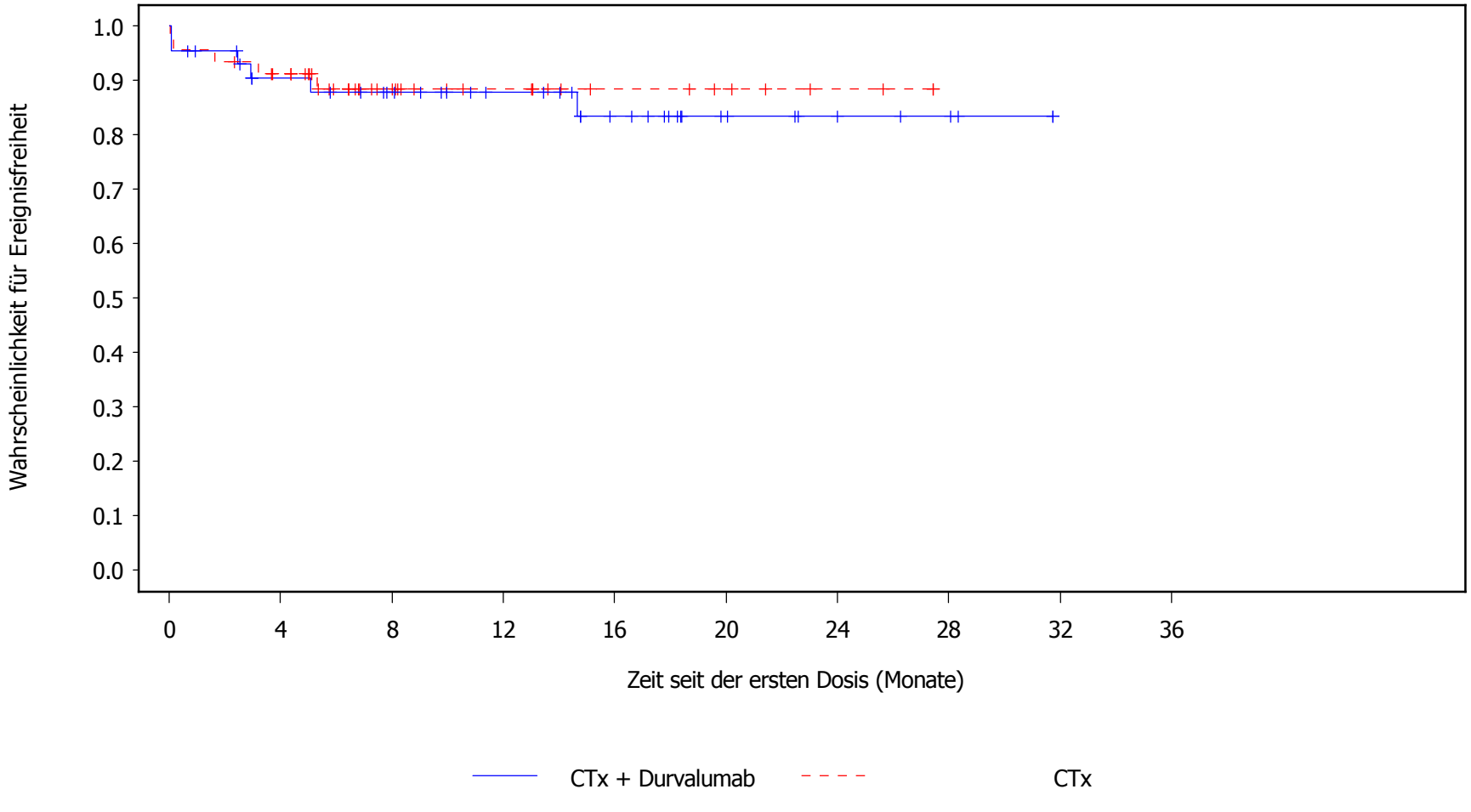
Figure 3.3.1.1D.37 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Periphere sensorische Neuropathie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	28	26	18	12	7	5	2	0	0	CTx + Durvalumab
46	24	14	10	7	5	2	0	0	0	CTx

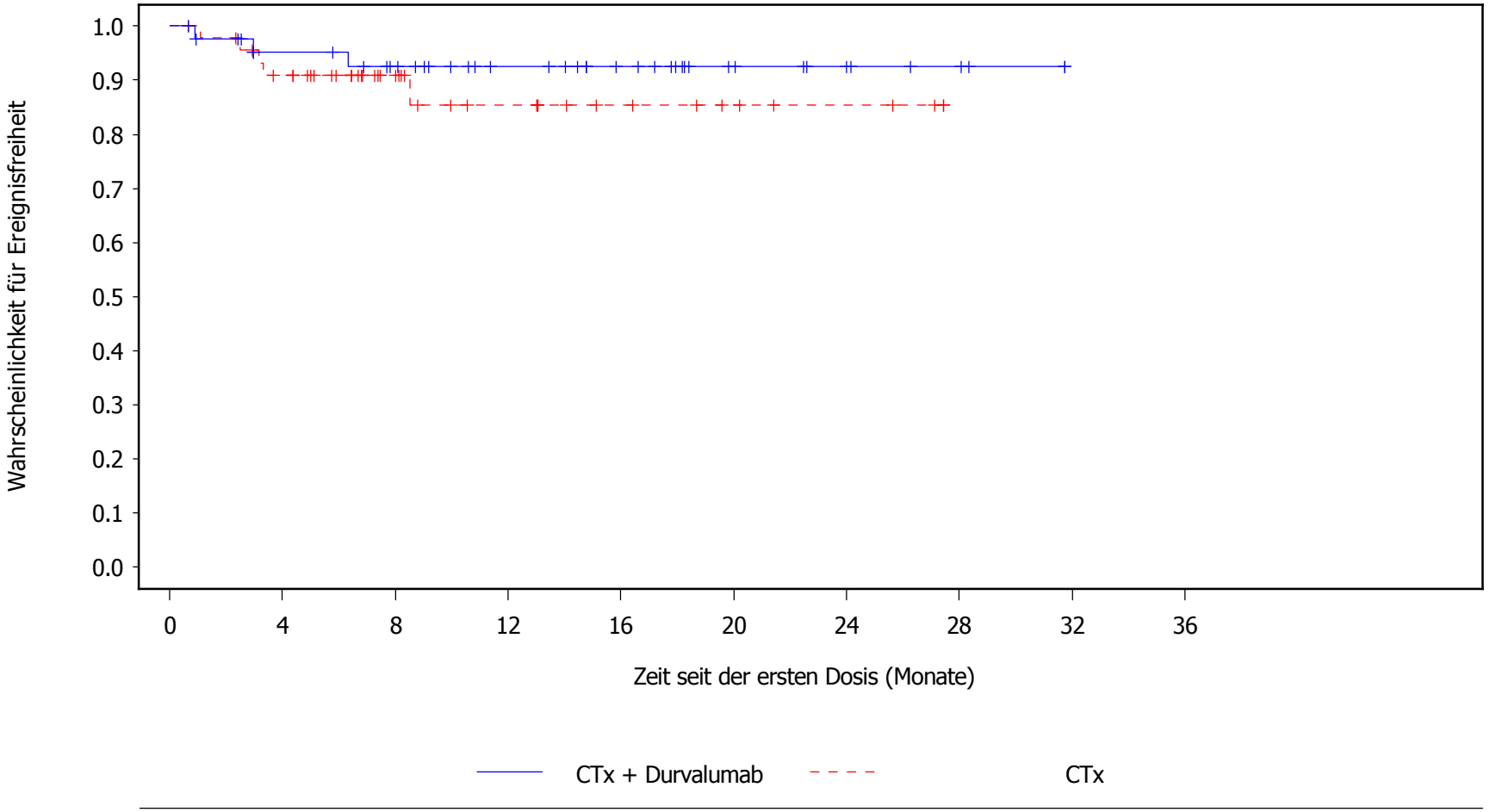
Figure 3.3.1.1D.38 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Schwindelgefuehl
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	29	23	16	8	5	3	0	0	CTx + Durvalumab
46	39	20	13	7	5	2	0	0	0	CTx

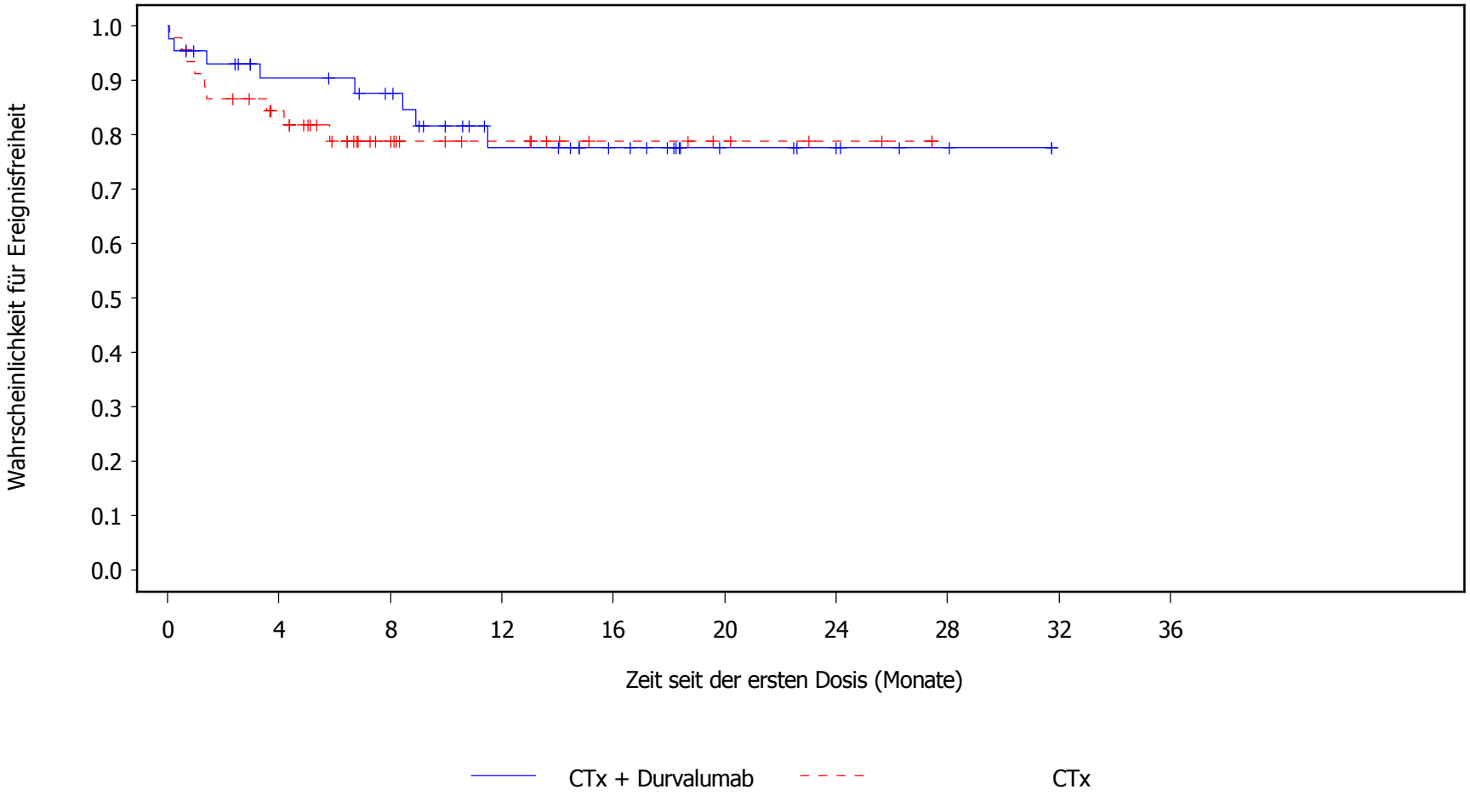
Figure 3.3.1.1D.39 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Ohrs und des Labyrinths
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	31	23	17	9	6	3	0	0	CTx + Durvalumab
46	38	21	13	8	5	3	0	0	0	CTx

Figure 3.3.1.1D.40 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Gefaesserkrankungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	30	20	15	7	5	2	0	0	CTx + Durvalumab
46	34	17	11	6	4	2	0	0	0	CTx

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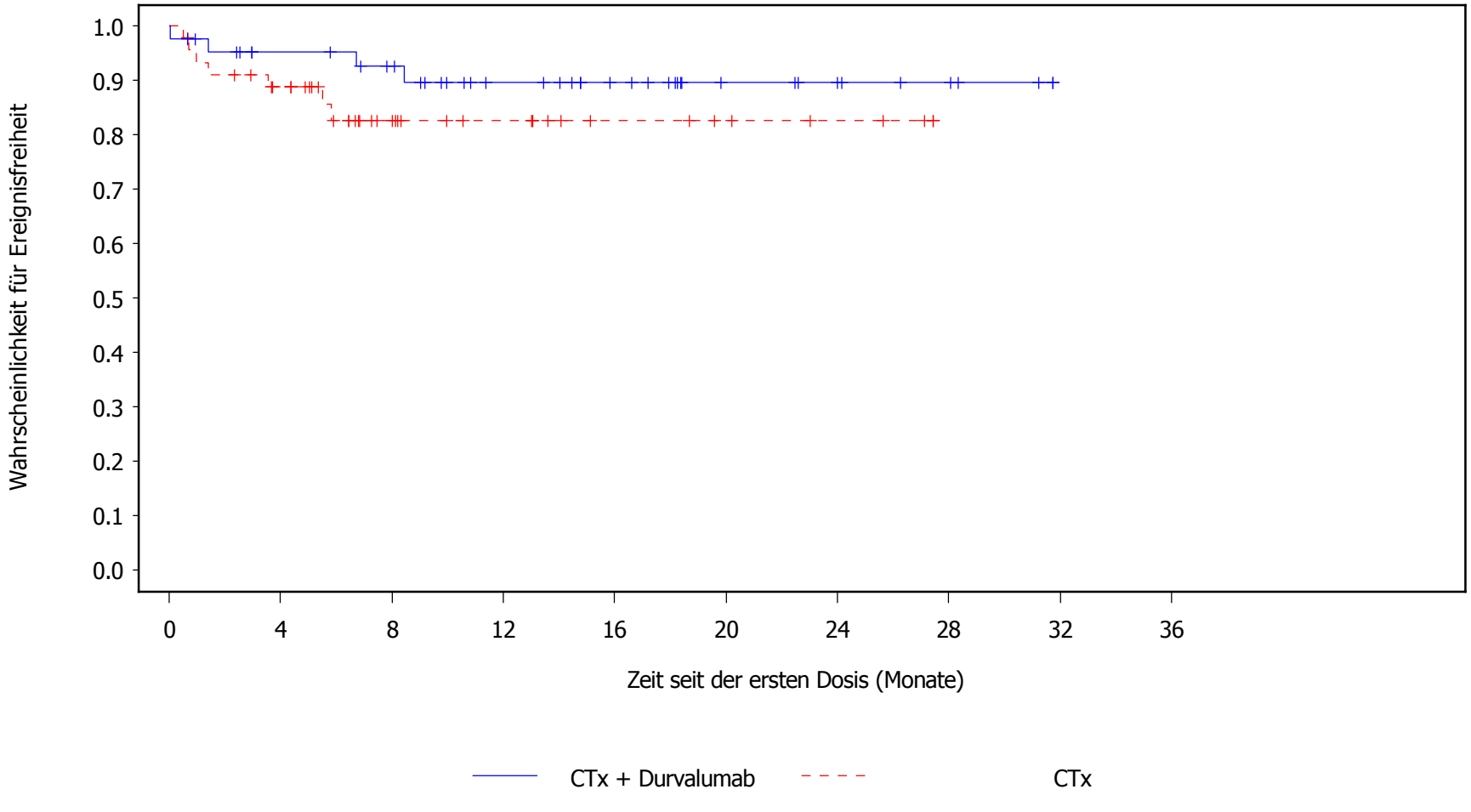
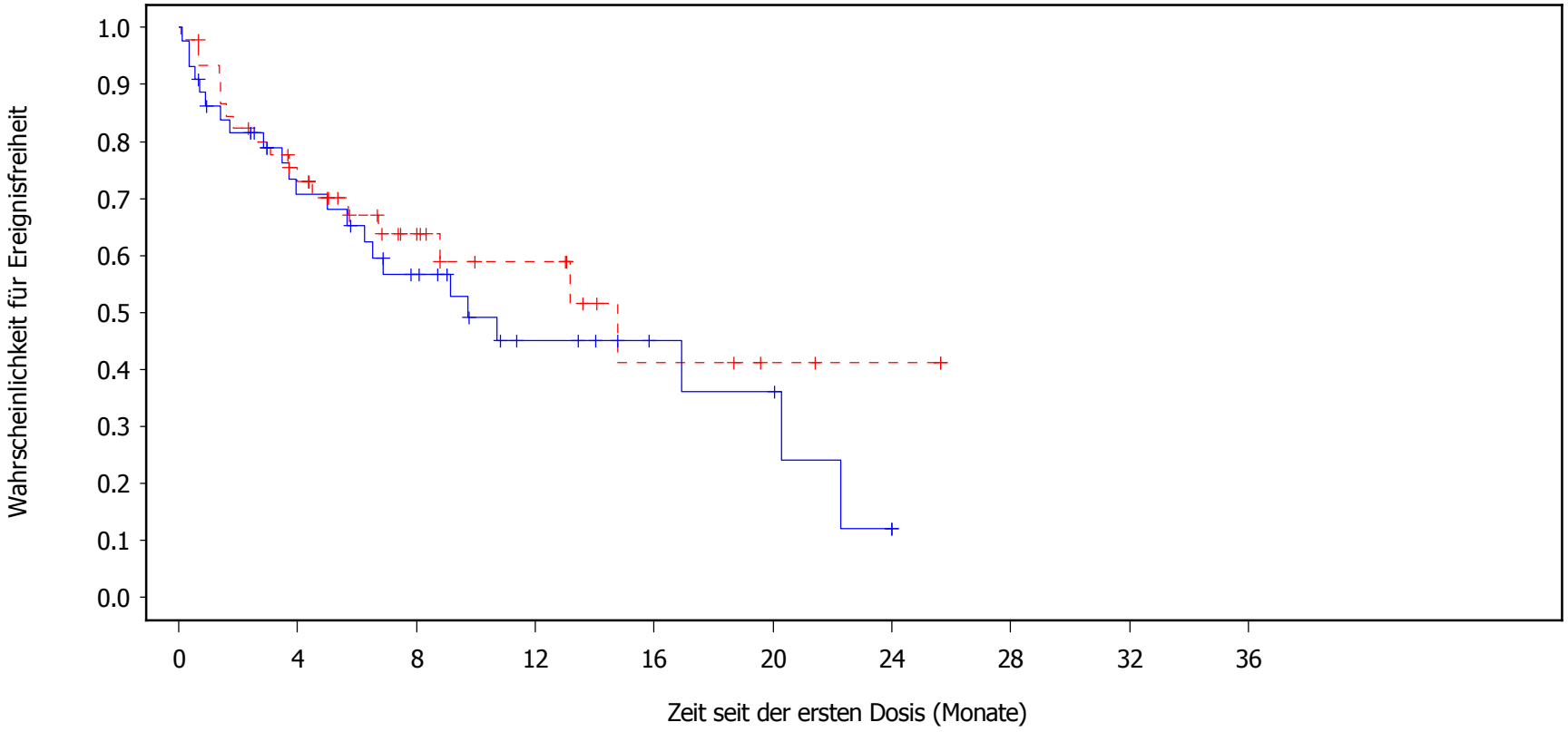
Figure 3.3.1.1D.41 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Hypertonie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	32	23	17	9	7	4	0	0	CTx + Durvalumab
46	36	19	13	7	5	3	0	0	0	CTx

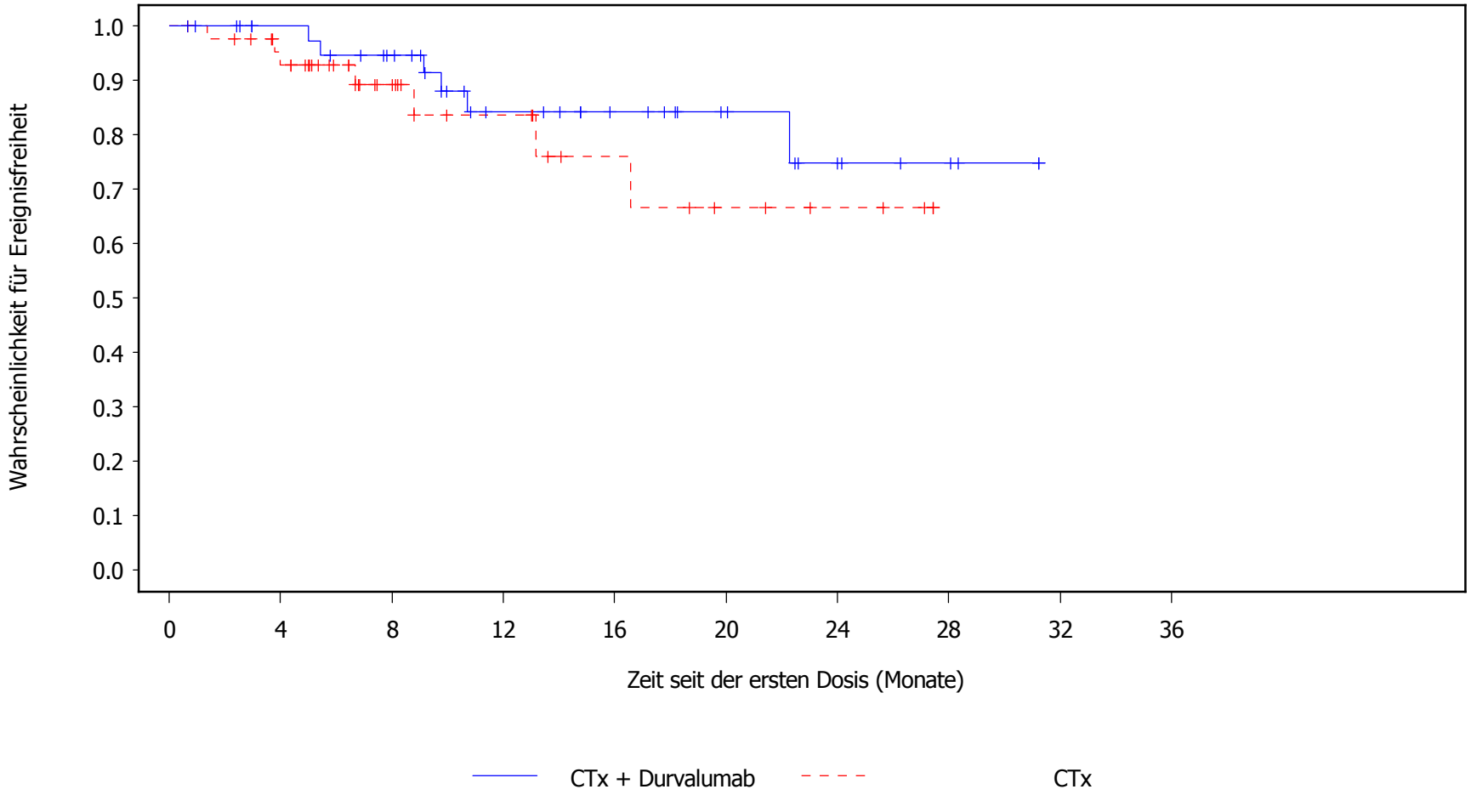
Figure 3.3.1.1D.42 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Infektionen und parasitaere Erkrankungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	26	18	9	5	4	1	0	0	0	CTx + Durvalumab
46	30	16	10	4	2	1	0	0	0	CTx

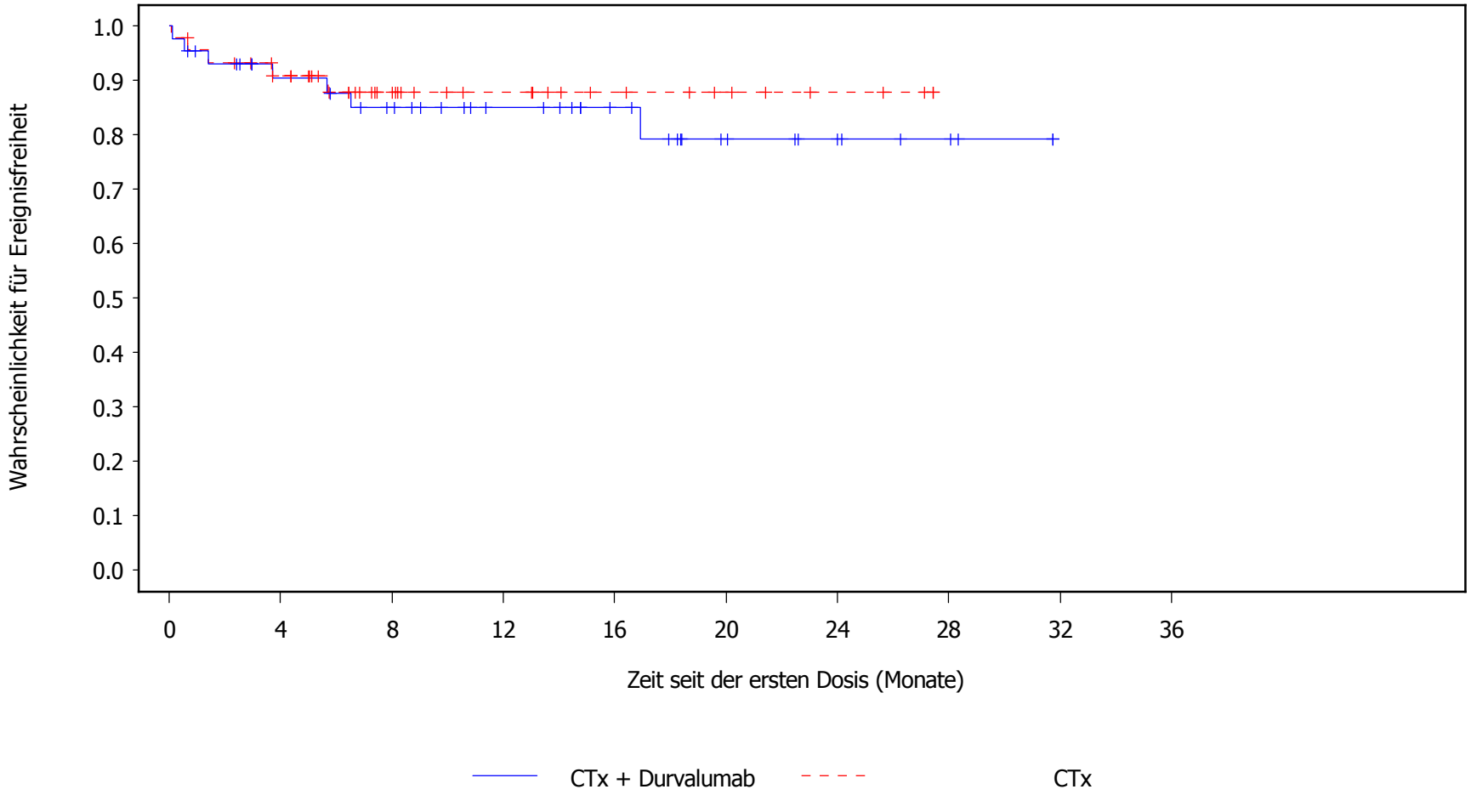
Figure 3.3.1.1D.43 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: COVID-19
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	32	20	15	10	6	3	0	0	CTx + Durvalumab
46	38	20	13	8	5	3	0	0	0	CTx

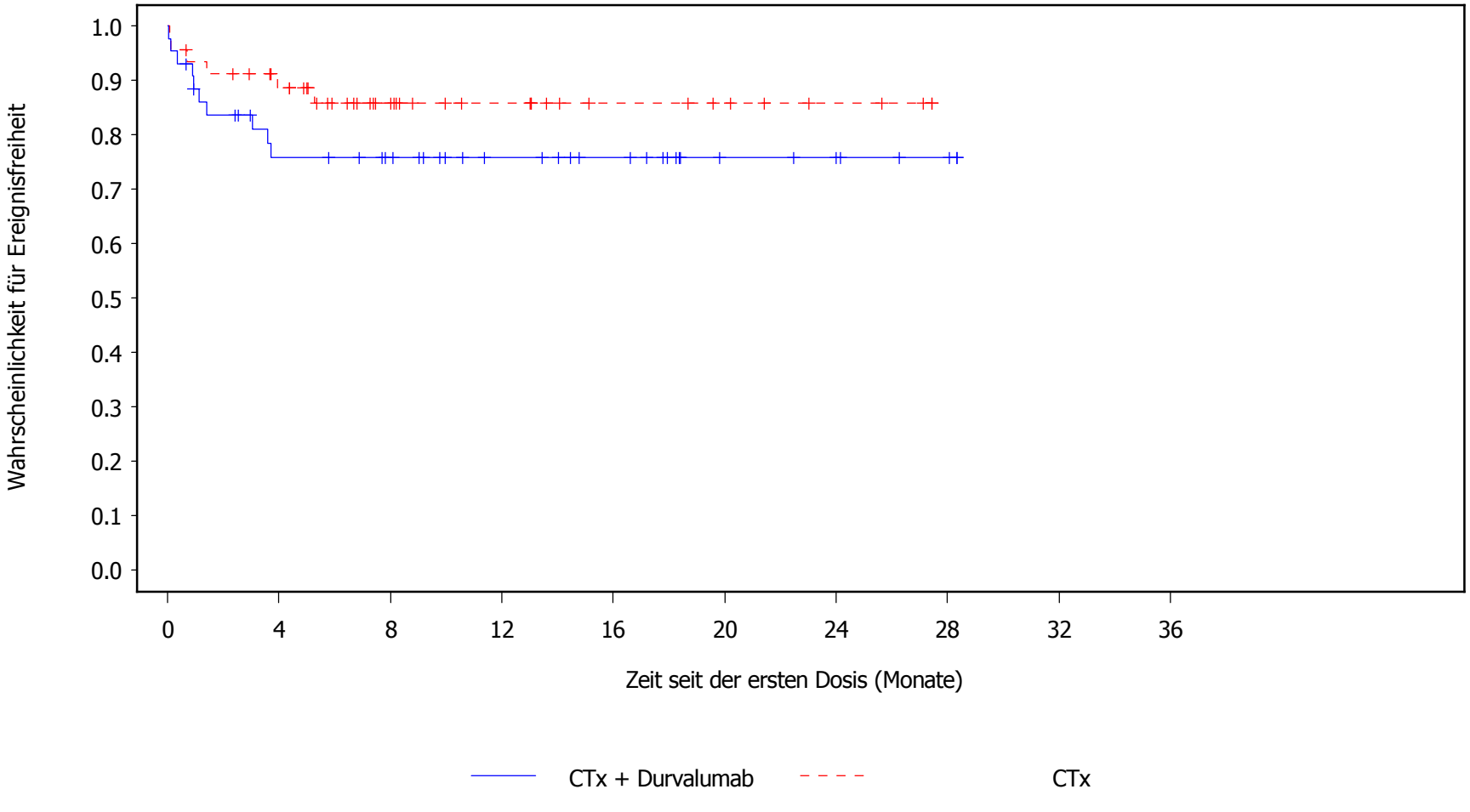
Figure 3.3.1.1D.44 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Harnwegsinfektion
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	29	22	16	9	6	3	0	0	CTx + Durvalumab
46	37	21	14	9	6	3	0	0	0	CTx

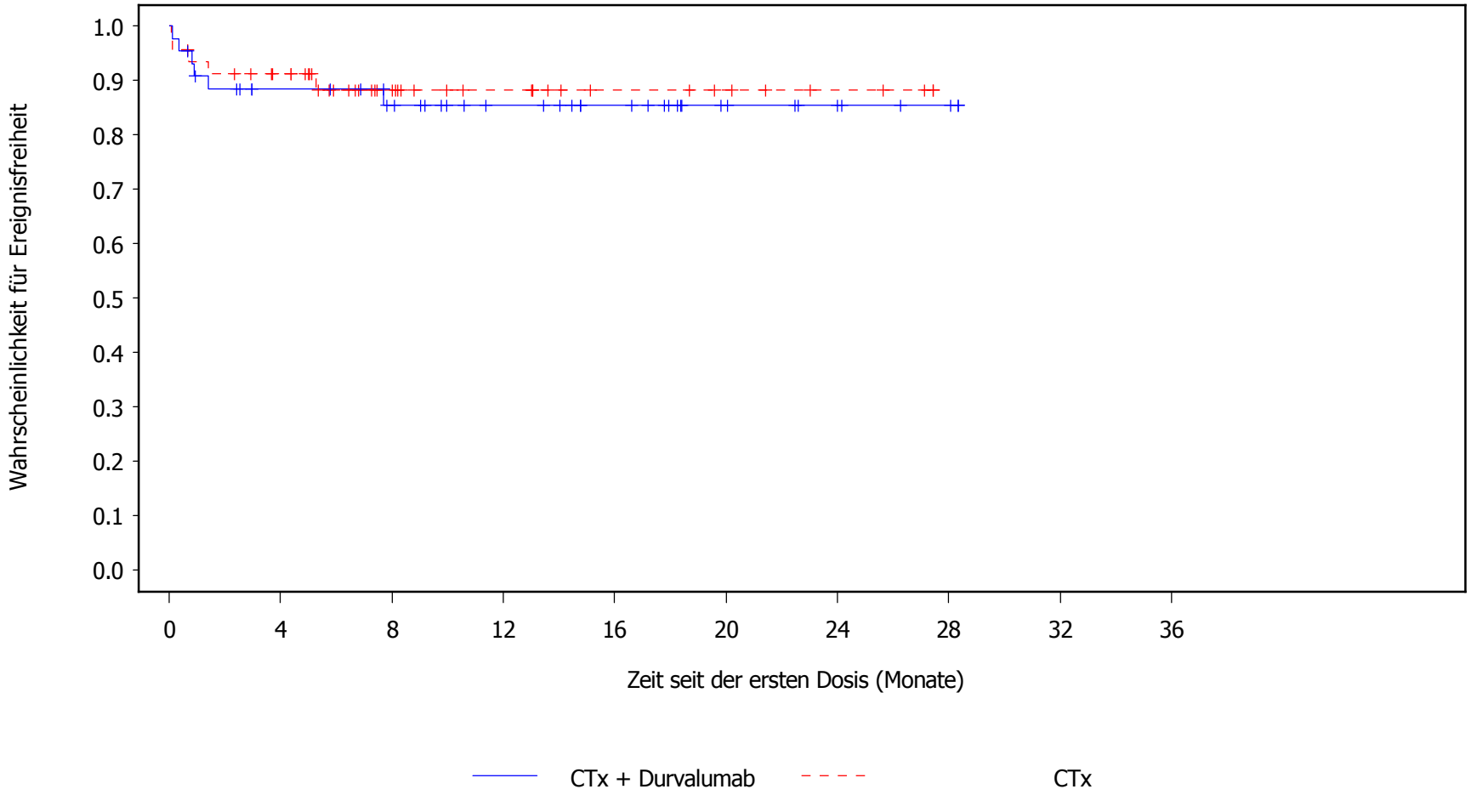
Figure 3.3.1.1D.45 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Psychiatrische Erkrankungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	29	25	18	14	6	5	2	0	0	CTx + Durvalumab
46	36	21	14	8	6	3	0	0	0	CTx

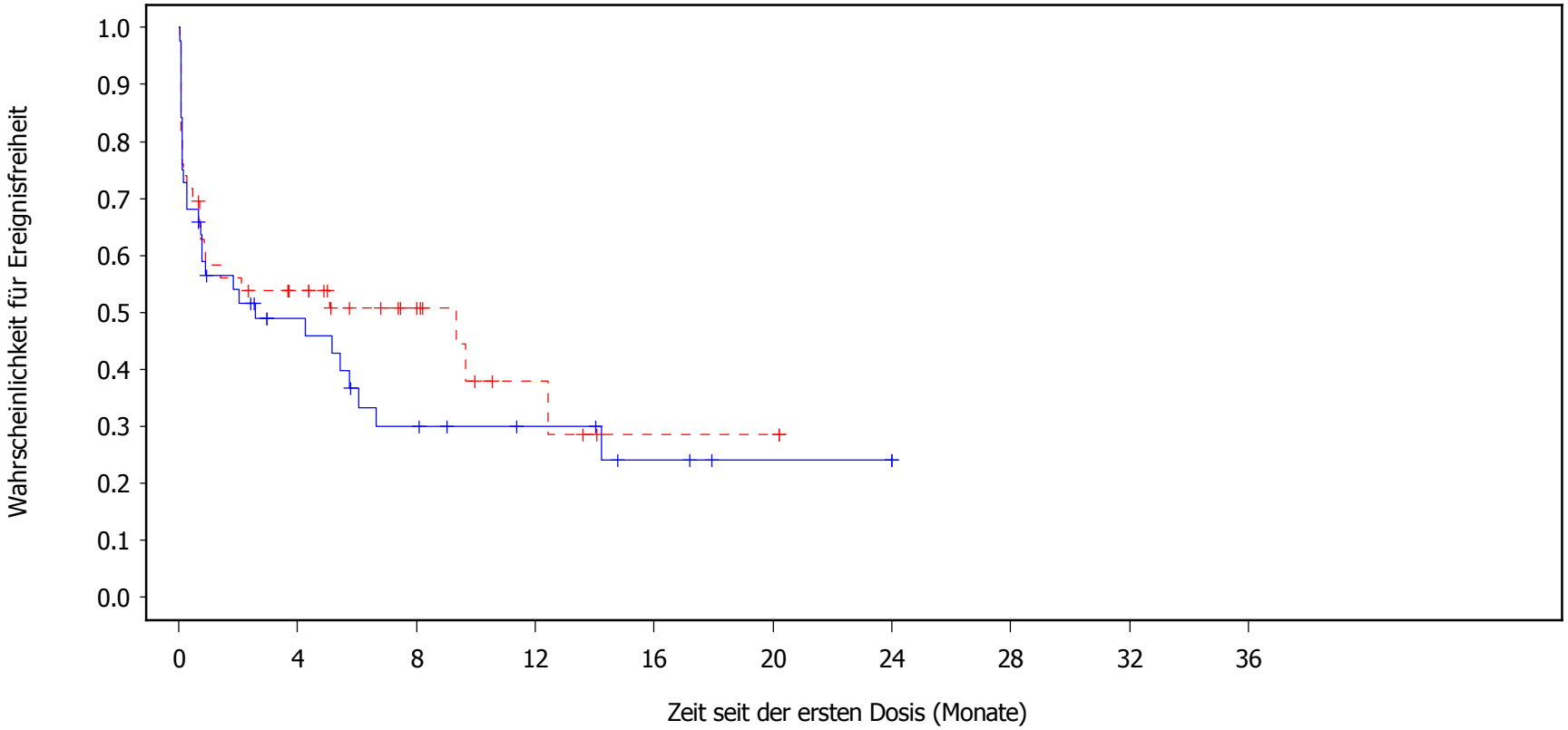
Figure 3.3.1.1D.46 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Schlaflosigkeit
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	33	28	21	16	8	5	2	0	0	CTx + Durvalumab
46	37	21	14	8	6	3	0	0	0	CTx

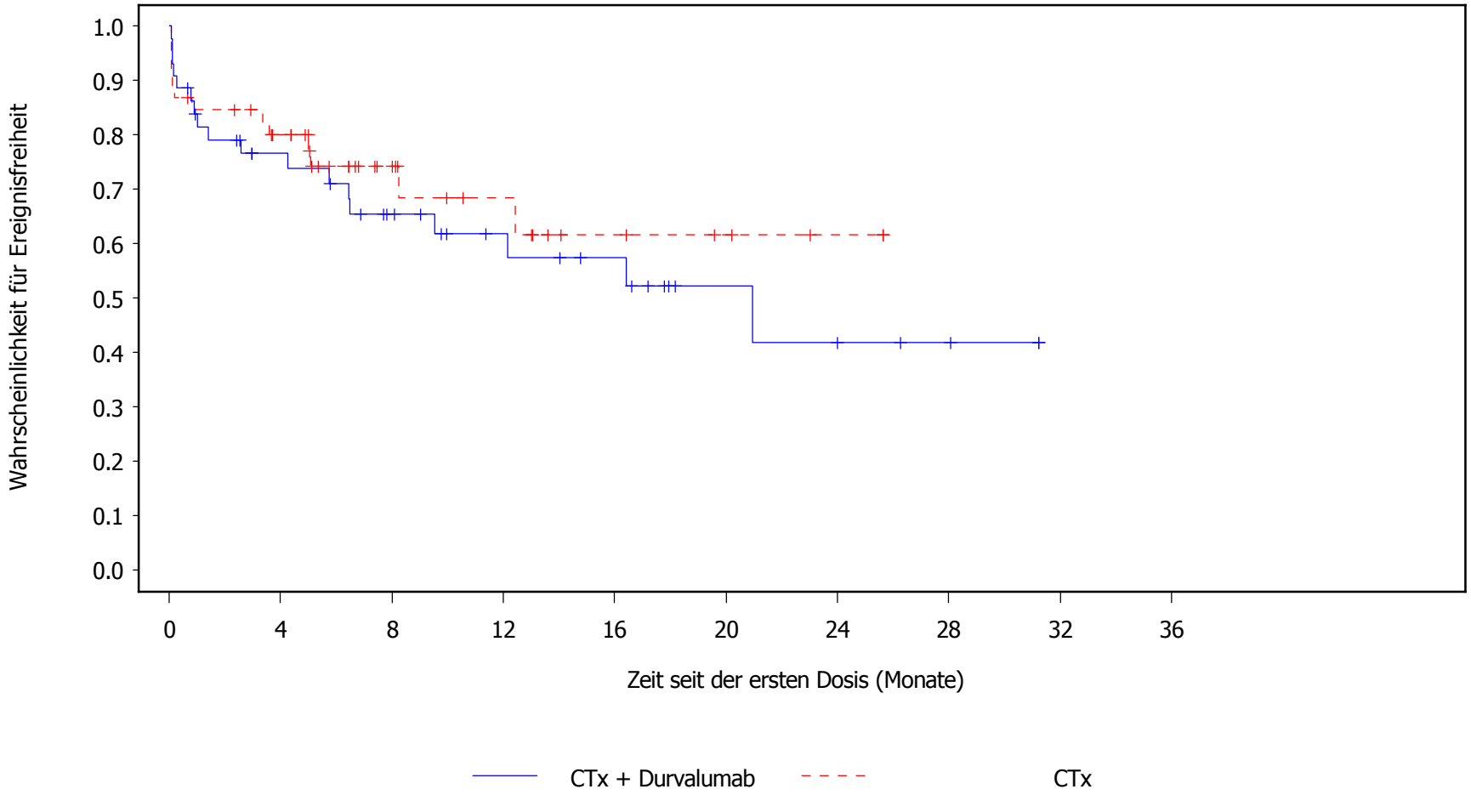
Figure 3.3.1.1D.47 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	16	9	6	3	1	1	0	0	0	CTx + Durvalumab
46	21	11	4	1	1	0	0	0	0	CTx

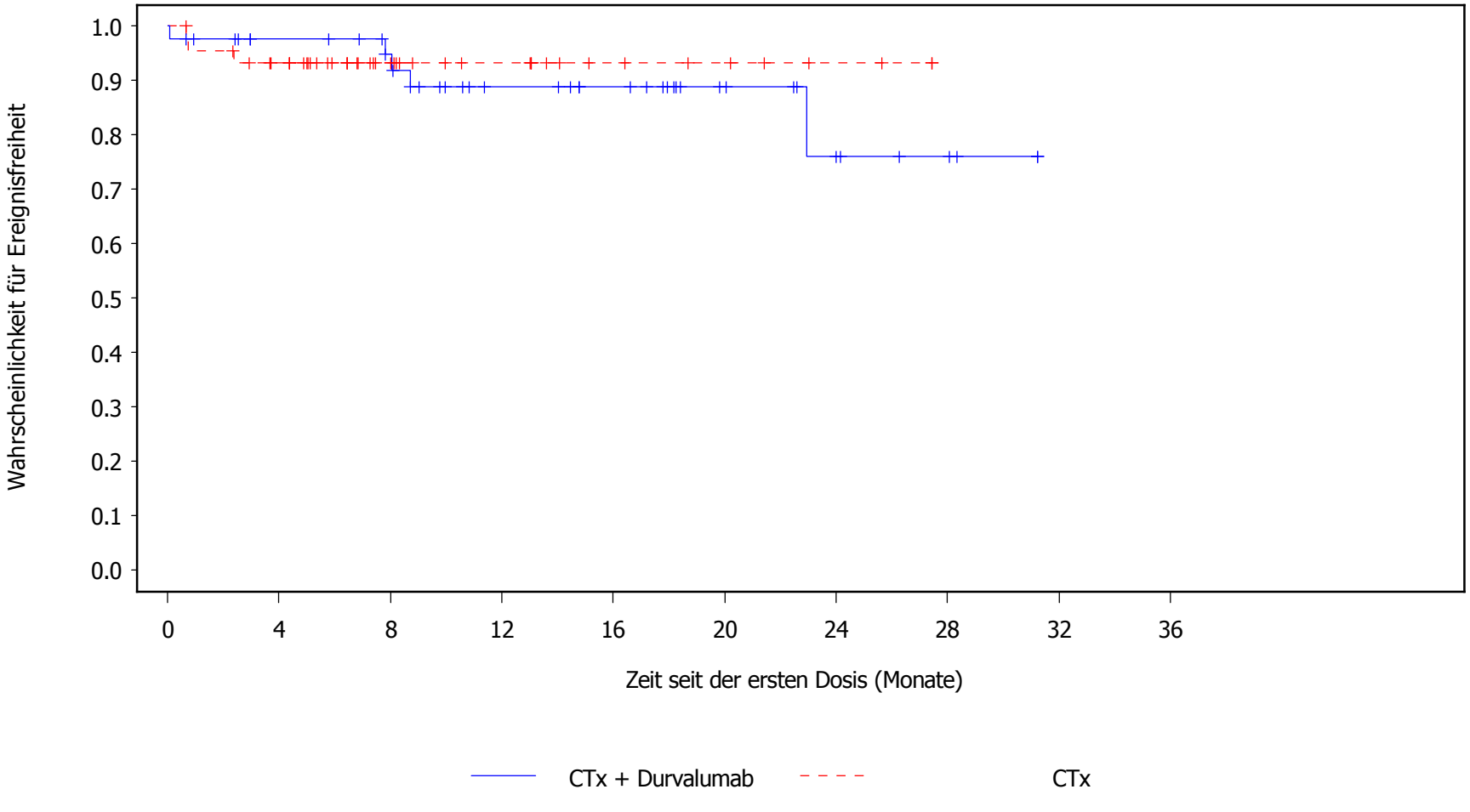
Figure 3.3.1.1D.48 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Arthralgie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	28	20	14	11	5	4	2	0	0	CTx + Durvalumab
46	32	16	10	5	3	1	0	0	0	CTx

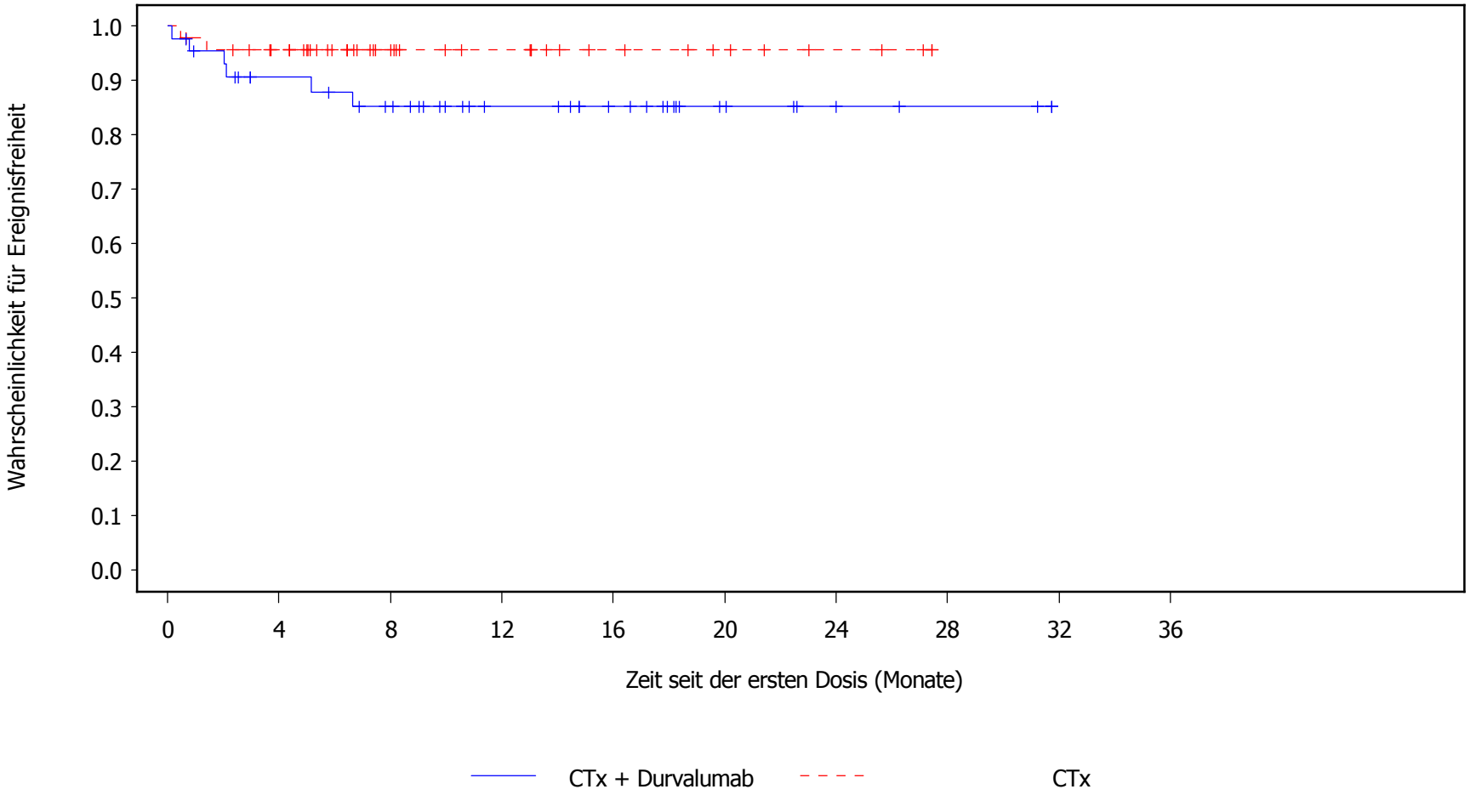
Figure 3.3.1.1D.49 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Muskelspasmen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	37	32	22	18	10	6	3	0	0	CTx + Durvalumab
46	38	20	13	7	5	2	0	0	0	CTx

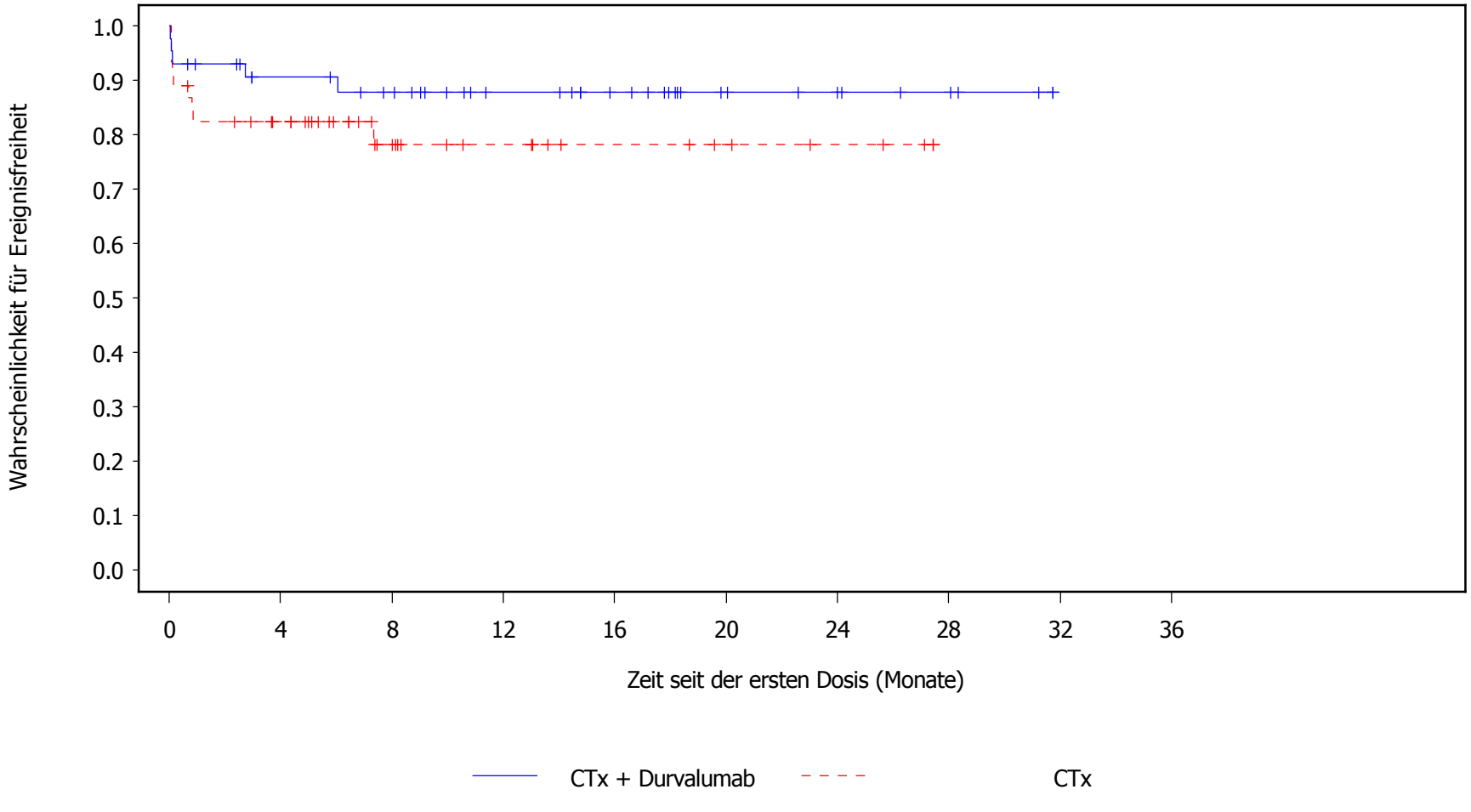
Figure 3.3.1.1D.50 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Muskulaere Schwaeche
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	29	20	15	7	4	2	0	0	CTx + Durvalumab
46	39	21	15	9	6	3	0	0	0	CTx

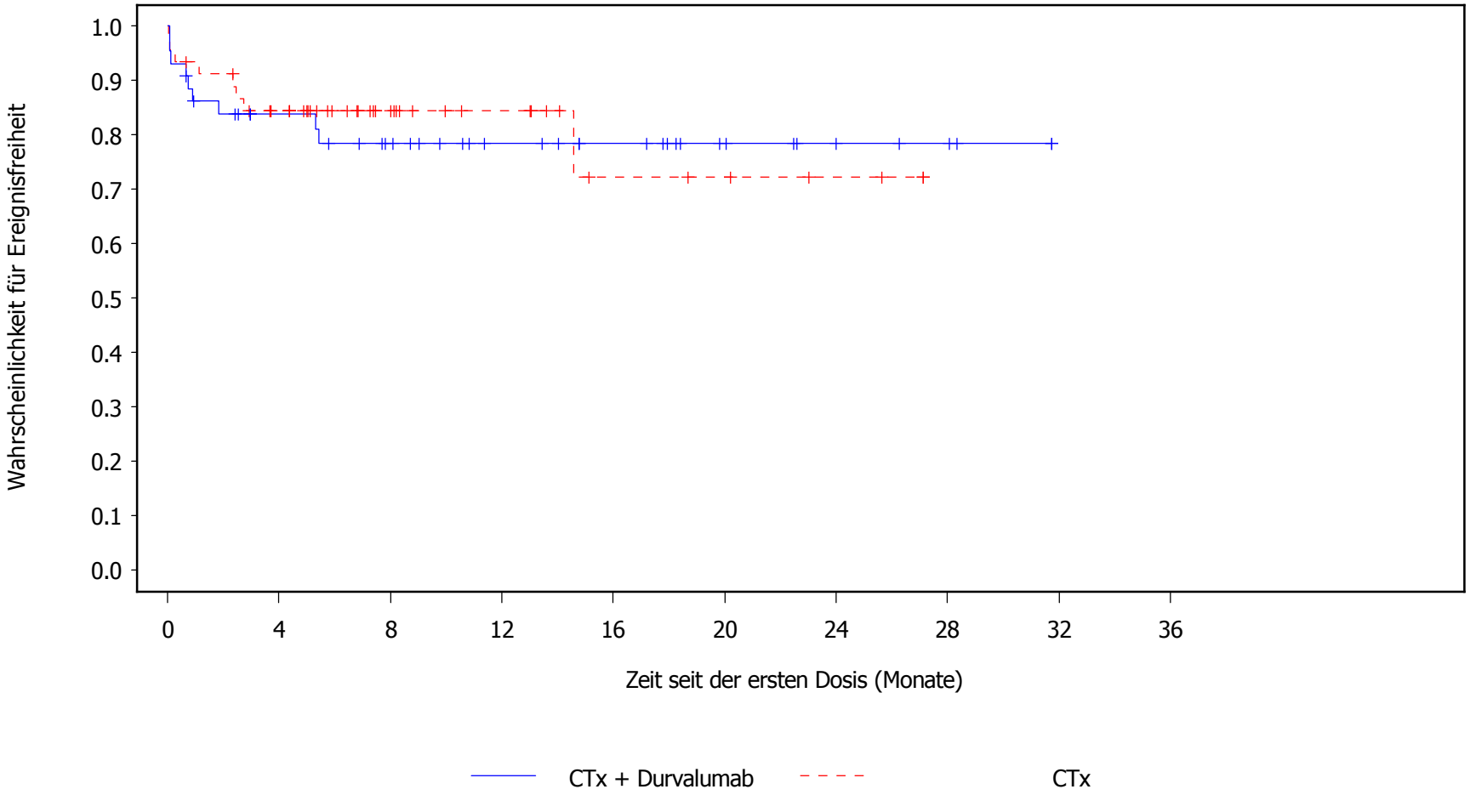
Figure 3.3.1.1D.51 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Myalgie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	30	22	17	9	7	4	0	0	CTx + Durvalumab
46	33	17	11	7	5	3	0	0	0	CTx

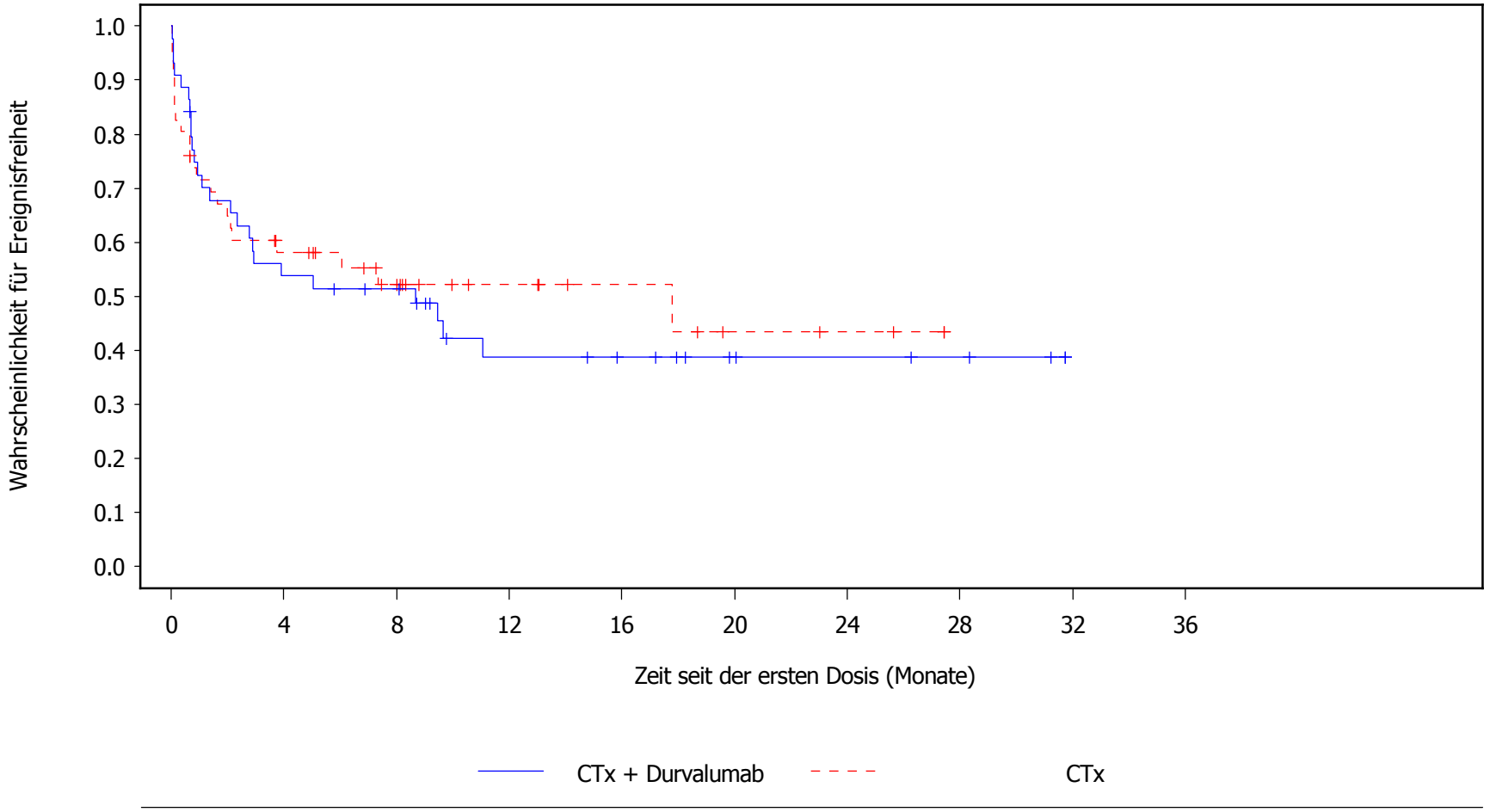
Figure 3.3.1.1D.52 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Schmerz in einer Extremitaet
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	31	25	18	14	8	5	3	0	0	CTx + Durvalumab
46	34	18	11	5	4	2	0	0	0	CTx

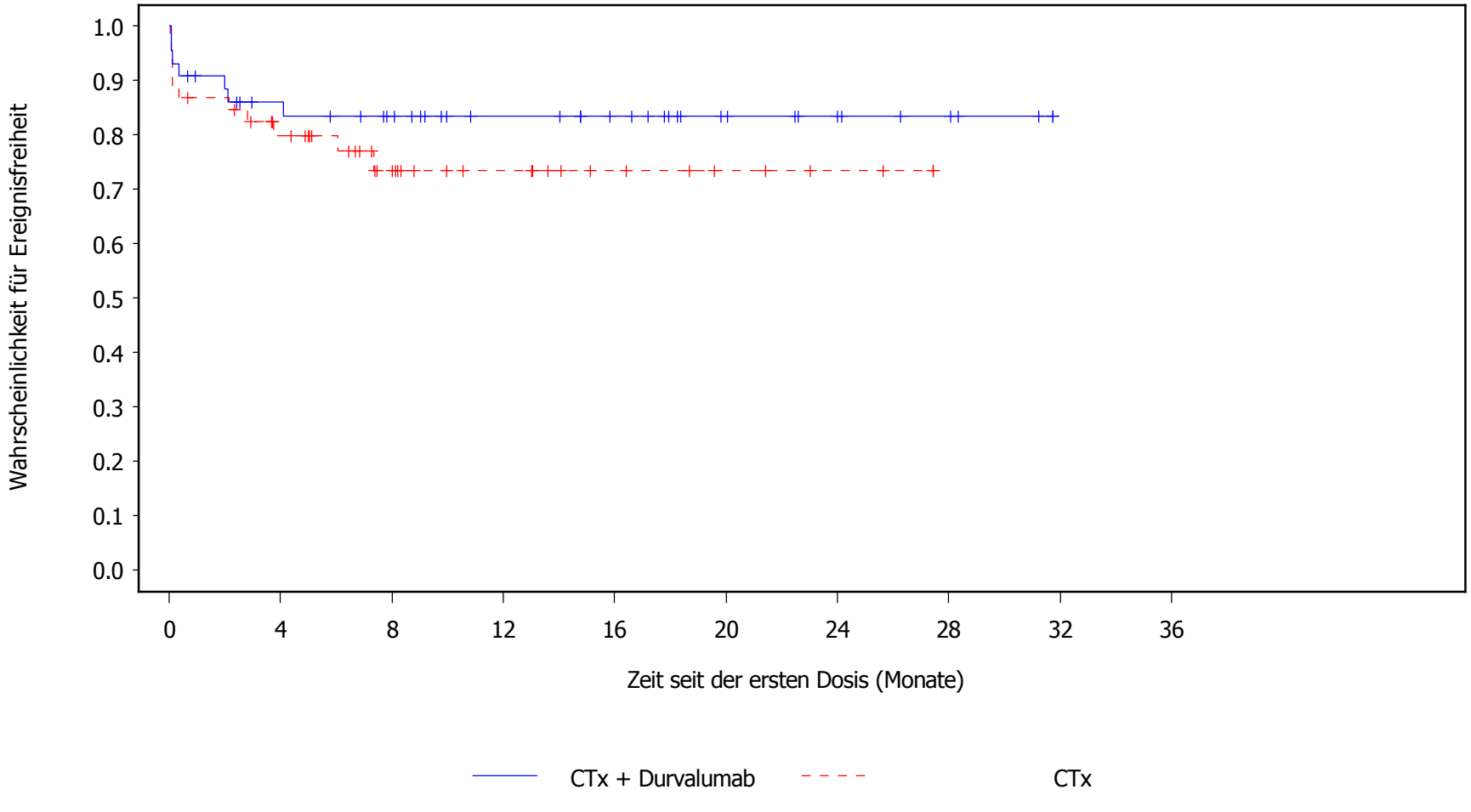
Figure 3.3.1.1D.53 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Stoffwechsel- und Ernaehrungsstoerungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	23	20	11	9	5	4	3	0	0	CTx + Durvalumab
46	24	16	9	6	3	2	0	0	0	CTx

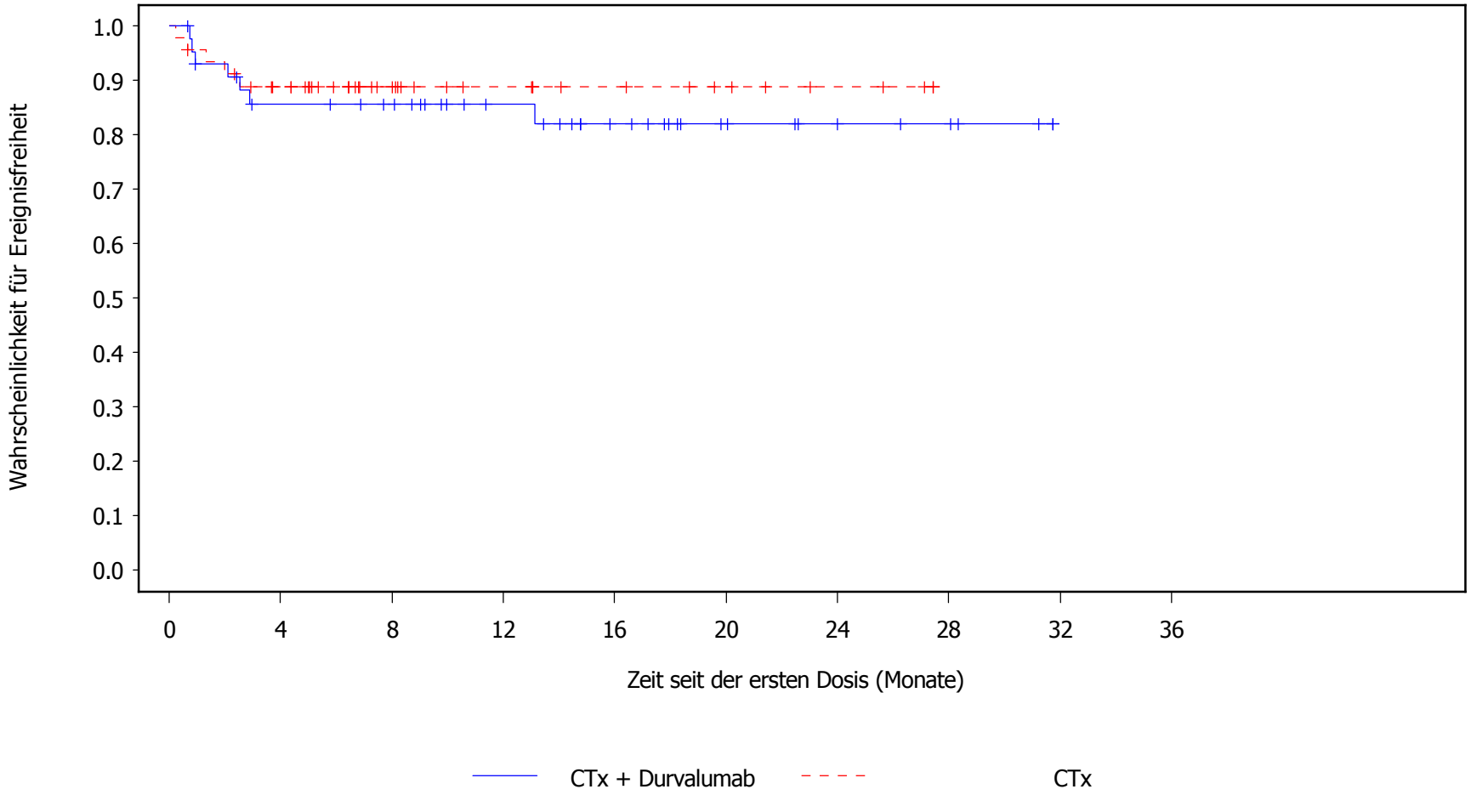
Figure 3.3.1.1D.54 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Appetit vermindert
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	33	28	21	17	10	7	4	0	0	CTx + Durvalumab
46	32	19	12	7	4	2	0	0	0	CTx

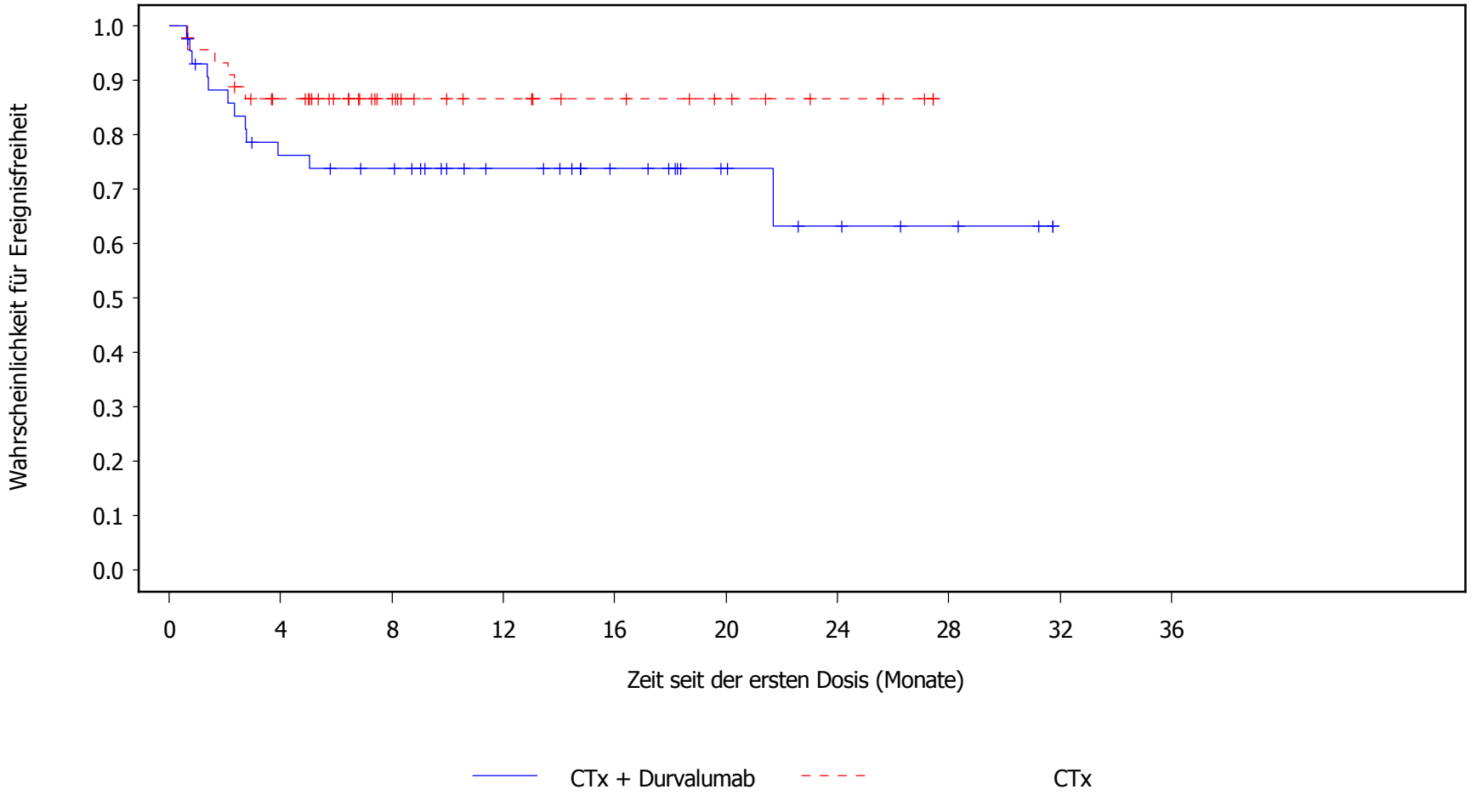
Figure 3.3.1.1D.55 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Hypokaliaemie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	31	23	16	9	6	4	0	0	CTx + Durvalumab
46	36	20	13	9	6	3	0	0	0	CTx

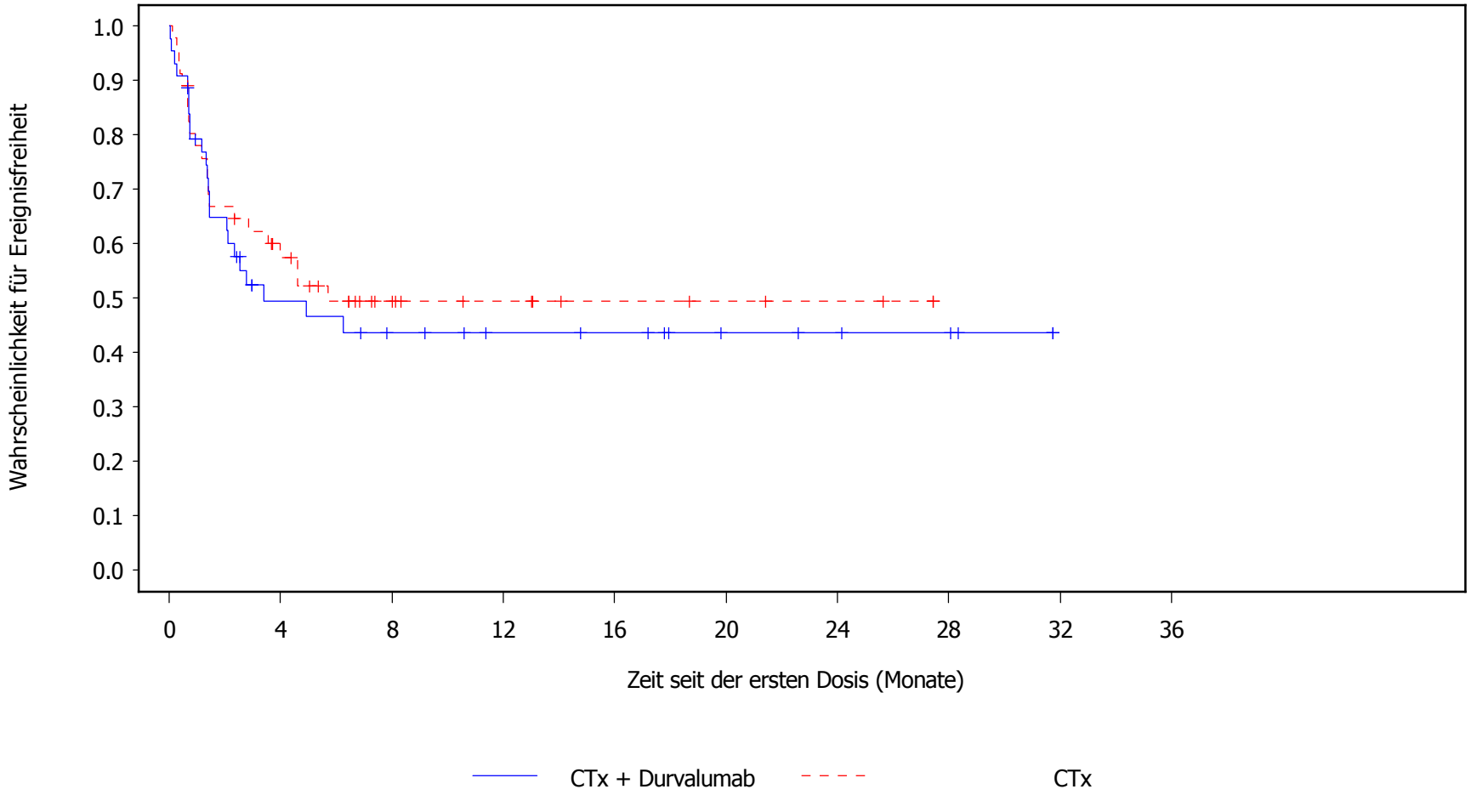
Figure 3.3.1.1D.56 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Hypomagnesiaemie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	31	28	20	14	8	5	3	0	0	CTx + Durvalumab
46	35	20	13	9	6	3	0	0	0	CTx

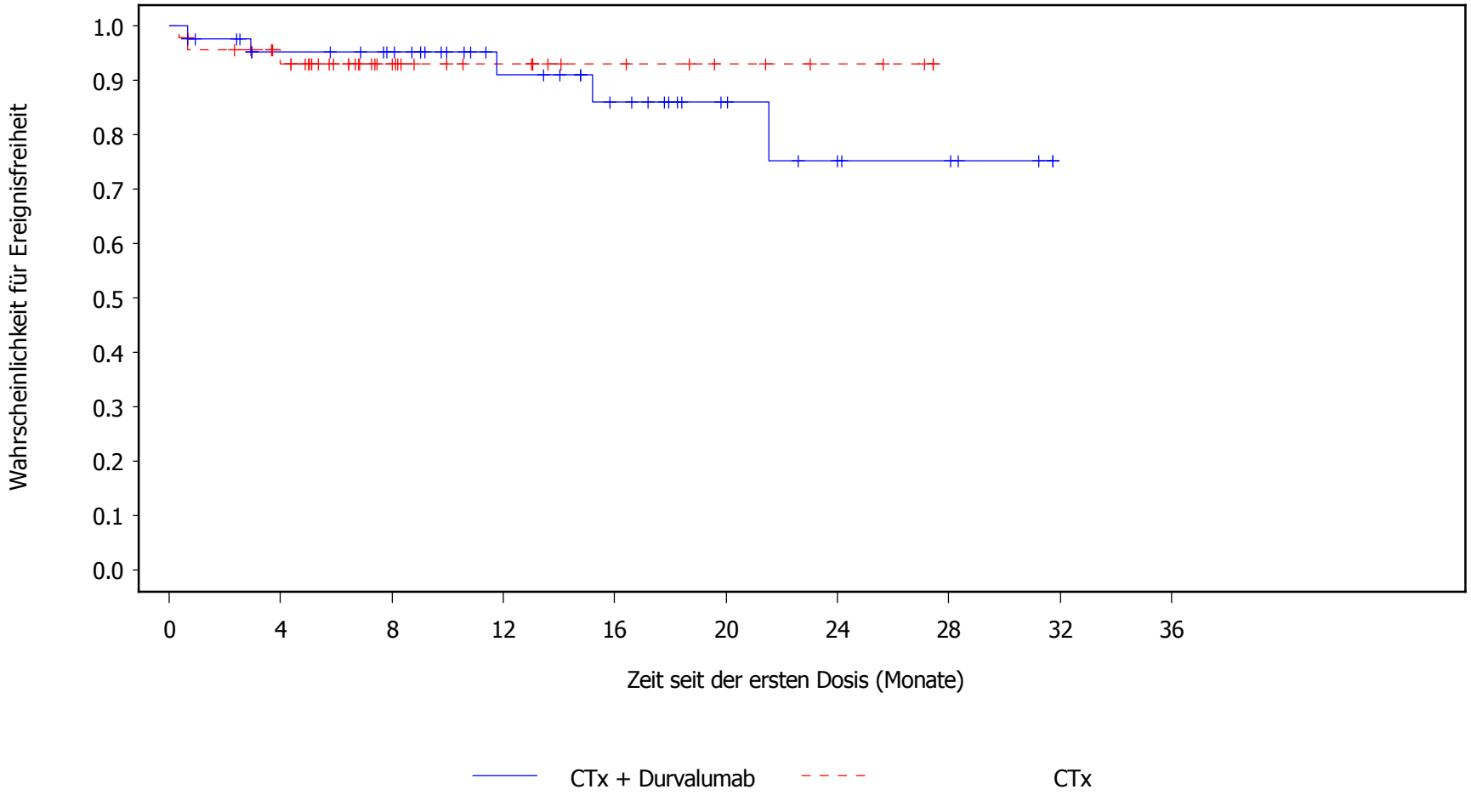
Figure 3.3.1.1D.57 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Untersuchungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	17	13	10	9	5	4	3	0	0	CTx + Durvalumab
46	24	11	7	4	3	2	0	0	0	CTx

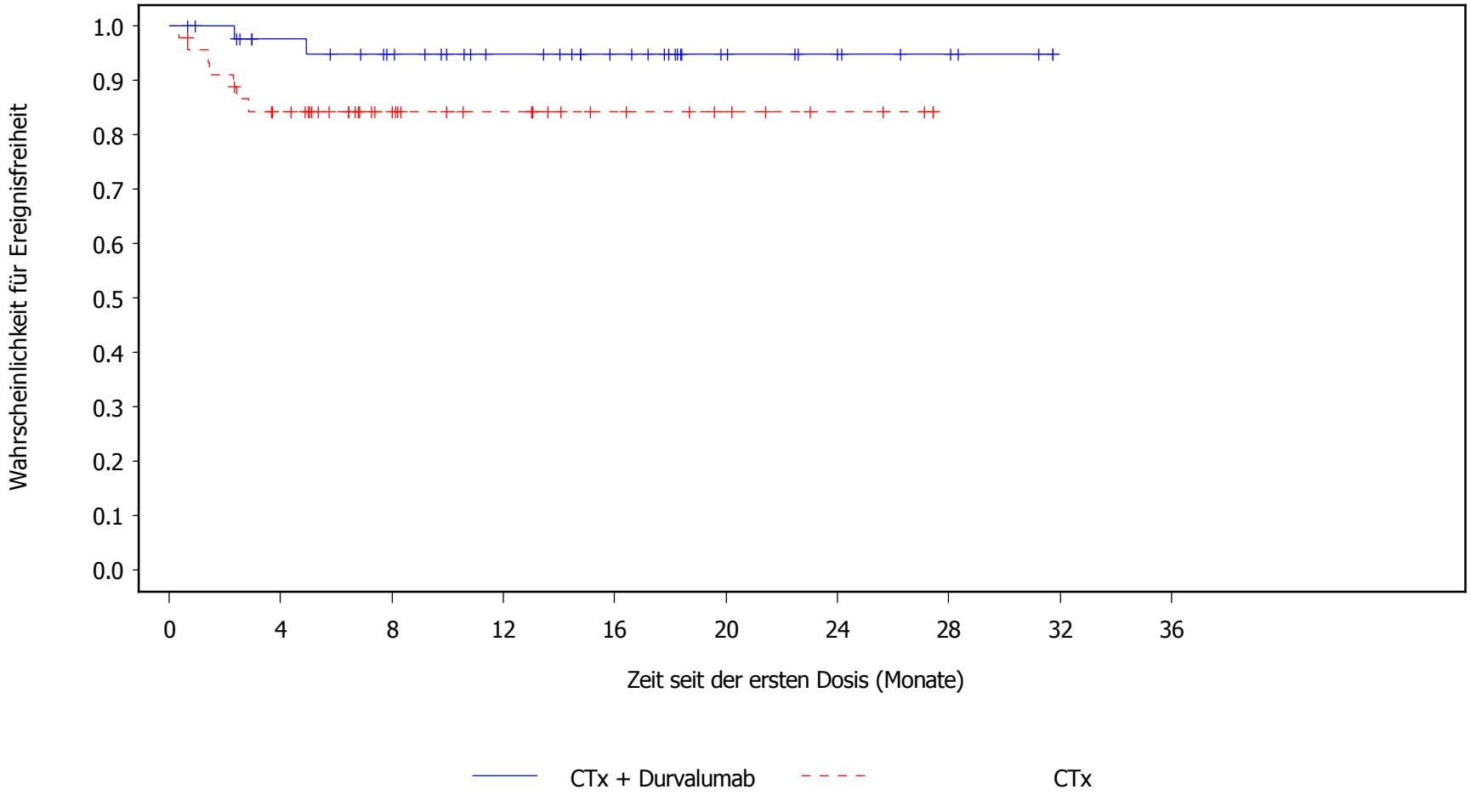
Figure 3.3.1.1D.58 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Alaninaminotransferase erhoeht
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	32	22	16	9	6	4	0	0	CTx + Durvalumab
46	39	20	13	8	5	3	0	0	0	CTx

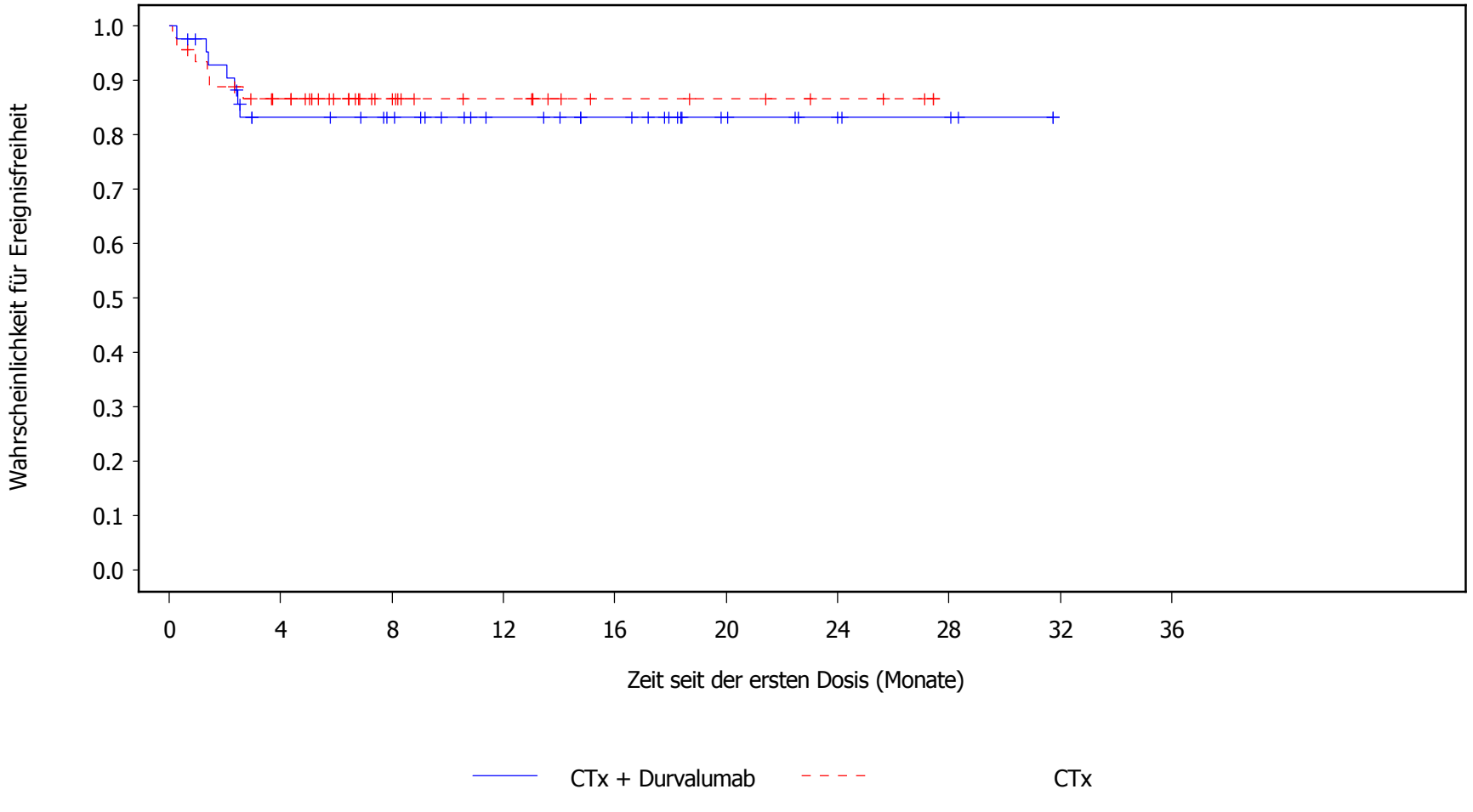
Figure 3.3.1.1D.59 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Gewicht erniedrigt
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	37	32	25	19	10	7	4	0	0	CTx + Durvalumab
46	35	21	15	9	6	3	0	0	0	CTx

Figure 3.3.1.1D.60 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Leukozytenzahl erniedrigt
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	31	27	20	16	8	5	3	0	0	CTx + Durvalumab
46	35	18	12	6	5	3	0	0	0	CTx

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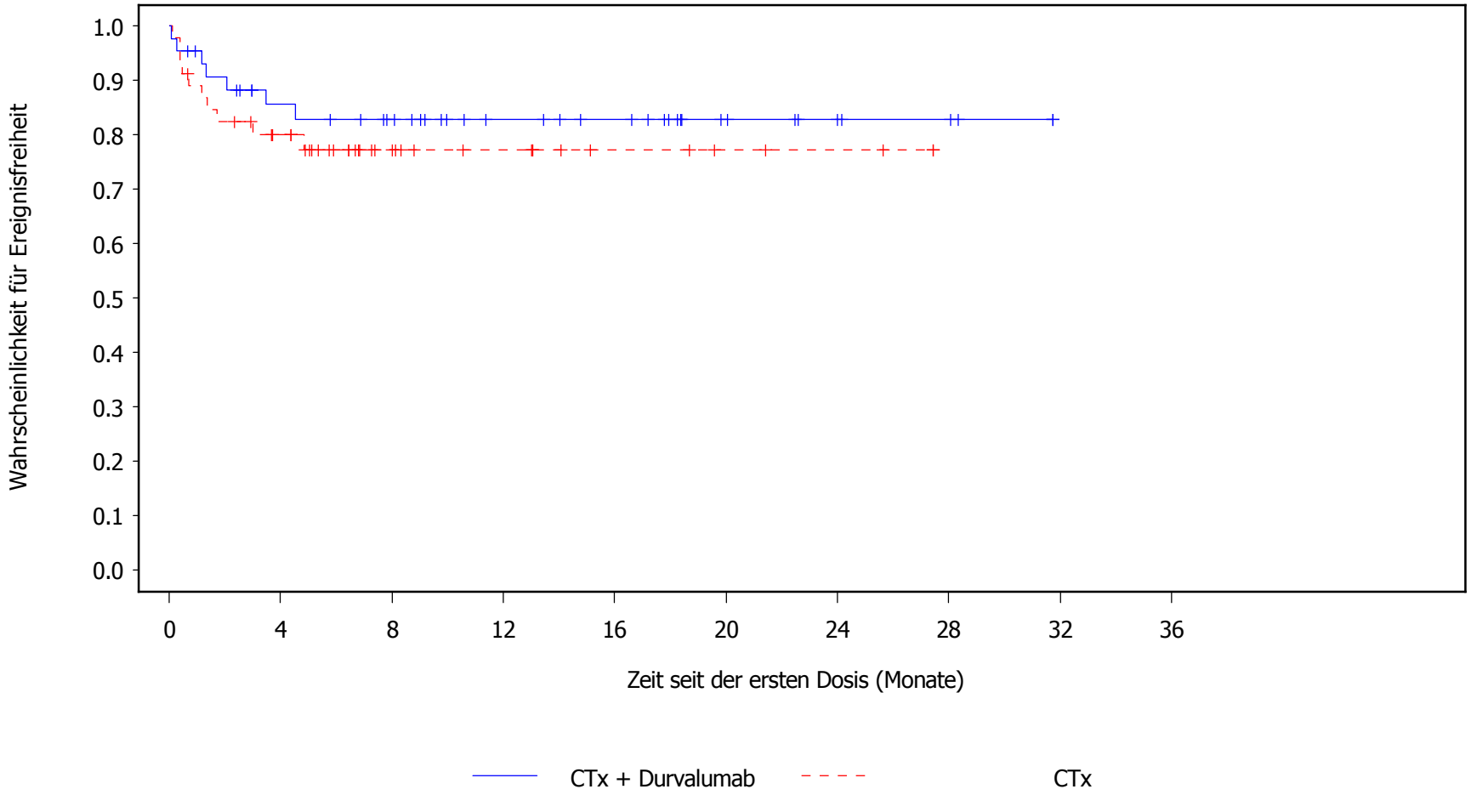
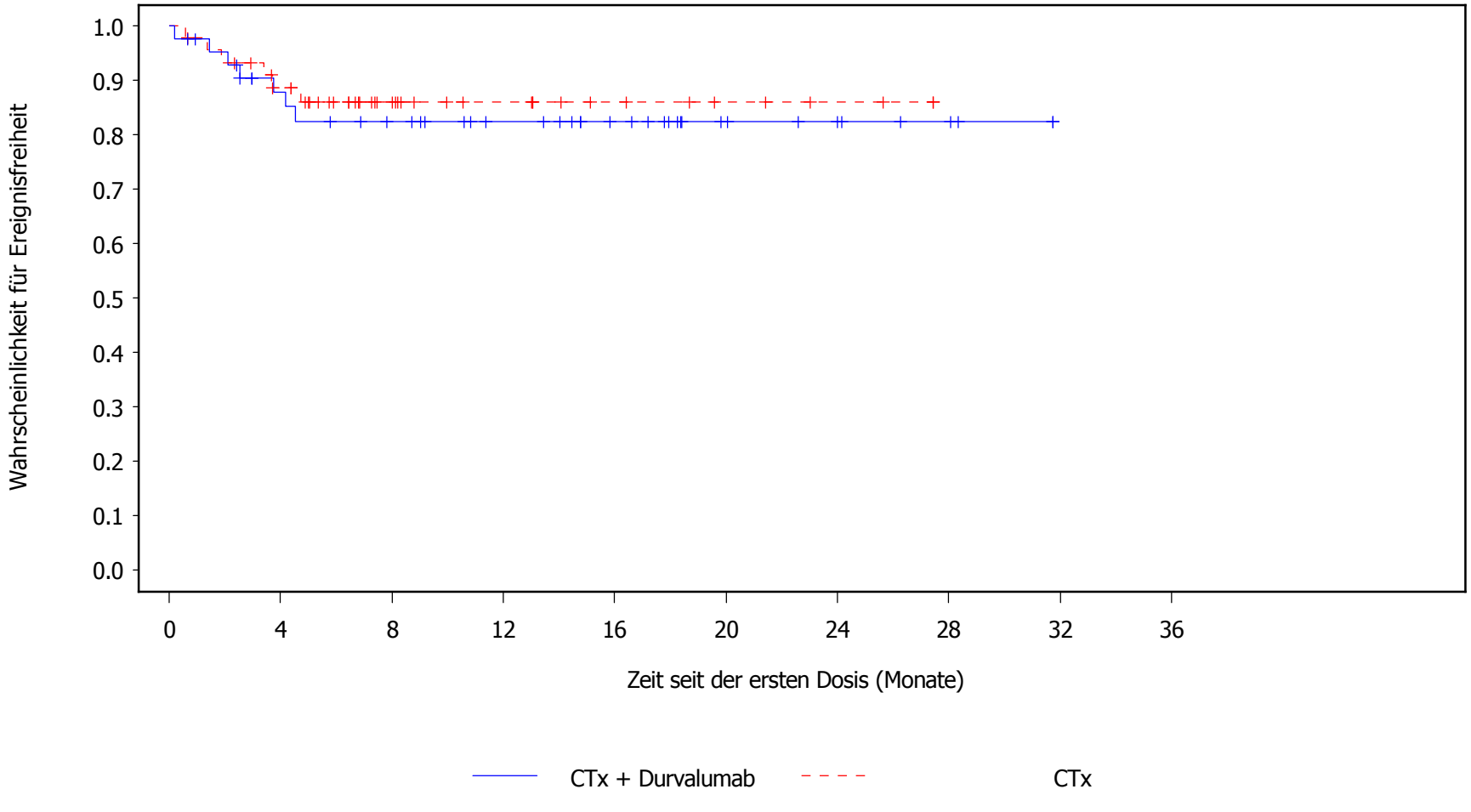
Figure 3.3.1.1D.61 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Neutrophilenzahl erniedrigt
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	32	27	19	16	8	5	3	0	0	CTx + Durvalumab
46	32	15	10	5	3	2	0	0	0	CTx

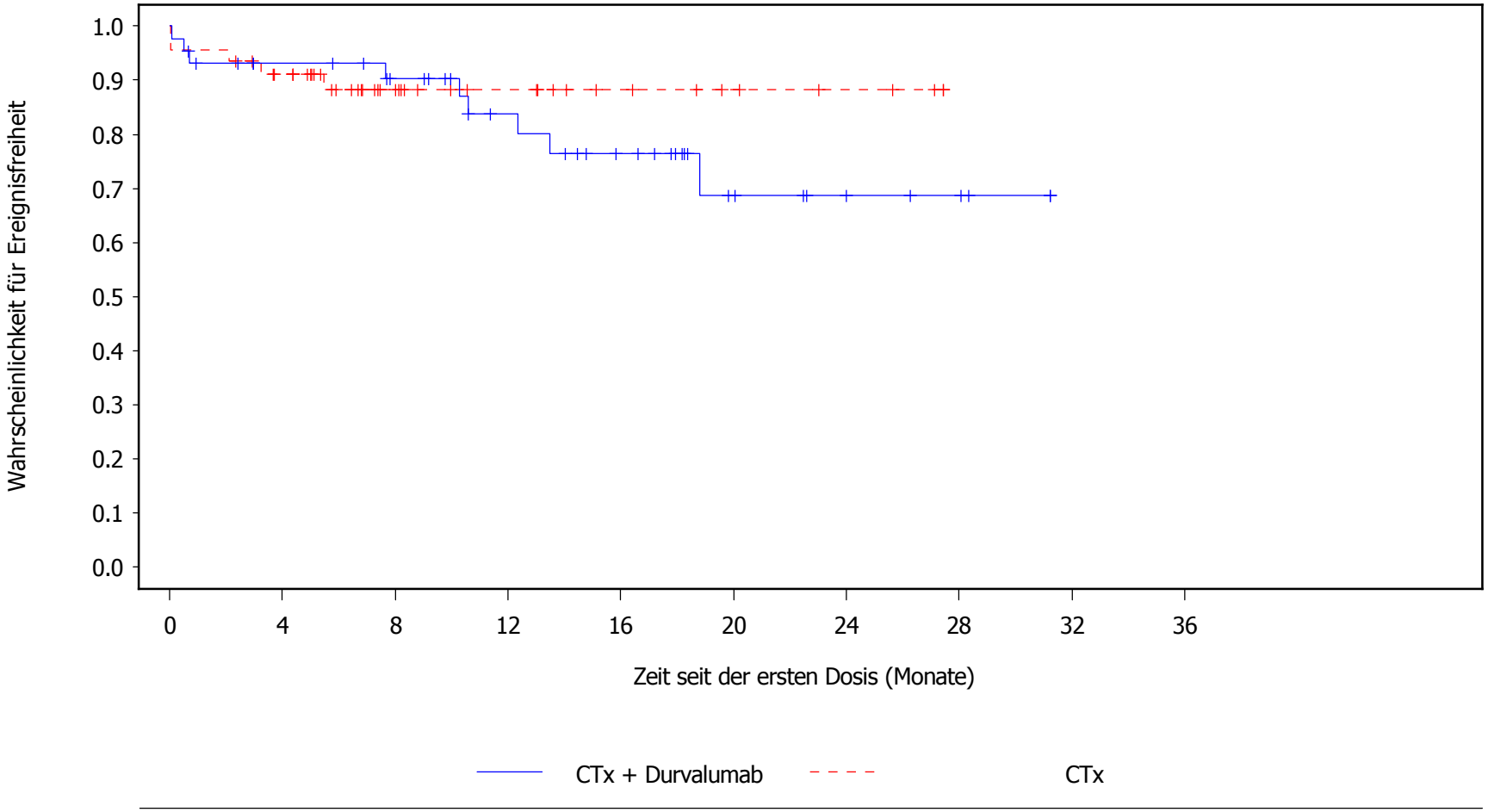
Figure 3.3.1.1D.62 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Thrombozytenzahl vermindert
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	33	28	22	16	8	6	3	0	0	CTx + Durvalumab
46	36	19	12	7	4	2	0	0	0	CTx

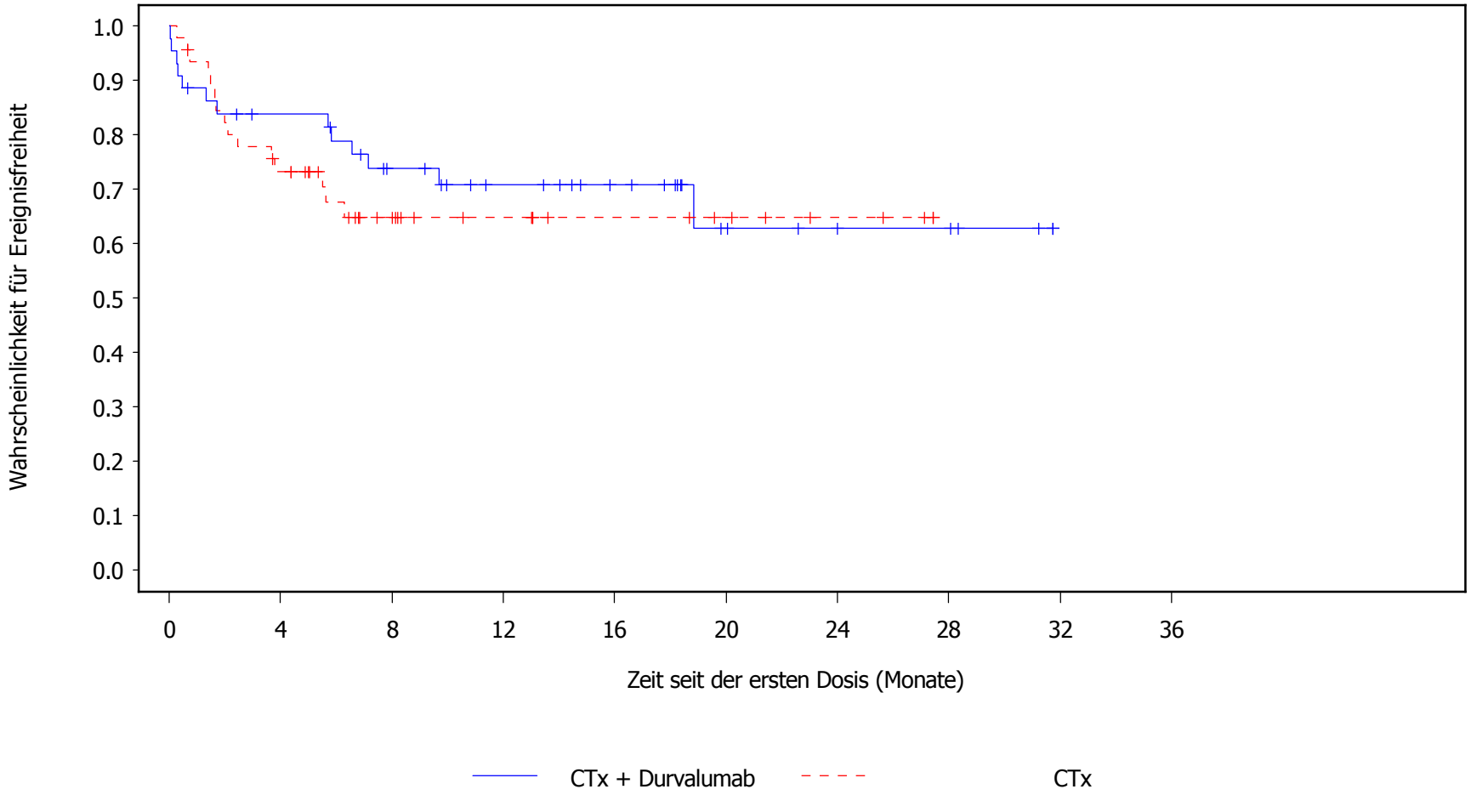
Figure 3.3.1.1D.63 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	31	23	17	8	5	3	0	0	CTx + Durvalumab
46	38	20	13	8	5	3	0	0	0	CTx

Figure 3.3.1.1D.64 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	26	20	15	7	5	4	0	0	CTx + Durvalumab
46	32	18	12	8	6	3	0	0	0	CTx

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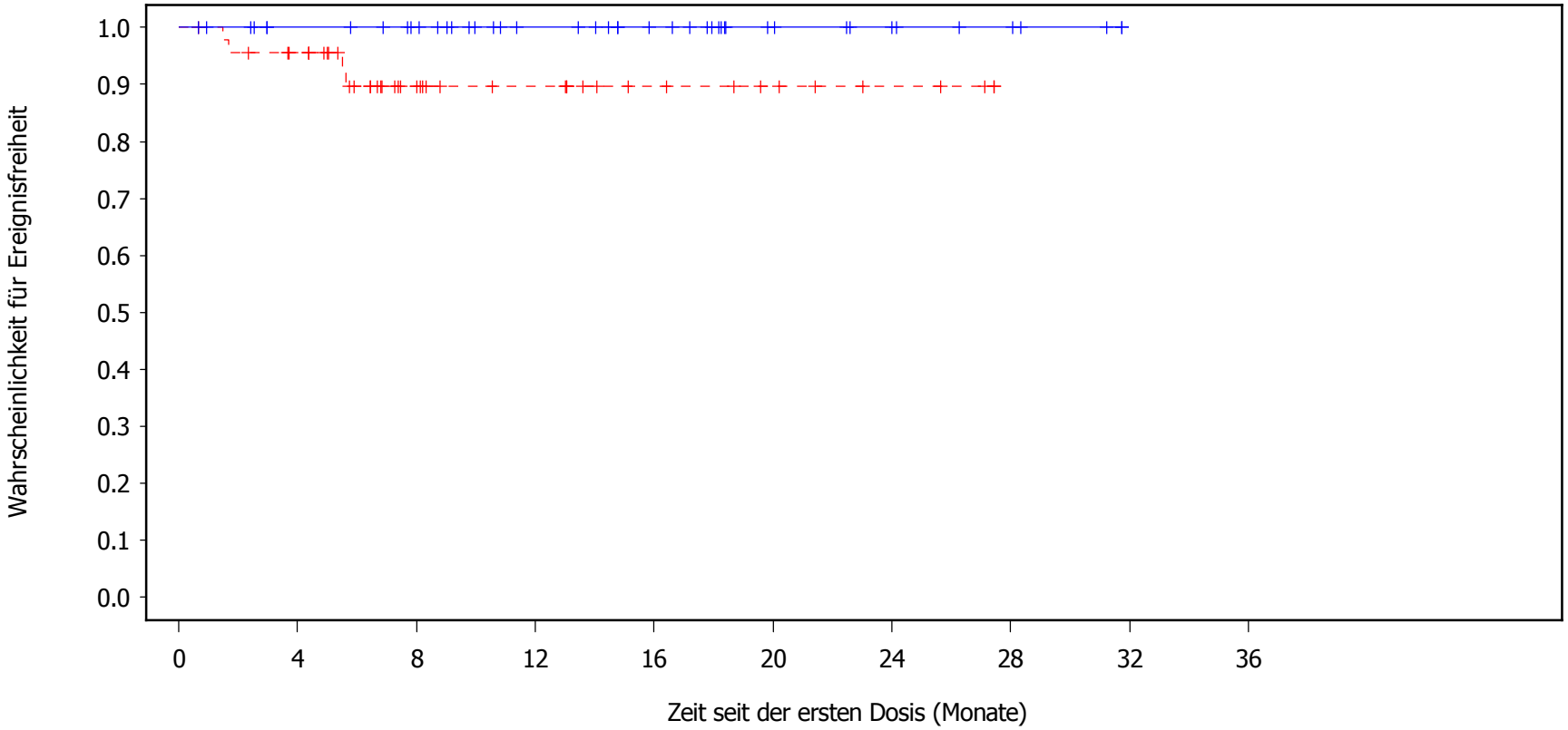
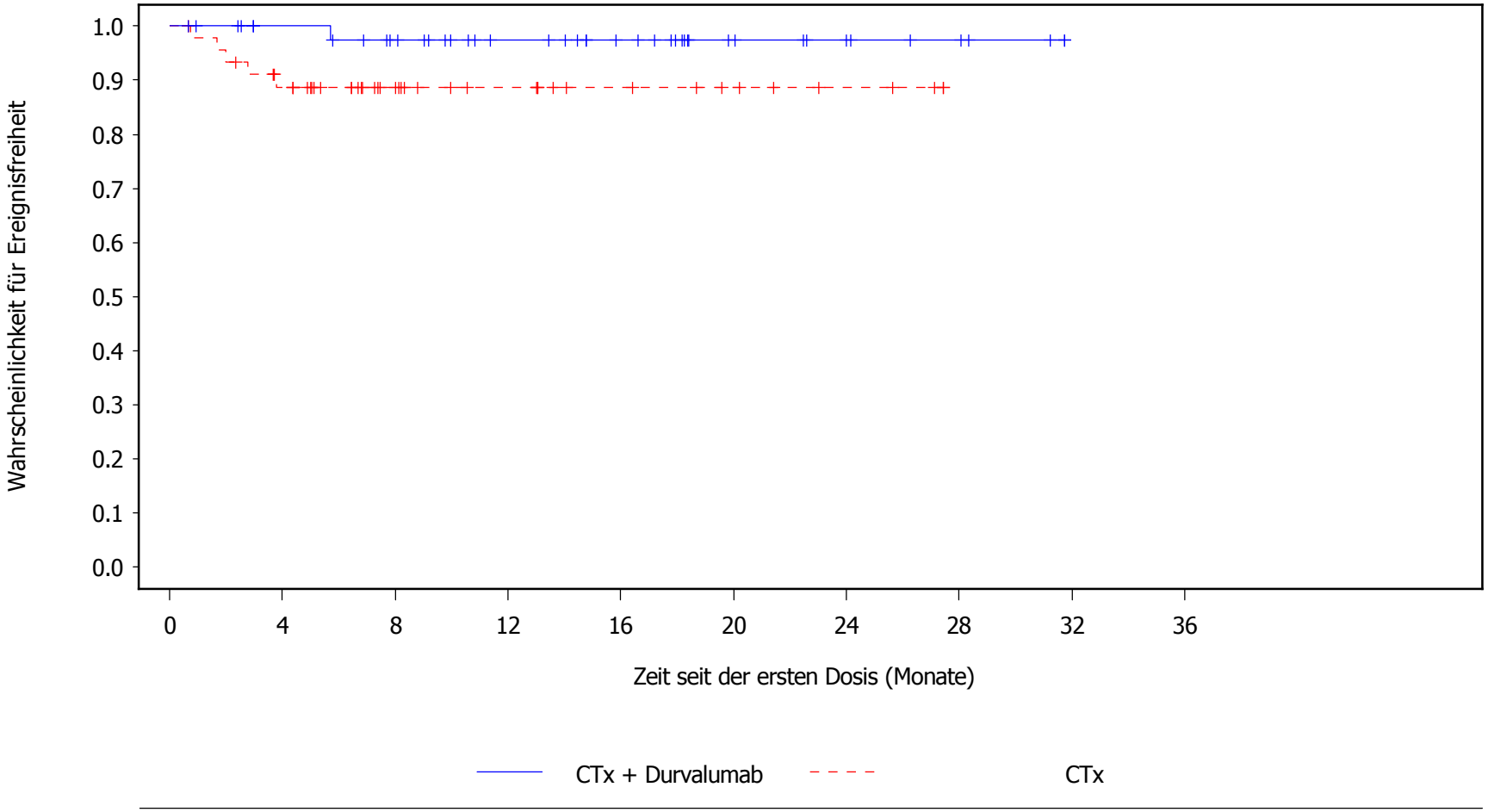
Figure 3.3.1.1D.65 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen der Nieren und Harnwege
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	34	25	19	10	7	4	0	0	CTx + Durvalumab
46	40	21	15	9	6	3	0	0	0	CTx

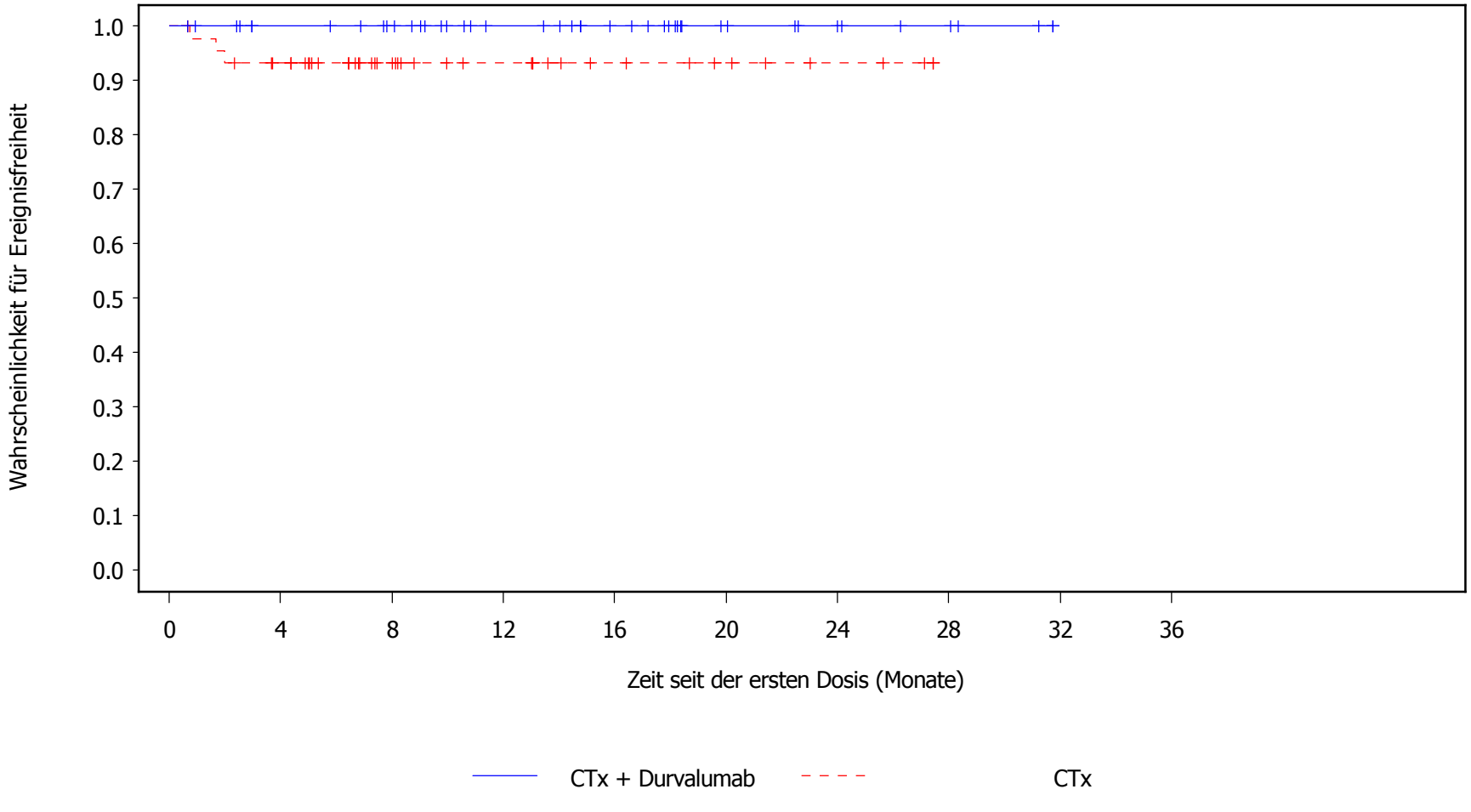
Figure 3.3.1.1D.66 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	33	25	19	10	7	4	0	0	CTx + Durvalumab
46	37	21	14	9	6	3	0	0	0	CTx

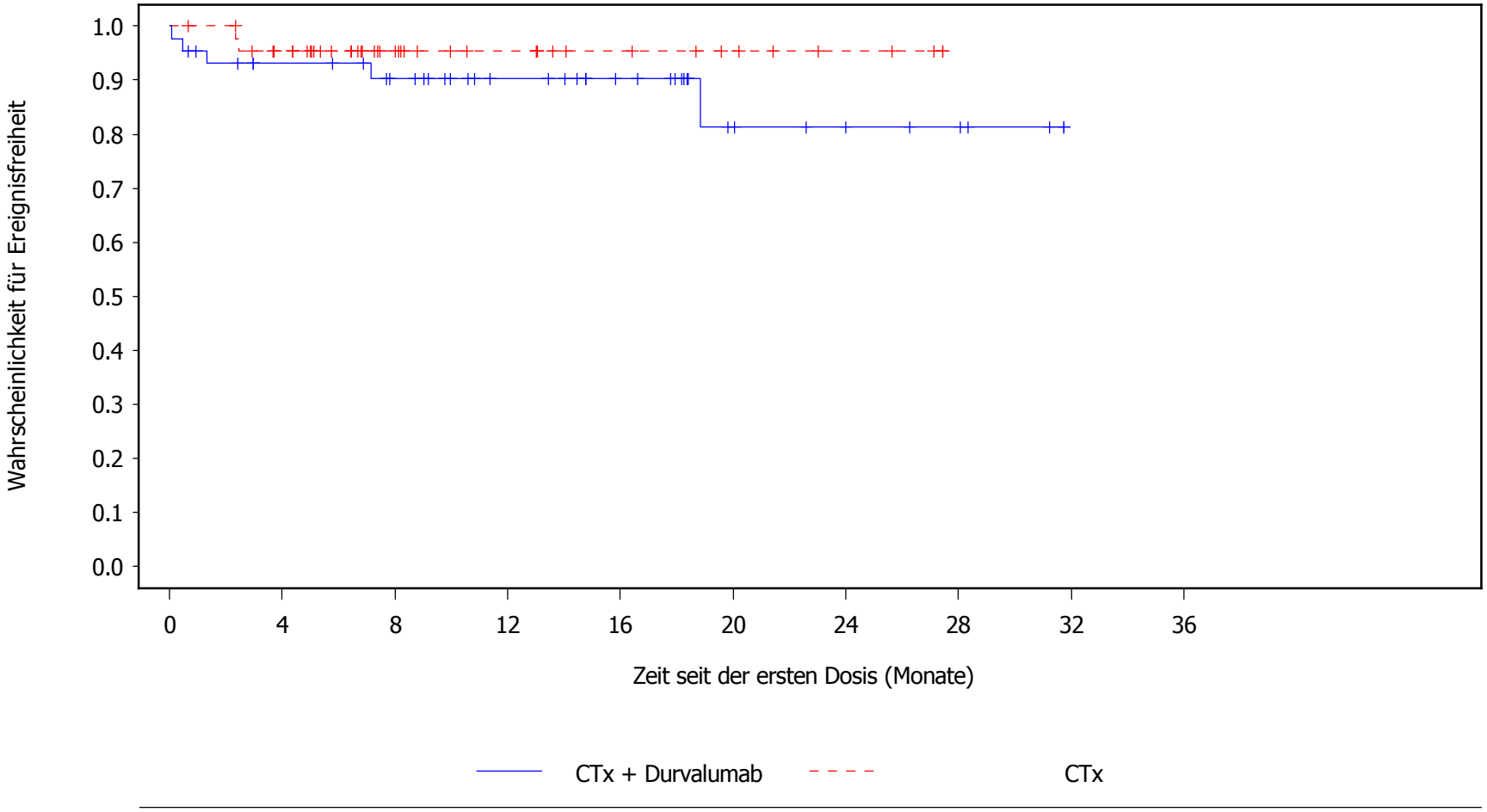
Figure 3.3.1.1D.67 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE PT: Anaemie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	34	25	19	10	7	4	0	0	CTx + Durvalumab
46	39	22	15	9	6	3	0	0	0	CTx

Figure 3.3.1.1D.68 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Gastrointestinaltrakts
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	31	23	17	8	6	4	0	0	CTx + Durvalumab
46	39	21	14	9	6	3	0	0	0	CTx

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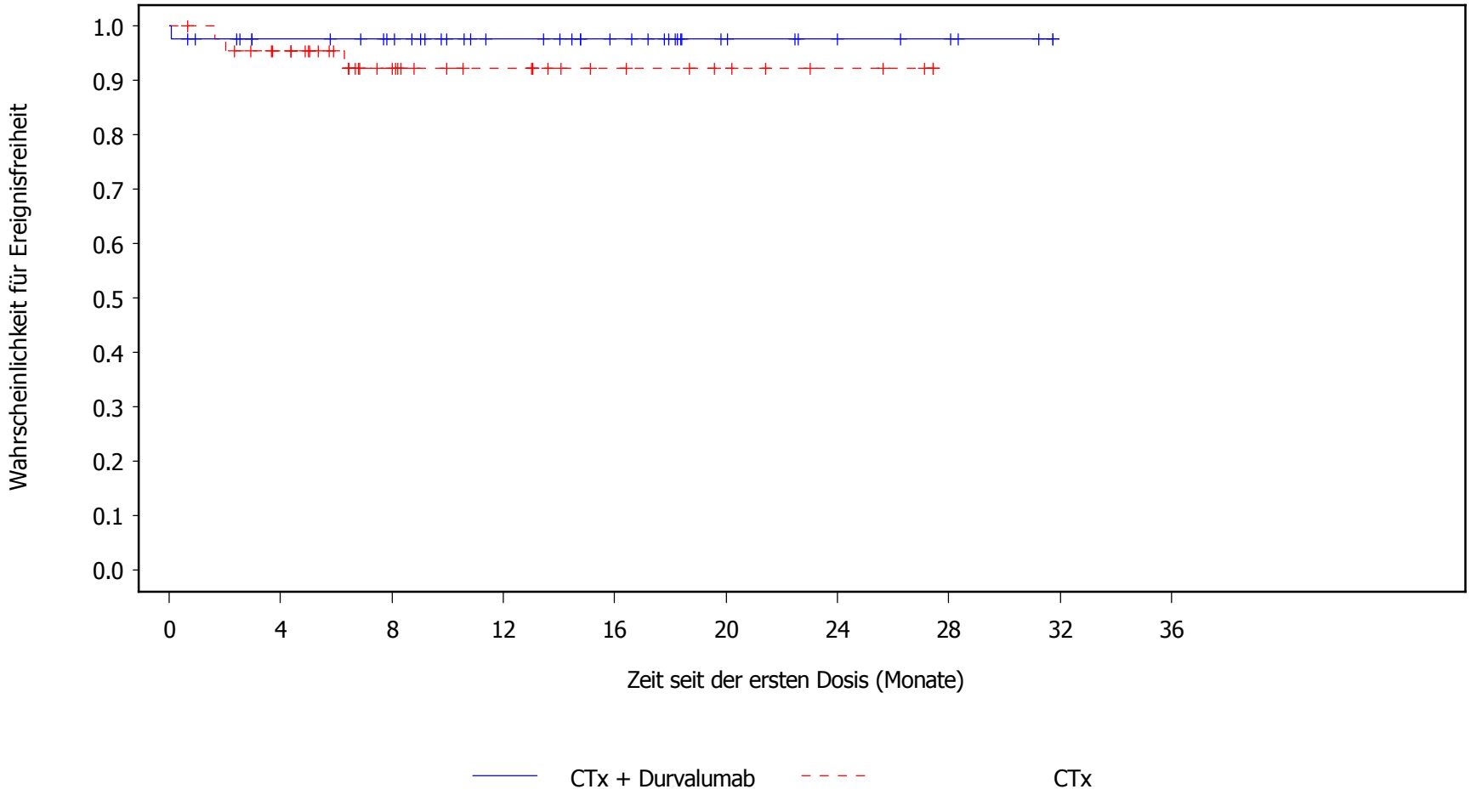
Figure 3.3.1.1D.69 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Nervensystems
Patients with dMMR tumour status, DCO 12APR2023

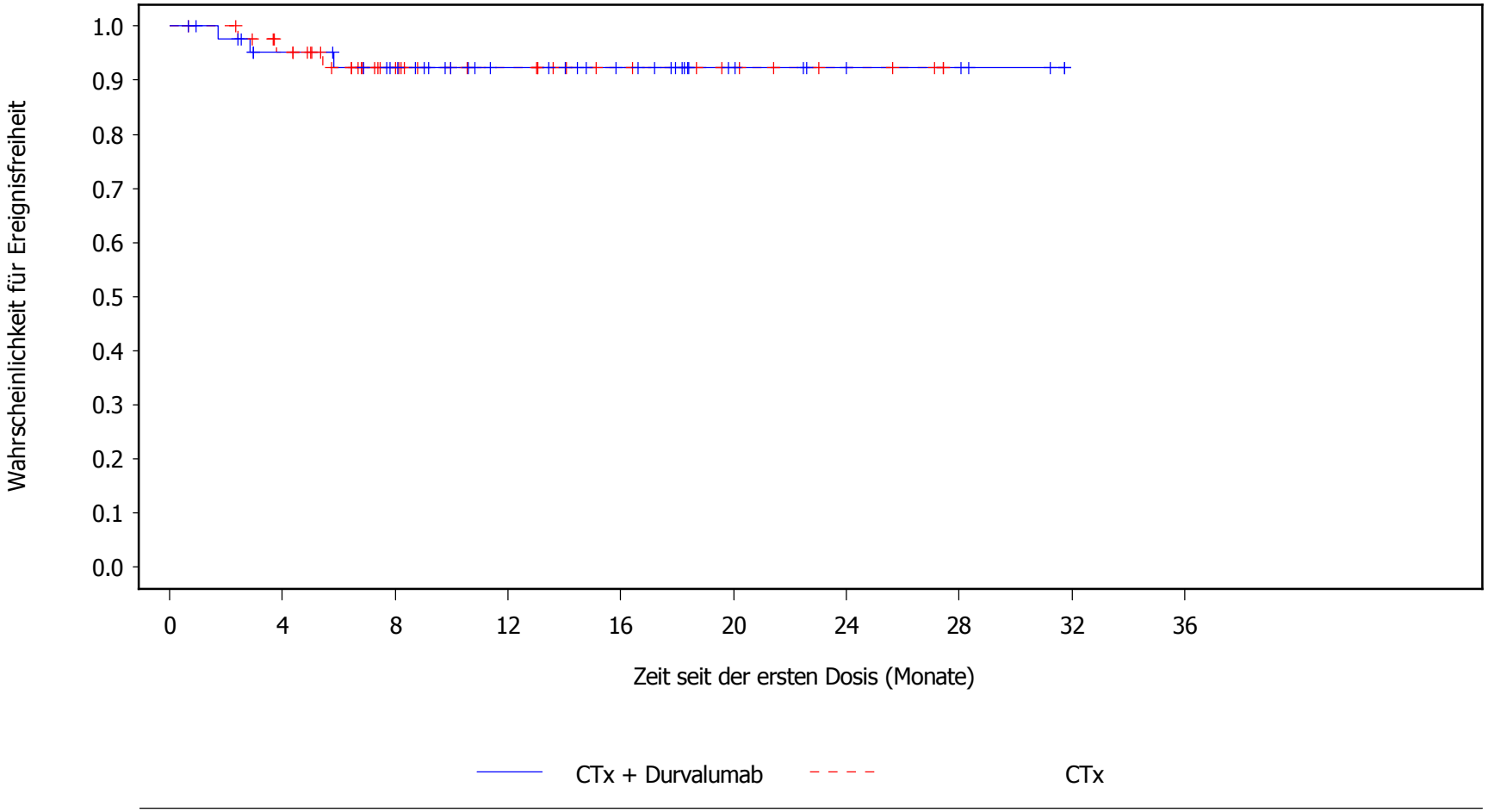


Anzahl an Patienten unter Risiko:

44	37	33	24	18	9	6	4	0	0	CTx + Durvalumab
46	39	22	15	9	6	3	0	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainaedc1.sas gttemainaedc1acq 17APR2024:11:32

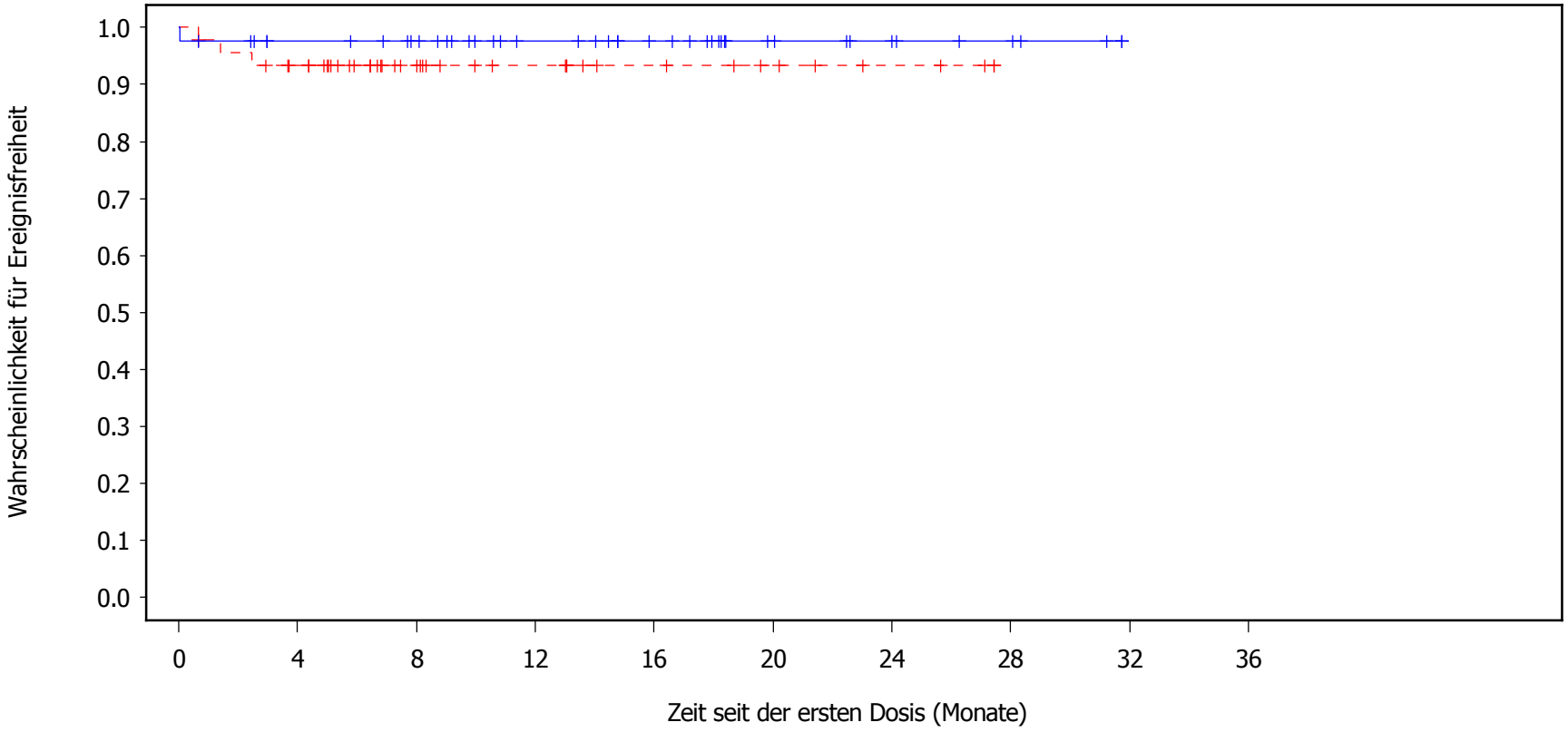
Figure 3.3.1.1D.70 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Infektionen und parasitaere Erkrankungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	31	22	17	8	5	4	0	0	CTx + Durvalumab
46	39	22	15	9	6	3	0	0	0	CTx

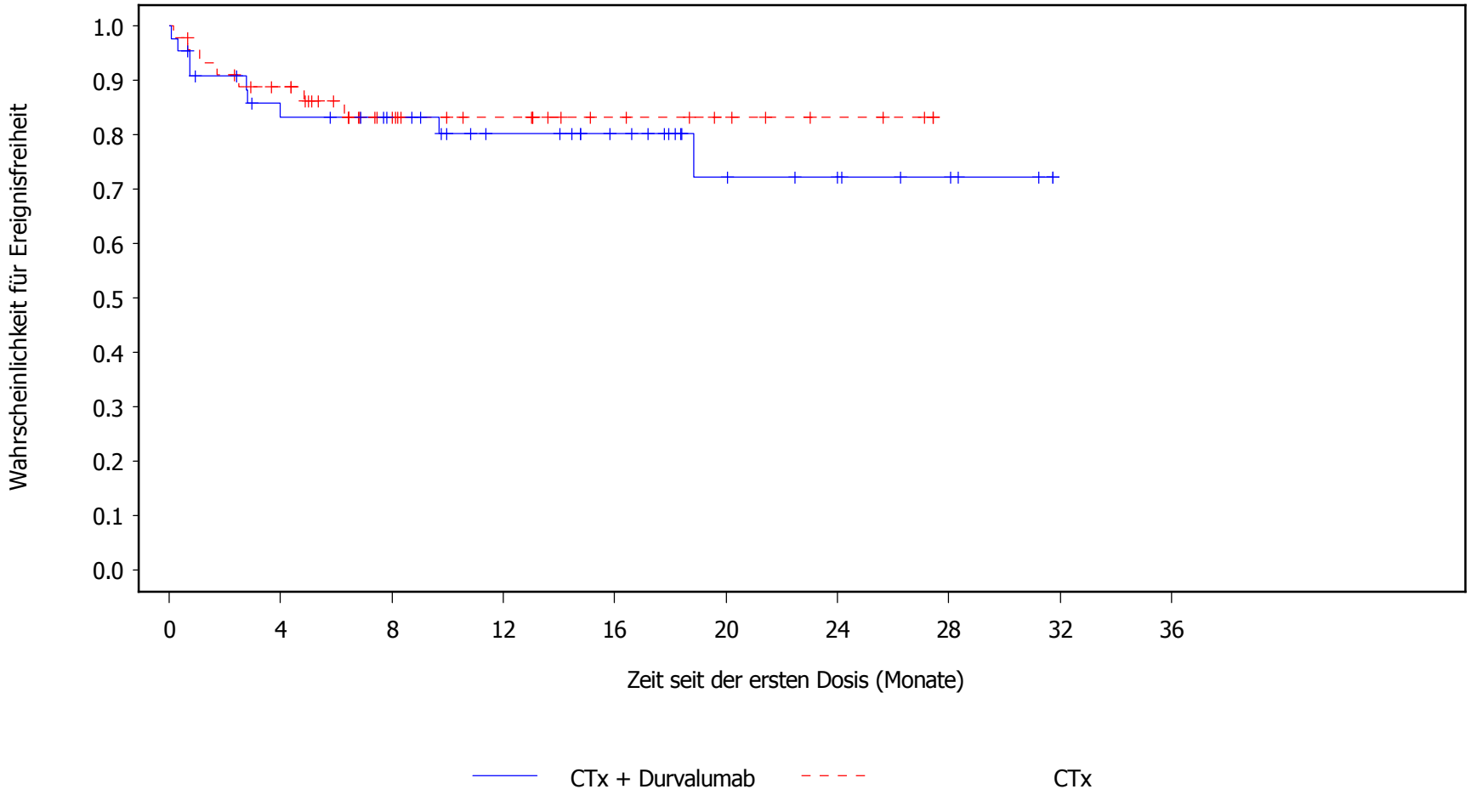
Figure 3.3.1.1D.71 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	34	25	19	10	7	4	0	0	CTx + Durvalumab
46	39	21	14	9	6	3	0	0	0	CTx

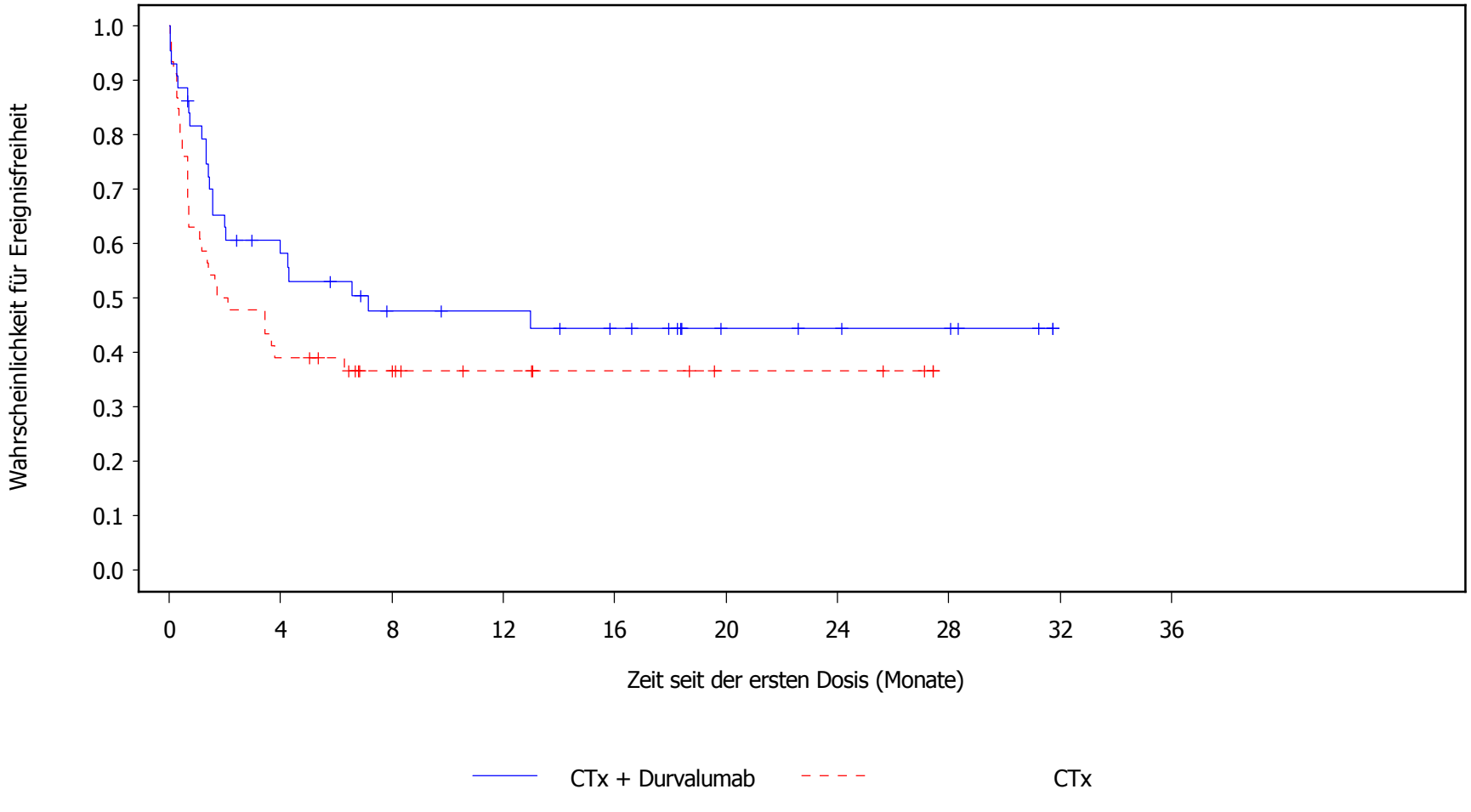
Figure 3.3.1.1D.72 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of Therapieabbruch aufgrund von UE
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	33	29	22	17	9	7	4	0	0	CTx + Durvalumab
46	37	21	15	9	6	3	0	0	0	CTx

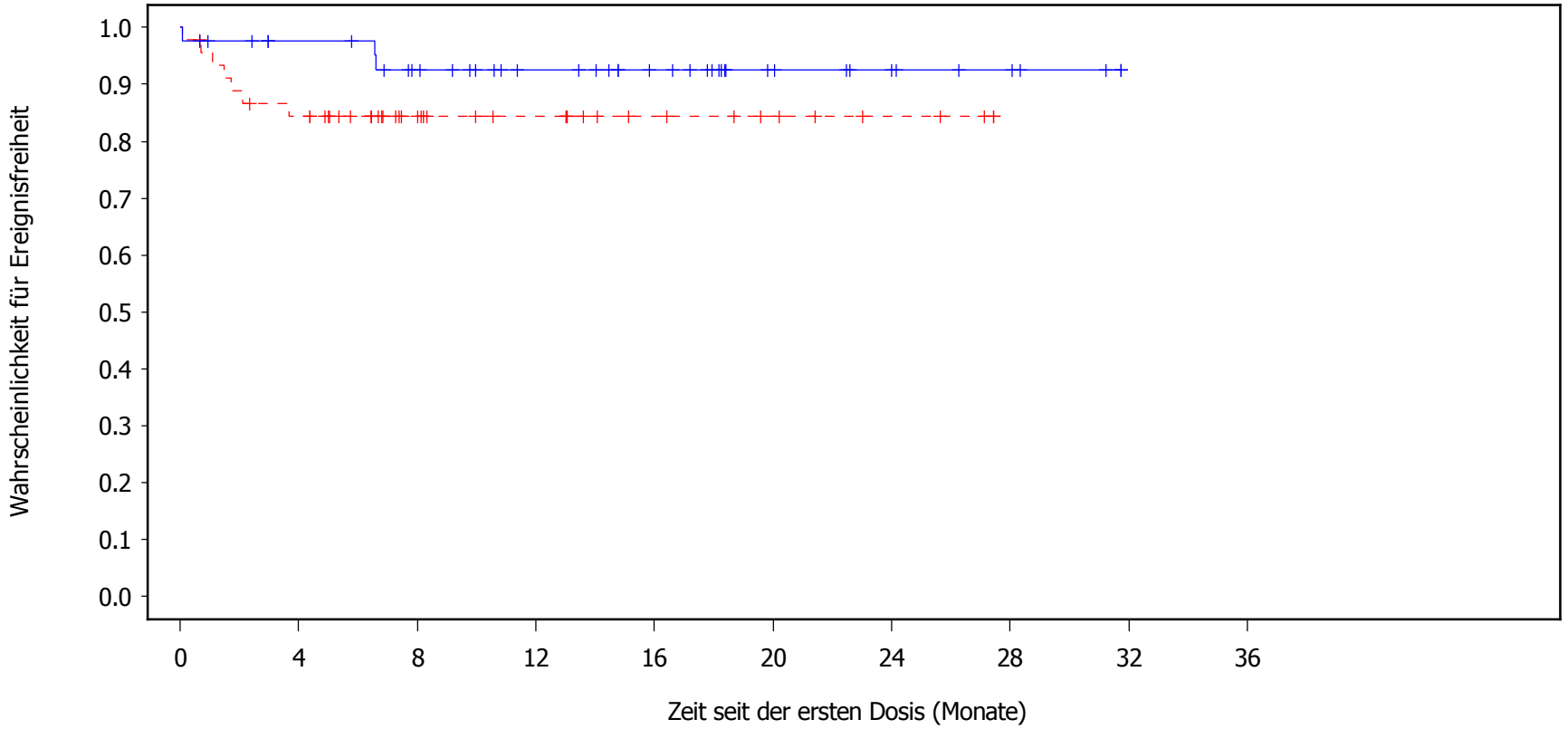
Figure 3.3.1.1D.73 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UE mit CTCAE Grad >=3
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	23	16	15	12	6	5	4	0	0	CTx + Durvalumab
46	18	11	7	5	3	3	0	0	0	CTx

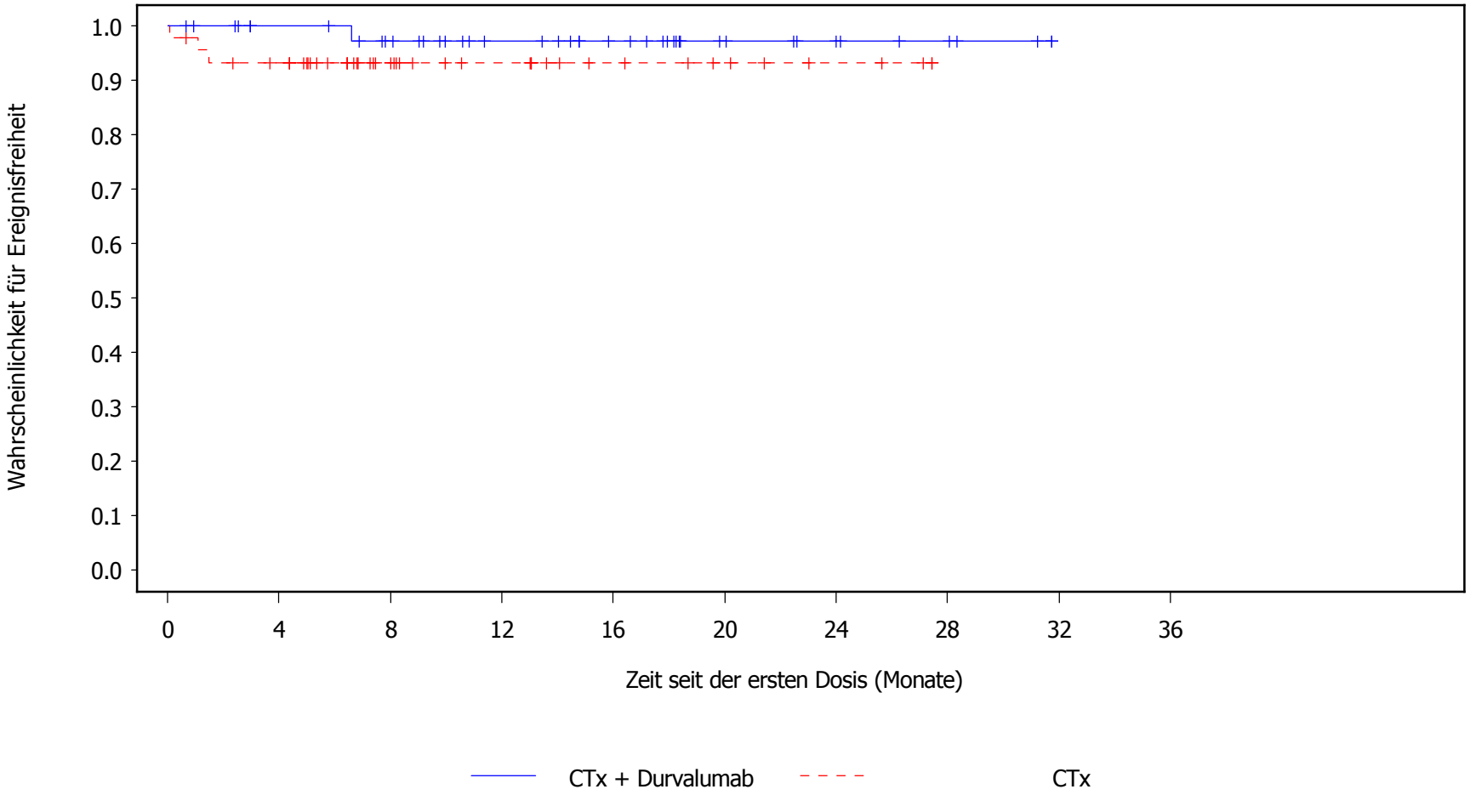
Figure 3.3.1.1D.74 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	32	25	19	10	7	4	0	0	CTx + Durvalumab
46	37	21	15	9	6	3	0	0	0	CTx

Figure 3.3.1.1D.75 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Asthenie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	33	25	19	10	7	4	0	0	CTx + Durvalumab
46	40	22	15	9	6	3	0	0	0	CTx

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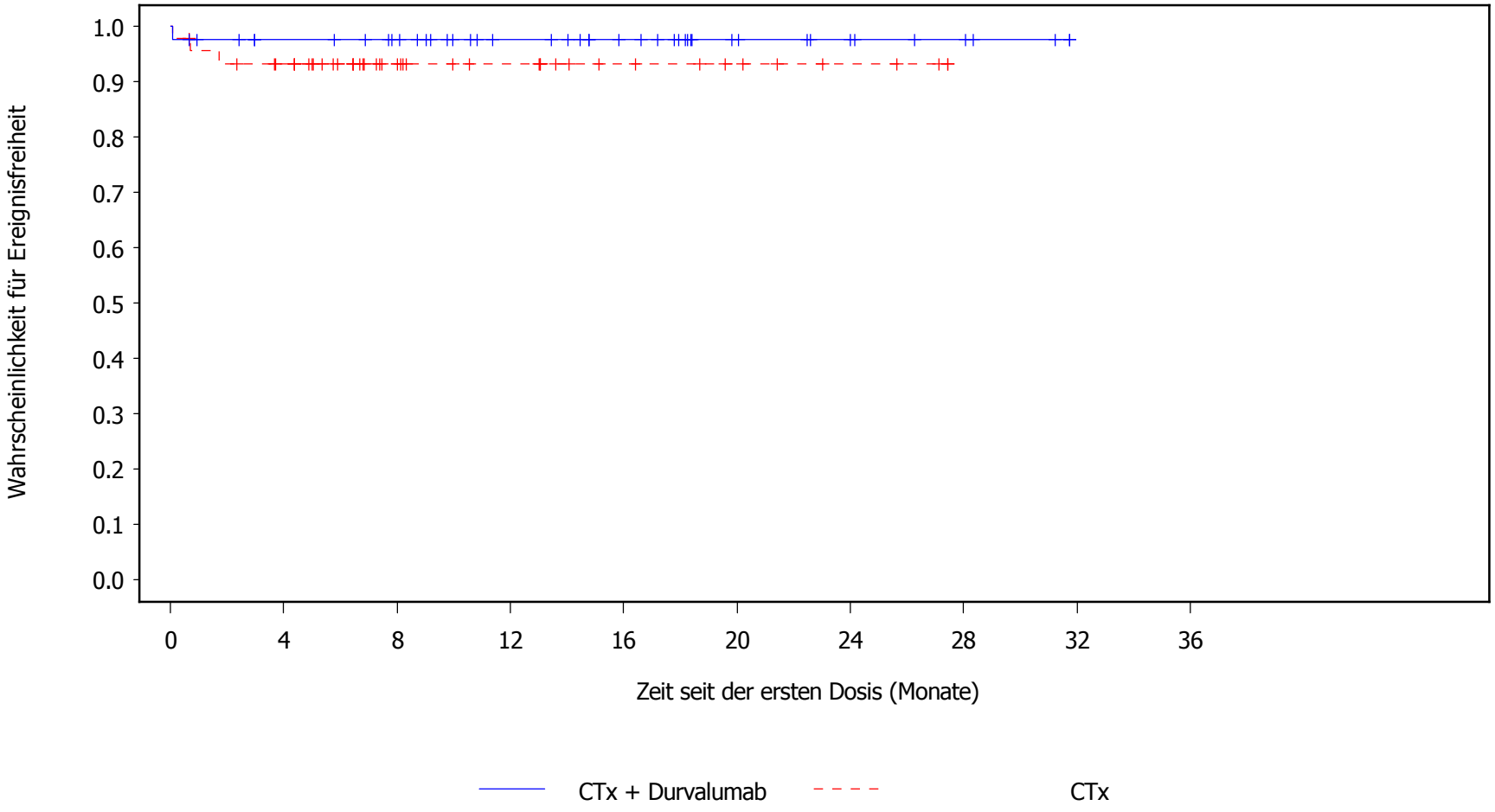
Figure 3.3.1.1D.76 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Ermuedung
Patients with dMMR tumour status, DCO 12APR2023

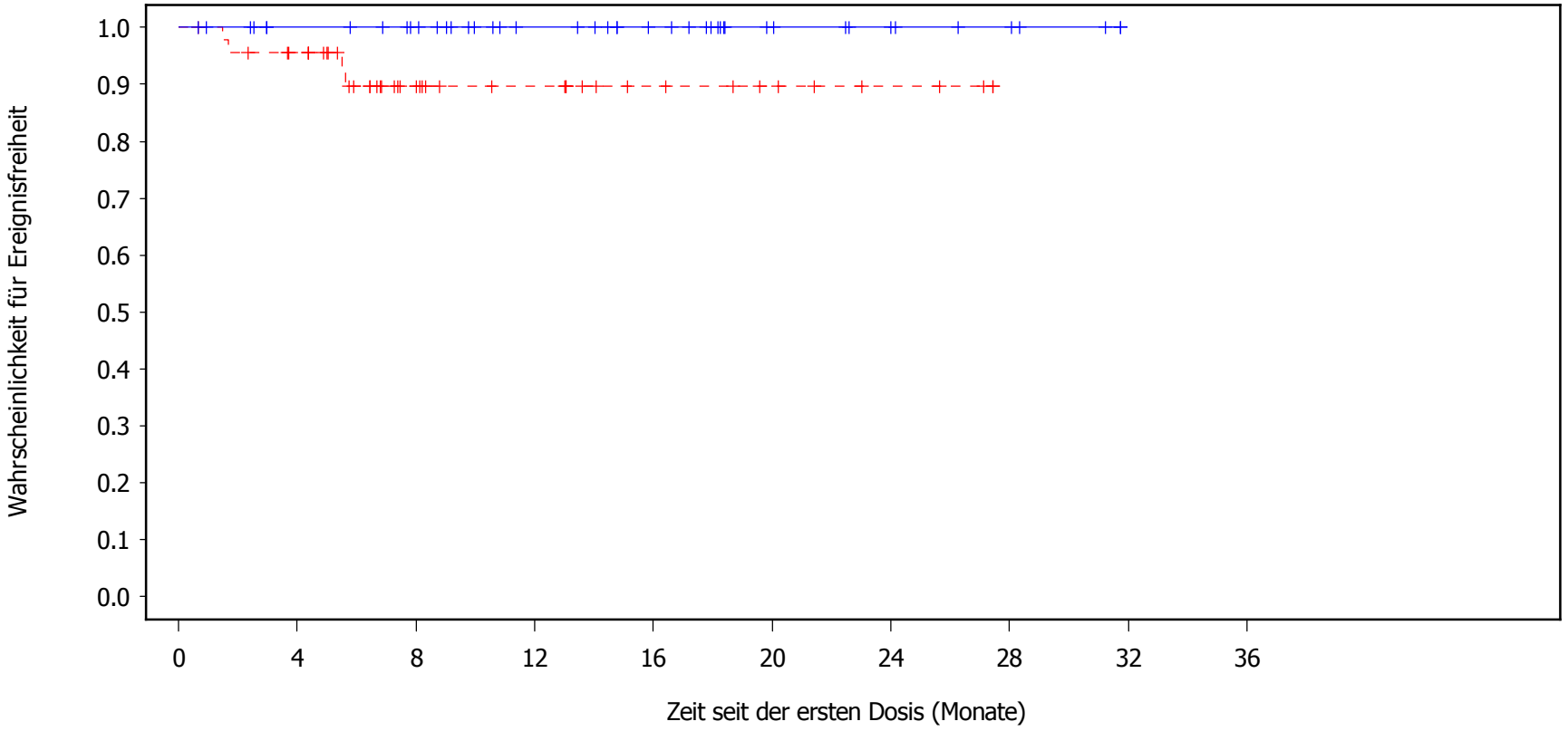


Anzahl an Patienten unter Risiko:

44	38	34	25	19	10	7	4	0	0	CTx + Durvalumab
46	39	21	15	9	6	3	0	0	0	CTx

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.1.1D.77 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen der Nieren und Harnwege
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	34	25	19	10	7	4	0	0	CTx + Durvalumab
46	40	21	15	9	6	3	0	0	0	CTx

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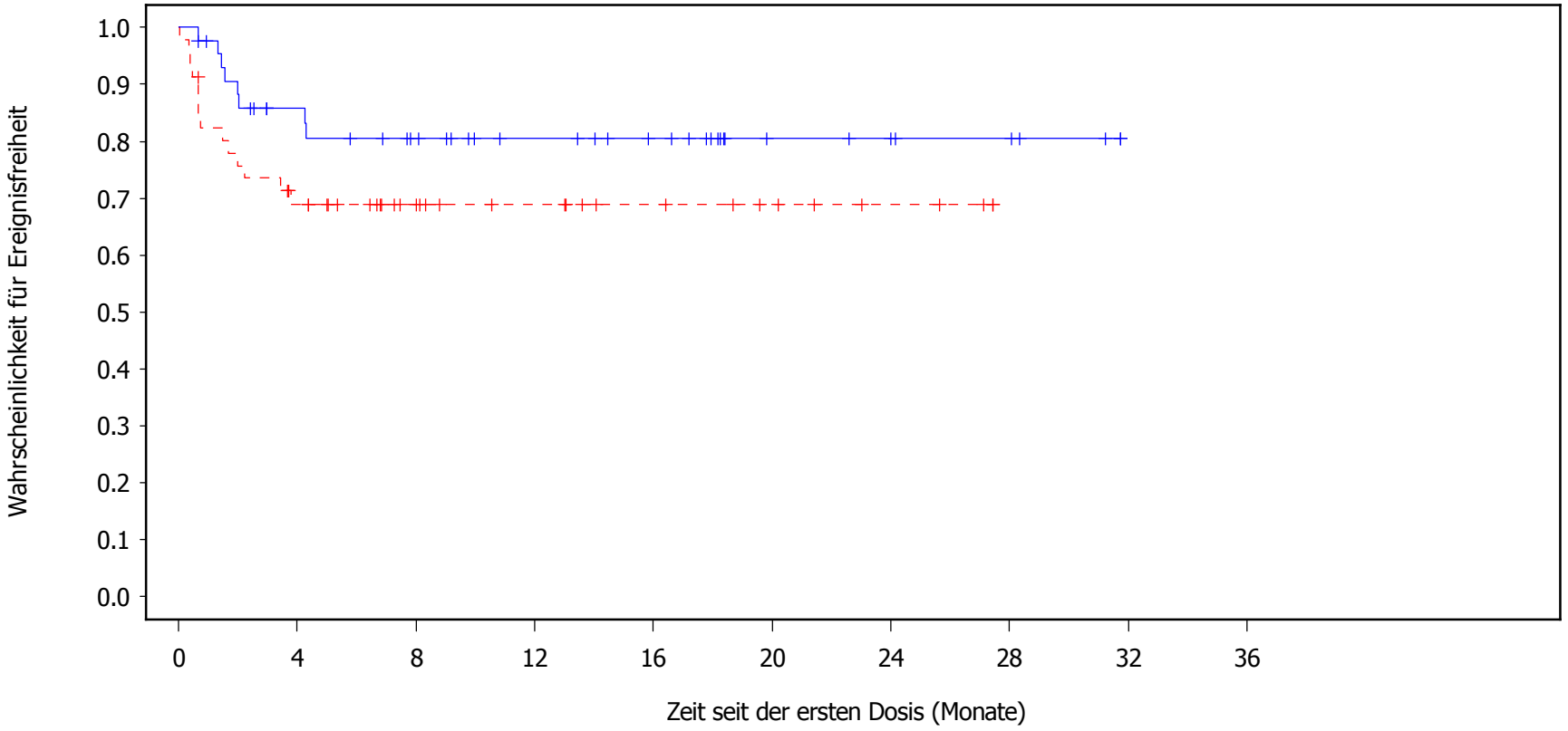
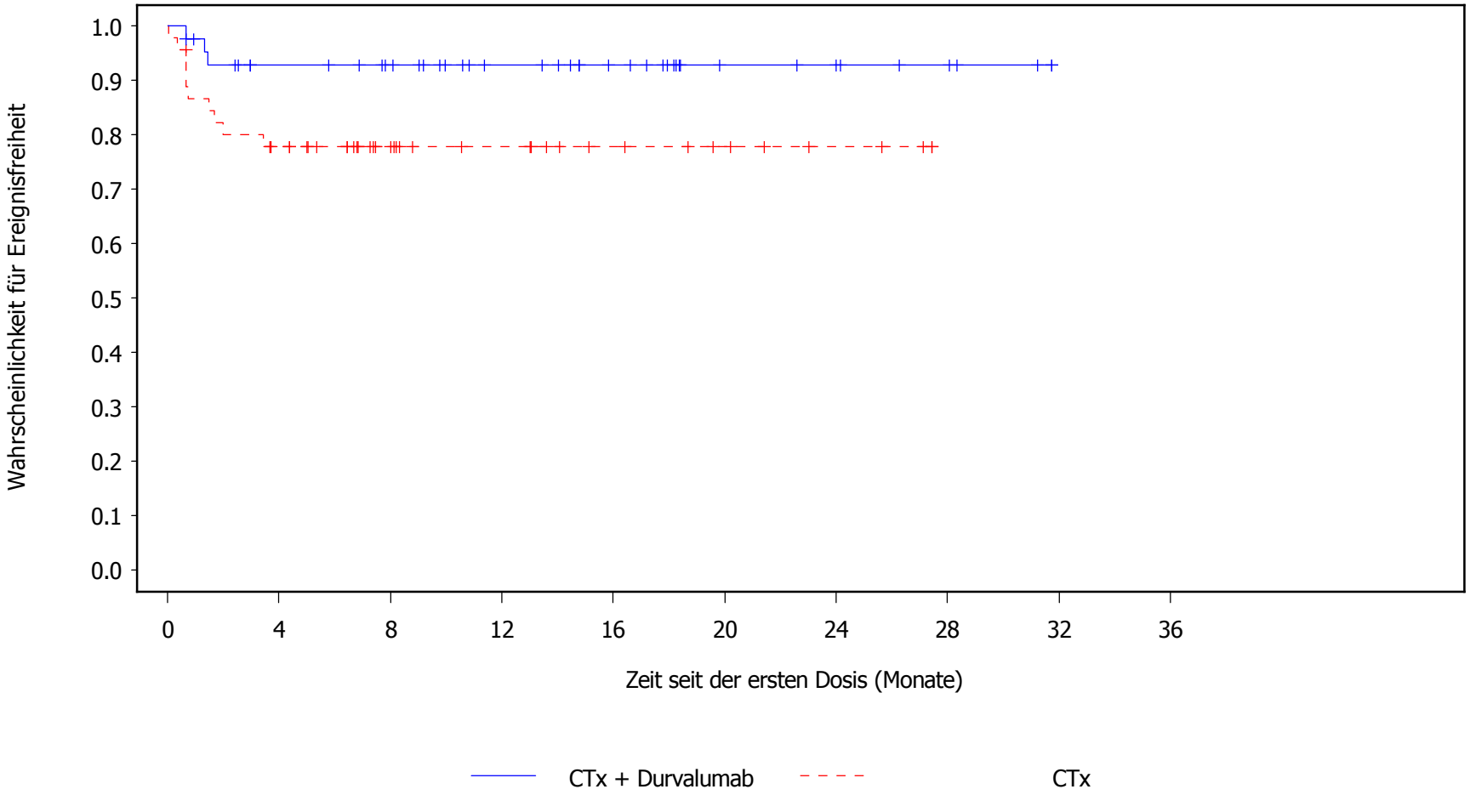
Figure 3.3.1.1D.78 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	32	26	20	16	7	6	4	0	0	CTx + Durvalumab
46	29	18	13	9	6	3	0	0	0	CTx

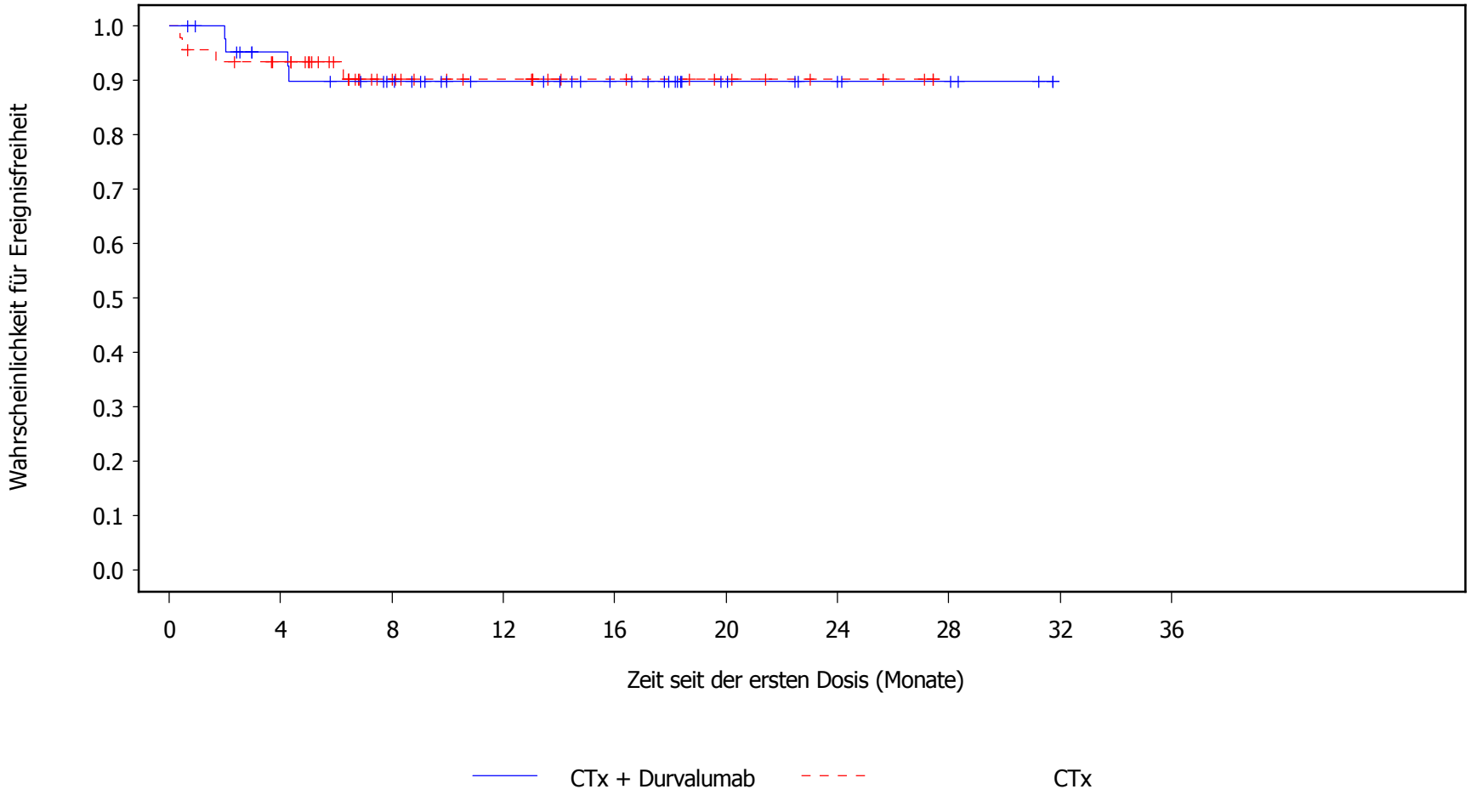
Figure 3.3.1.1D.79 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Anaemie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	35	31	23	17	8	7	4	0	0	CTx + Durvalumab
46	33	20	14	9	6	3	0	0	0	CTx

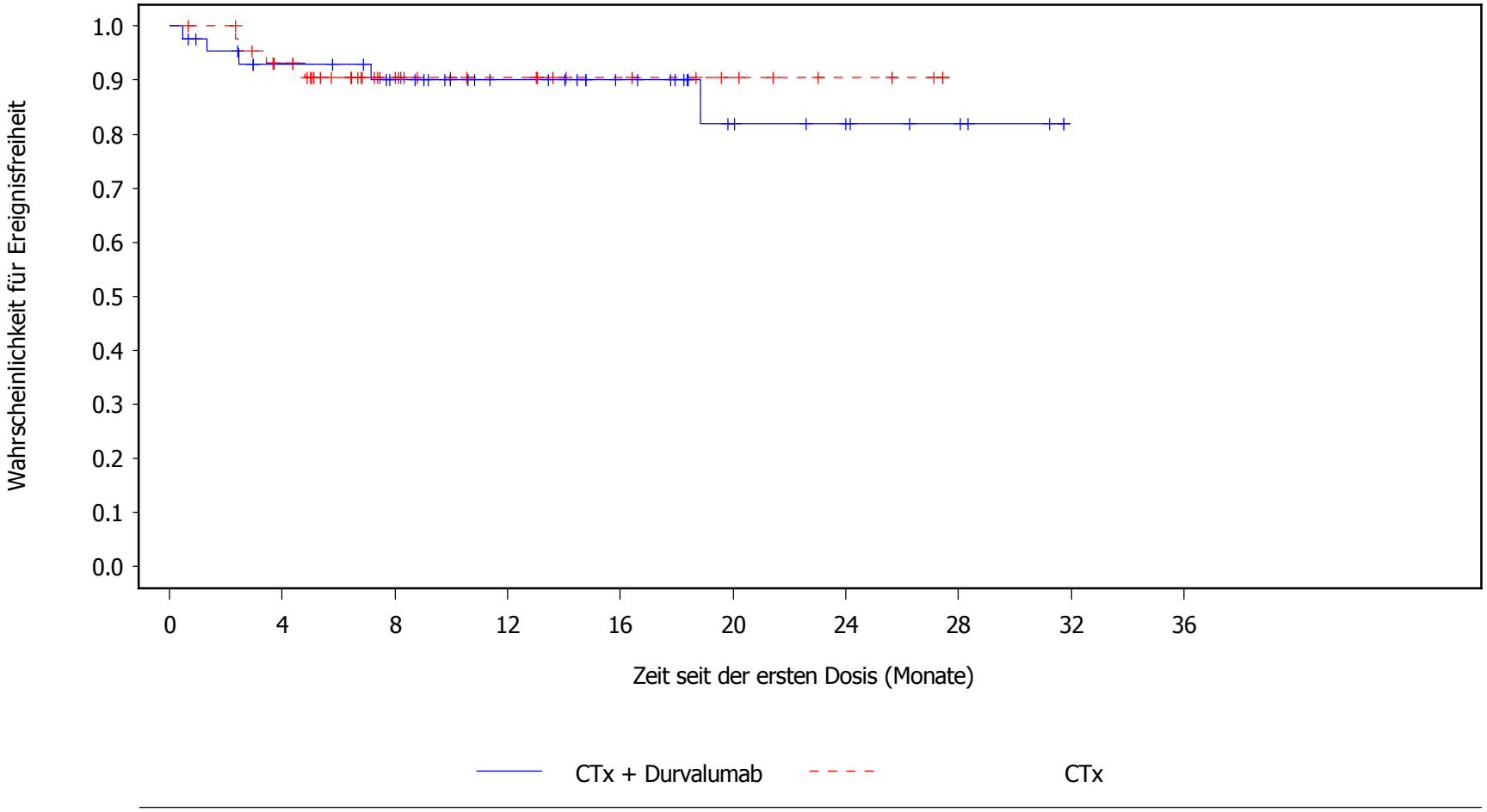
Figure 3.3.1.1D.80 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Neutropenie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	30	23	18	9	6	4	0	0	CTx + Durvalumab
46	39	20	14	9	6	3	0	0	0	CTx

Figure 3.3.1.1D.81 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Gastrointestinaltrakts
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	31	23	17	9	7	4	0	0	CTx + Durvalumab
46	38	20	13	9	6	3	0	0	0	CTx

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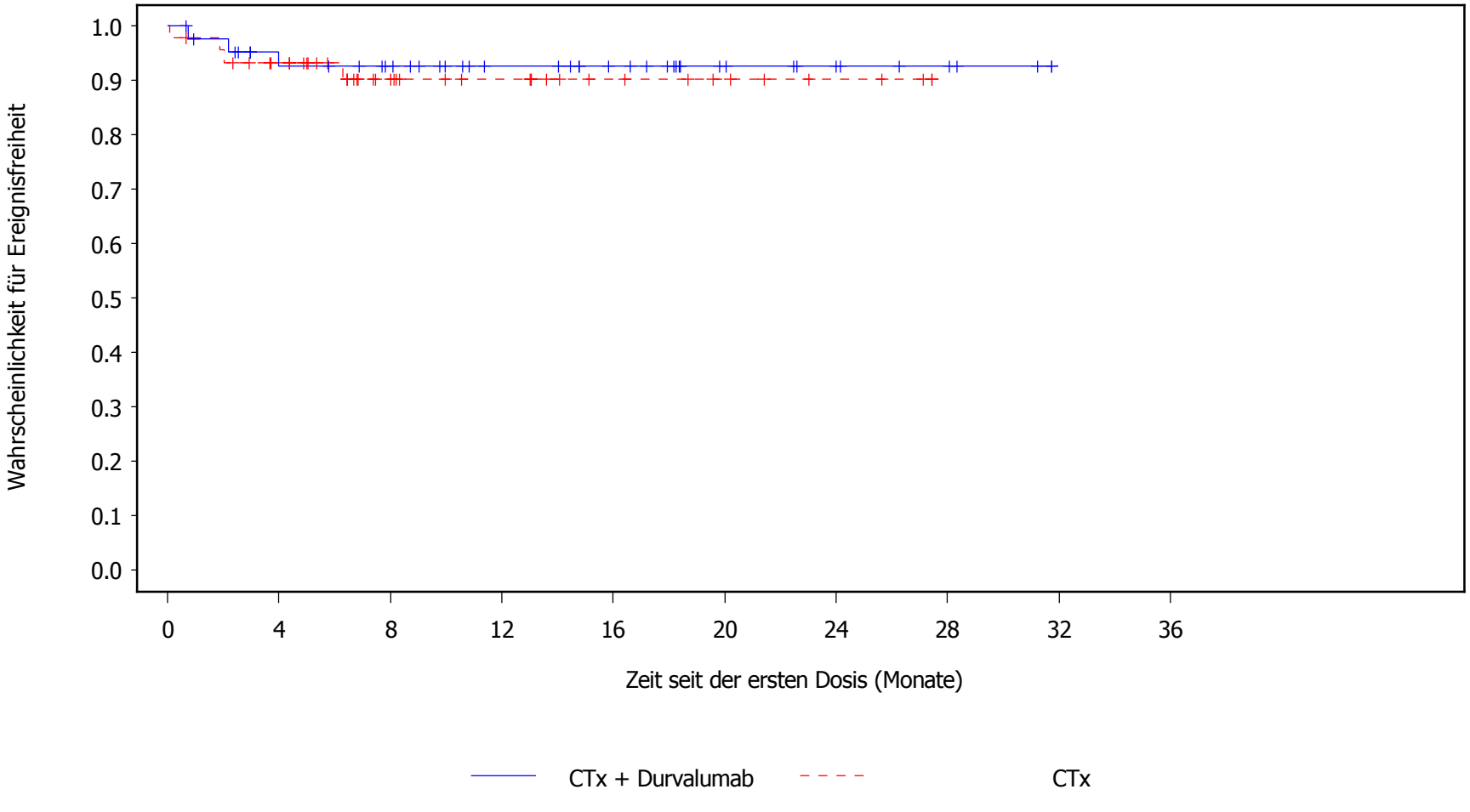
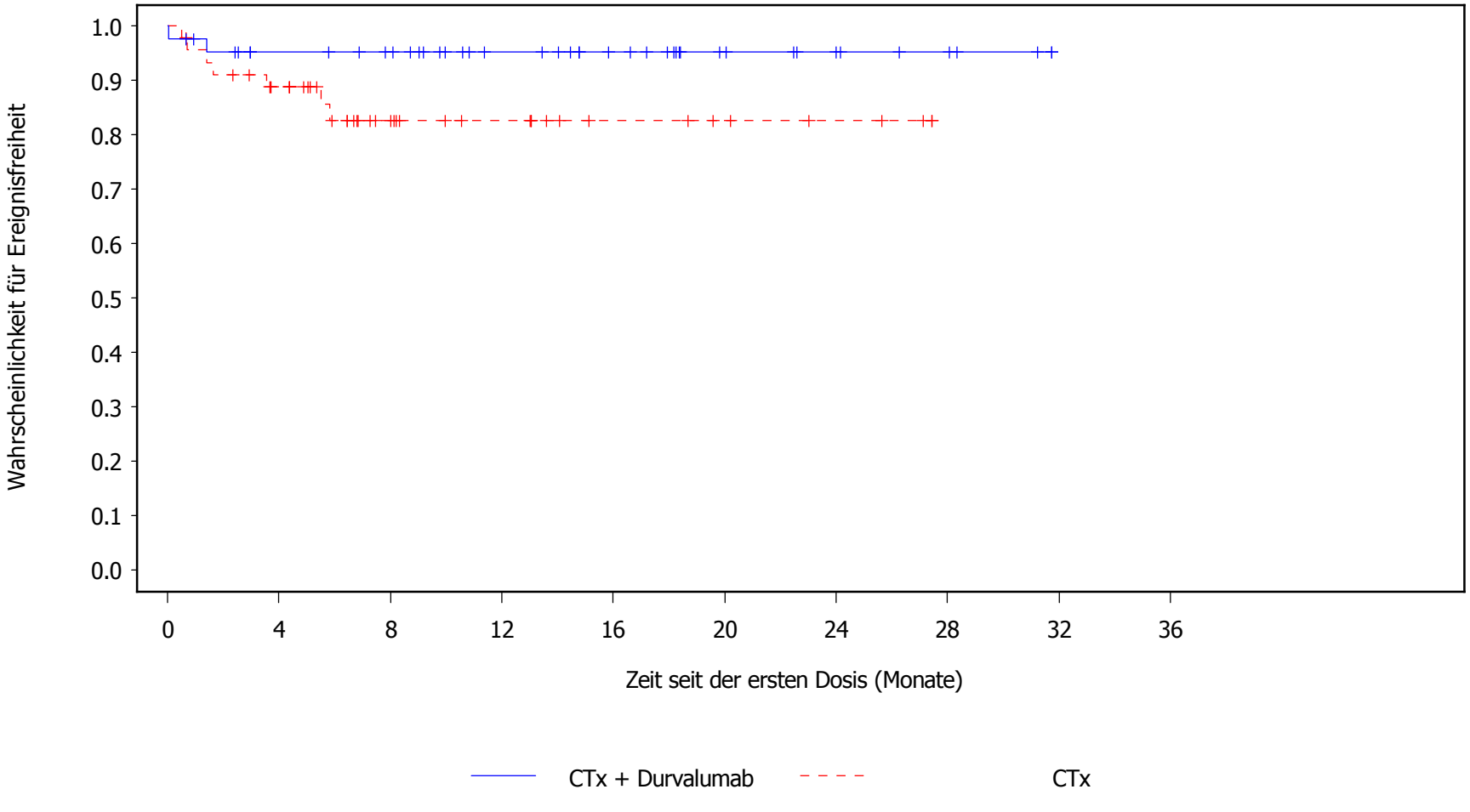
Figure 3.3.1.1D.82 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Nervensystems
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	35	31	23	18	10	7	4	0	0	CTx + Durvalumab
46	38	21	15	9	6	3	0	0	0	CTx

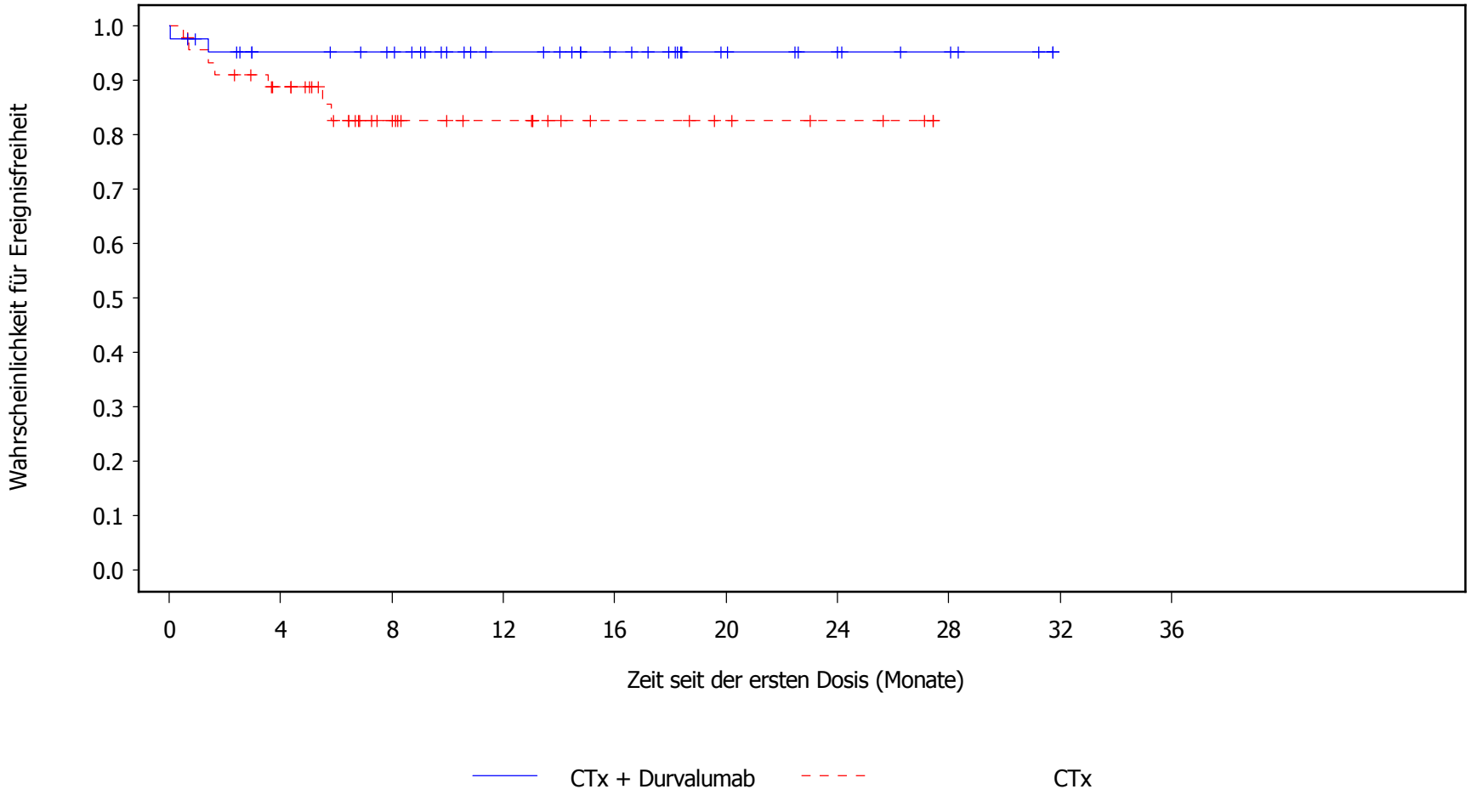
Figure 3.3.1.1D.83 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Gefaesserkrankungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	33	24	18	10	7	4	0	0	CTx + Durvalumab
46	36	19	13	7	5	3	0	0	0	CTx

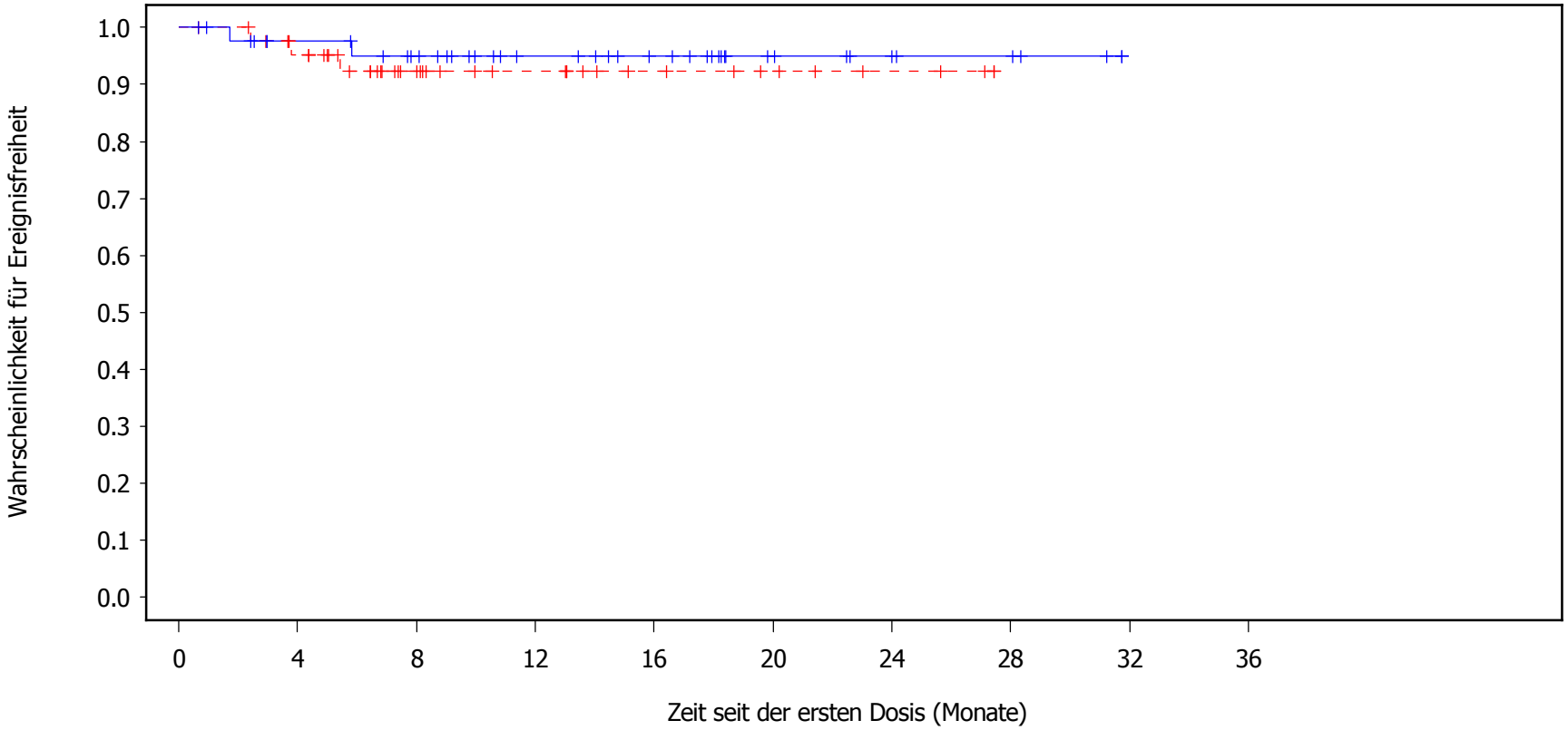
Figure 3.3.1.1D.84 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Hypertonie
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	33	24	18	10	7	4	0	0	CTx + Durvalumab
46	36	19	13	7	5	3	0	0	0	CTx

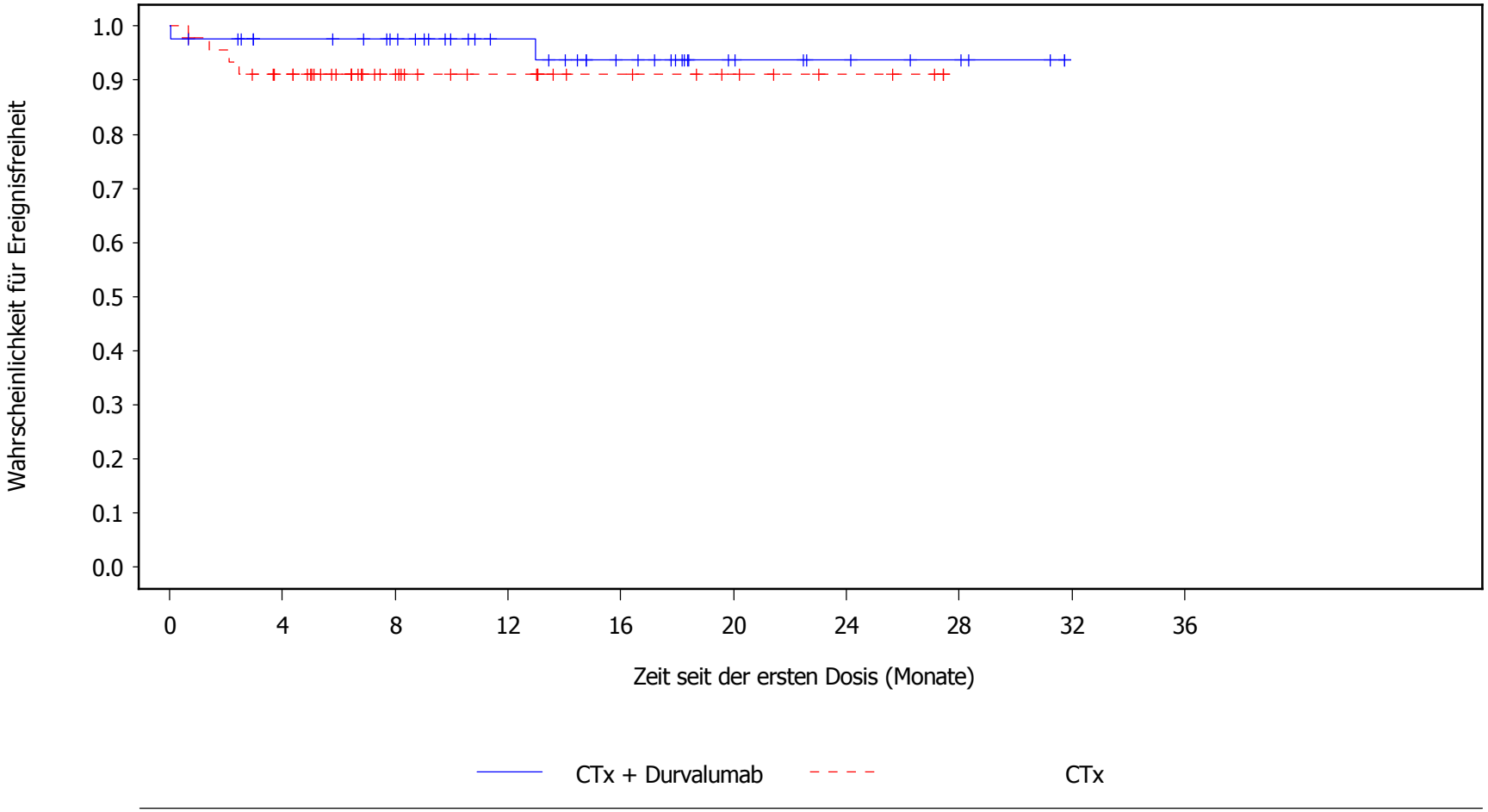
Figure 3.3.1.1D.85 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Infektionen und parasitaere Erkrankungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	37	32	23	18	9	6	4	0	0	CTx + Durvalumab
46	39	22	15	9	6	3	0	0	0	CTx

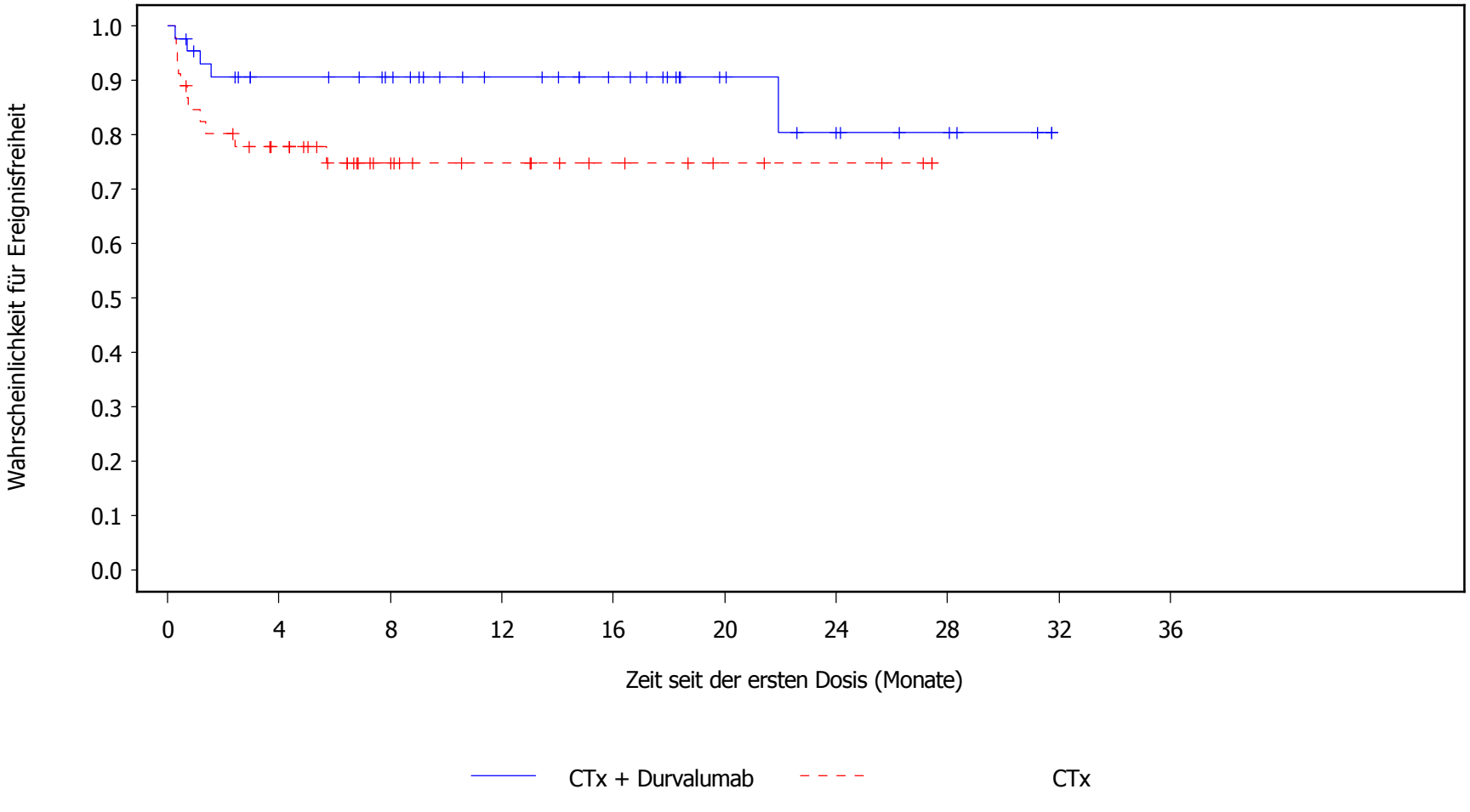
Figure 3.3.1.1D.86 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Stoffwechsel- und Ernaehrungsstoerungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	34	25	18	9	6	4	0	0	CTx + Durvalumab
46	38	21	14	9	6	3	0	0	0	CTx

Figure 3.3.1.1D.87 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Untersuchungen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	30	23	18	10	7	4	0	0	CTx + Durvalumab
46	31	16	11	7	4	3	0	0	0	CTx

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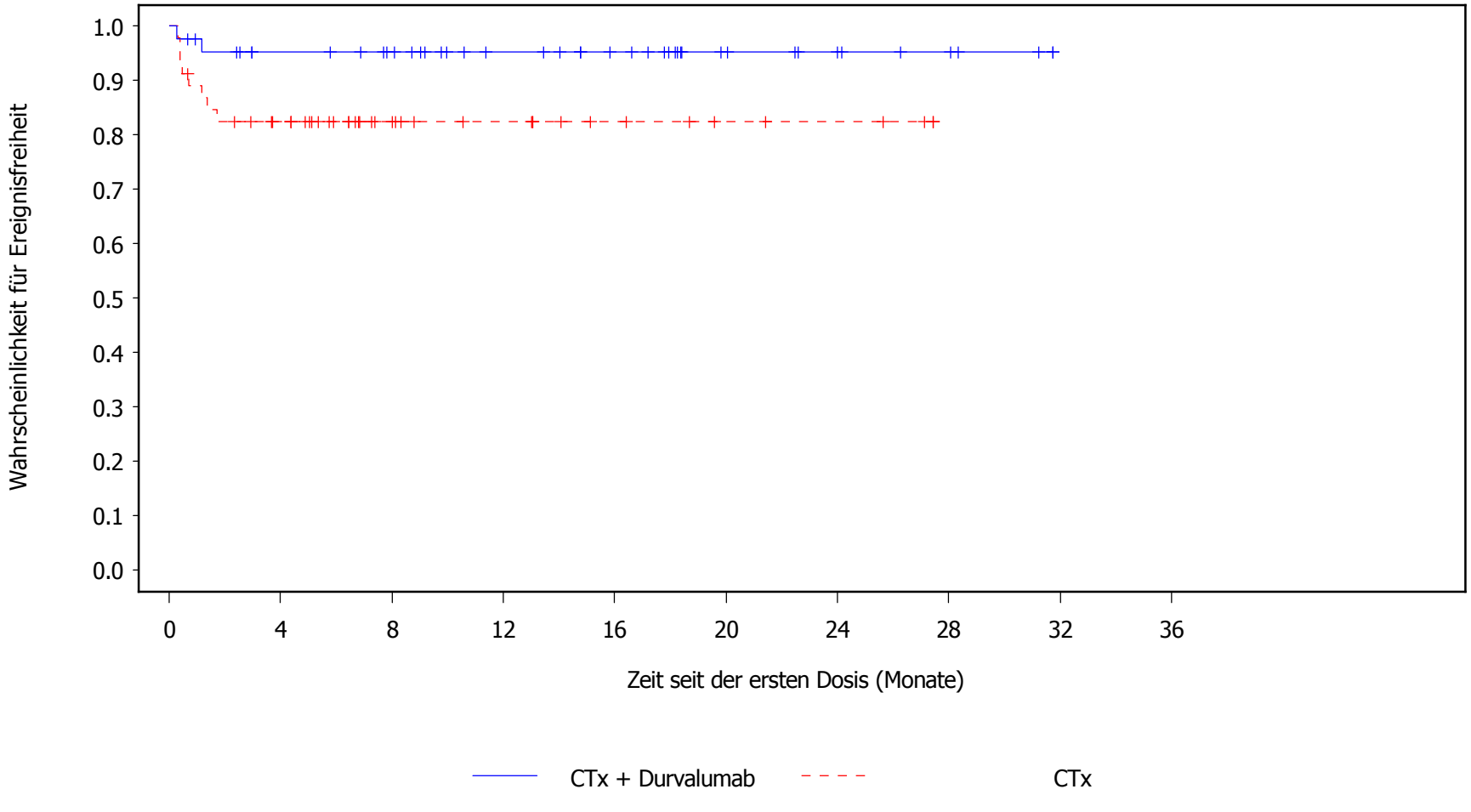
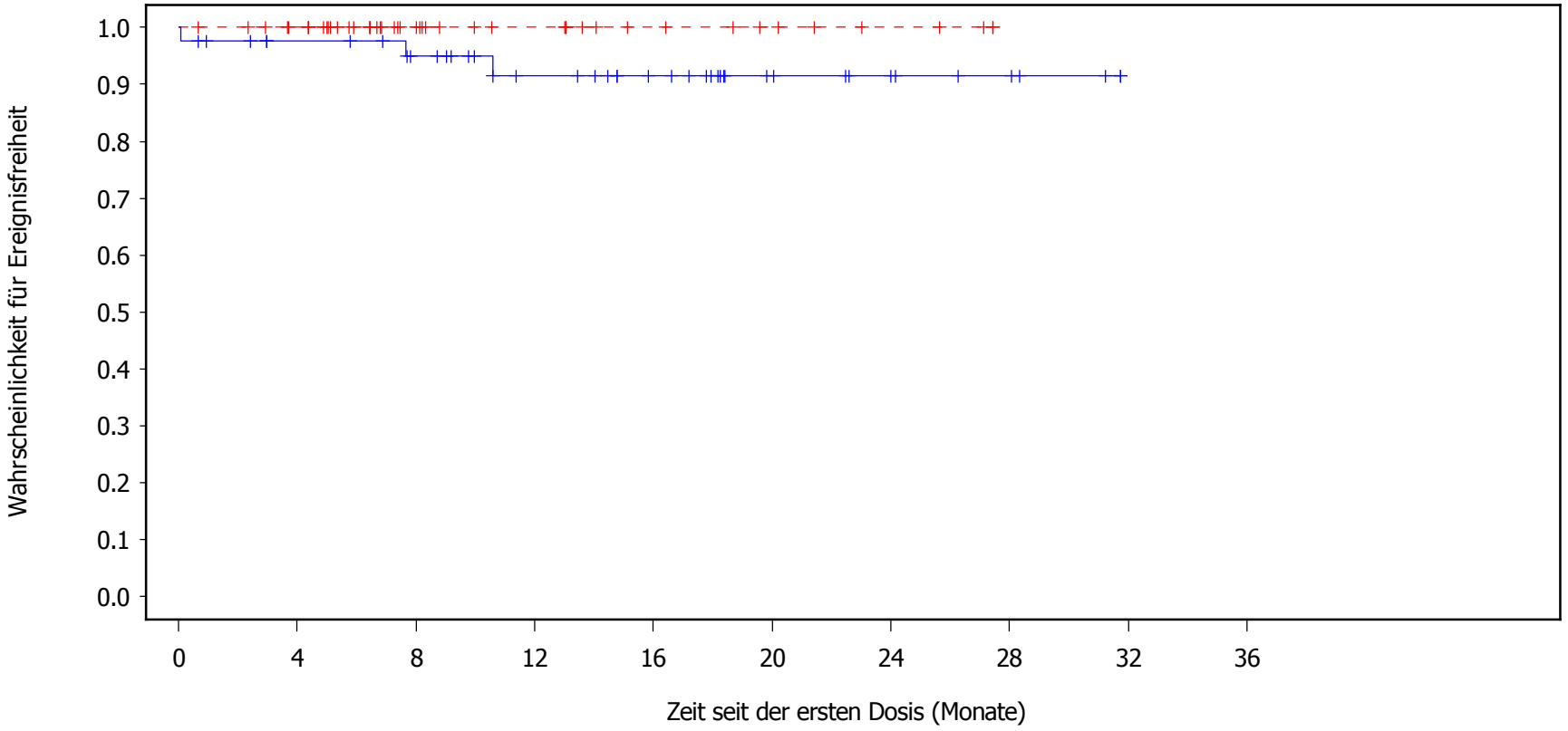
Figure 3.3.1.1D.88 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Neutrophilenzahl erniedrigt
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	32	24	19	10	7	4	0	0	CTx + Durvalumab
46	33	17	12	7	4	3	0	0	0	CTx

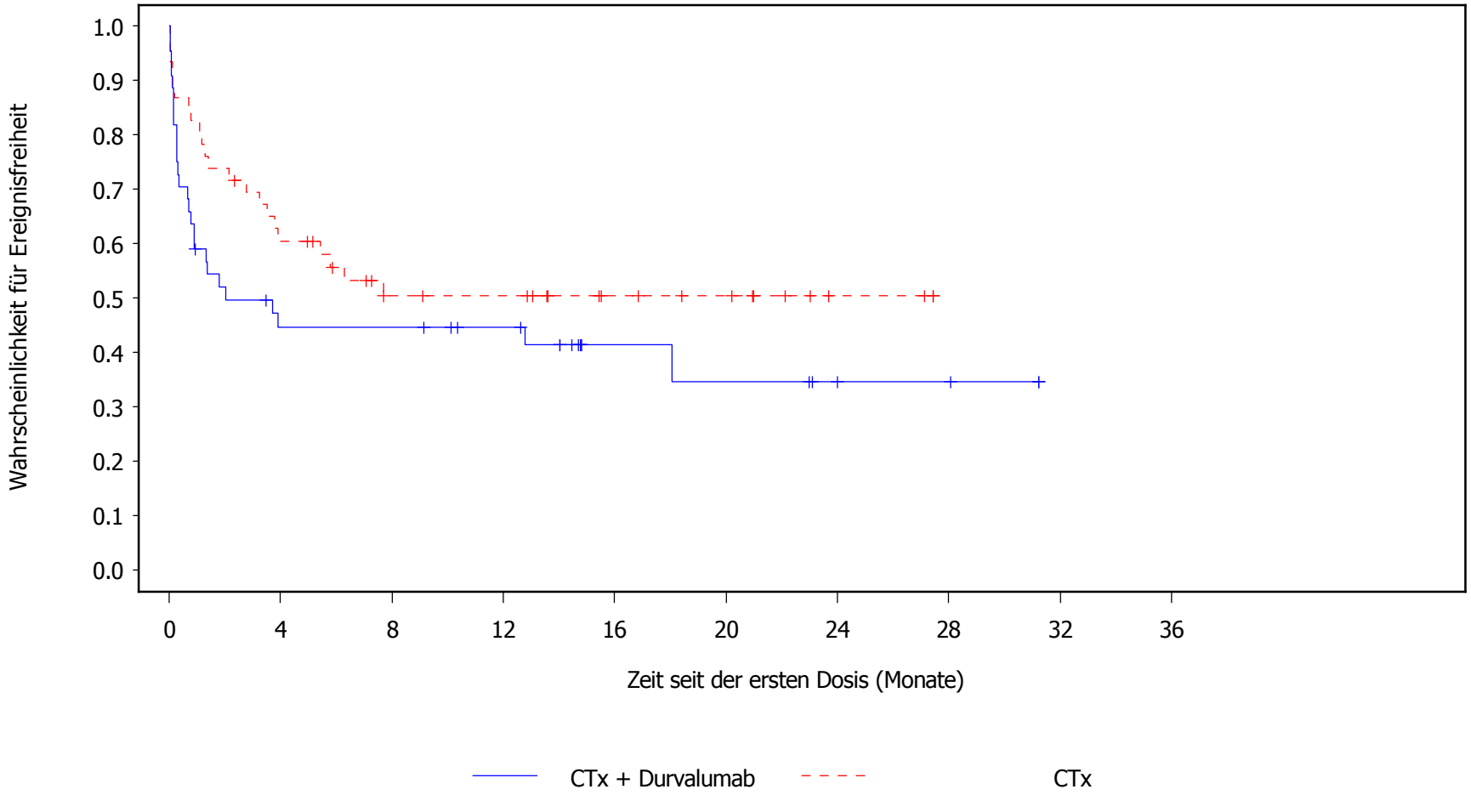
Figure 3.3.1.1D.89 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	33	25	19	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

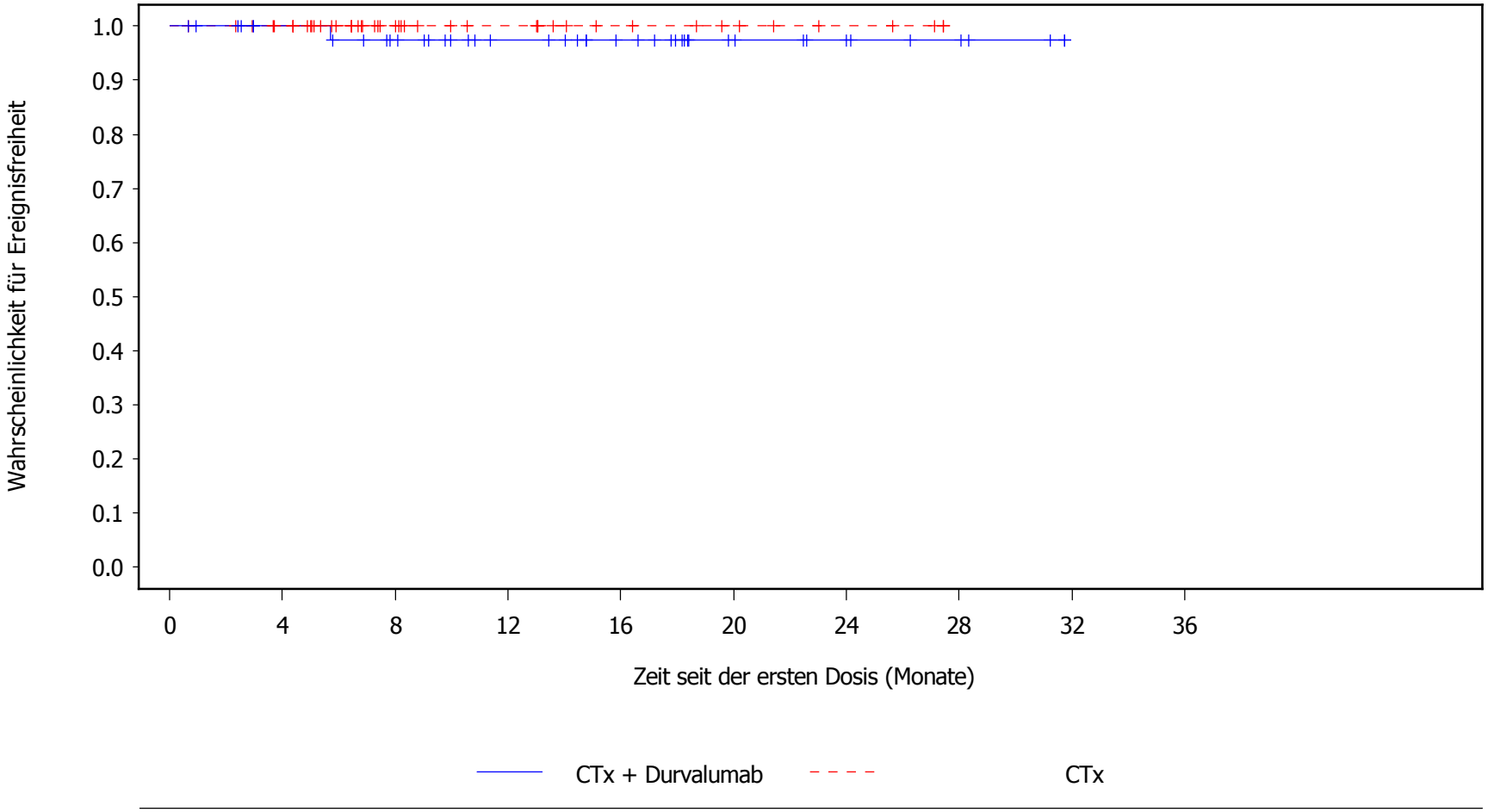
Figure 3.3.1.1D.90 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	18	18	15	6	5	3	2	0	0	CTx + Durvalumab
46	27	17	16	10	8	2	0	0	0	CTx

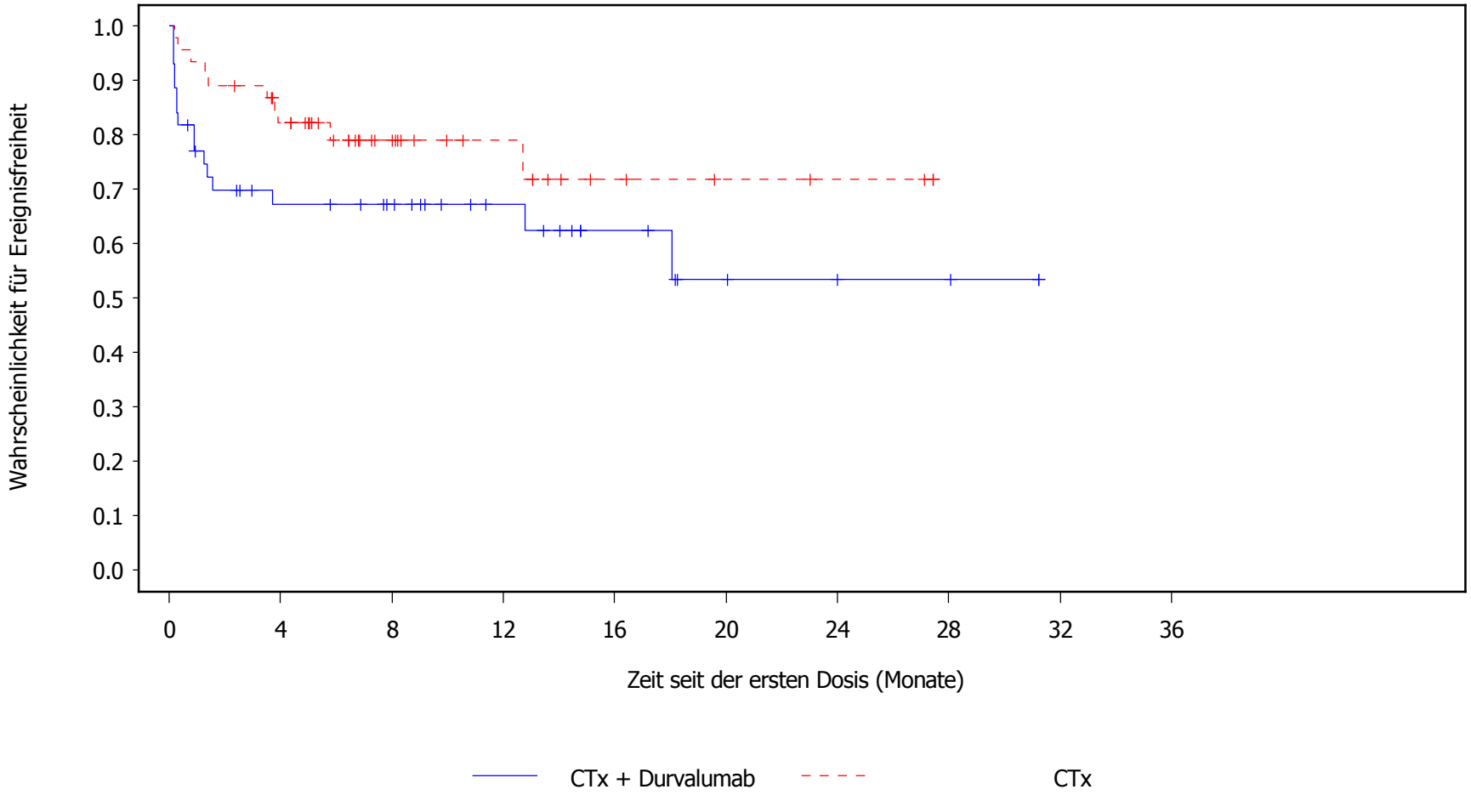
Figure 3.3.1.1D.91 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Andere seltene/sonstige Ereignisse
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	33	25	19	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

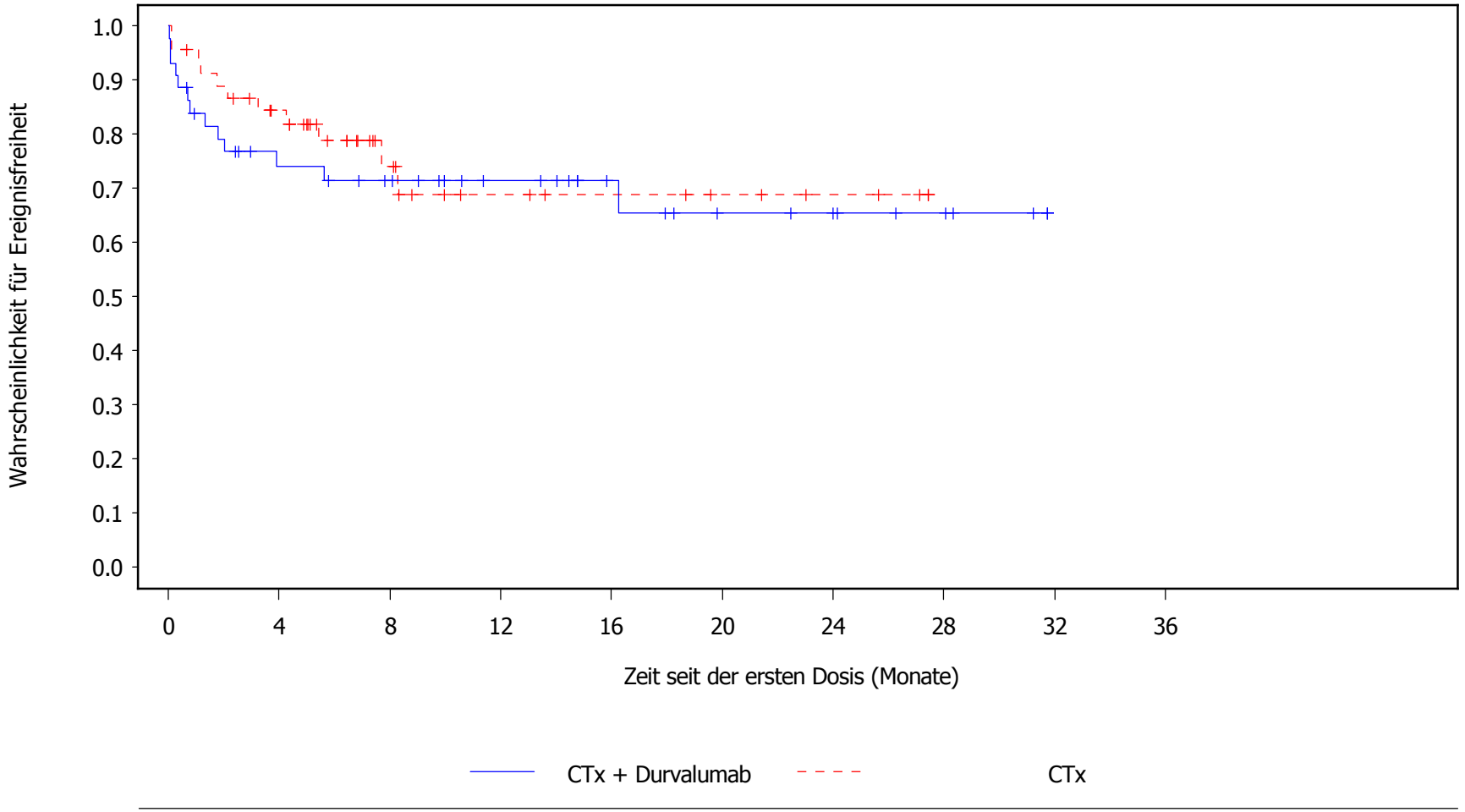
Figure 3.3.1.1D.92 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Dermatitis/Hautausschlag
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	25	21	14	8	4	3	2	0	0	CTx + Durvalumab
46	35	18	11	5	3	2	0	0	0	CTx

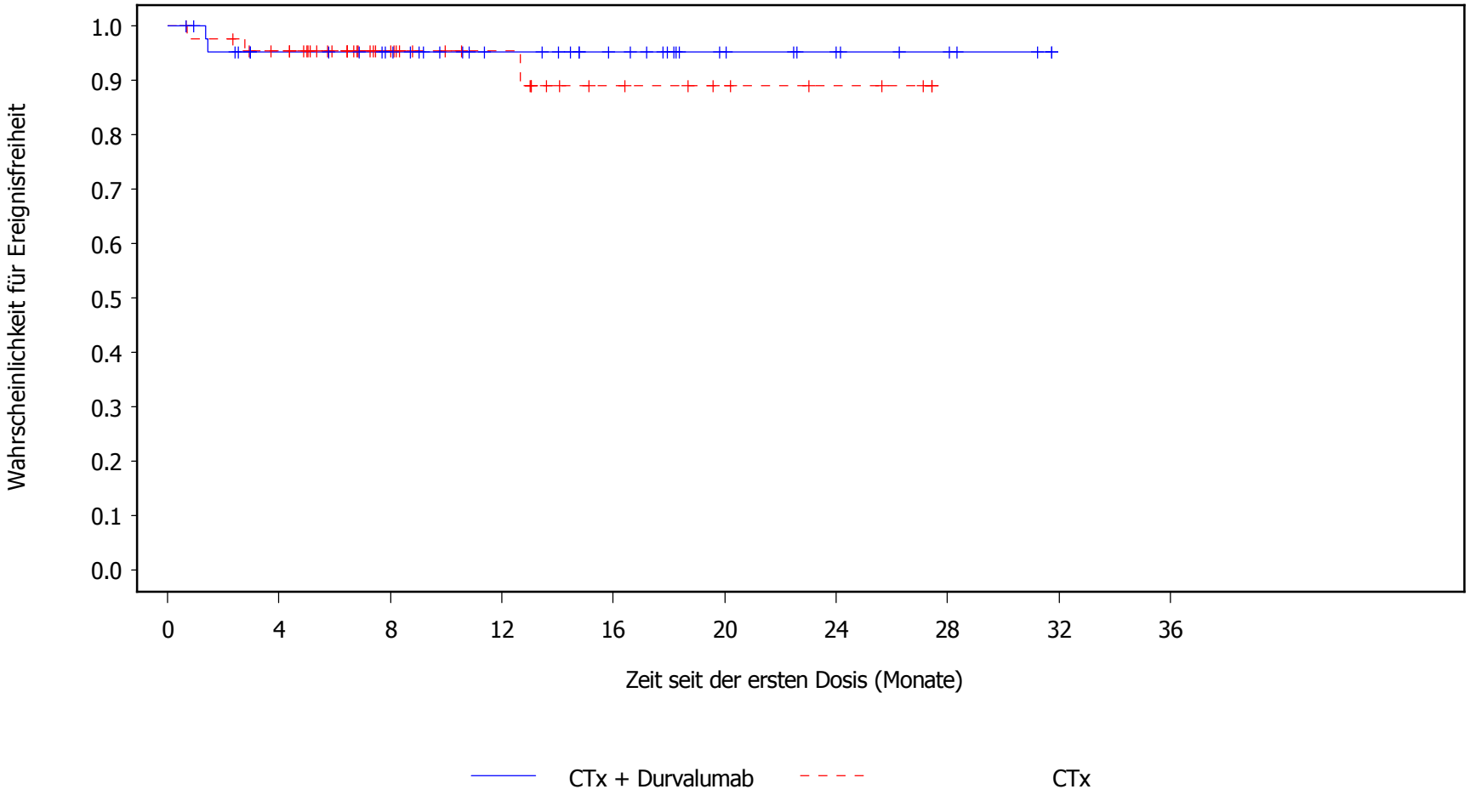
Figure 3.3.1.1D.93 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Diarrhö/Kolitis
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	28	24	18	12	8	7	4	0	0	CTx + Durvalumab
46	34	16	9	7	5	3	0	0	0	CTx

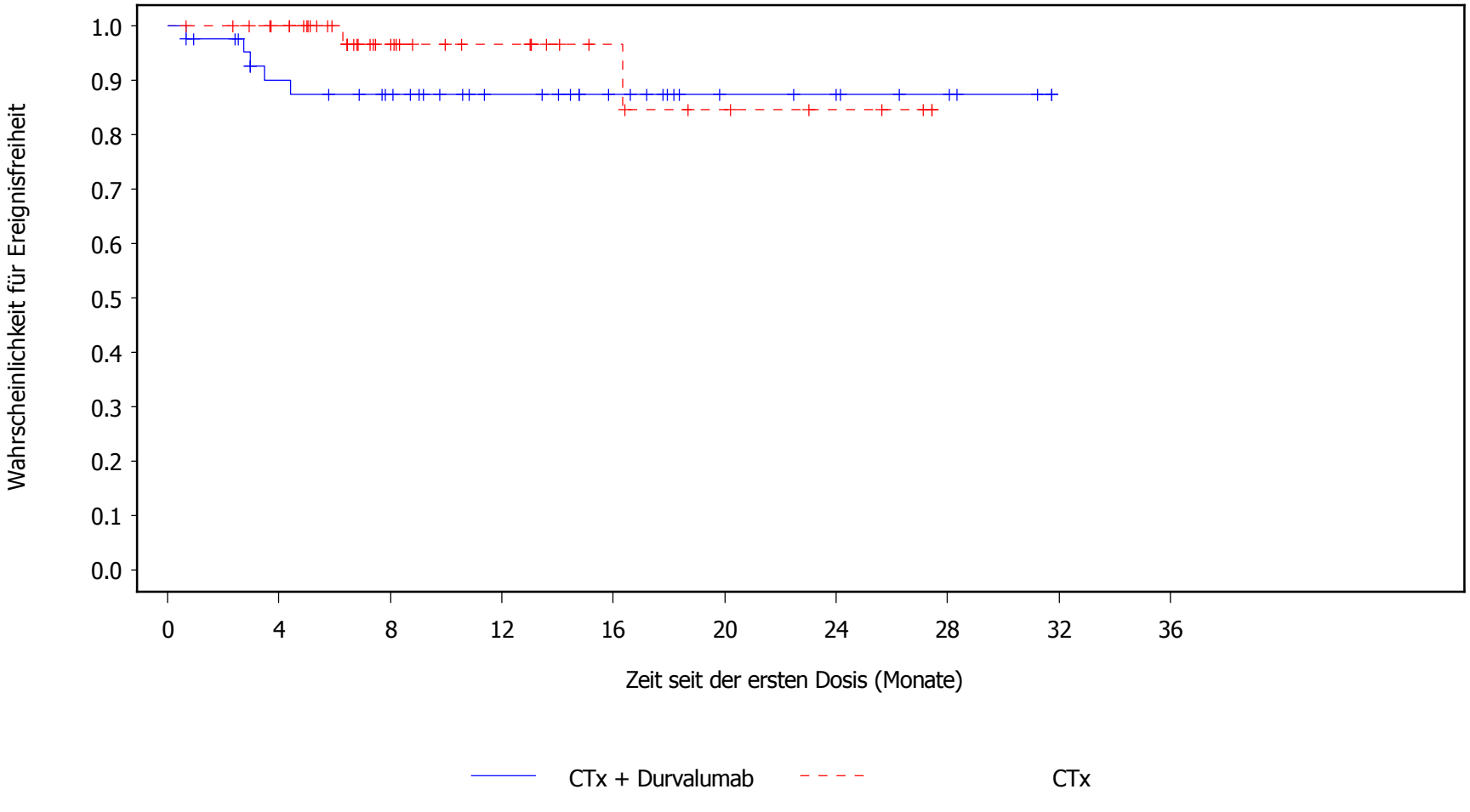
Figure 3.3.1.1D.94 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Hyperthyreose Ereignisse
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	32	24	18	10	7	4	0	0	CTx + Durvalumab
46	40	22	15	8	5	3	0	0	0	CTx

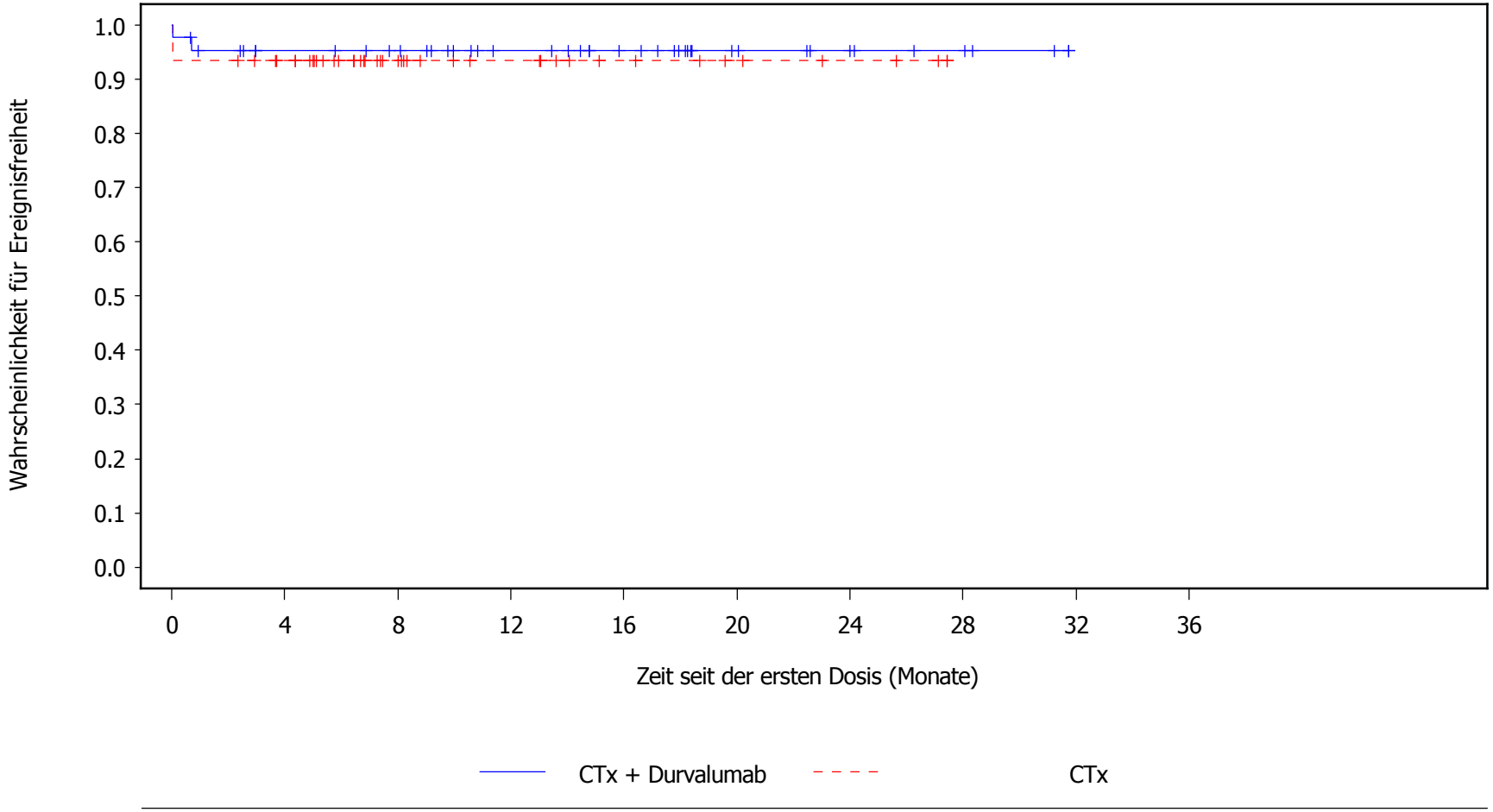
Figure 3.3.1.1D.95 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Hypothyreose Ereignisse
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	34	29	21	15	8	7	4	0	0	CTx + Durvalumab
46	41	21	14	8	5	3	0	0	0	CTx

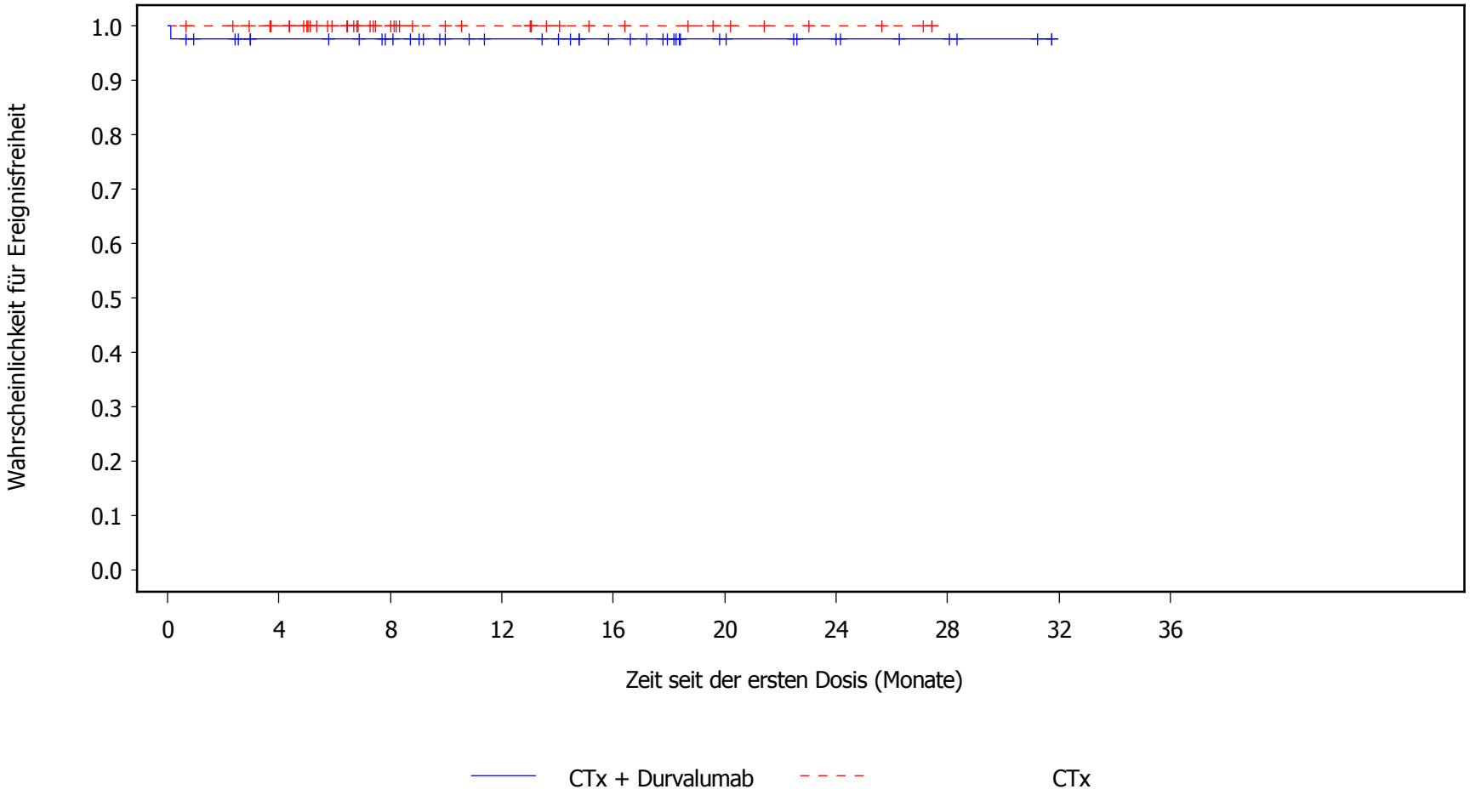
Figure 3.3.1.1D.96 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	33	25	19	10	7	4	0	0	CTx + Durvalumab
46	39	20	13	8	5	3	0	0	0	CTx

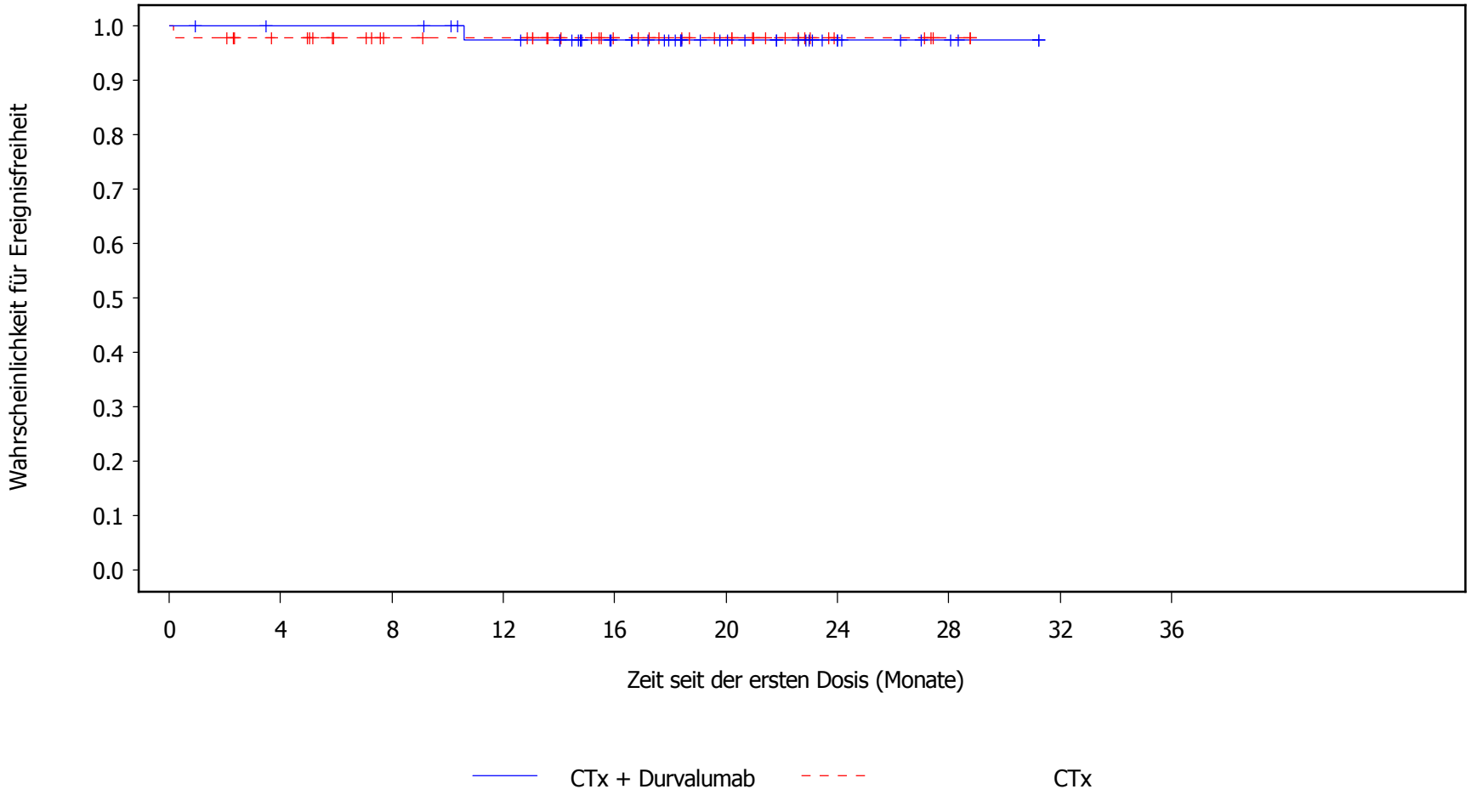
Figure 3.3.1.1D.97 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Myositis
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	37	33	25	19	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

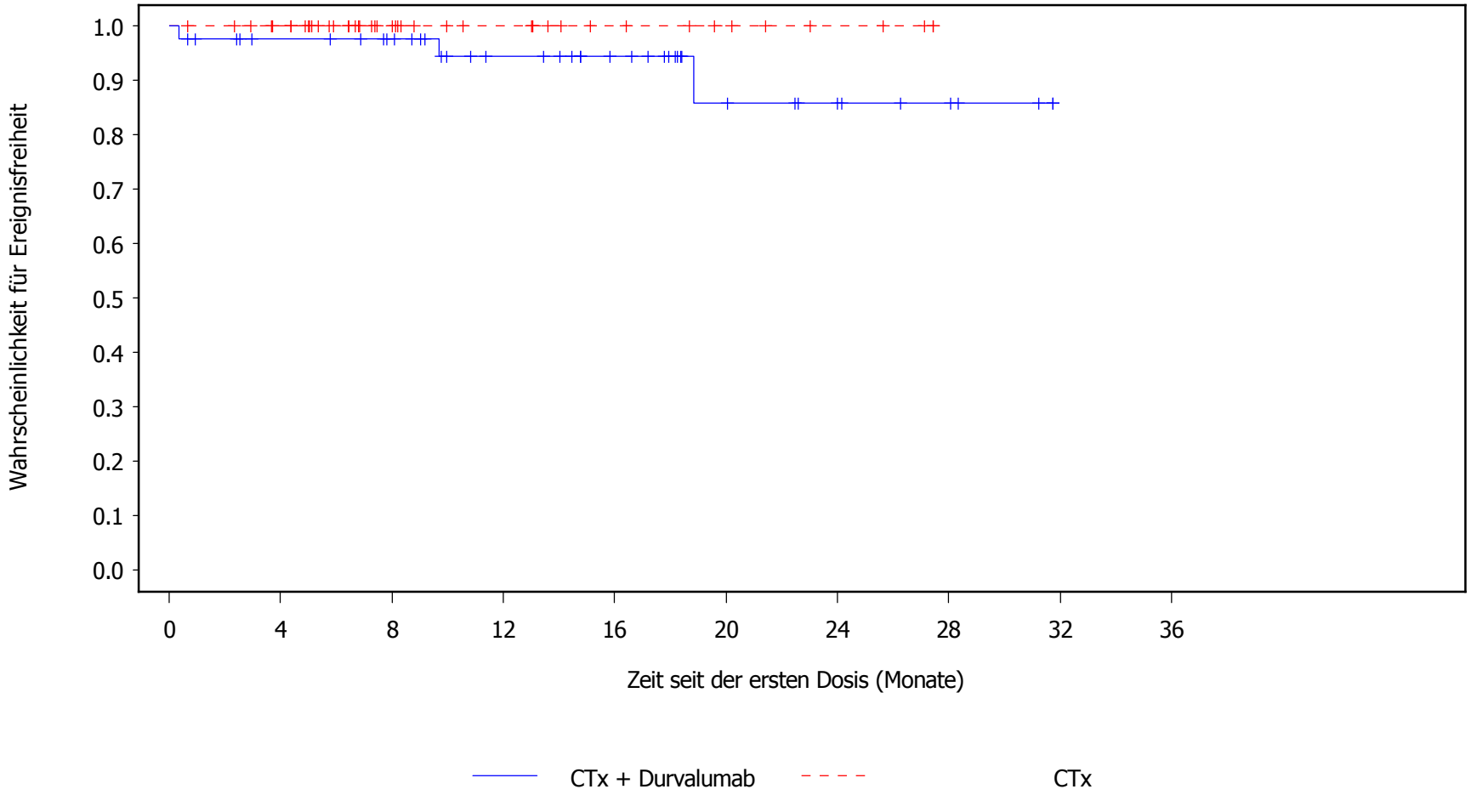
Figure 3.3.1.1D.98 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Neue primäre Malignität
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	42	42	38	28	17	7	3	0	0	CTx + Durvalumab
46	41	32	31	21	15	4	1	0	0	CTx

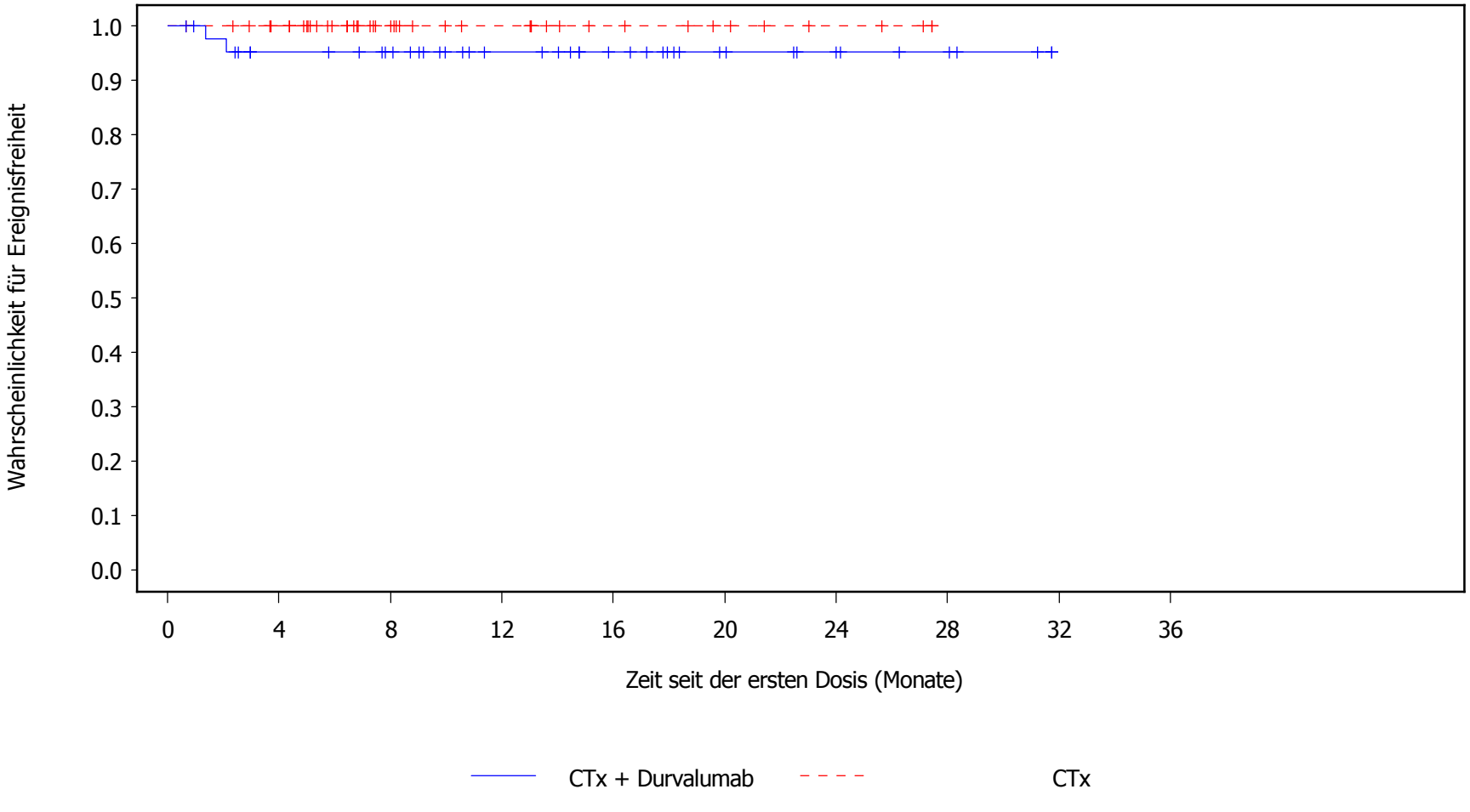
Figure 3.3.1.1D.99 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Pneumonitis
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	34	25	19	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

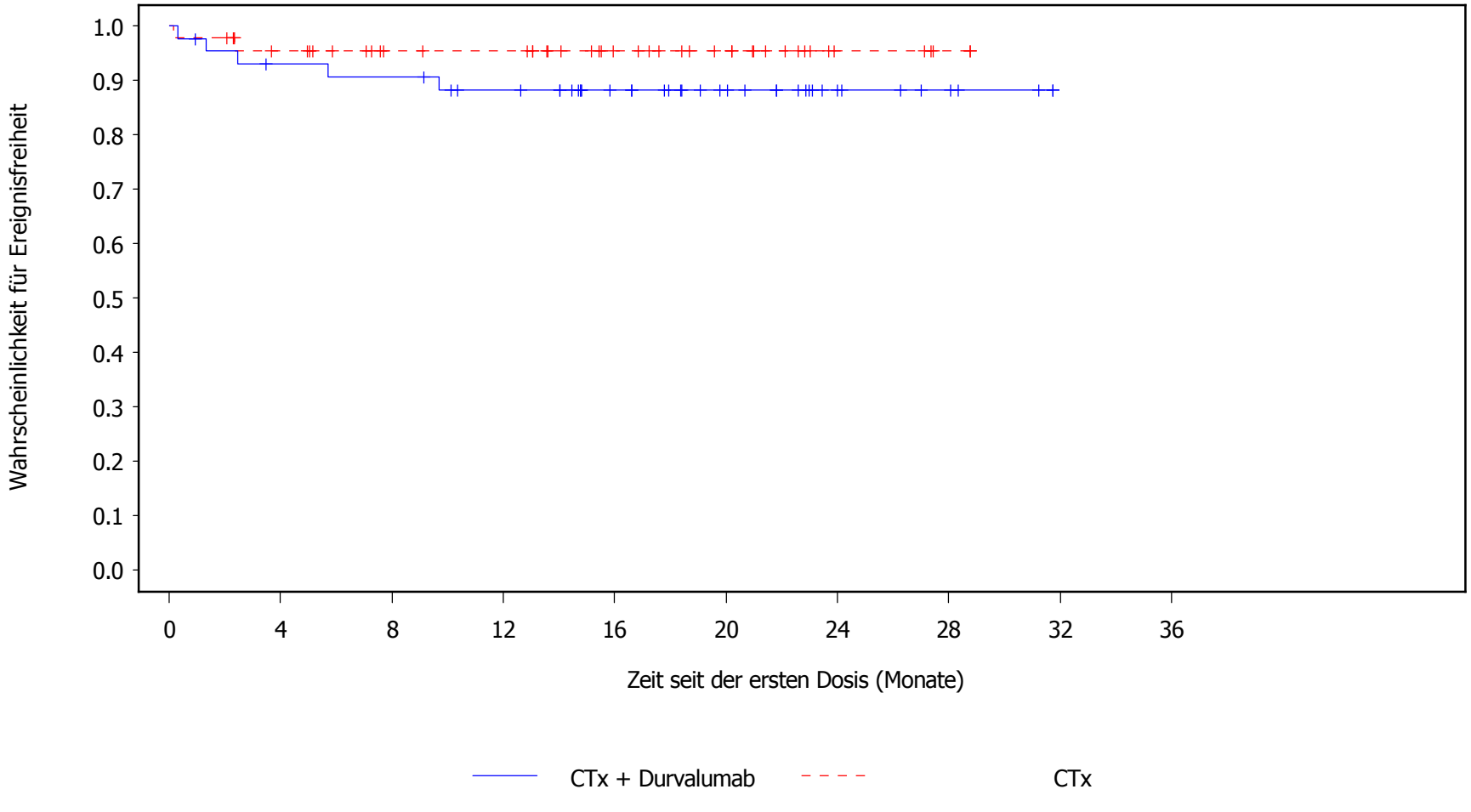
Figure 3.3.1.1D.100 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Thyreoiditis
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	32	23	17	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

Figure 3.3.1.1D.101 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	39	38	34	25	17	8	4	0	0	CTx + Durvalumab
46	40	32	31	21	15	4	1	0	0	CTx

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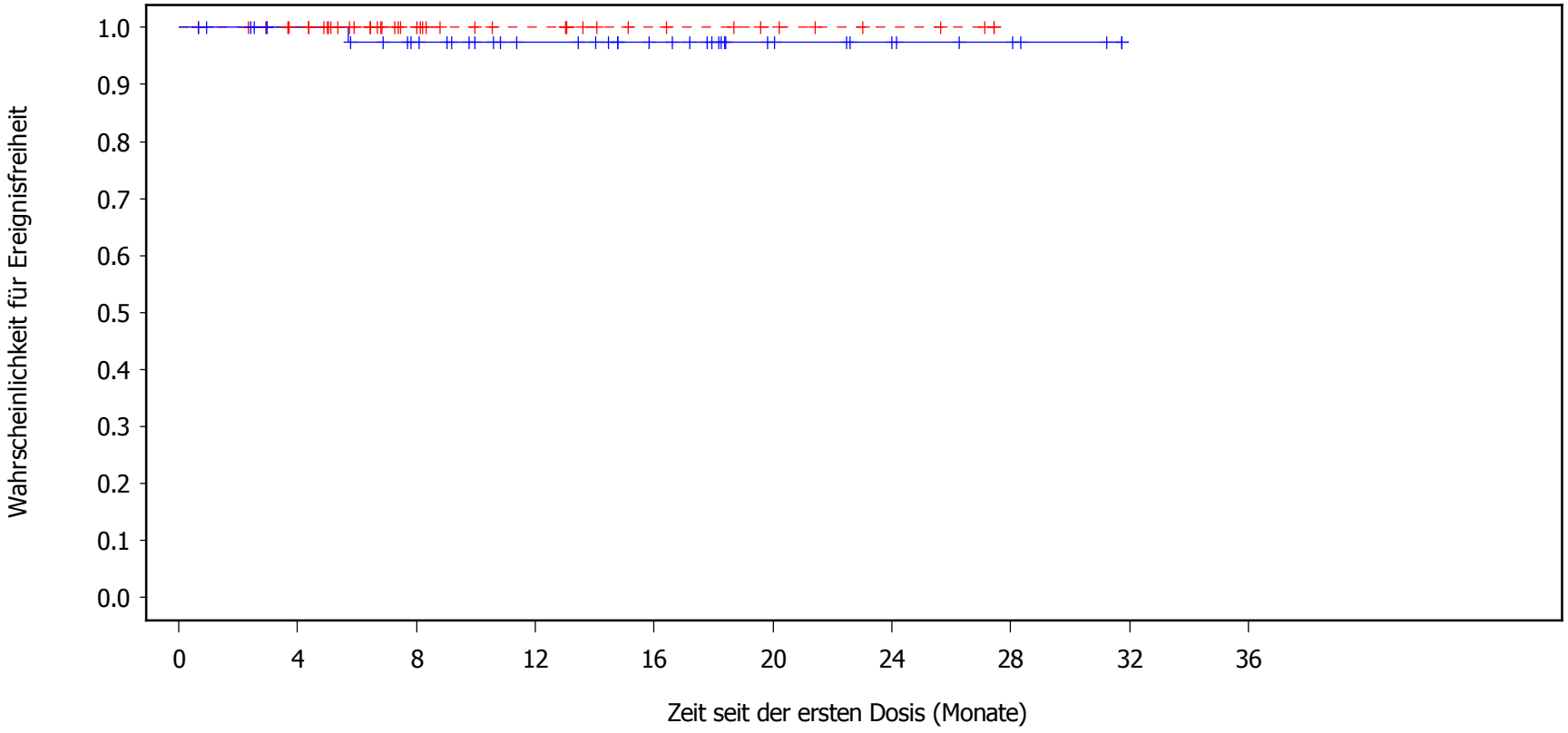
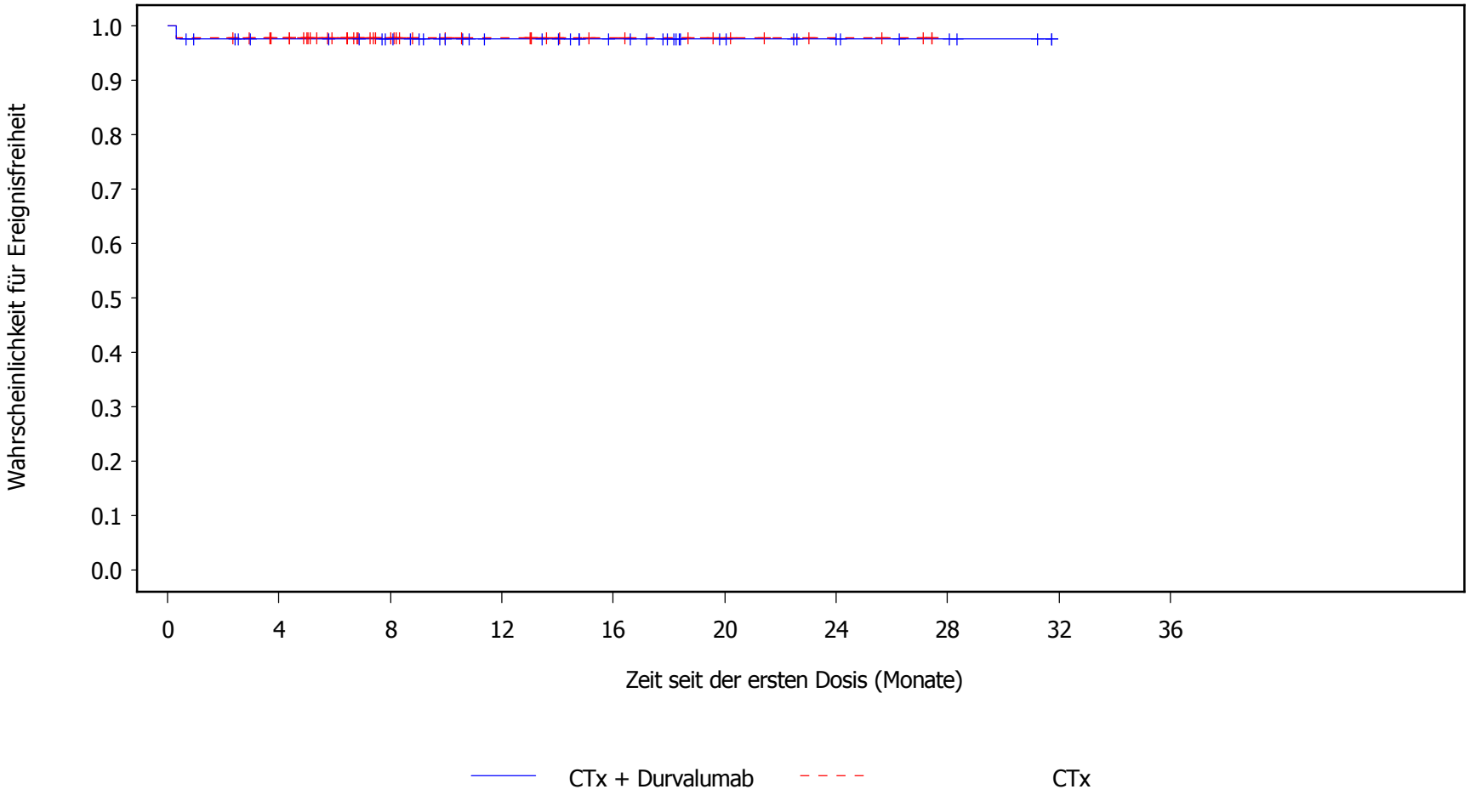
Figure 3.3.1.1D.102 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	33	25	19	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

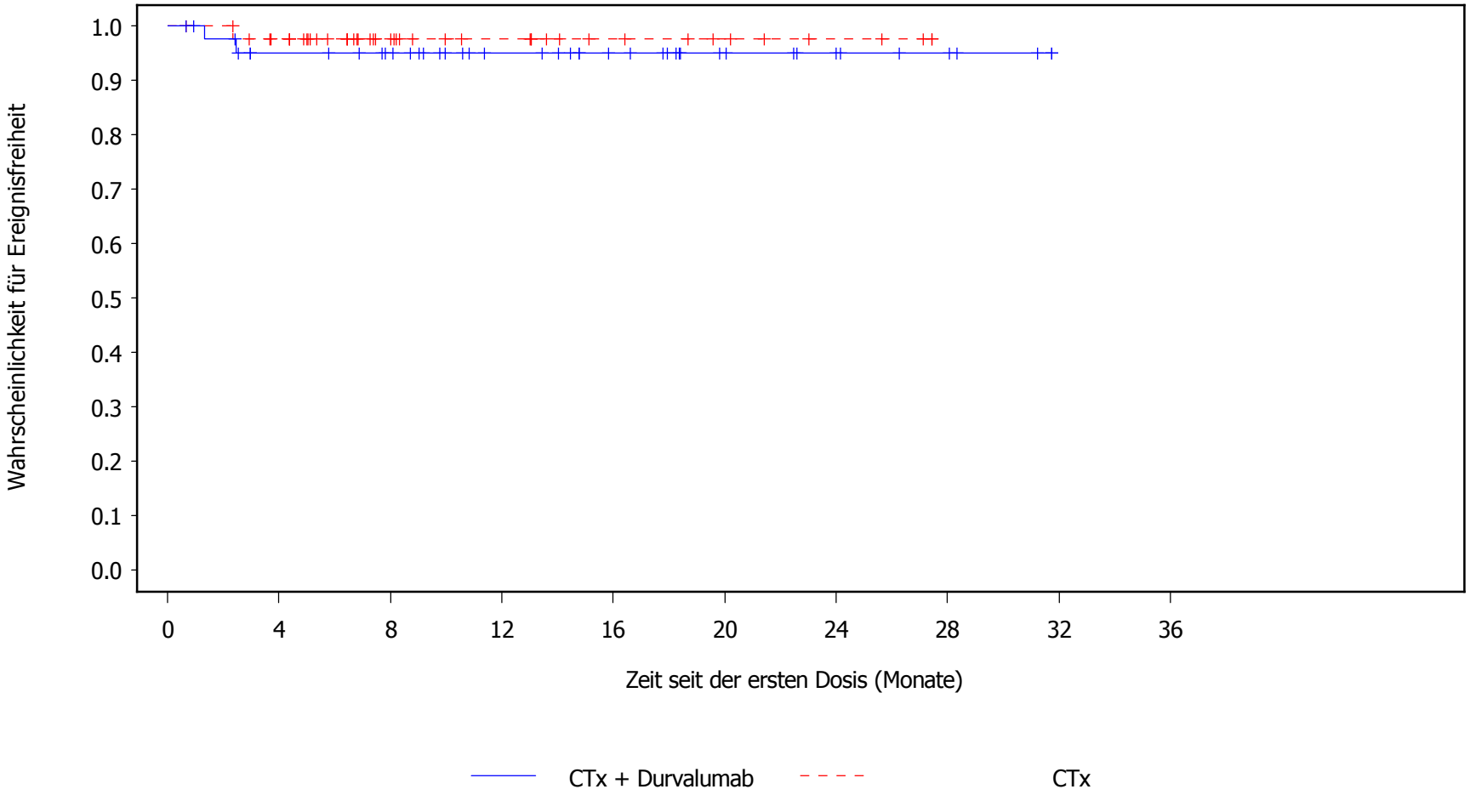
Figure 3.3.1.1D.103 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Dermatitis/Hautausschlag
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	34	25	19	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

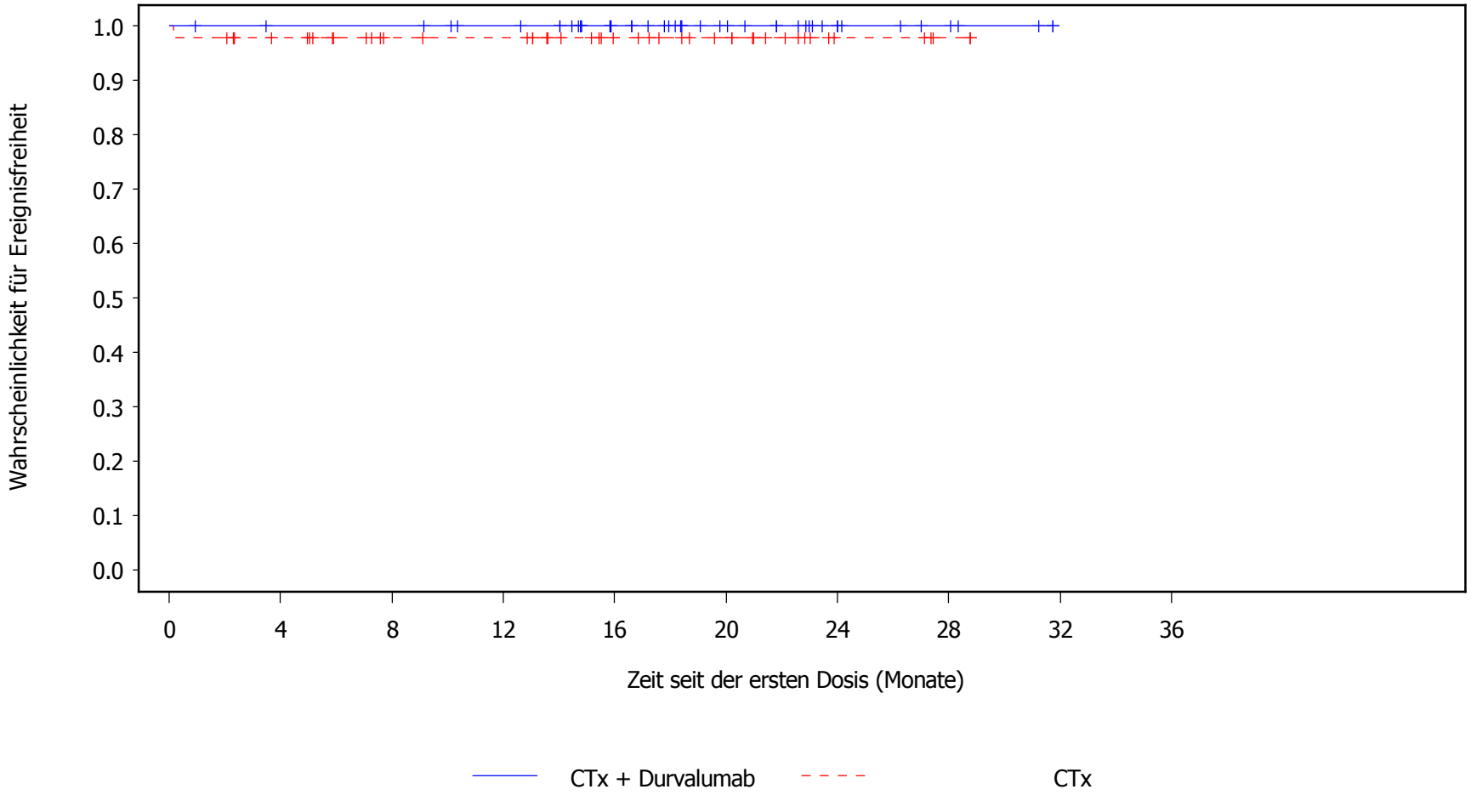
Figure 3.3.1.1D.104 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Diarrhö/Kolitis
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	36	32	23	17	10	7	4	0	0	CTx + Durvalumab
46	40	22	15	9	6	3	0	0	0	CTx

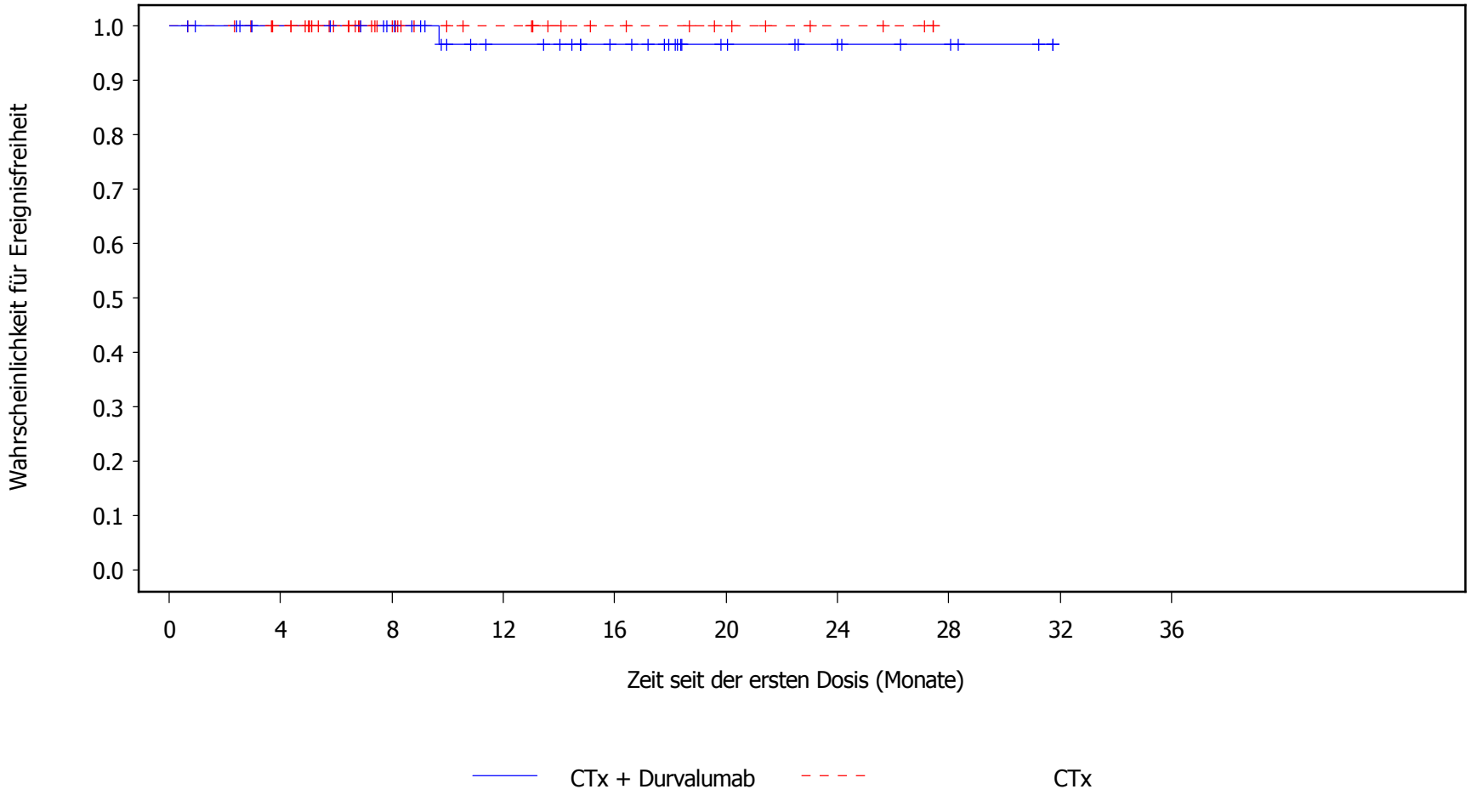
Figure 3.3.1.1D.105 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Neue primäre Malignität
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	42	42	39	29	18	8	4	0	0	CTx + Durvalumab
46	41	32	31	21	15	4	1	0	0	CTx

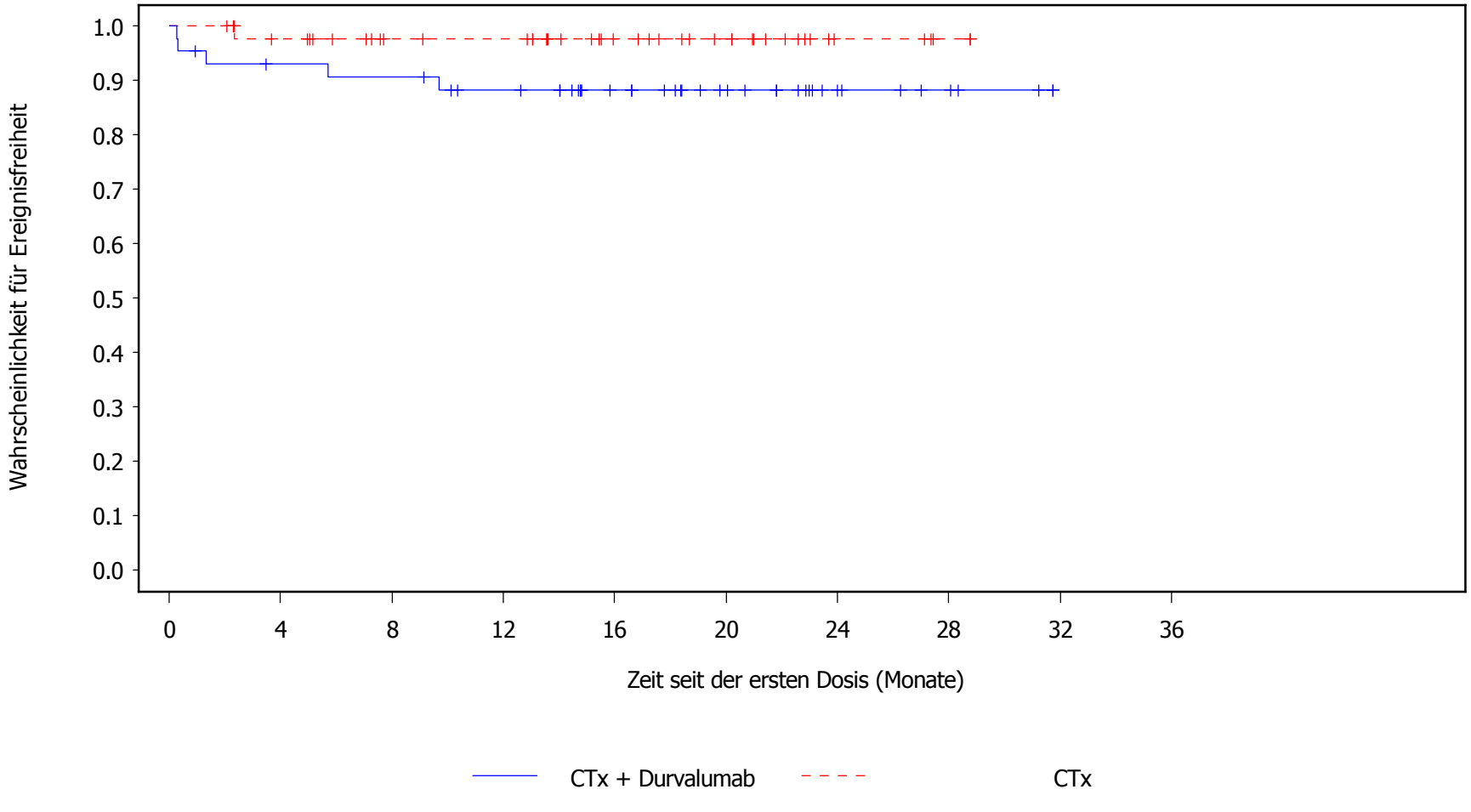
Figure 3.3.1.1D.106 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Pneumonitis
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	34	25	19	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

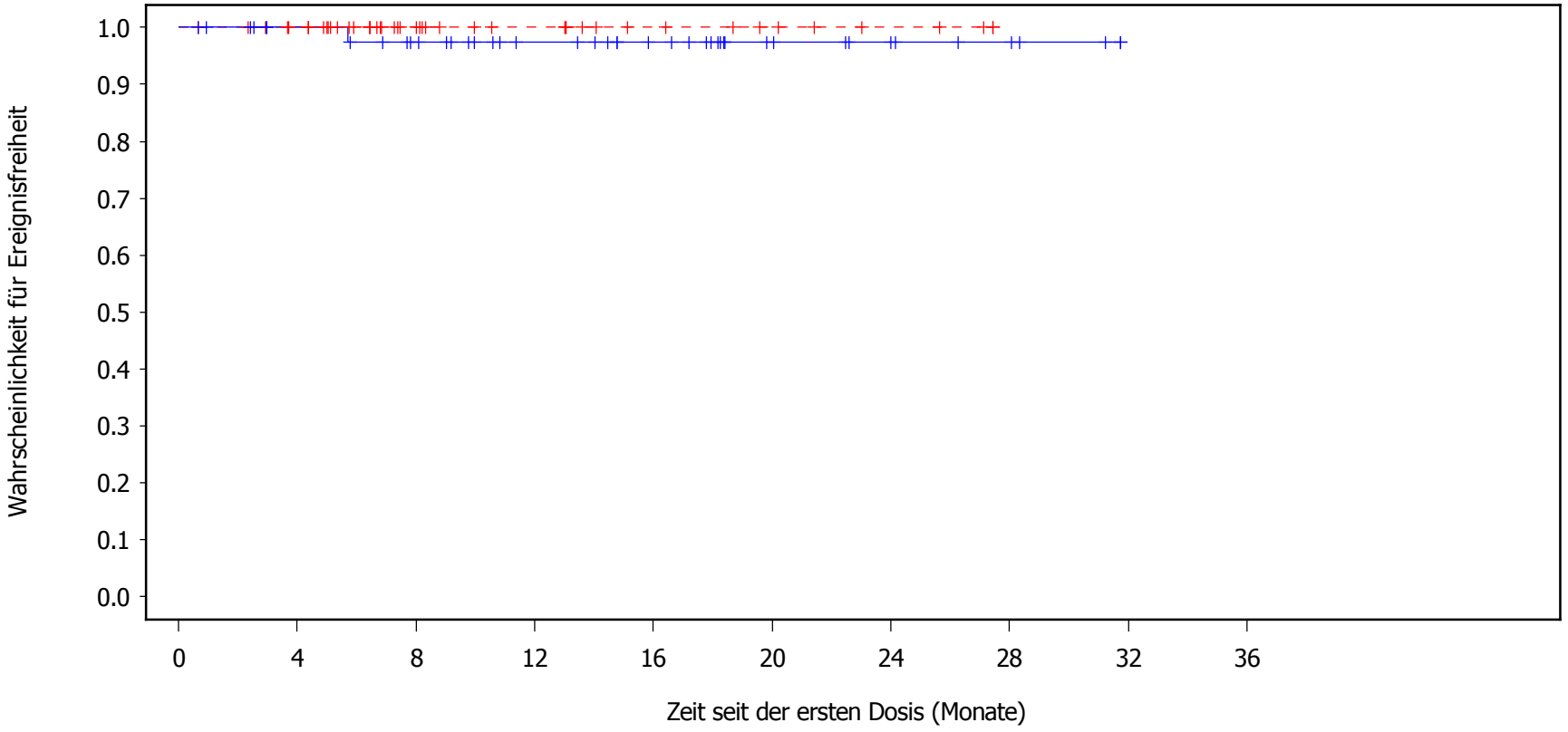
Figure 3.3.1.1D.107 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUESI
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	39	38	34	25	17	8	4	0	0	CTx + Durvalumab
46	41	33	32	21	15	4	1	0	0	CTx

Figure 3.3.1.1D.108 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUESI GT: Andere seltene/sonstige Ereignisse
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	33	25	19	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

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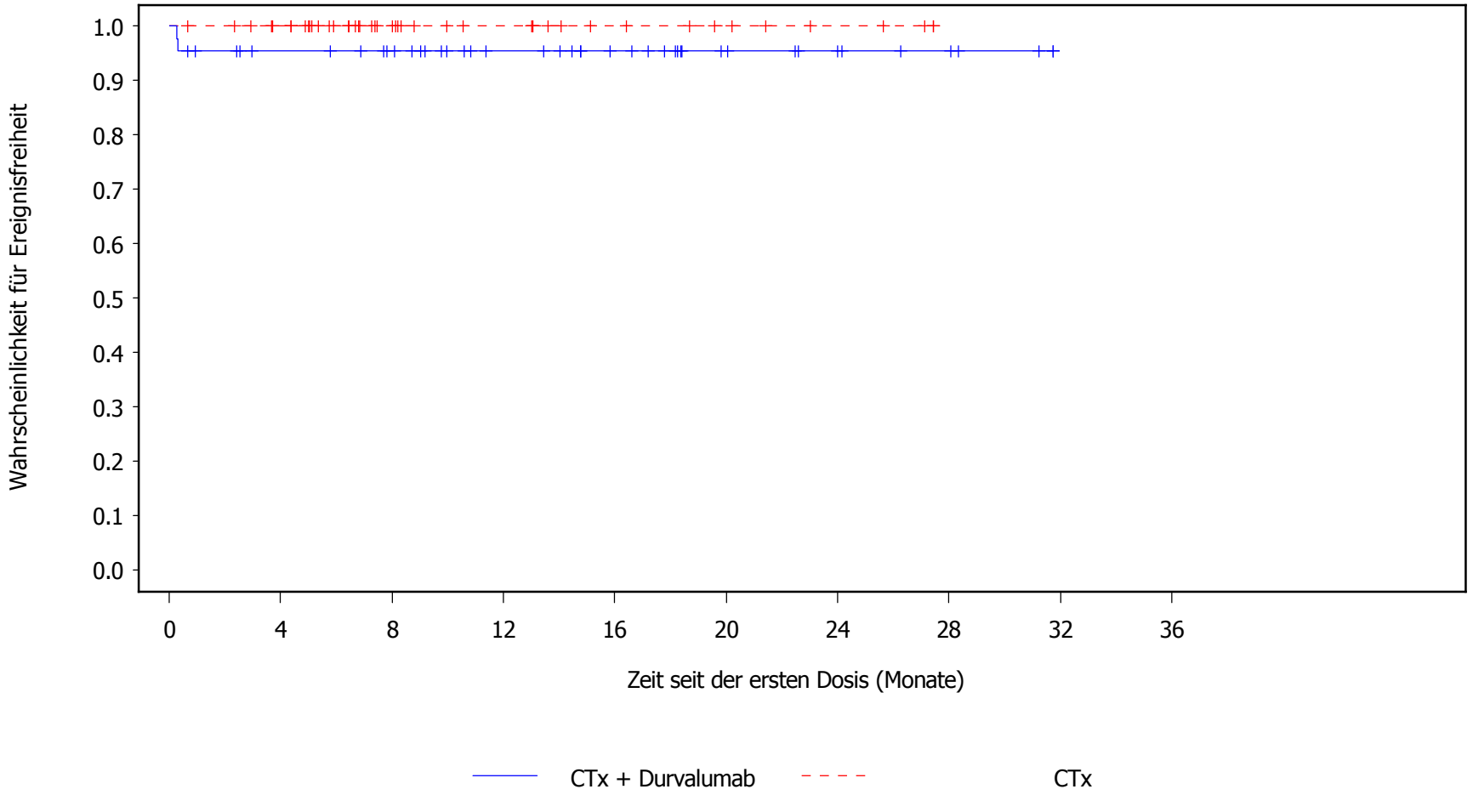
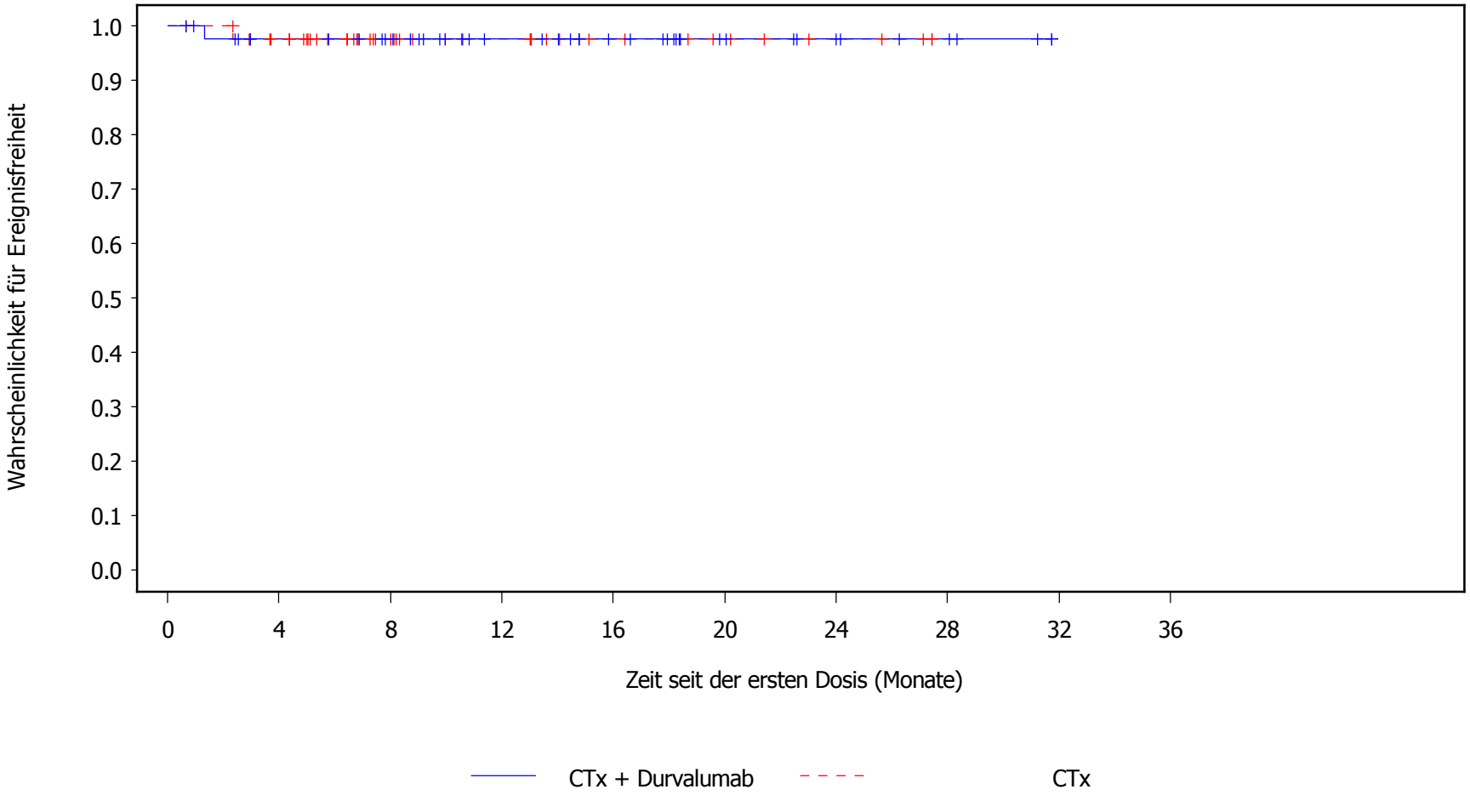
Figure 3.3.1.1D.109 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUESI GT: Dermatitis/Hautausschlag
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	37	33	24	18	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

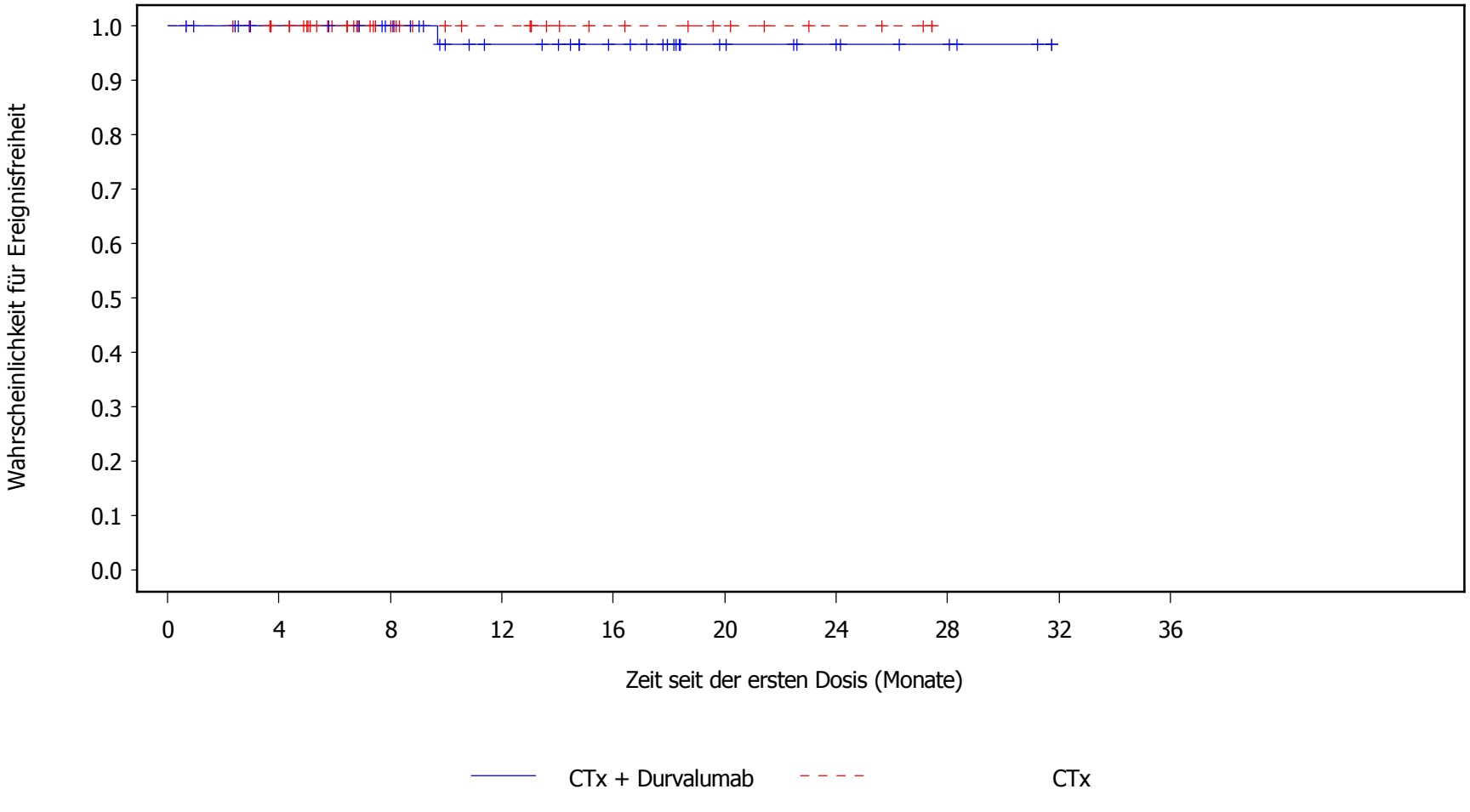
Figure 3.3.1.1D.110 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUESI GT: Diarrhö/Kolitis
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	37	33	24	18	10	7	4	0	0	CTx + Durvalumab
46	40	22	15	9	6	3	0	0	0	CTx

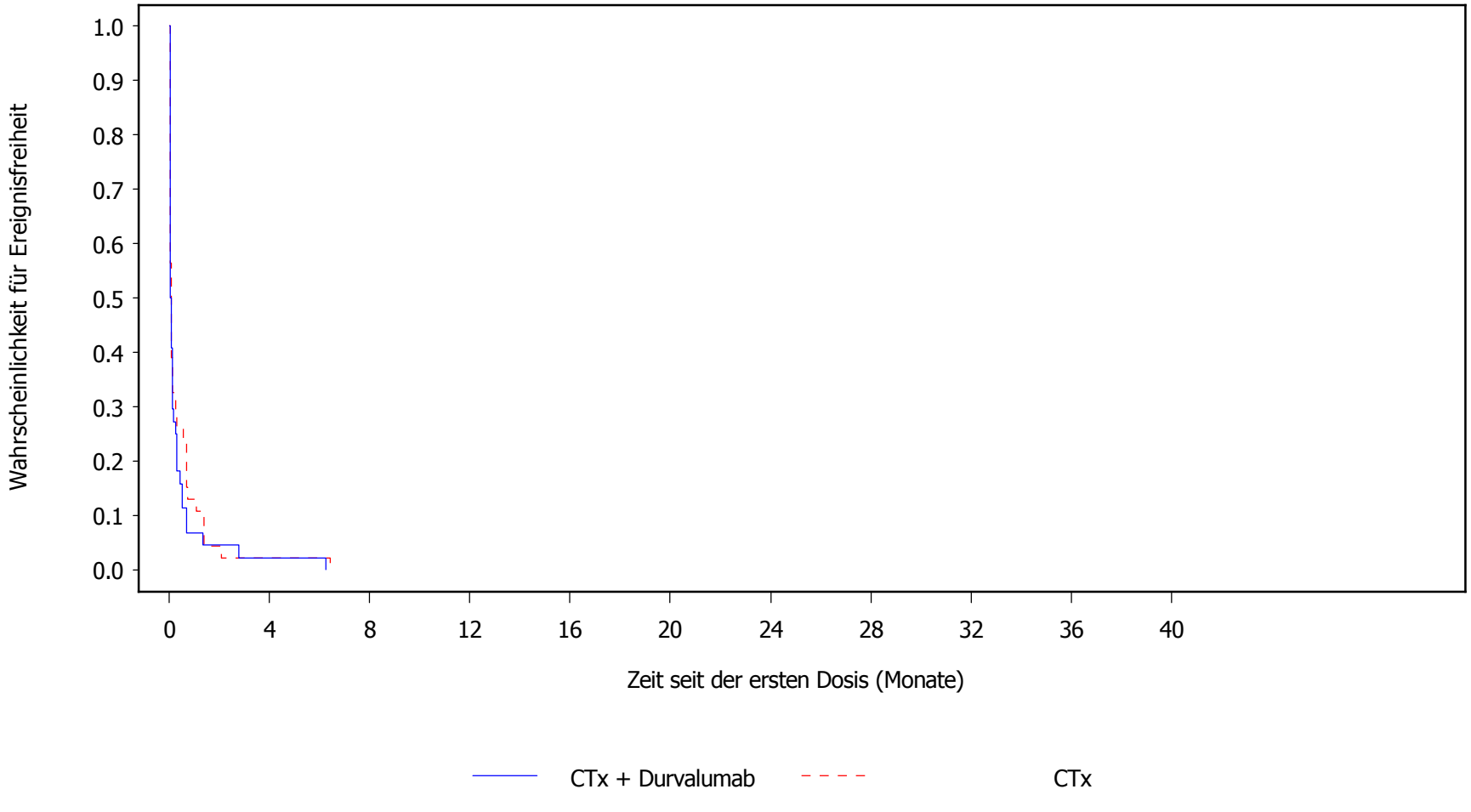
Figure 3.3.1.1D.111 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUESI GT: Pneumonitis
Patients with dMMR tumour status, DCO 12APR2023



Anzahl an Patienten unter Risiko:

44	38	34	25	19	10	7	4	0	0	CTx + Durvalumab
46	41	22	15	9	6	3	0	0	0	CTx

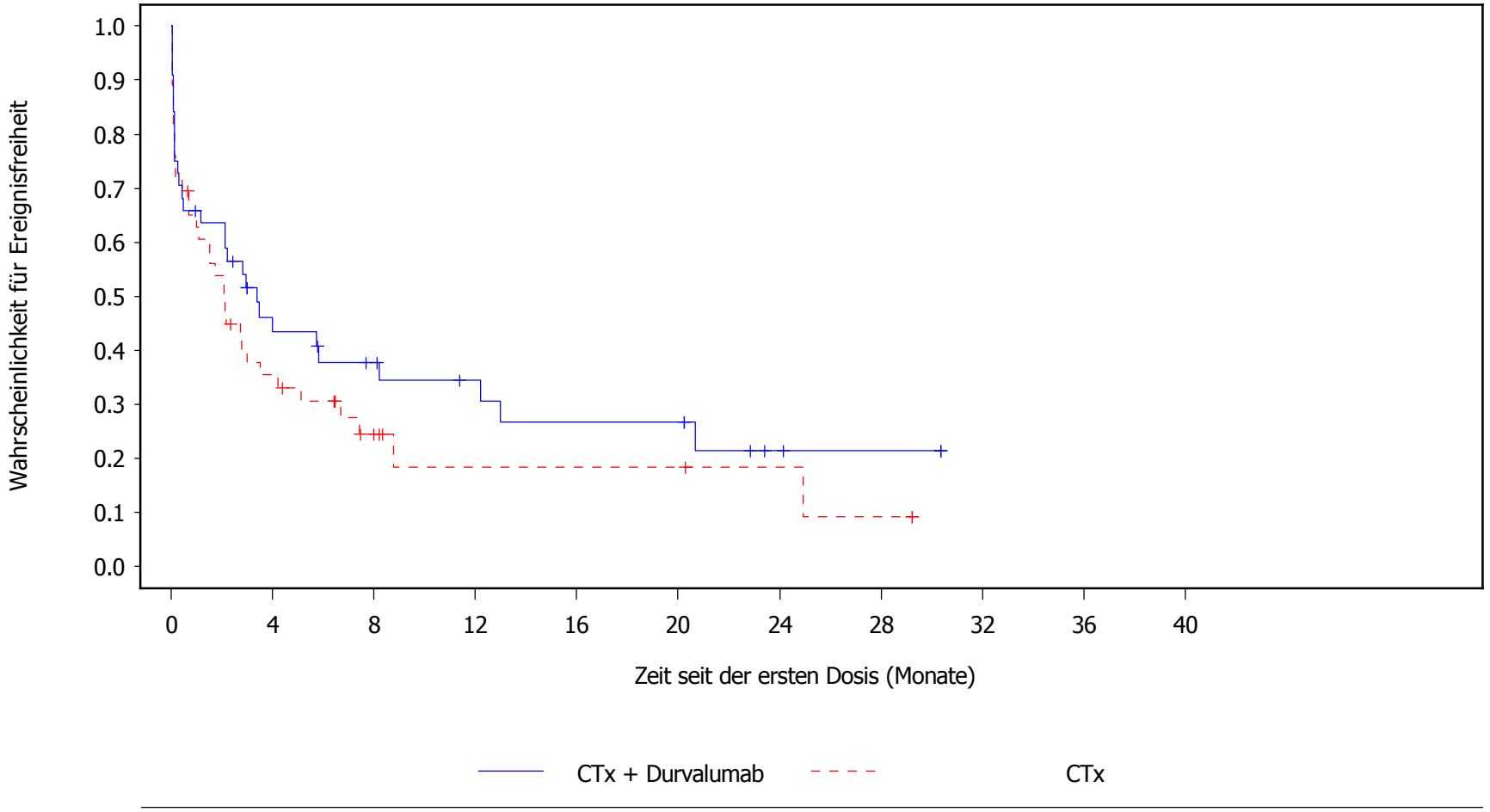
Figure 3.3.1.2D.1 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UE
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	1	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
46	1	0	0	0	0	0	0	0	0	0	CTx

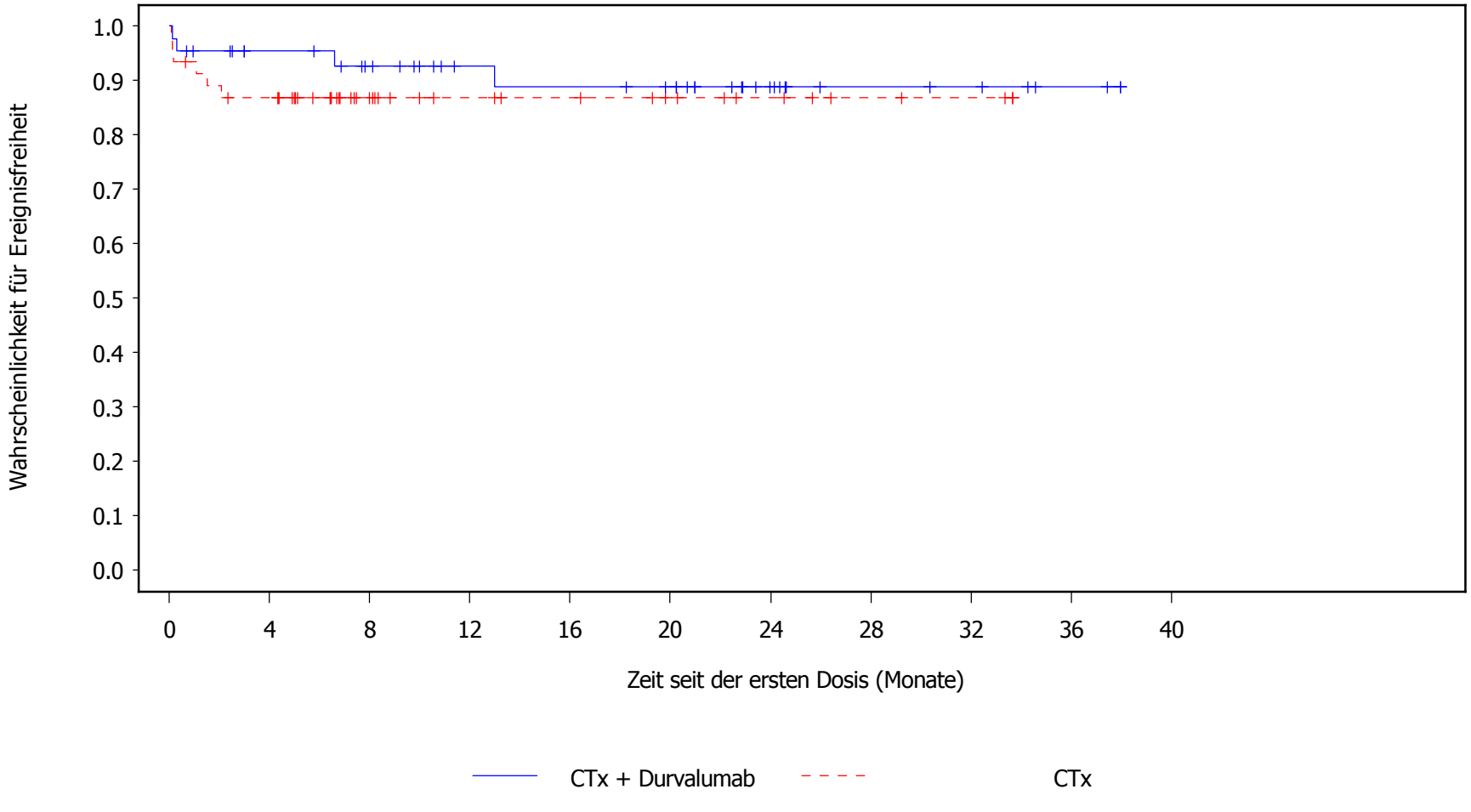
Figure 3.3.1.2D.2 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	17	12	9	7	7	2	1	0	0	0	CTx + Durvalumab
46	15	7	3	3	3	2	1	0	0	0	CTx

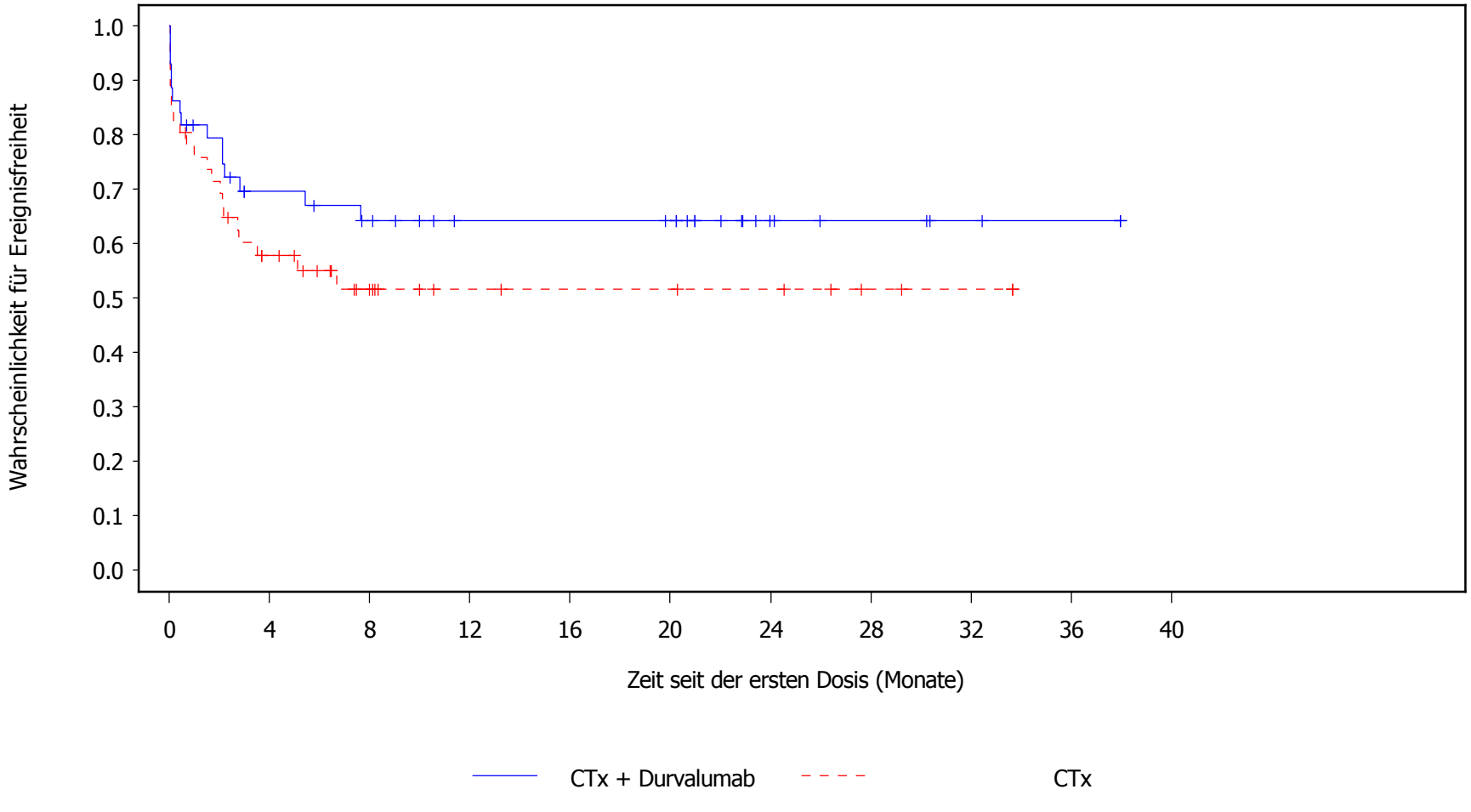
Figure 3.3.1.2D.3 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Asthenie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	31	24	23	21	11	6	5	2	0	CTx + Durvalumab
46	38	21	14	12	9	6	3	2	0	0	CTx

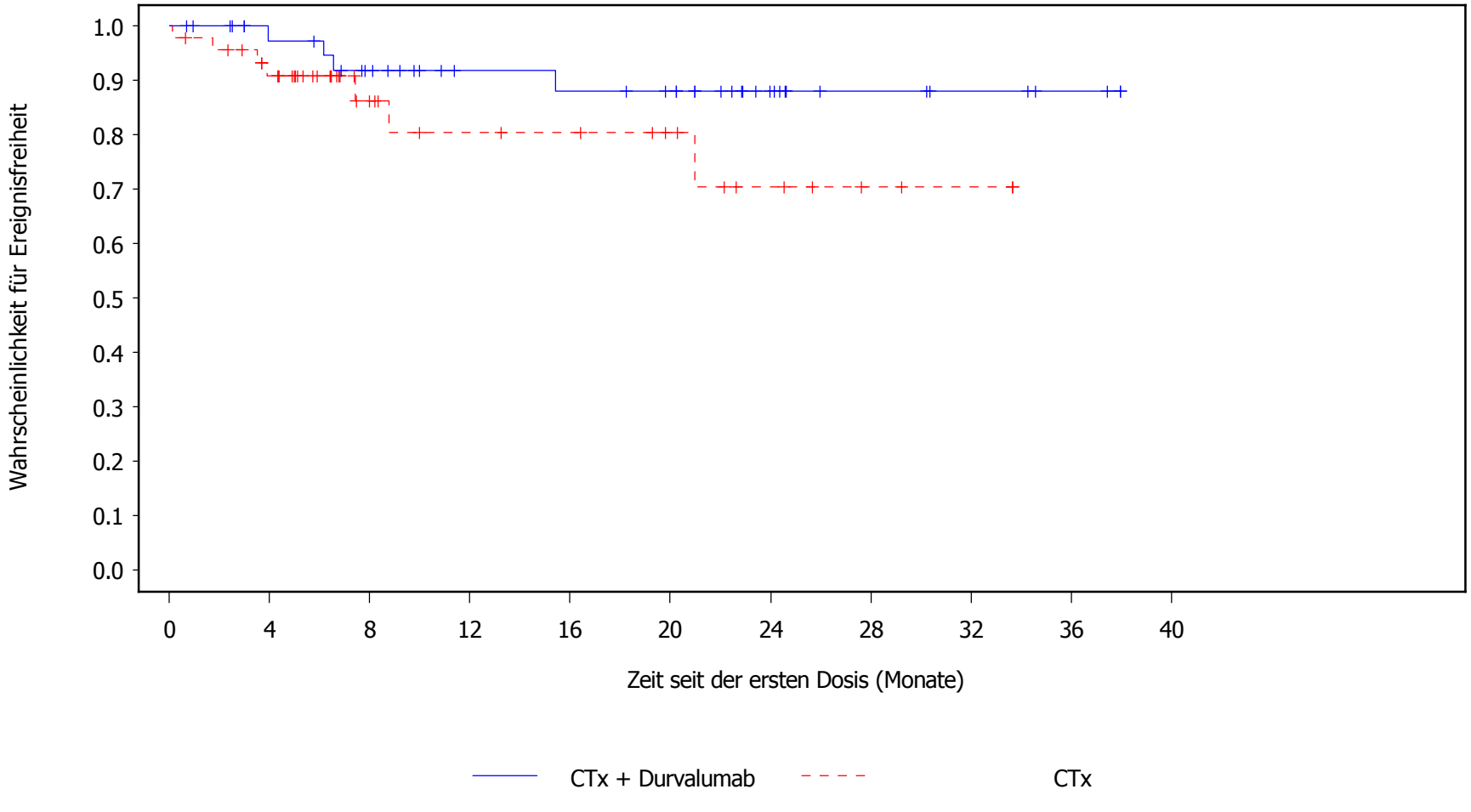
Figure 3.3.1.2D.4 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Ermuedung
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	26	22	17	17	16	6	4	2	1	0	CTx + Durvalumab
46	23	13	7	6	6	5	2	1	0	0	CTx

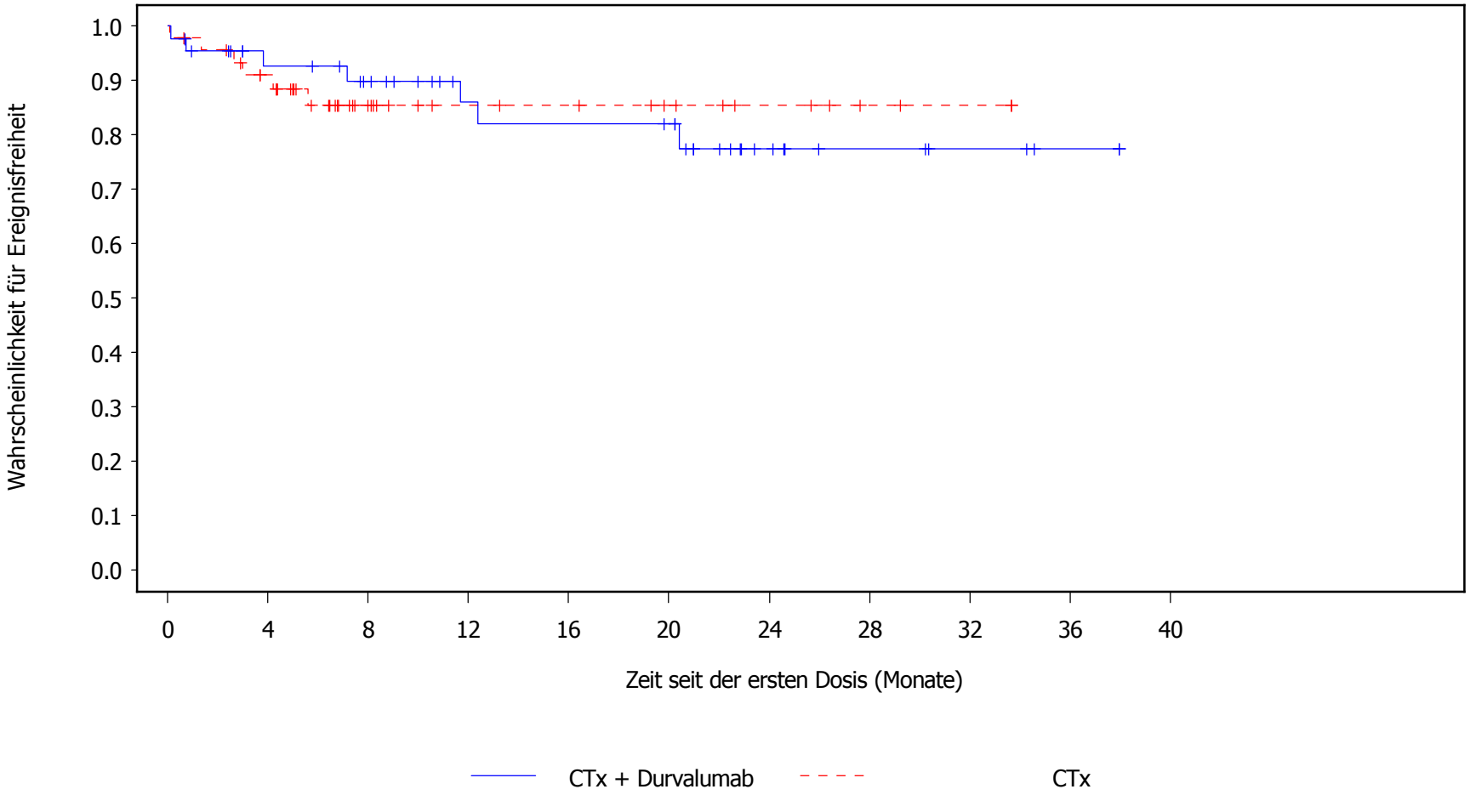
Figure 3.3.1.2D.5 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Fieber
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	37	31	24	23	21	11	6	4	2	0	CTx + Durvalumab
46	37	18	13	12	9	5	2	1	0	0	CTx

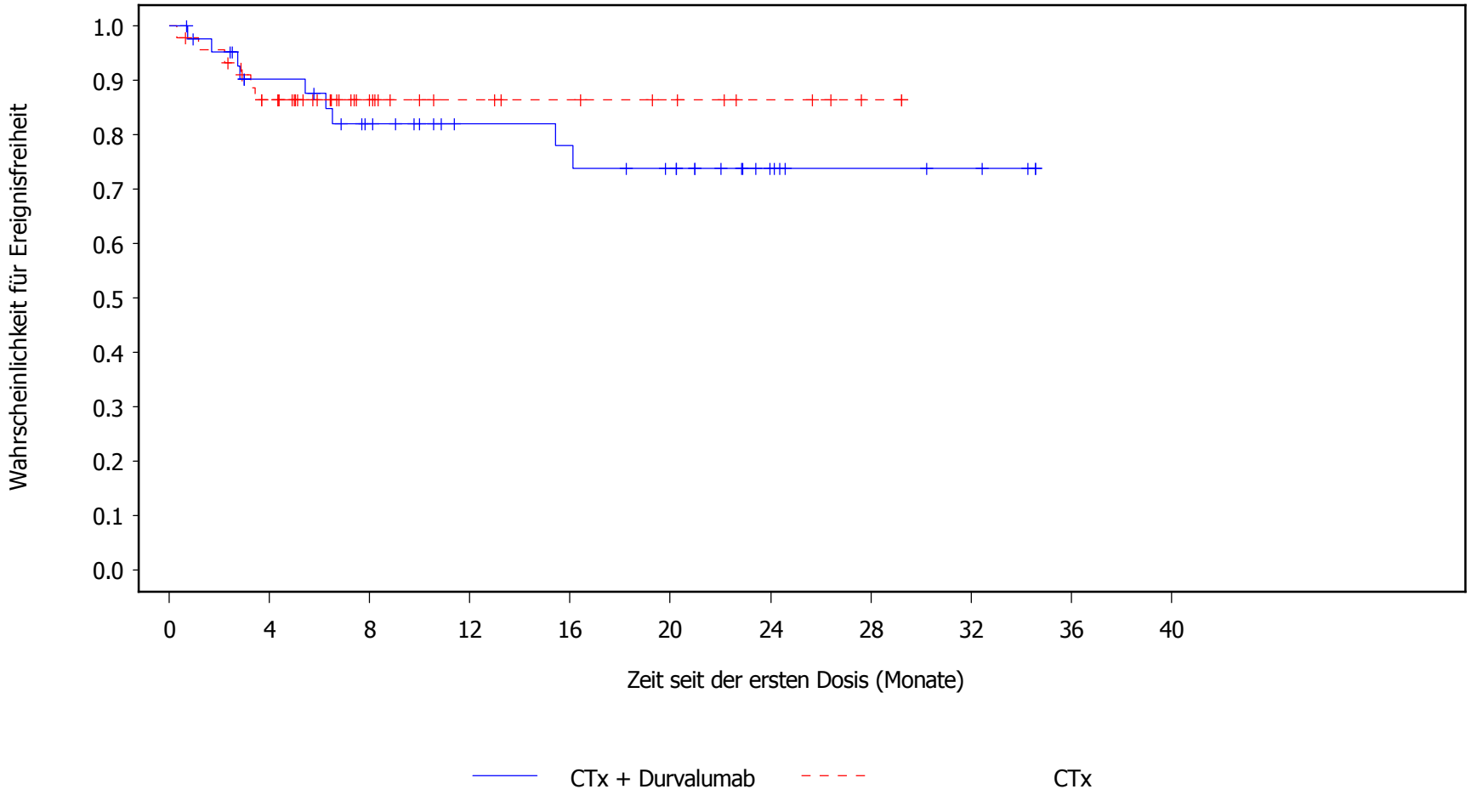
Figure 3.3.1.2D.6 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Oedem peripher
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	35	30	22	21	20	9	5	3	1	0	CTx + Durvalumab
46	37	19	12	11	8	5	2	1	0	0	CTx

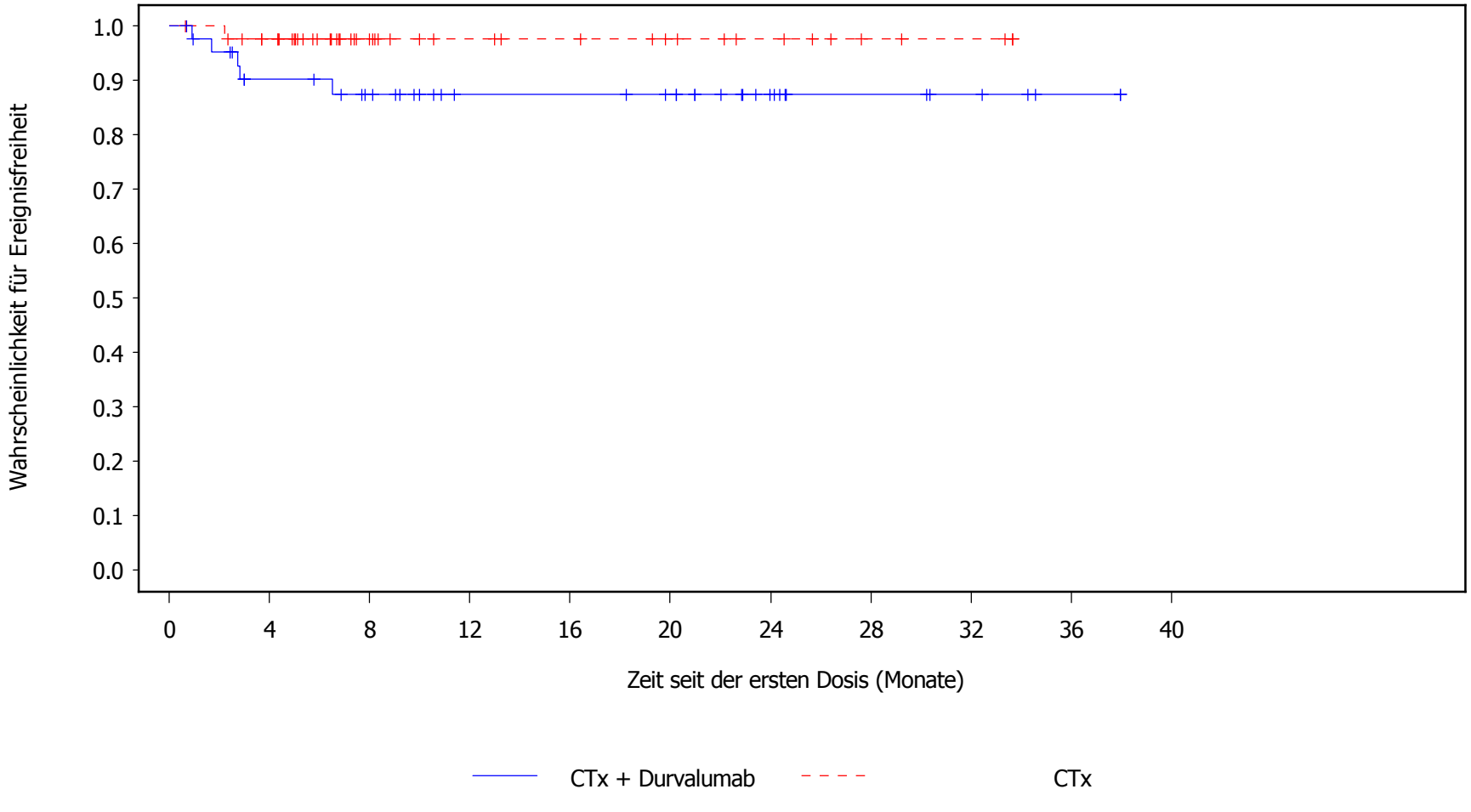
Figure 3.3.1.2D.7 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Augenerkrankungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	27	20	19	16	7	4	3	0	0	CTx + Durvalumab
46	35	18	11	9	7	4	1	0	0	0	CTx

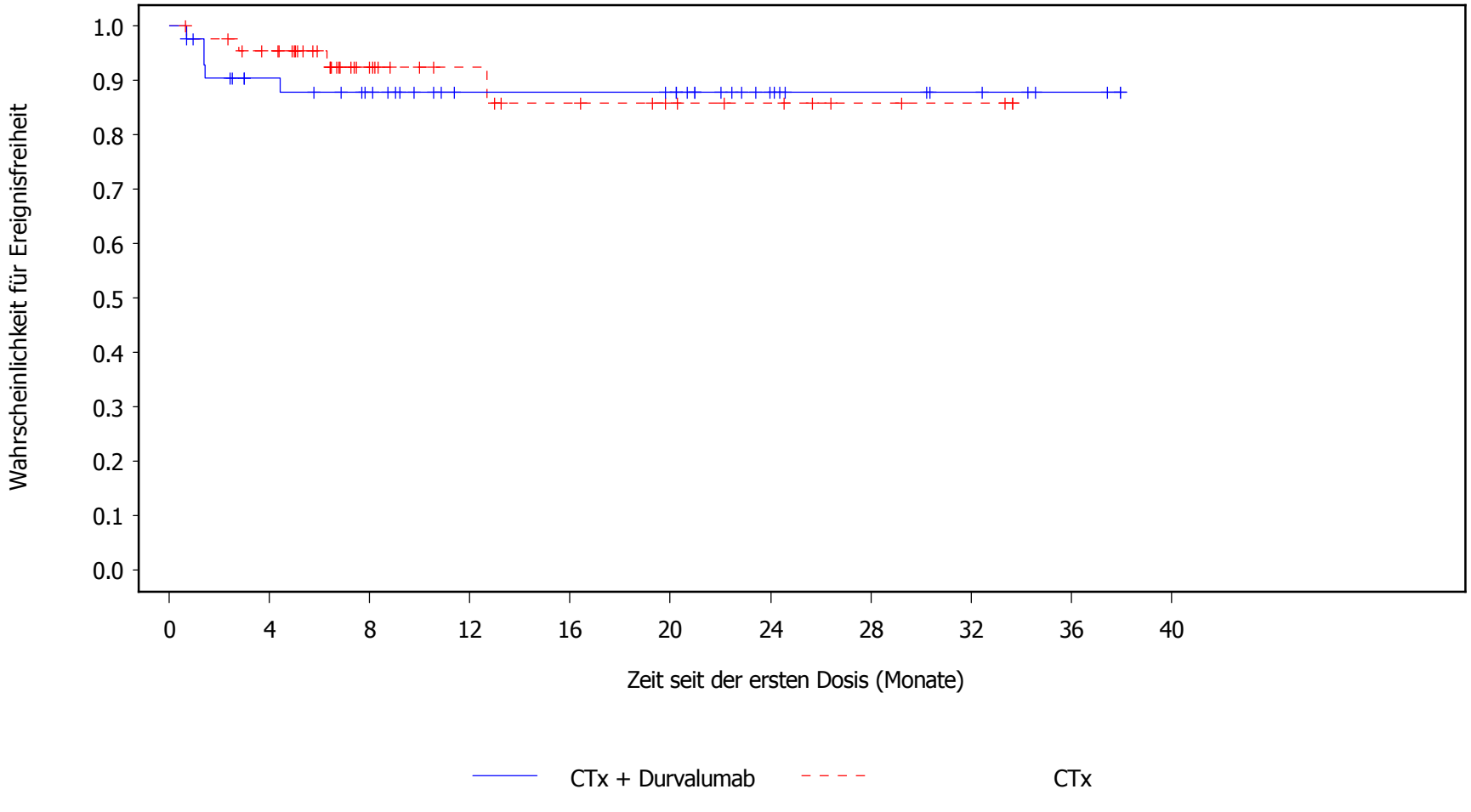
Figure 3.3.1.2D.8 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Sehen verschwommen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	29	21	21	19	10	6	4	1	0	CTx + Durvalumab
46	40	22	15	13	10	7	3	2	0	0	CTx

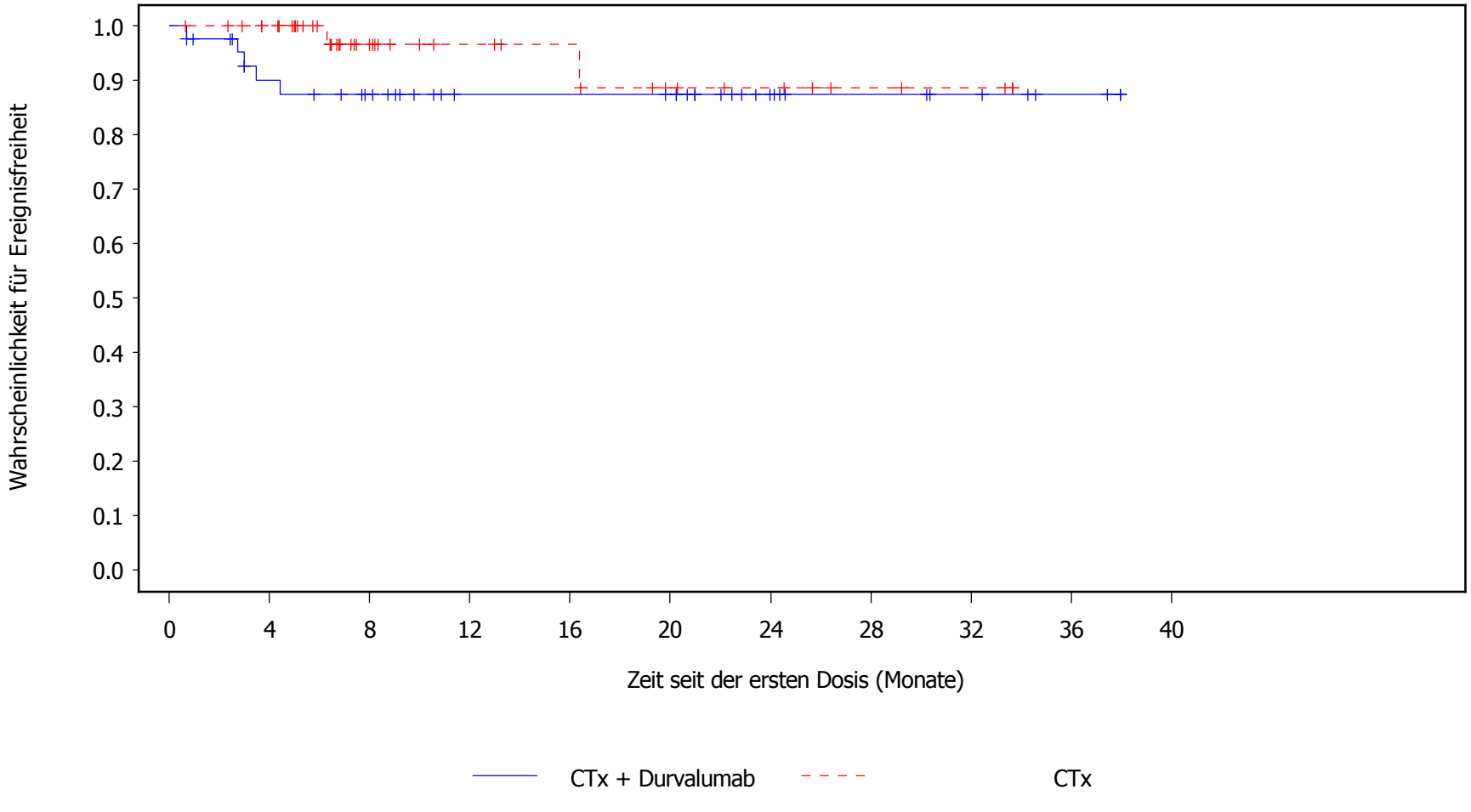
Figure 3.3.1.2D.9 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Endokrine Erkrankungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	29	21	21	20	10	7	5	2	0	CTx + Durvalumab
46	40	21	14	11	8	6	3	2	0	0	CTx

Figure 3.3.1.2D.10 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Hypothyreose
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	29	21	21	20	10	7	5	2	0	CTx + Durvalumab
46	41	21	14	12	8	6	3	2	0	0	CTx

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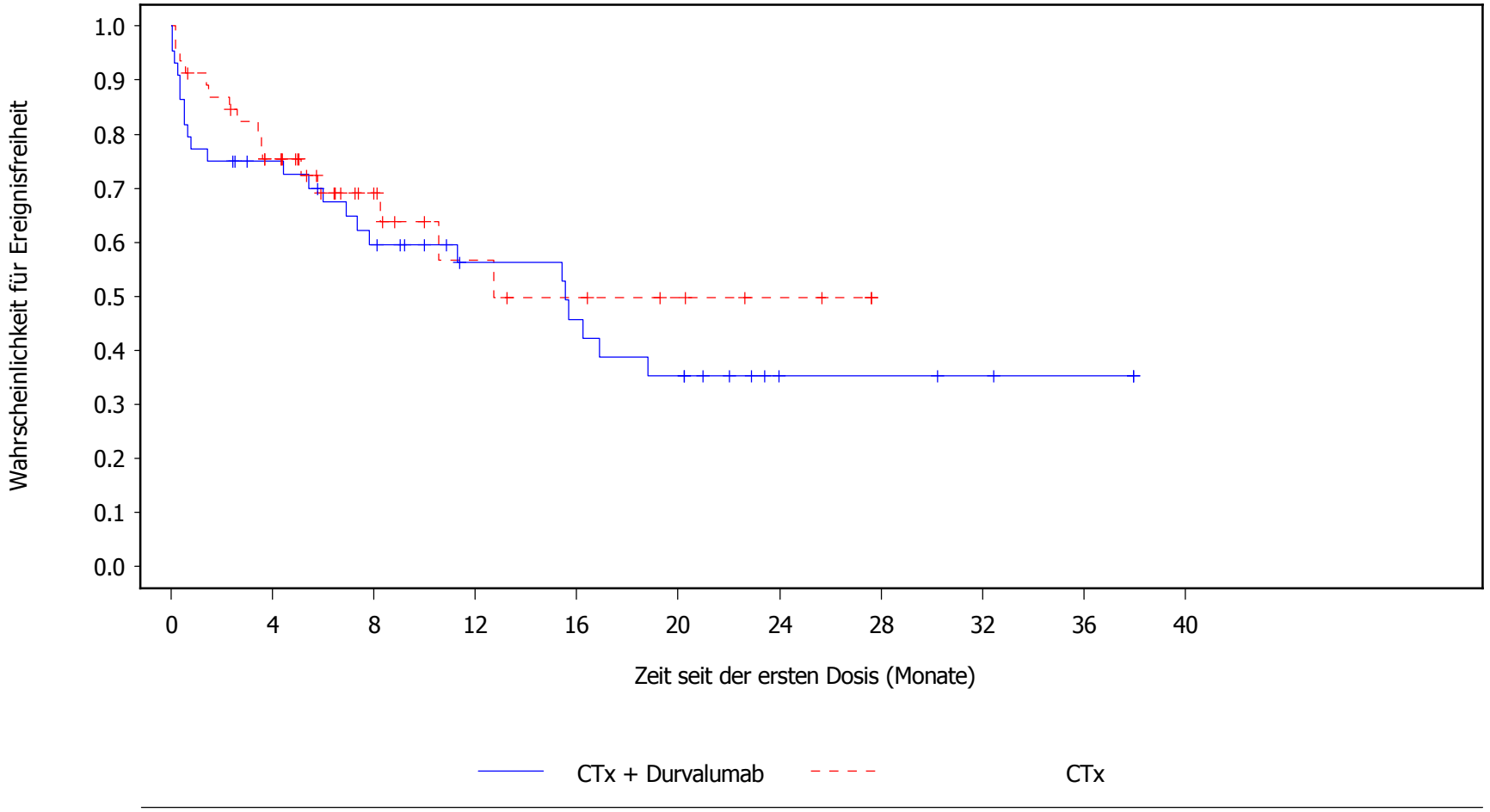
Figure 3.3.1.2D.11 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums
Patients with dMMR tumour status, DCO 18OCT2023

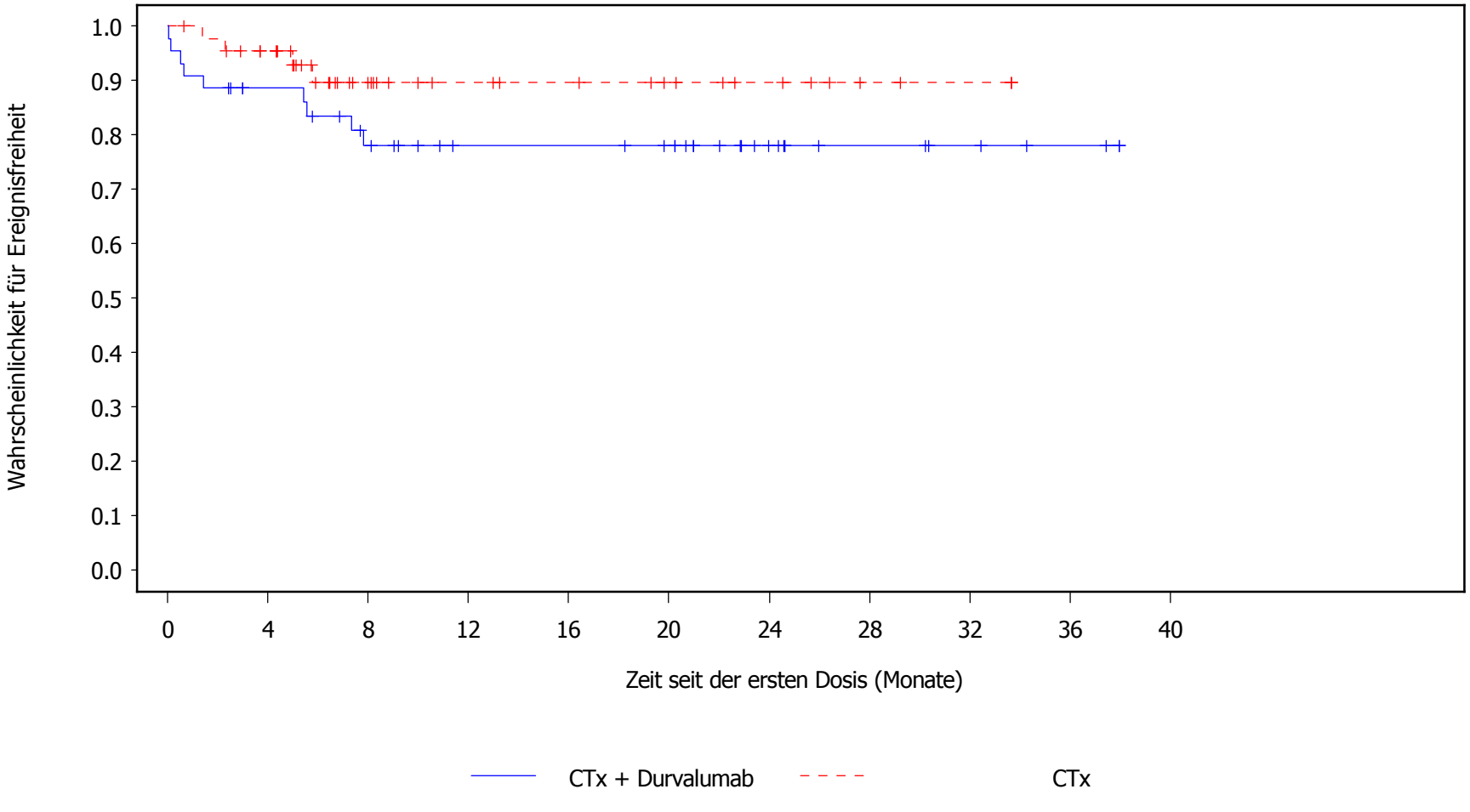


Anzahl an Patienten unter Risiko:

44	30	23	16	13	10	3	3	2	1	0	CTx + Durvalumab
46	31	15	8	6	4	2	0	0	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaeaak 15APR2024:10:33

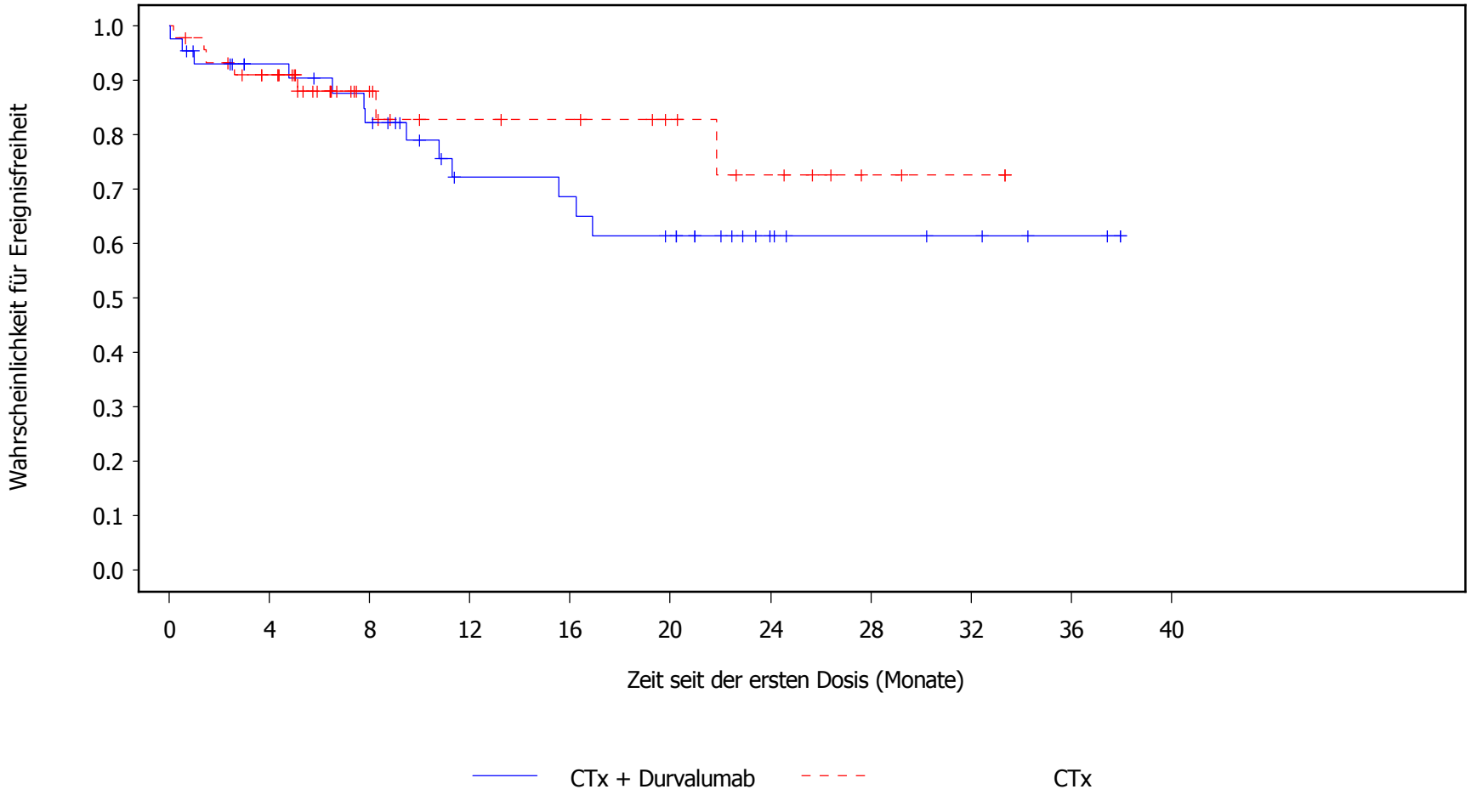
Figure 3.3.1.2D.12 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Dyspnoe
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	35	28	22	22	20	10	6	4	2	0	CTx + Durvalumab
46	39	21	14	12	9	6	2	1	0	0	CTx

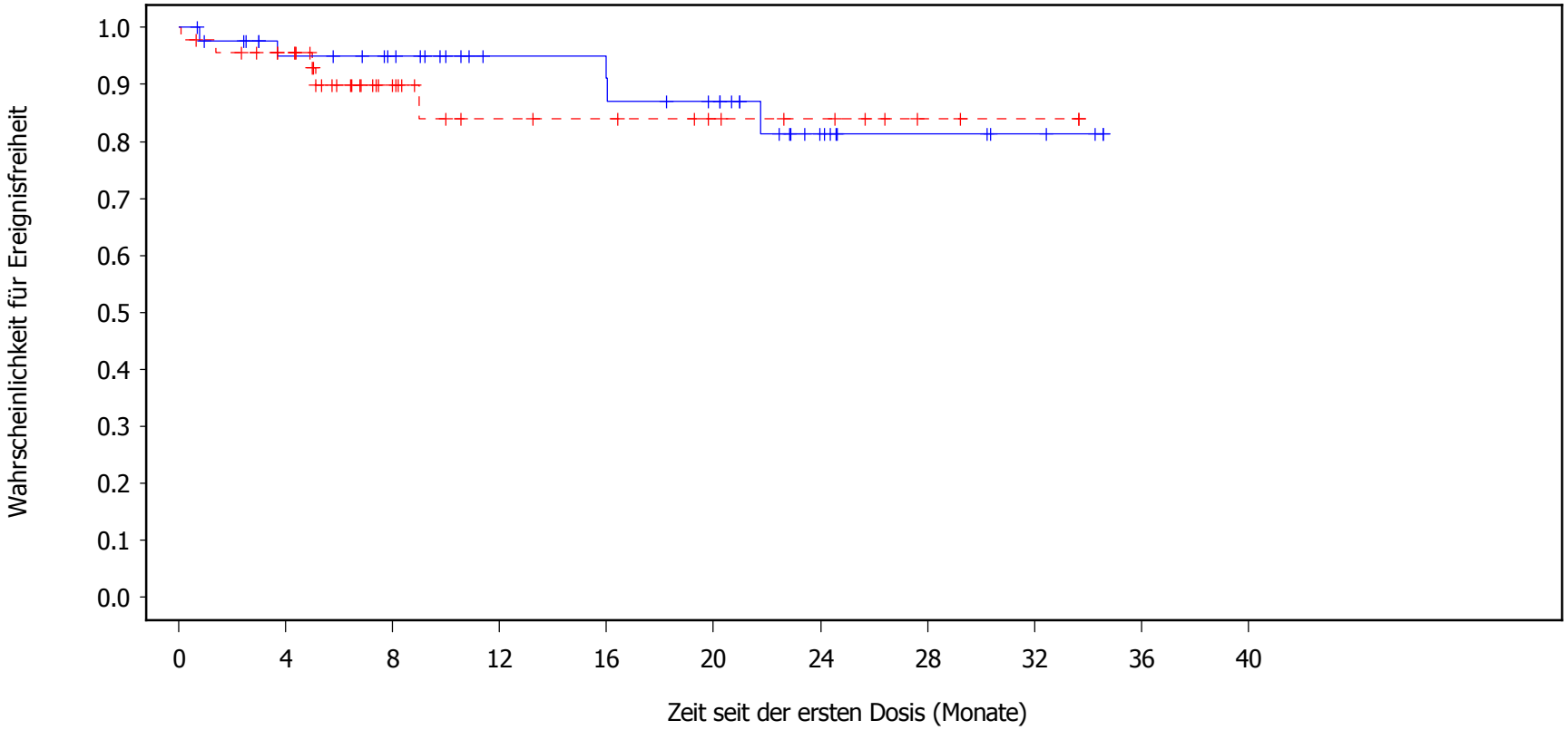
Figure 3.3.1.2D.13 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Husten
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	35	30	20	19	16	7	5	4	2	0	CTx + Durvalumab
46	37	19	13	12	9	6	2	1	0	0	CTx

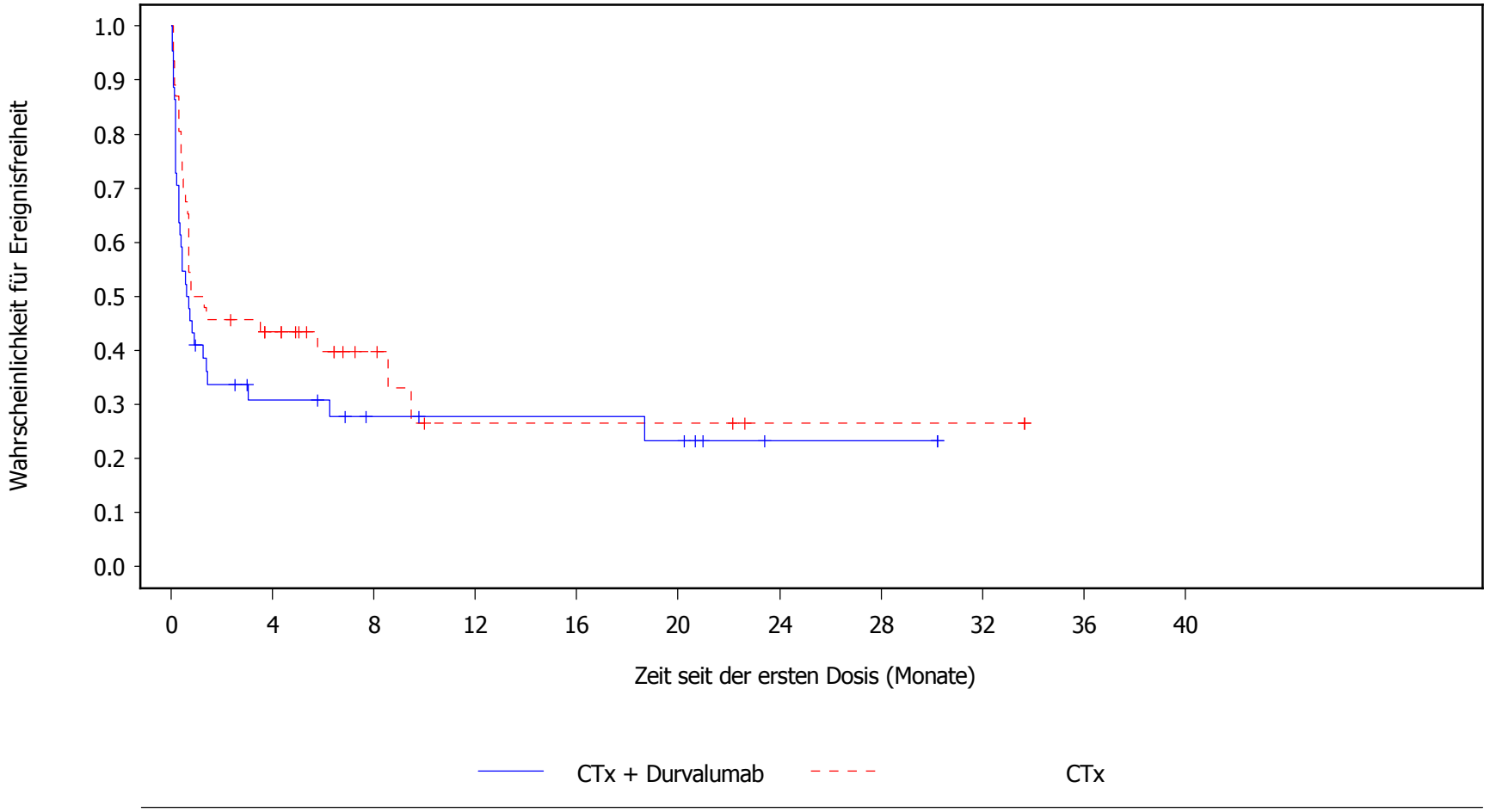
Figure 3.3.1.2D.14 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	32	24	23	20	9	5	3	0	0	CTx + Durvalumab
46	39	20	12	11	8	6	2	1	0	0	CTx

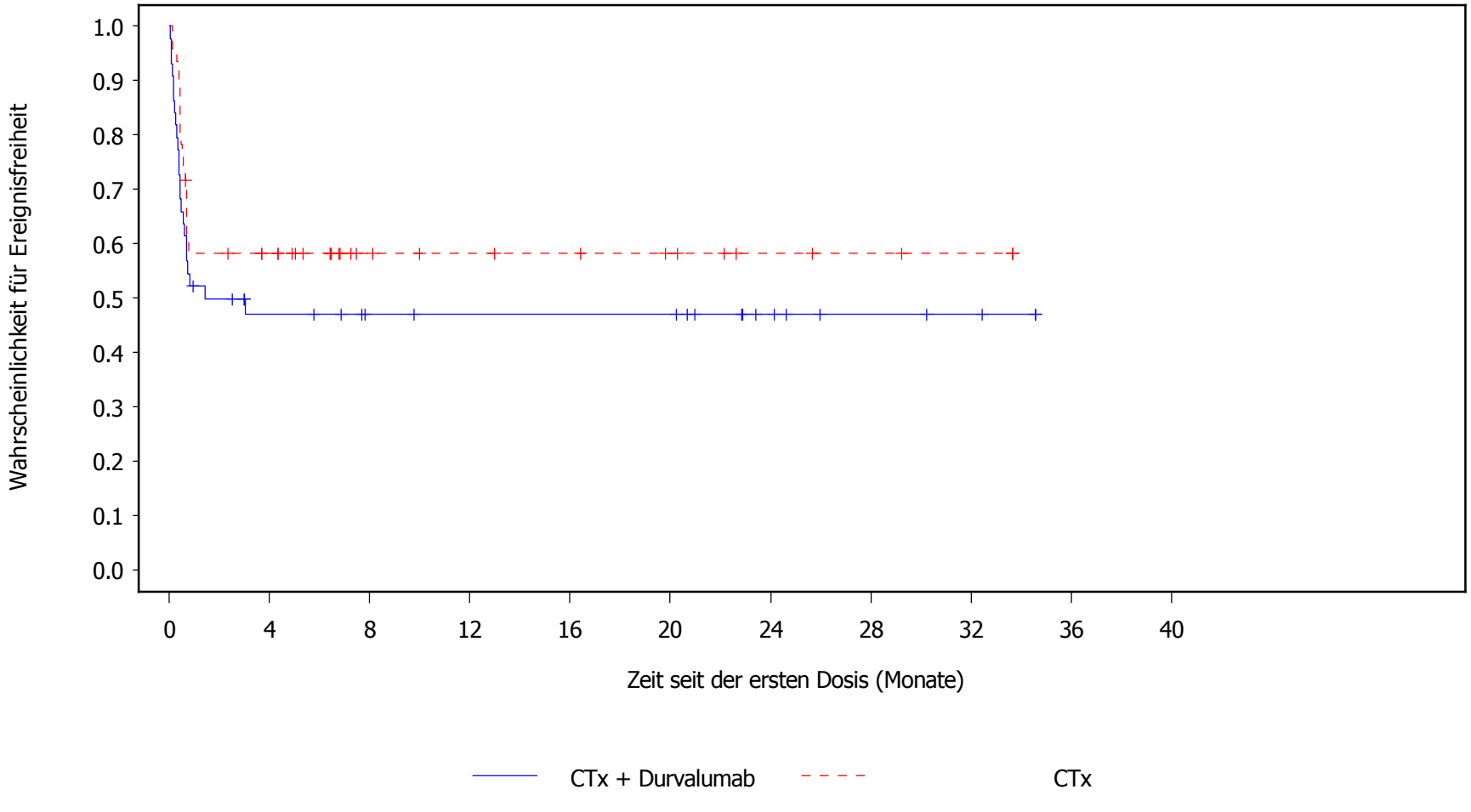
Figure 3.3.1.2D.15 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Haut und des Unterhautgewebes
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	11	7	6	6	5	1	1	0	0	0	CTx + Durvalumab
46	17	7	3	3	3	1	1	1	0	0	CTx

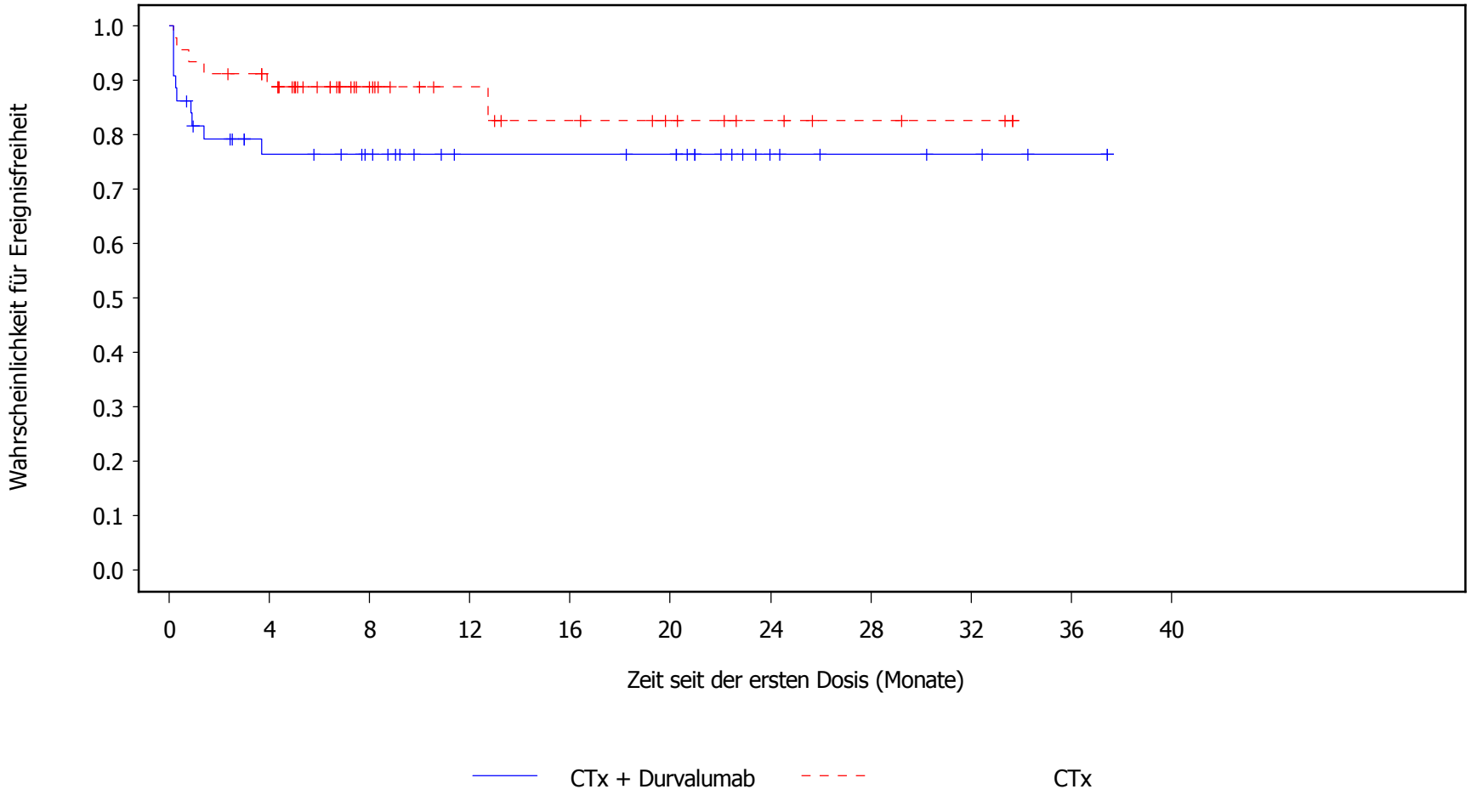
Figure 3.3.1.2D.16 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Alopezie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	17	13	12	12	12	6	3	2	0	0	CTx + Durvalumab
46	23	11	9	8	6	3	2	1	0	0	CTx

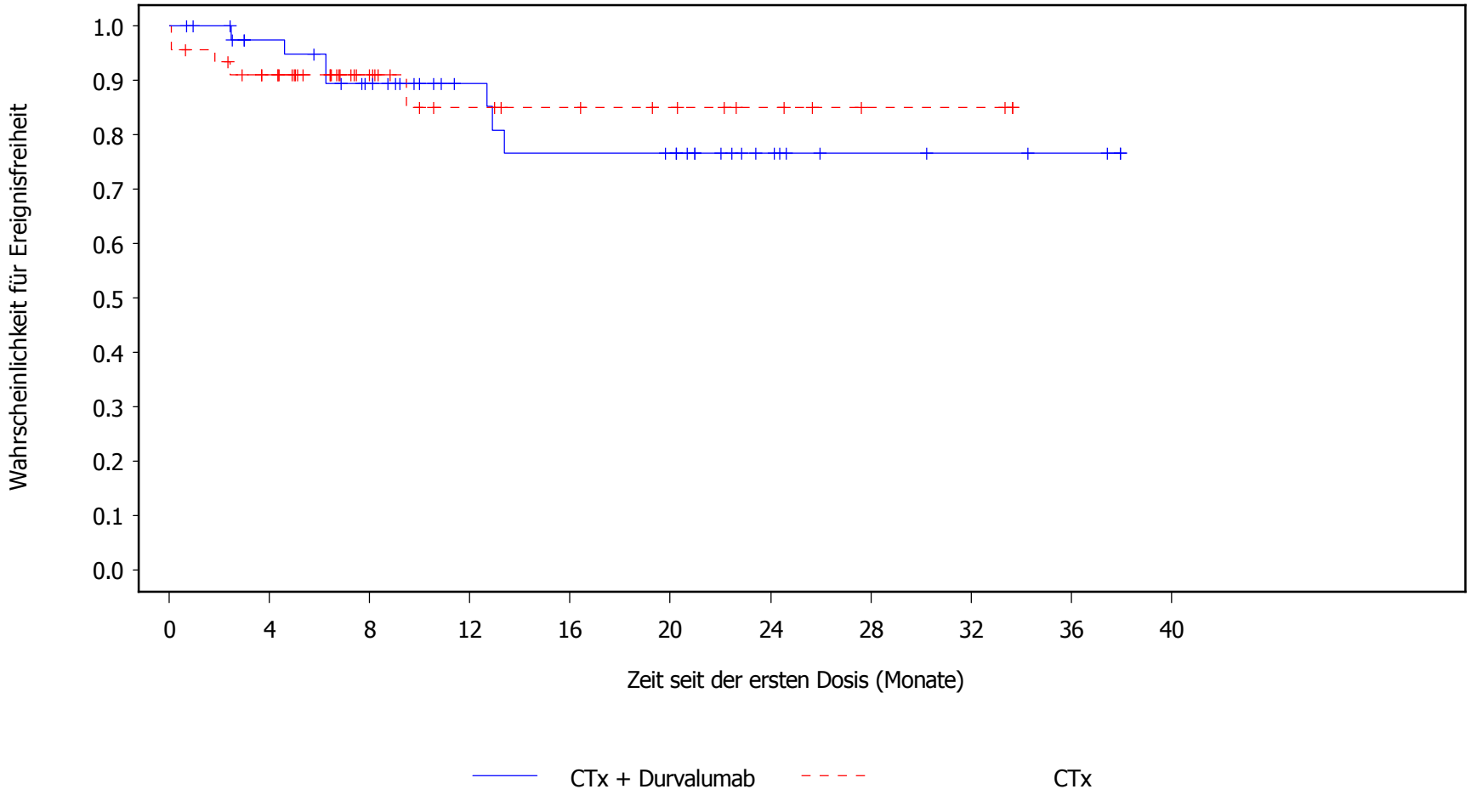
Figure 3.3.1.2D.17 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Ausschlag
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	28	24	17	17	16	6	4	3	1	0	CTx + Durvalumab
46	38	21	14	11	8	5	3	2	0	0	CTx

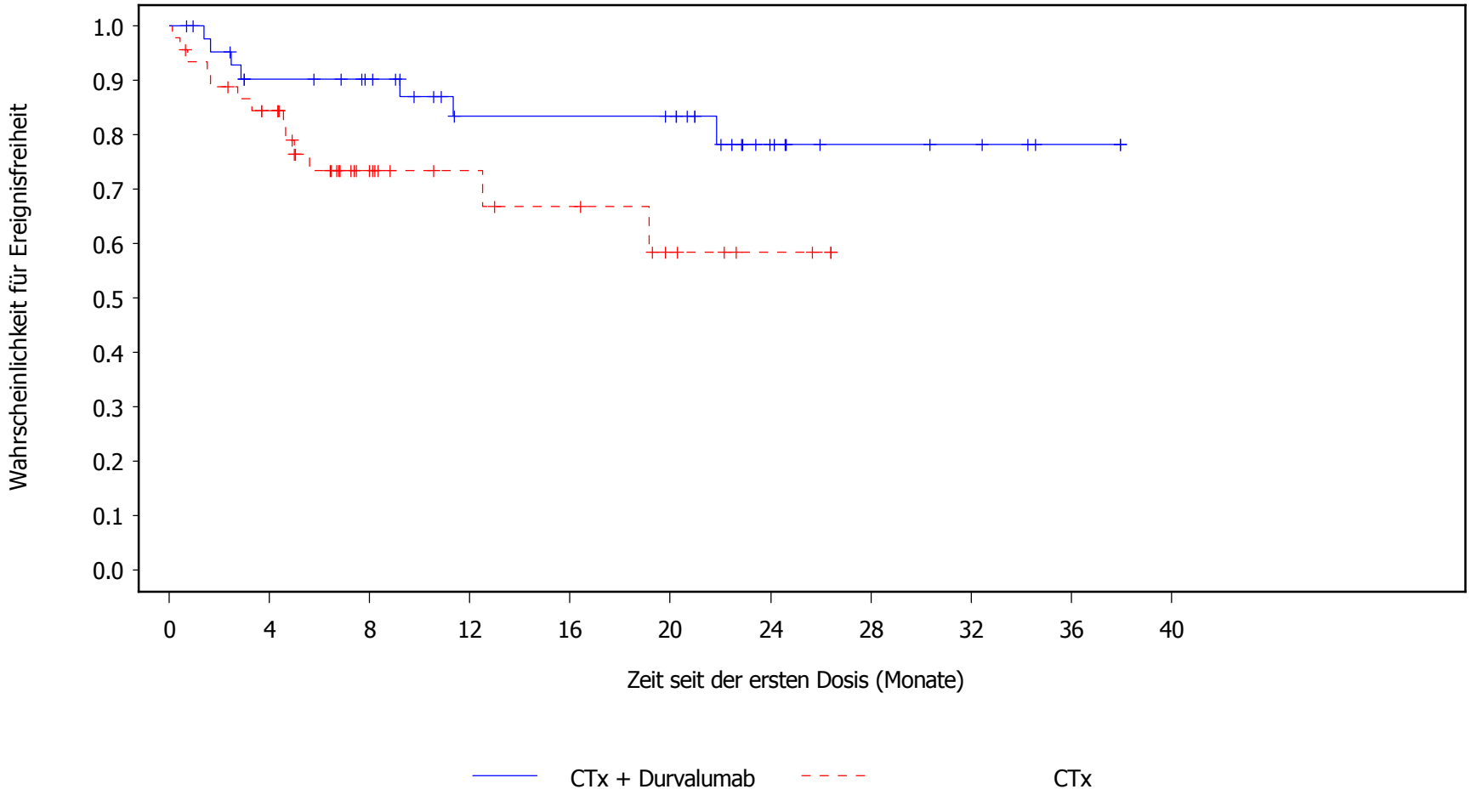
Figure 3.3.1.2D.18 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Pruritus
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	37	30	21	18	17	8	4	3	2	0	CTx + Durvalumab
46	37	20	12	10	8	5	2	2	0	0	CTx

Figure 3.3.1.2D.19 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen der Nieren und Harnwege
Patients with dMMR tumour status, DCO 18OCT2023

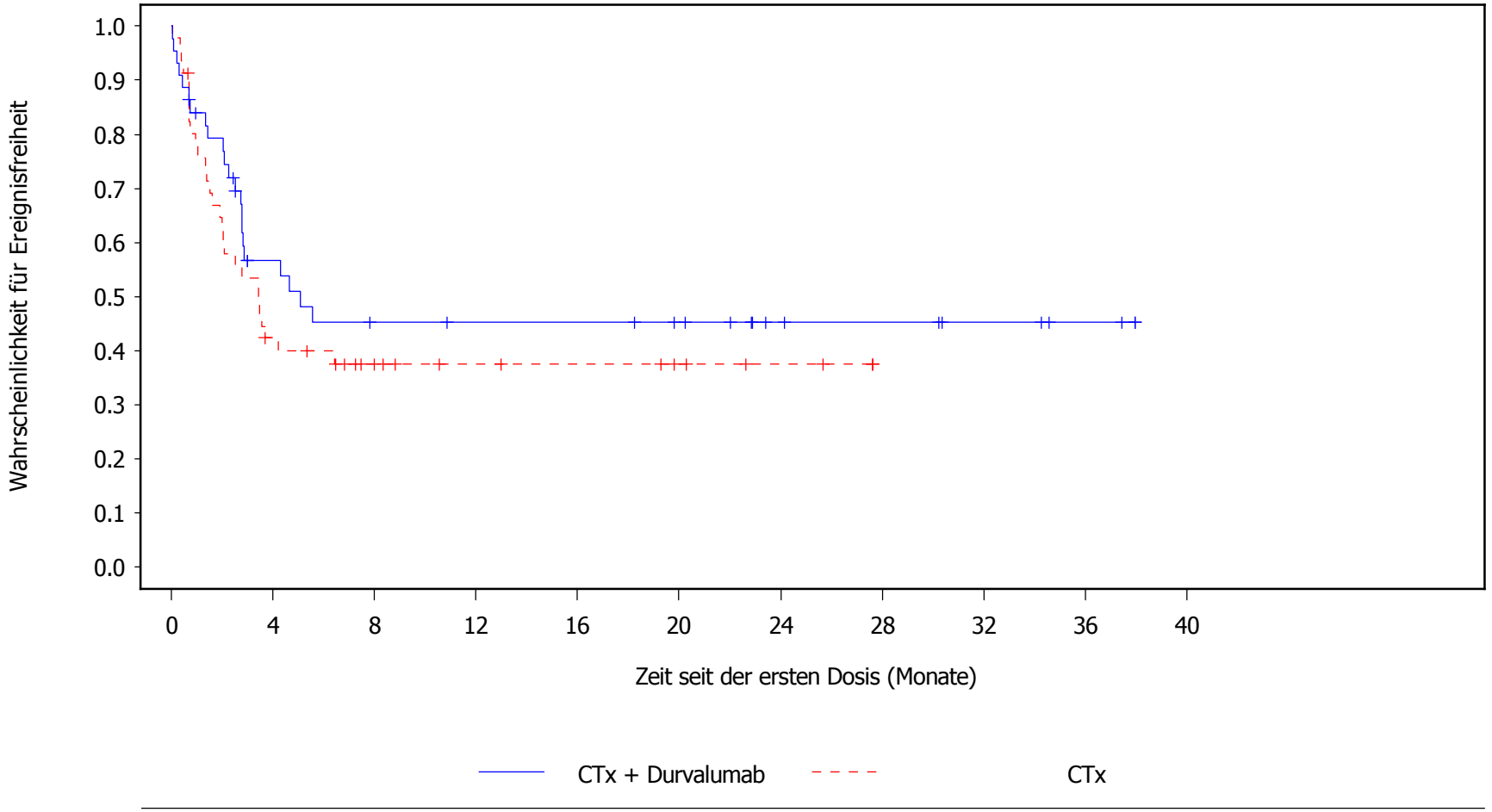


Anzahl an Patienten unter Risiko:

44	35	31	22	22	21	9	5	4	1	0	CTx + Durvalumab
46	35	17	11	9	5	2	0	0	0	0	CTx

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.1.2D.20 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with dMMR tumour status, DCO 18OCT2023

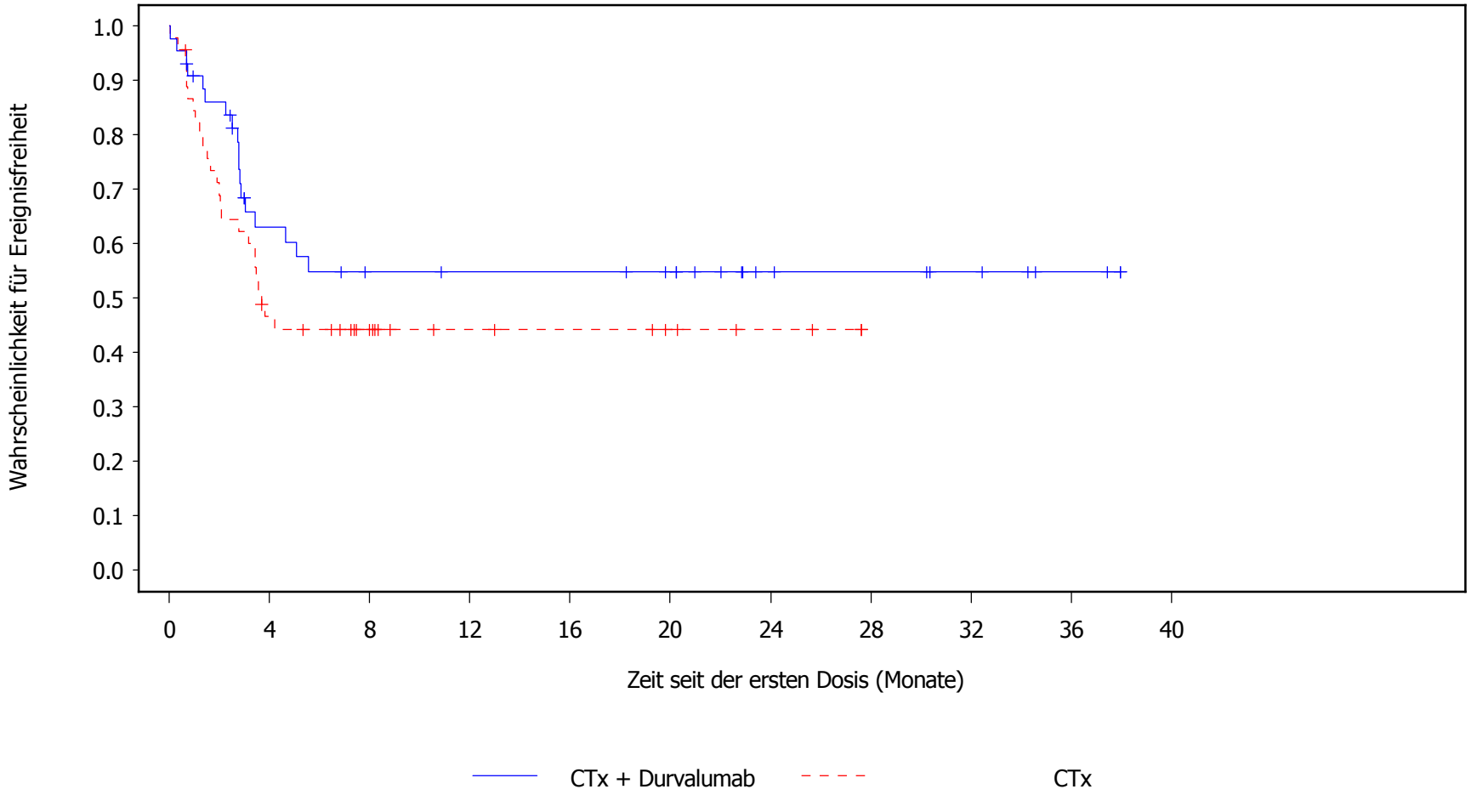


Anzahl an Patienten unter Risiko:

44	20	15	14	14	12	7	6	4	2	0	CTx + Durvalumab
46	18	11	7	6	4	2	0	0	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaeaat 15APR2024:10:33

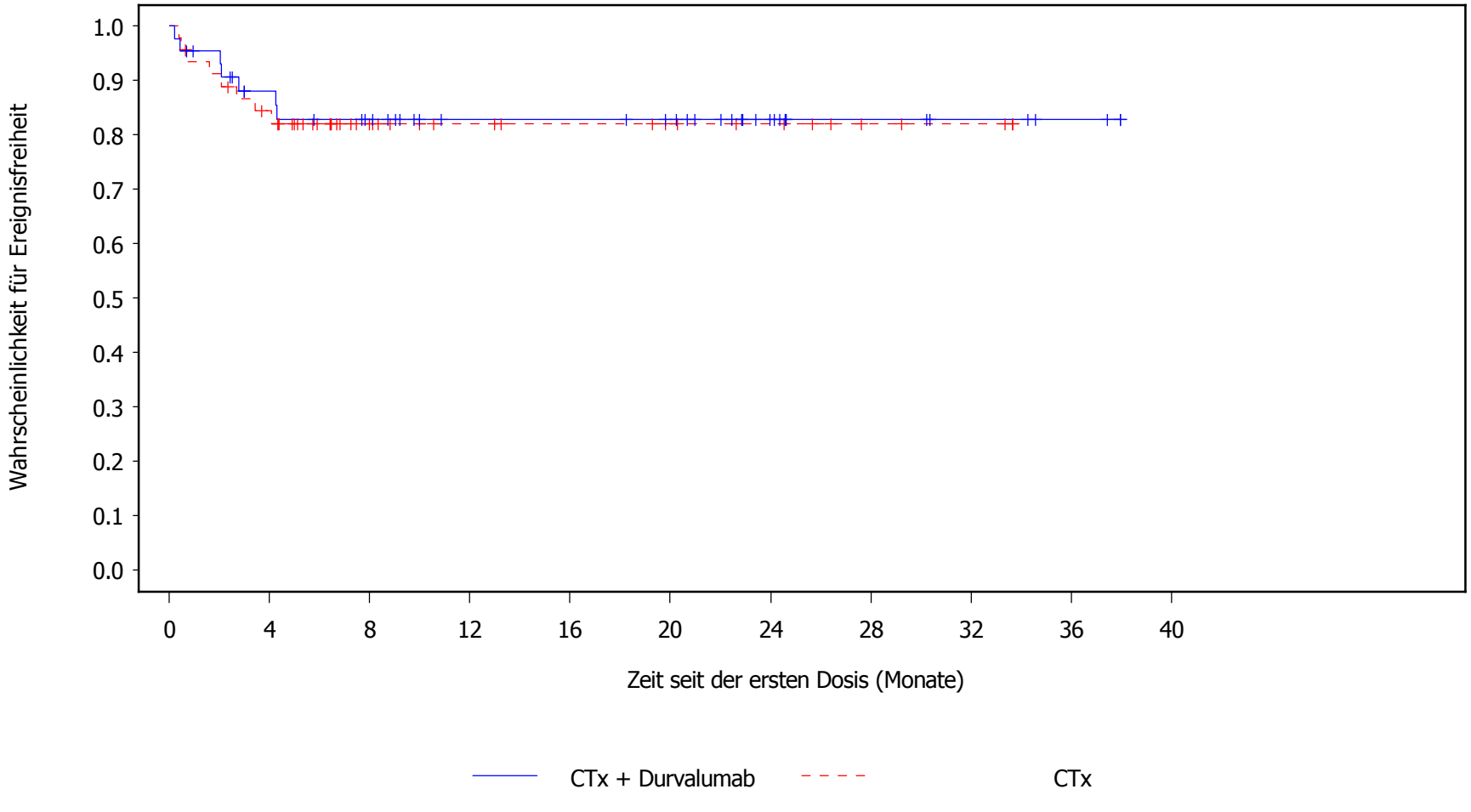
Figure 3.3.1.2D.21 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Anaemie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	23	18	17	17	15	8	7	5	2	0	CTx + Durvalumab
46	20	13	7	6	4	2	0	0	0	0	CTx

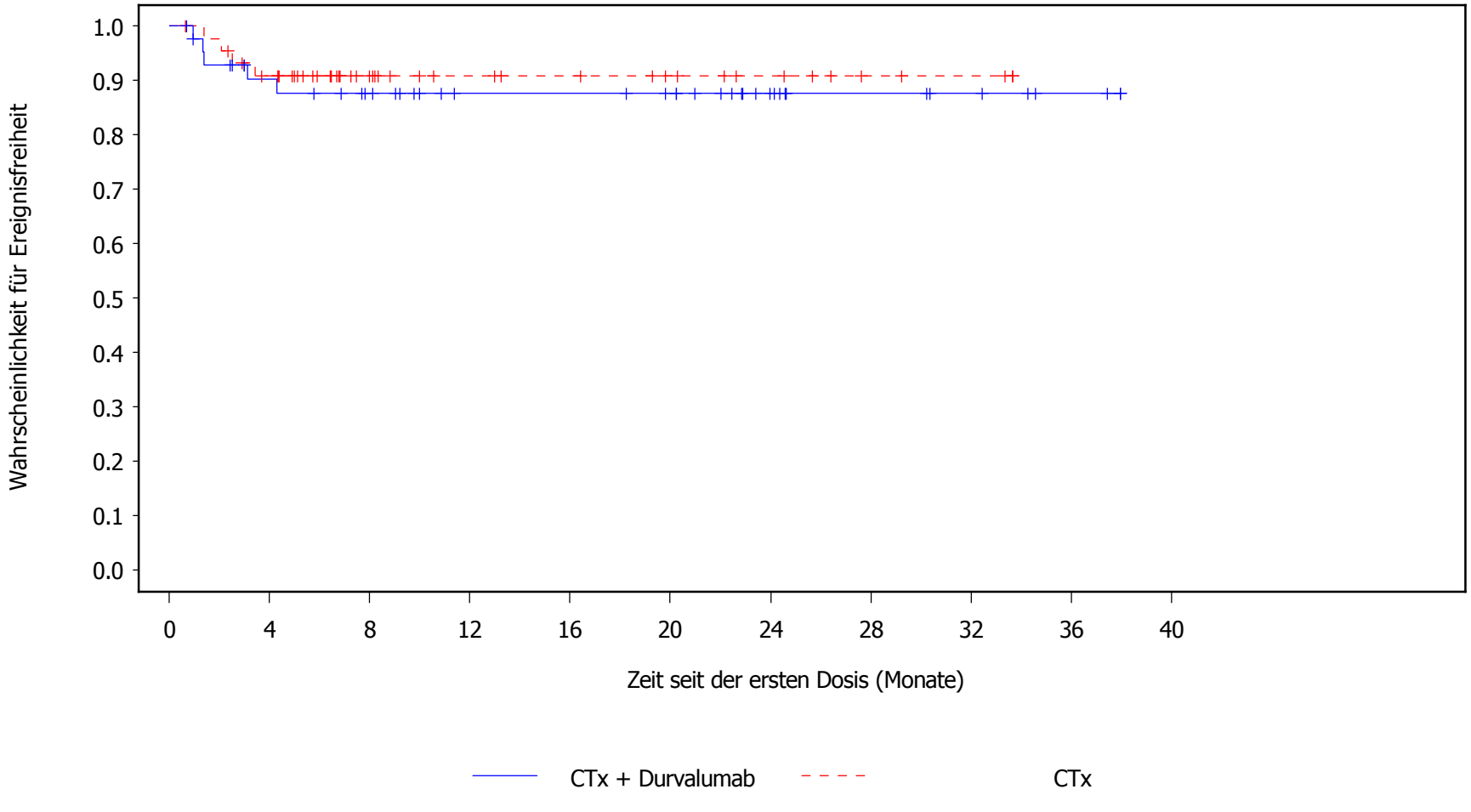
Figure 3.3.1.2D.22 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Neutropenie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	33	28	21	21	19	10	6	4	2	0	CTx + Durvalumab
46	36	19	13	11	9	7	3	2	0	0	CTx

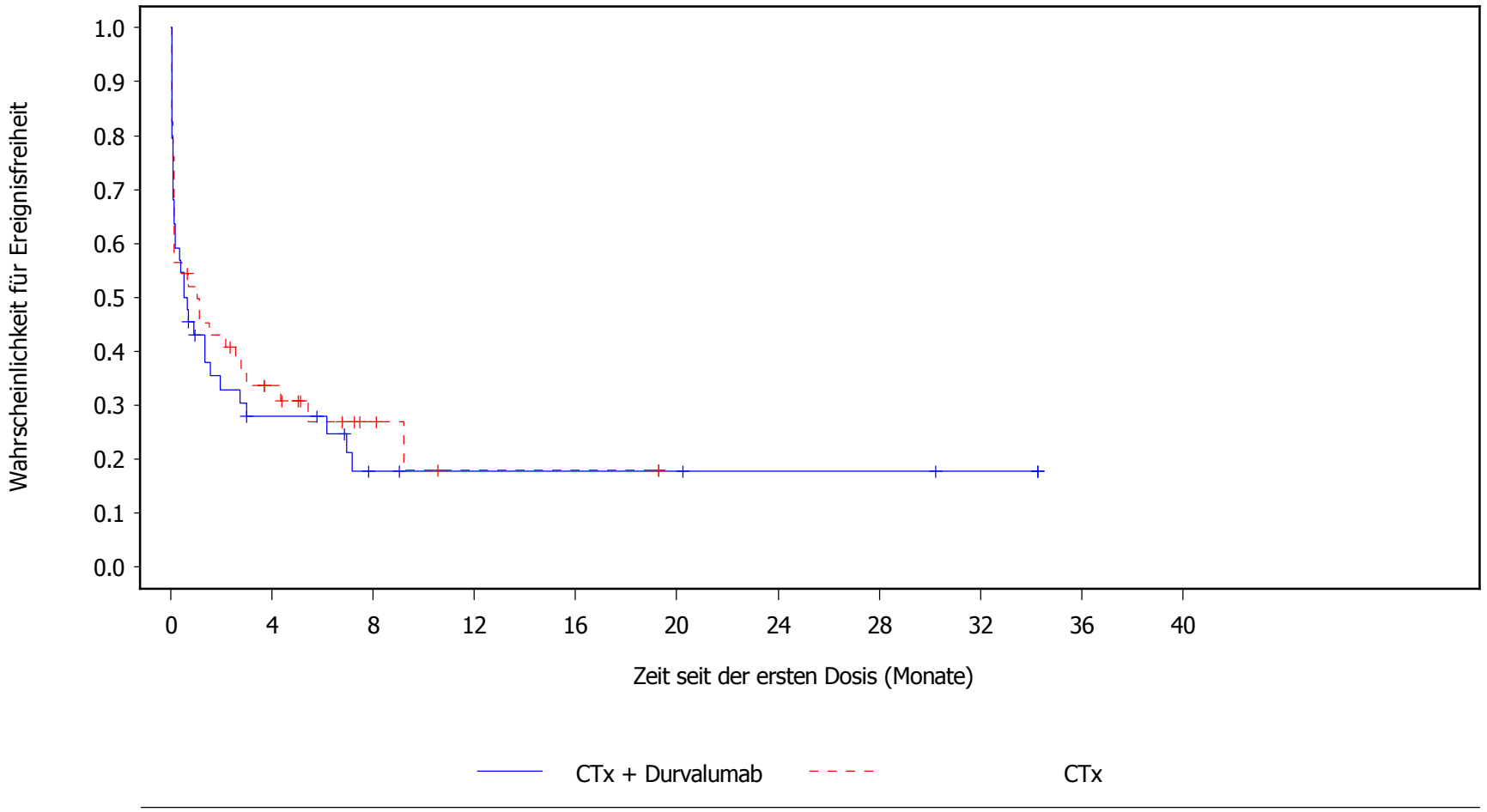
Figure 3.3.1.2D.23 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Thrombozytopenie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	29	22	22	20	11	7	5	2	0	CTx + Durvalumab
46	38	22	15	13	10	7	3	2	0	0	CTx

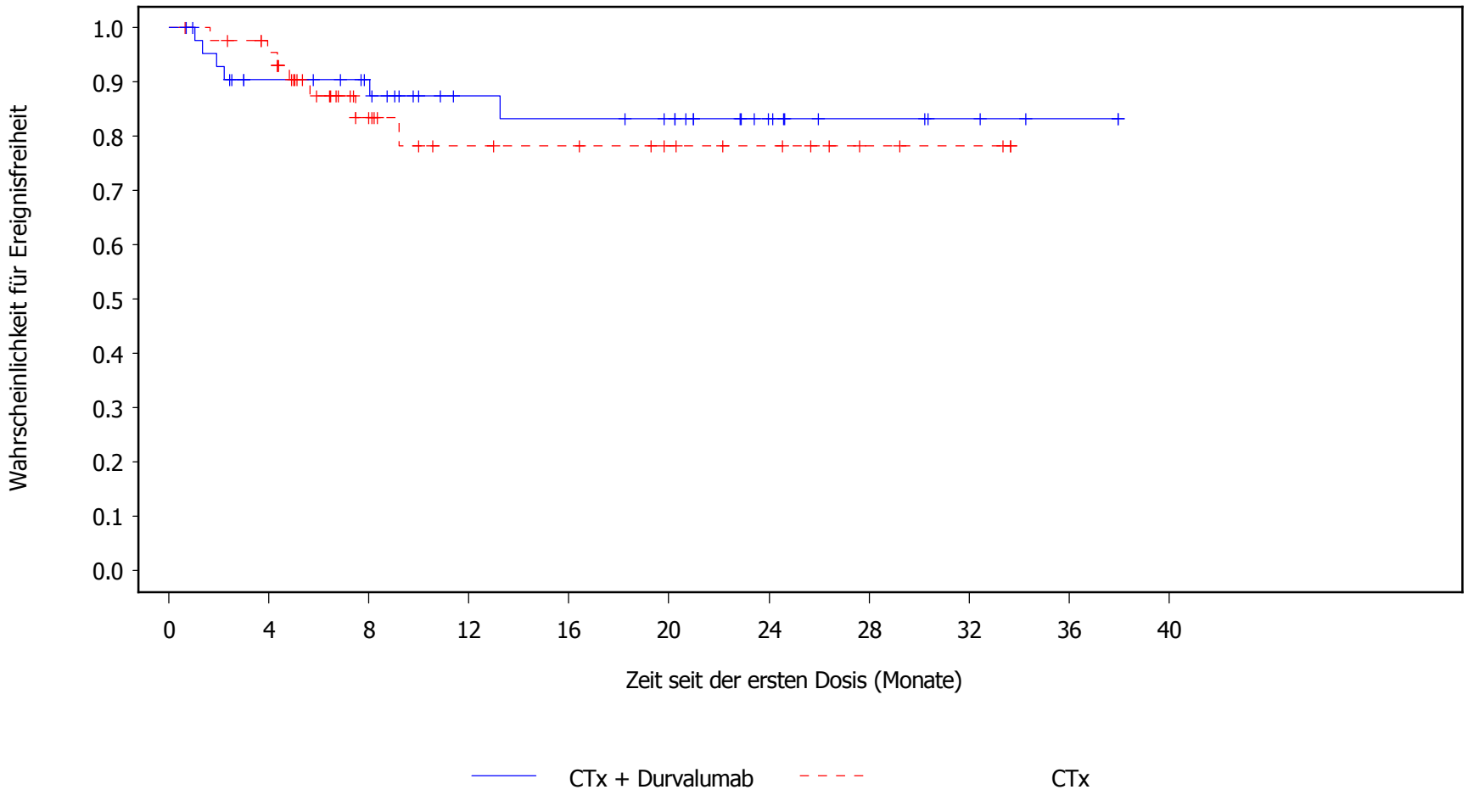
Figure 3.3.1.2D.24 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Gastrointestinaltrakts
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	10	4	3	3	3	2	2	1	0	0	CTx + Durvalumab
46	12	4	1	1	0	0	0	0	0	0	CTx

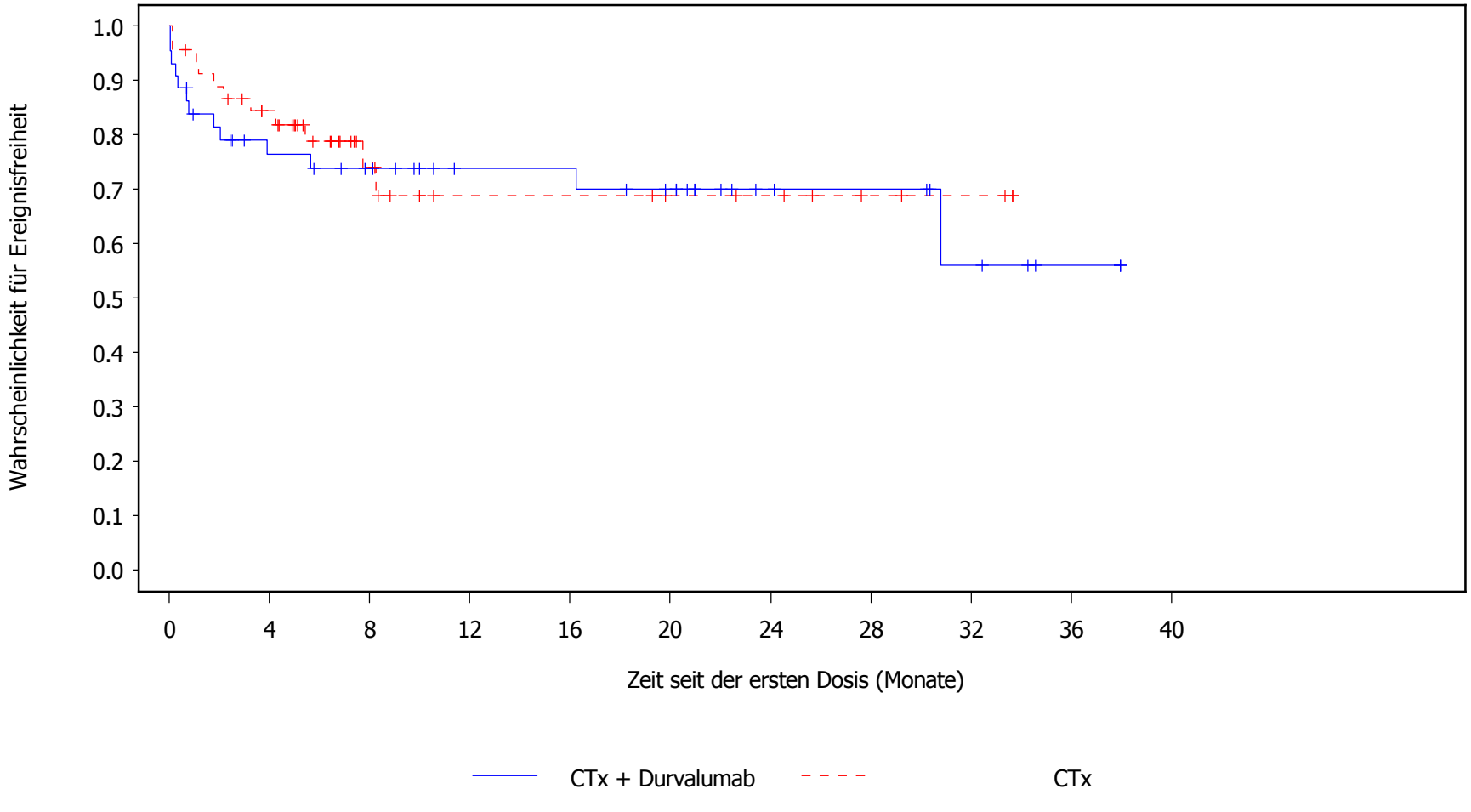
Figure 3.3.1.2D.25 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Abdominalschmerz
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	30	21	20	18	9	5	3	1	0	CTx + Durvalumab
46	40	20	13	12	9	7	3	2	0	0	CTx

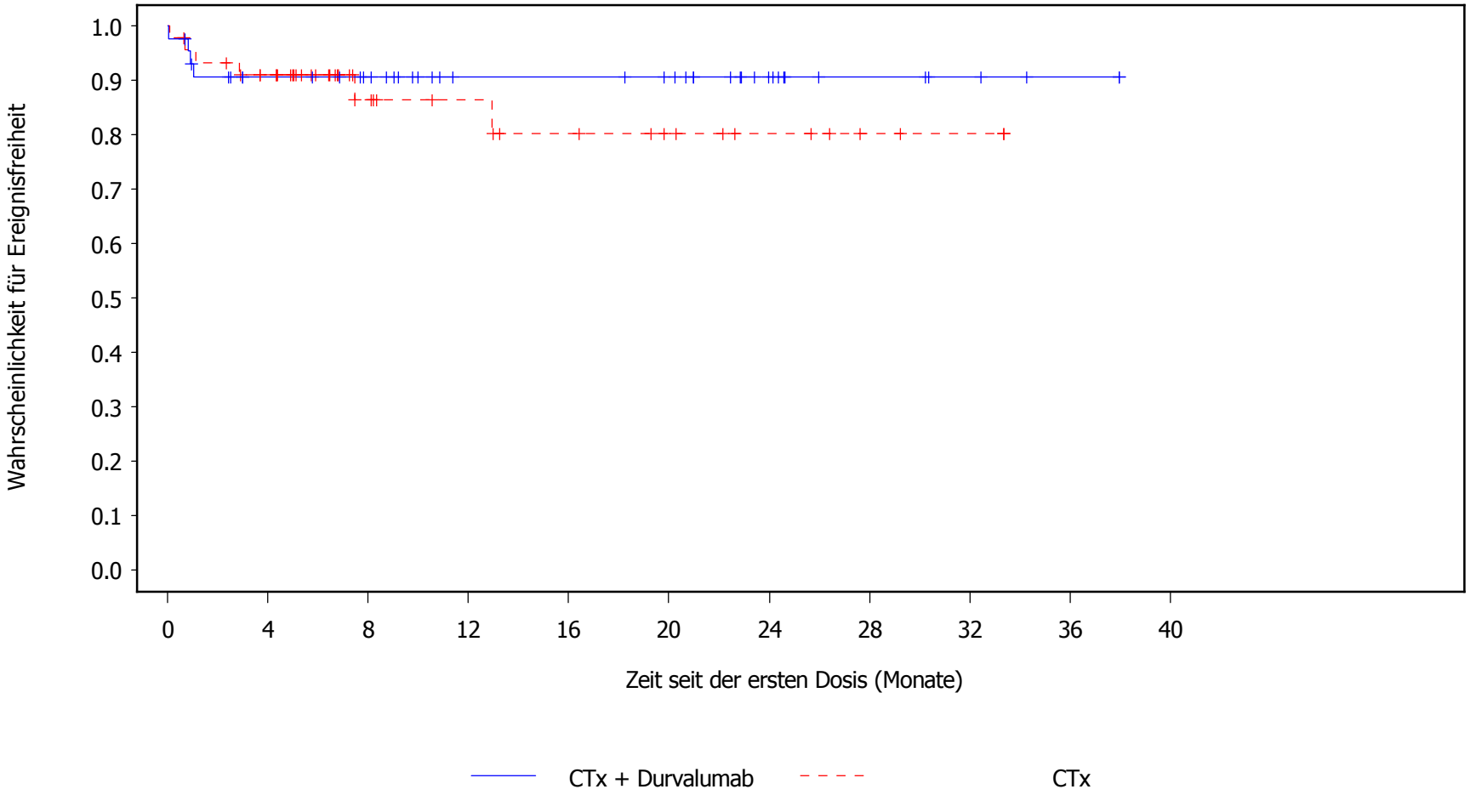
Figure 3.3.1.2D.26 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Diarrhoe
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	29	25	19	19	16	8	7	4	1	0	CTx + Durvalumab
46	34	16	9	9	7	6	3	2	0	0	CTx

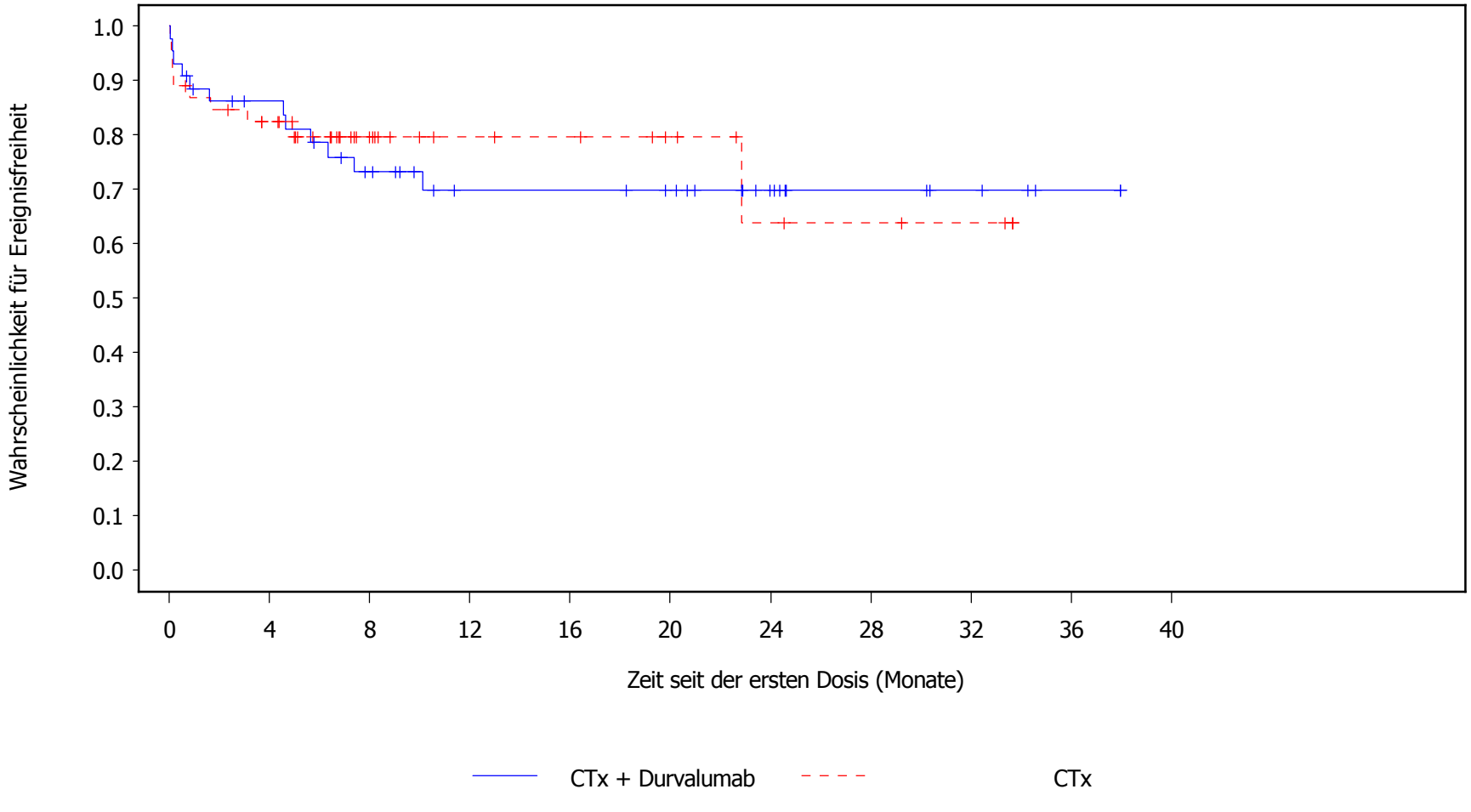
Figure 3.3.1.2D.27 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Dyspepsie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	30	21	21	19	10	5	3	1	0	CTx + Durvalumab
46	37	18	14	11	8	5	2	1	0	0	CTx

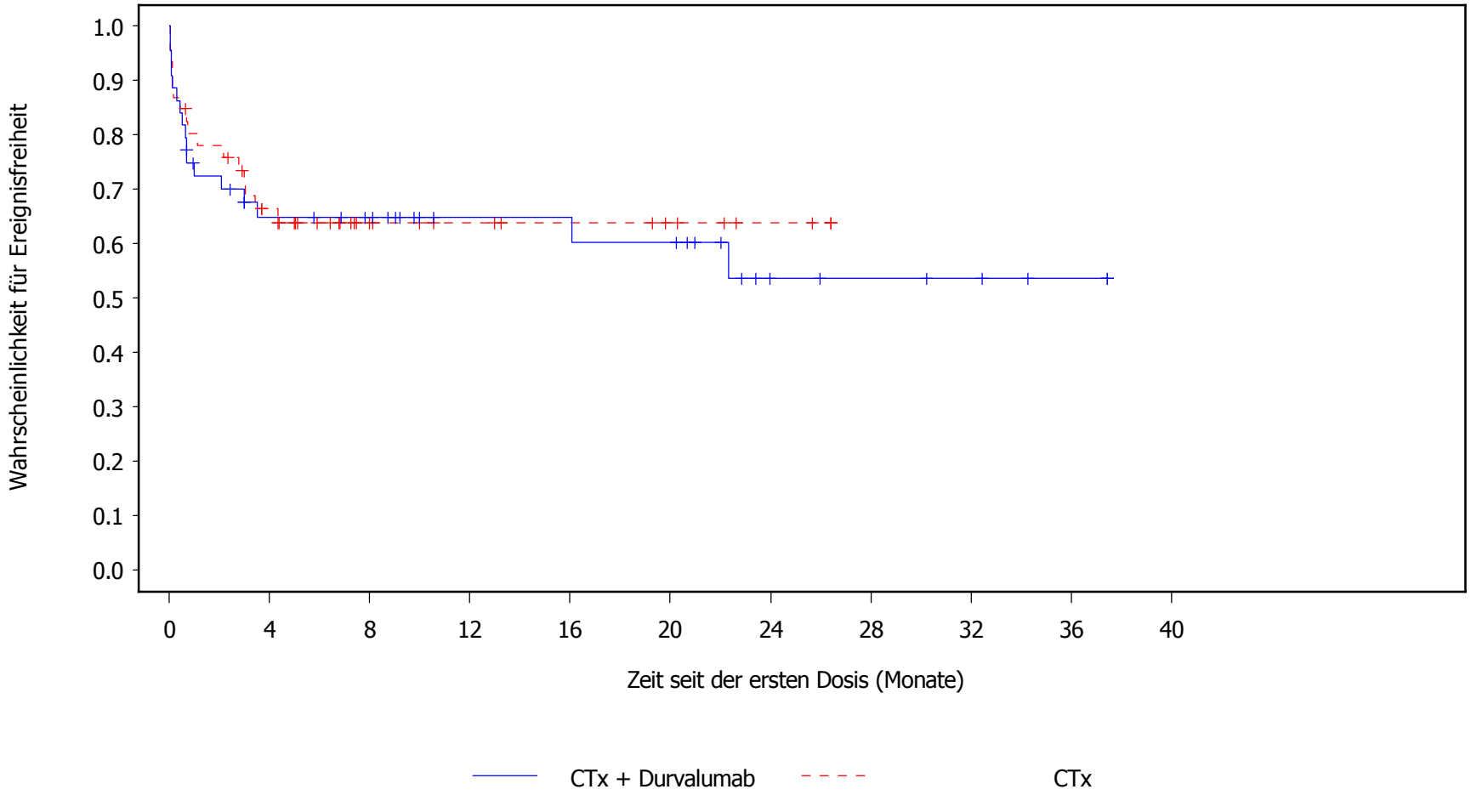
Figure 3.3.1.2D.28 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Erbrechen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	26	19	19	17	10	6	4	1	0	CTx + Durvalumab
46	34	18	11	10	7	4	3	2	0	0	CTx

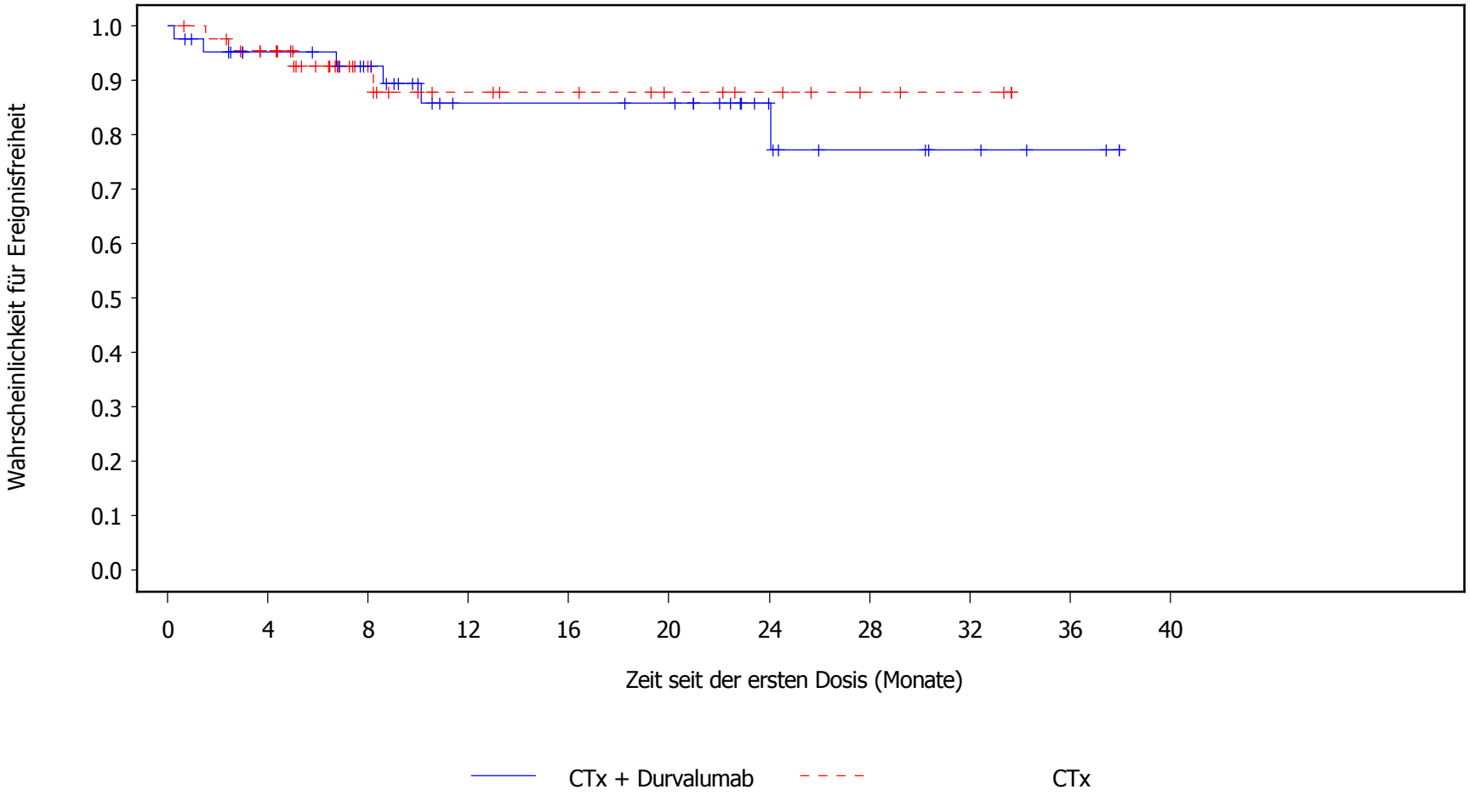
Figure 3.3.1.2D.29 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Obstipation
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	24	21	14	14	13	5	4	3	1	0	CTx + Durvalumab
46	26	13	9	7	5	2	0	0	0	0	CTx

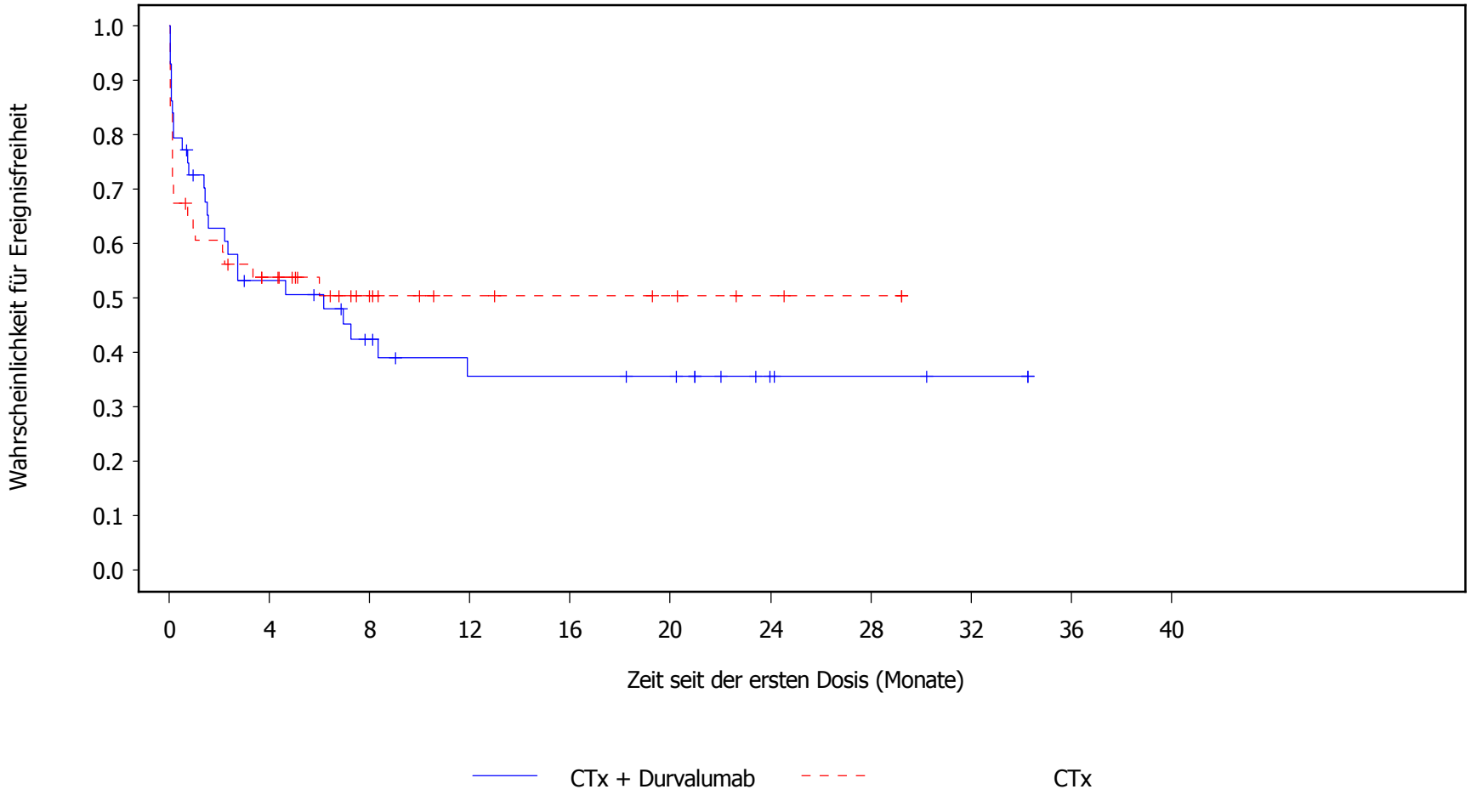
Figure 3.3.1.2D.30 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Schmerzen Oberbauch
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	31	20	20	19	10	6	4	2	0	CTx + Durvalumab
46	39	21	13	11	8	6	3	2	0	0	CTx

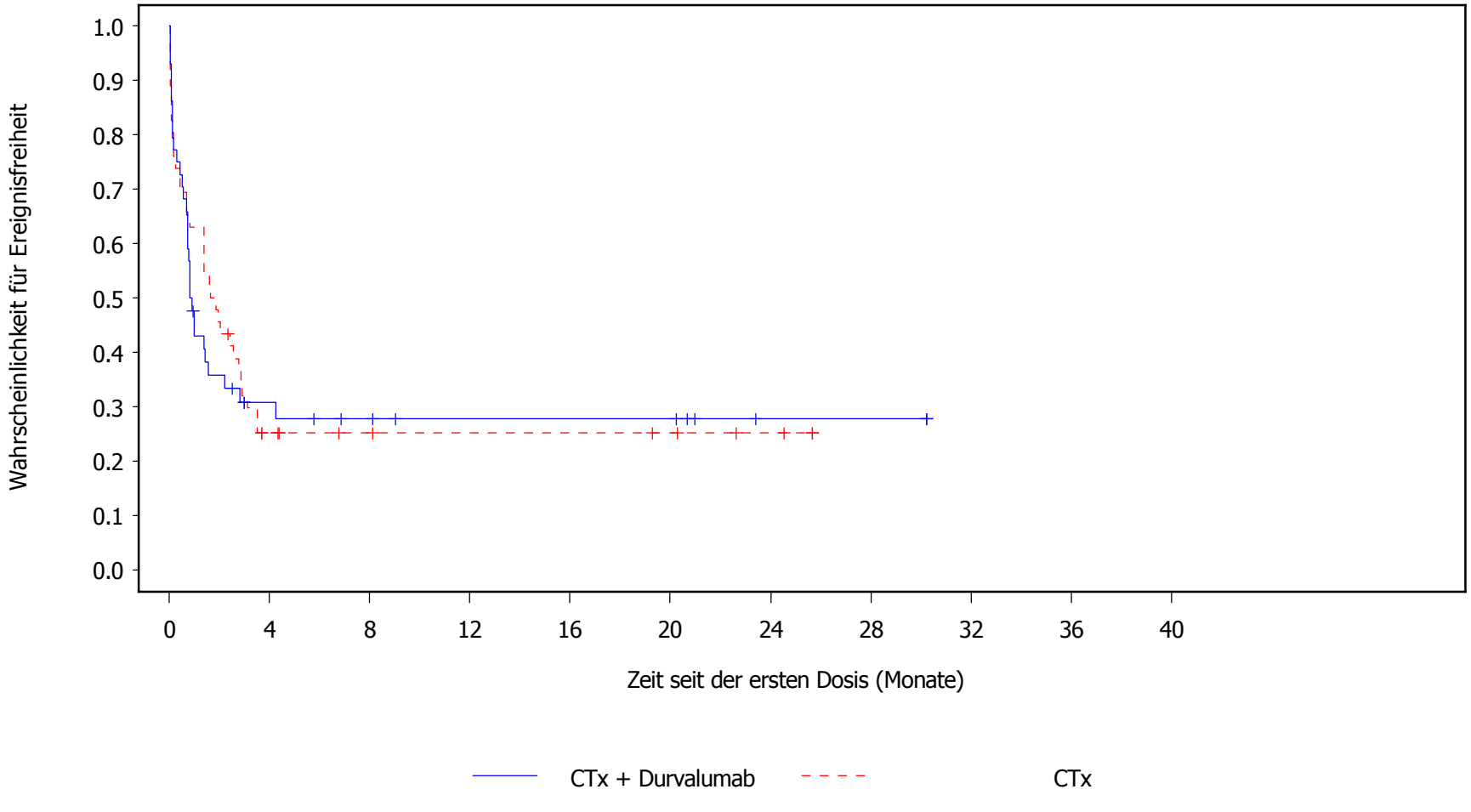
Figure 3.3.1.2D.31 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Uebelkeit
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	21	14	10	10	9	3	2	1	0	0	CTx + Durvalumab
46	21	11	6	5	4	2	1	0	0	0	CTx

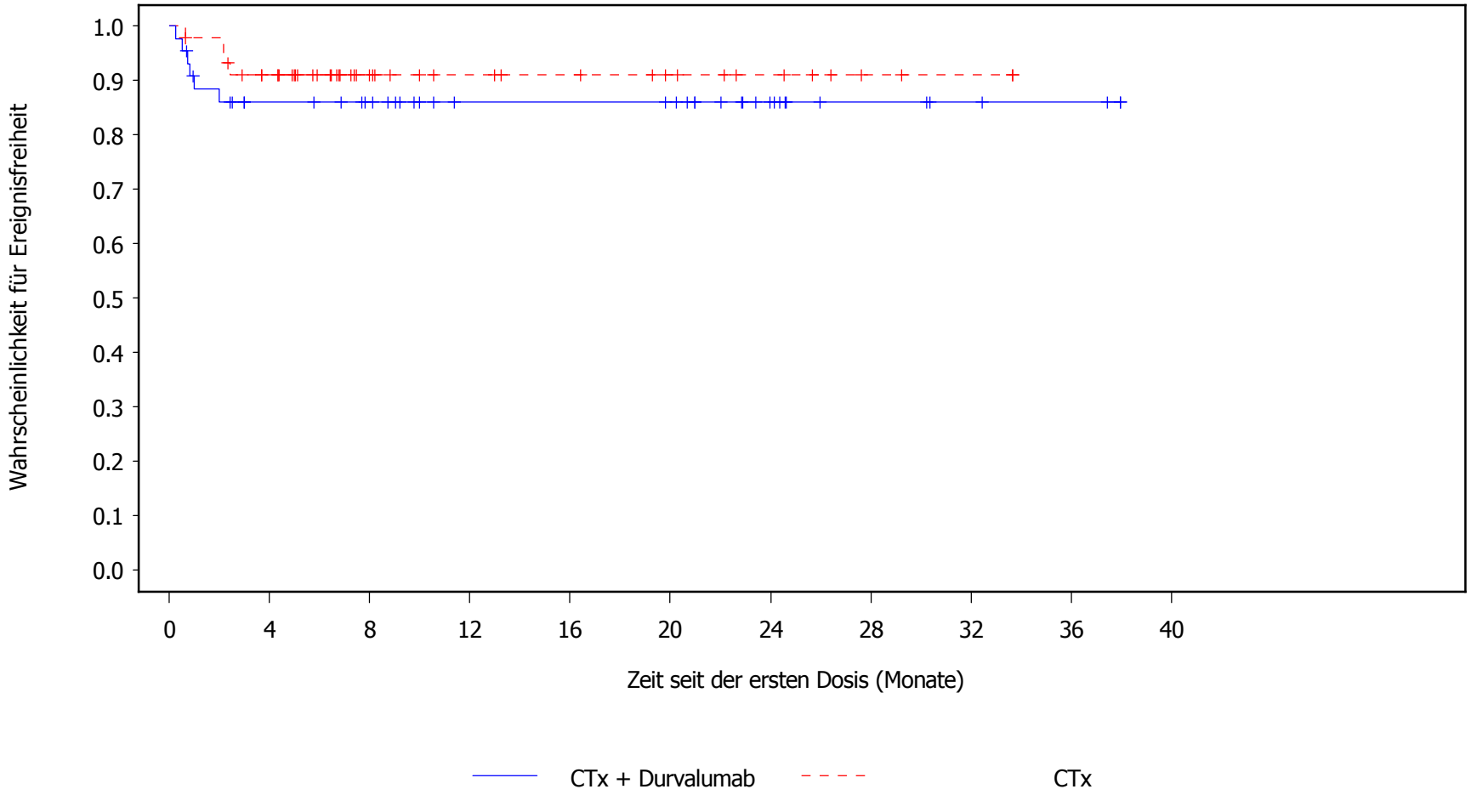
Figure 3.3.1.2D.32 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Nervensystems
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	10	7	5	5	5	1	1	0	0	0	CTx + Durvalumab
46	9	6	5	5	4	2	0	0	0	0	CTx

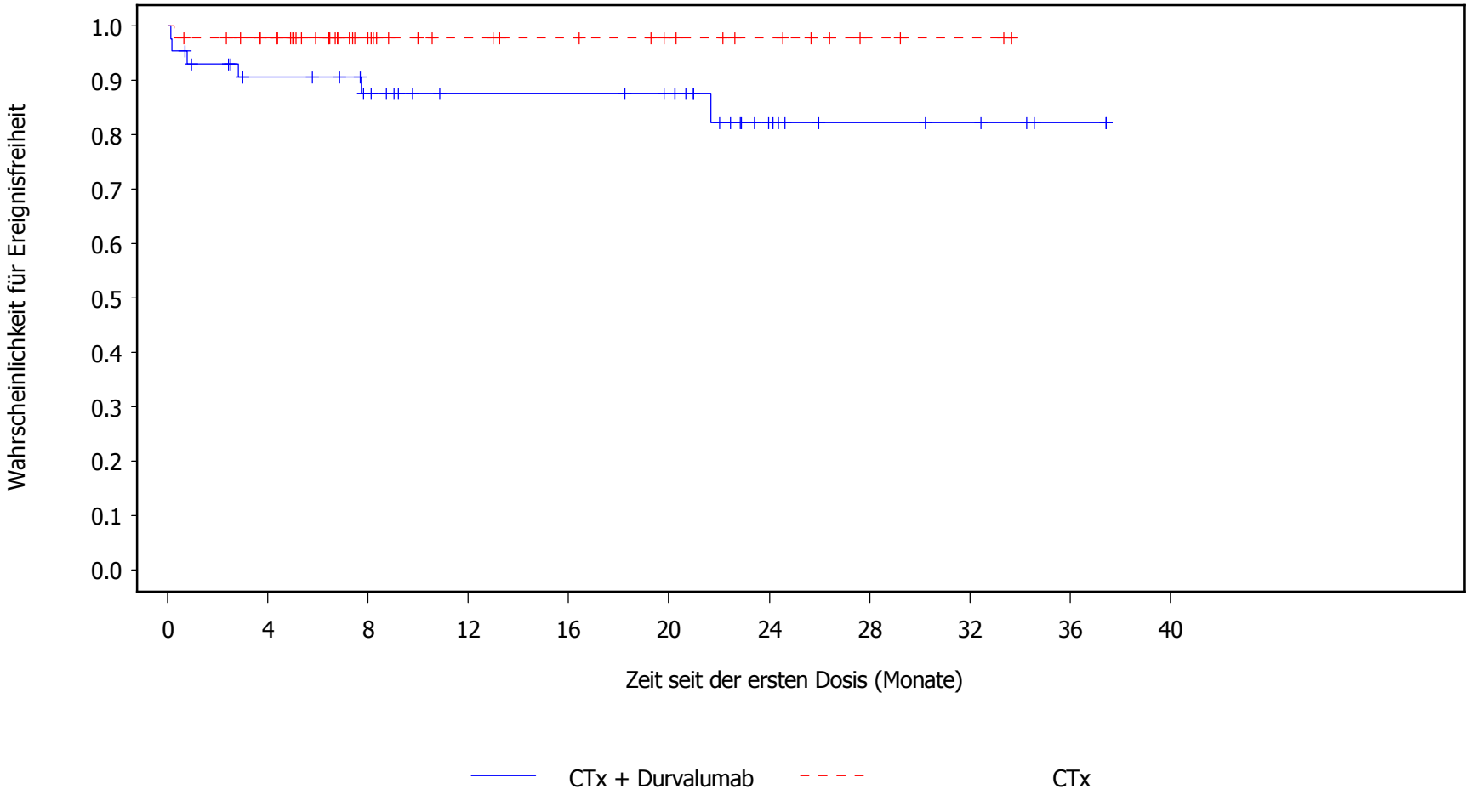
Figure 3.3.1.2D.33 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Dysgeusie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	32	28	20	20	19	10	5	3	2	0	CTx + Durvalumab
46	37	20	14	12	9	6	2	1	0	0	CTx

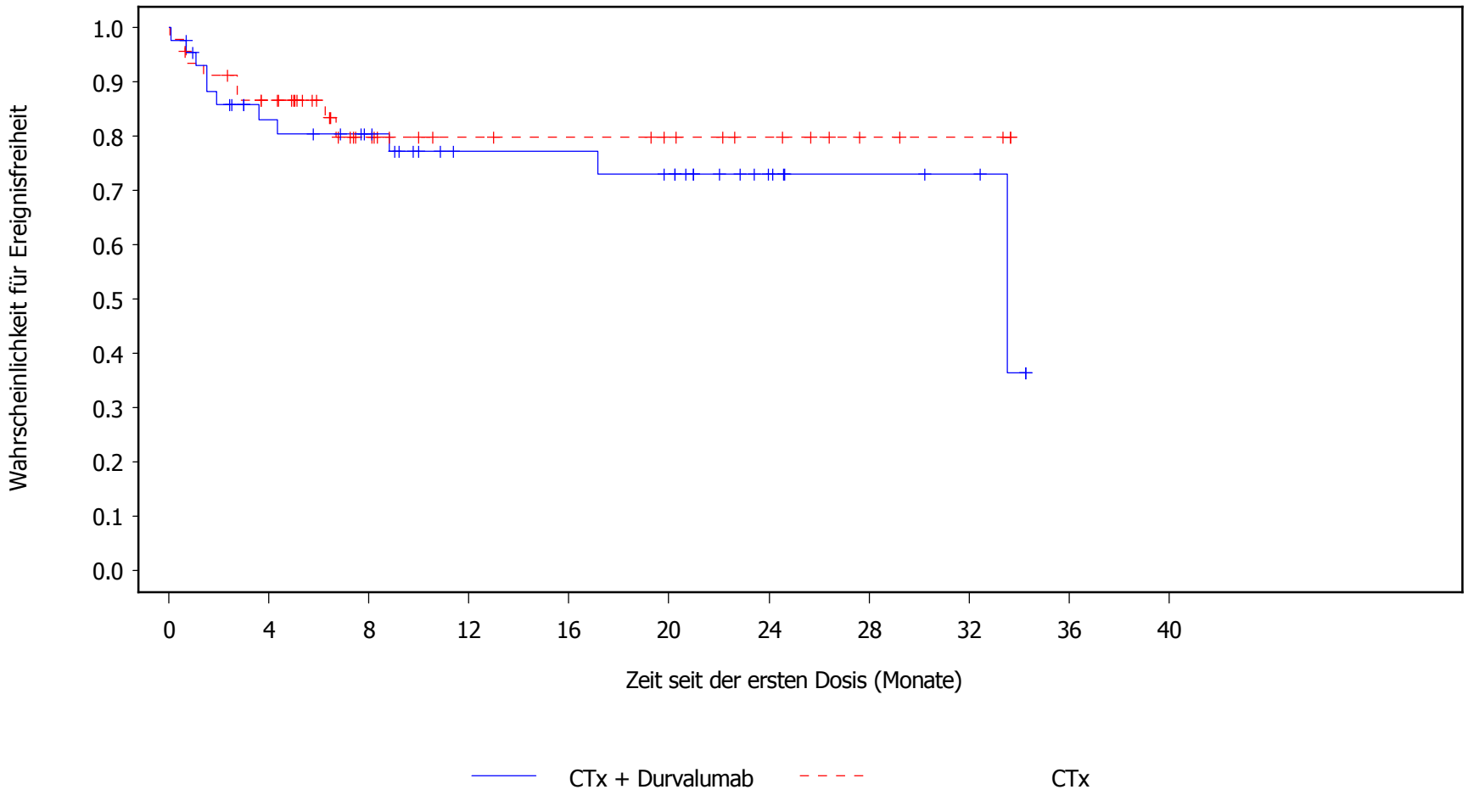
Figure 3.3.1.2D.34 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Hypoaesthesie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	29	23	23	21	9	5	4	1	0	CTx + Durvalumab
46	40	22	15	13	10	7	3	2	0	0	CTx

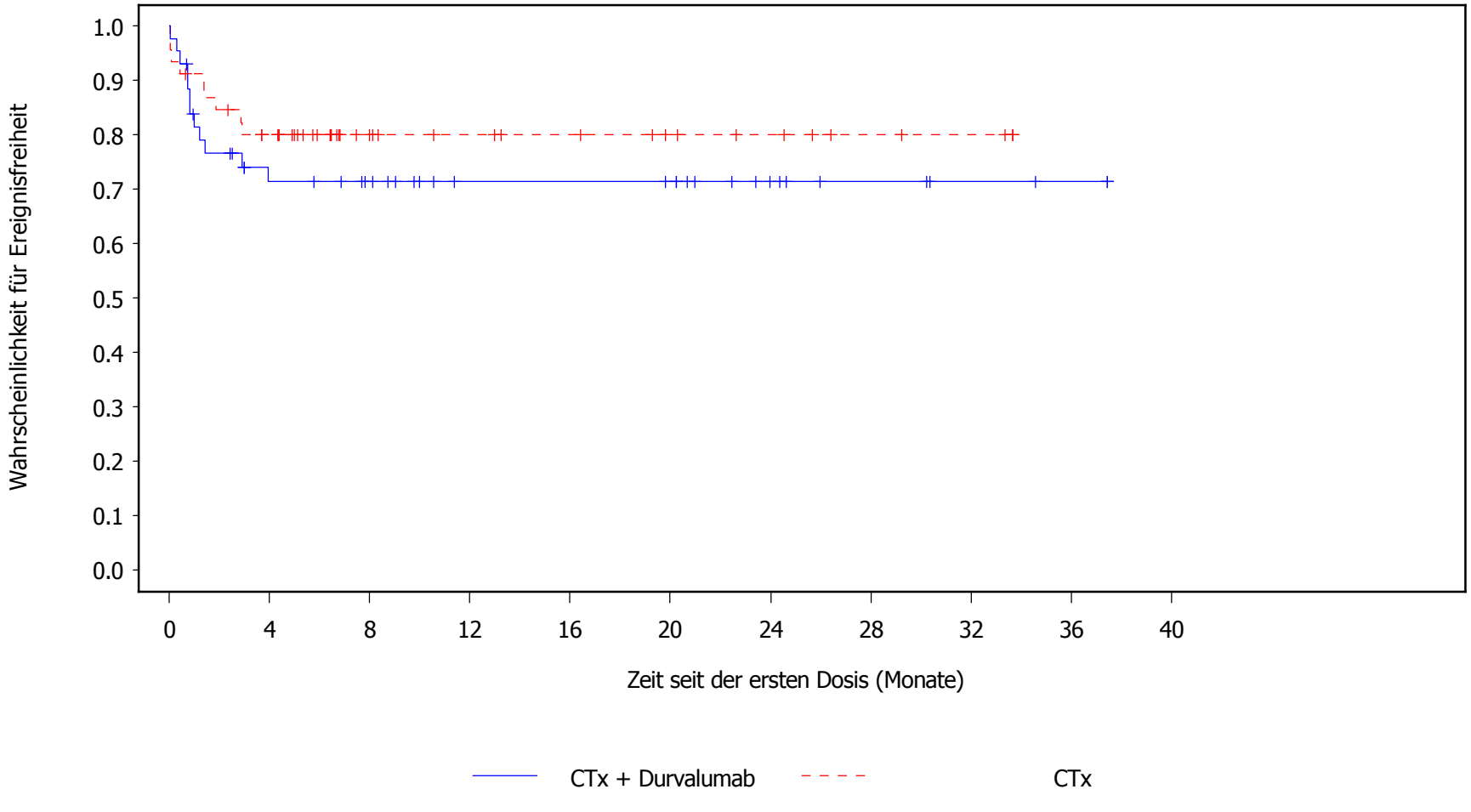
Figure 3.3.1.2D.35 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Kopfschmerzen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	31	26	18	18	16	7	4	3	0	0	CTx + Durvalumab
46	36	19	13	12	10	7	3	2	0	0	CTx

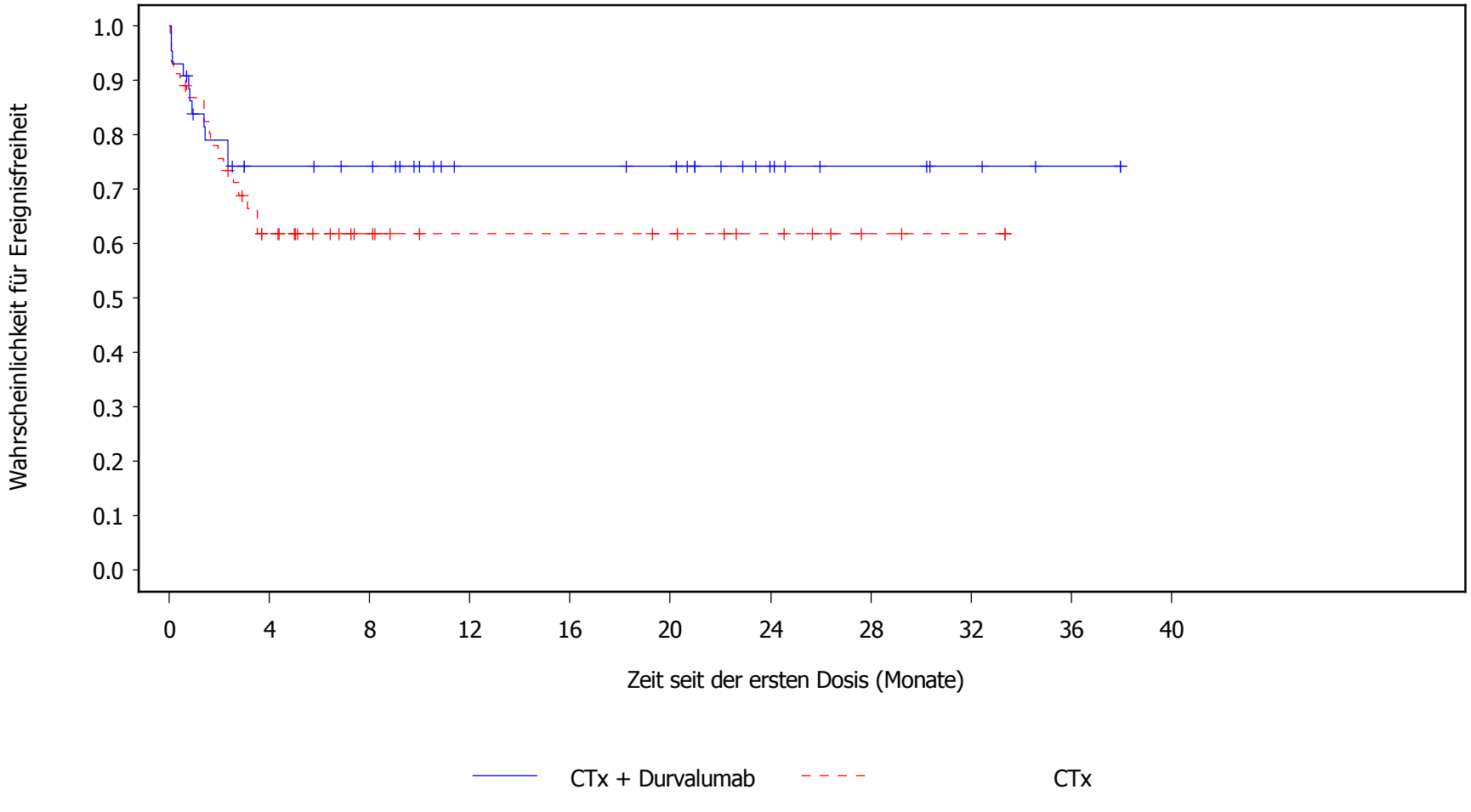
Figure 3.3.1.2D.36 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Periphere Neuropathie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	26	22	15	15	14	7	4	2	1	0	CTx + Durvalumab
46	33	17	13	11	8	6	3	2	0	0	CTx

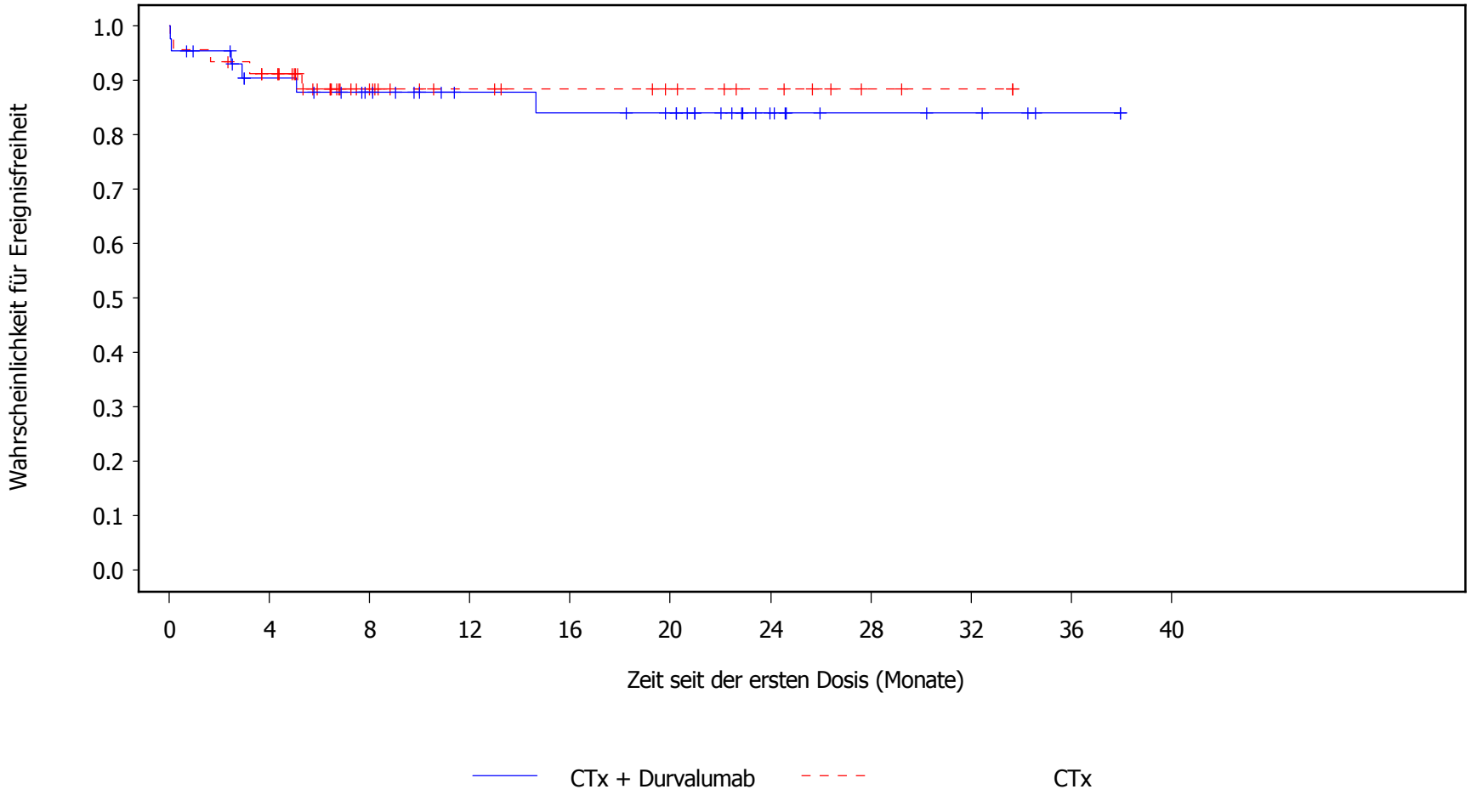
Figure 3.3.1.2D.37 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Periphere sensorische Neuropathie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	28	26	18	18	17	8	5	3	1	0	CTx + Durvalumab
46	24	14	10	10	9	6	2	1	0	0	CTx

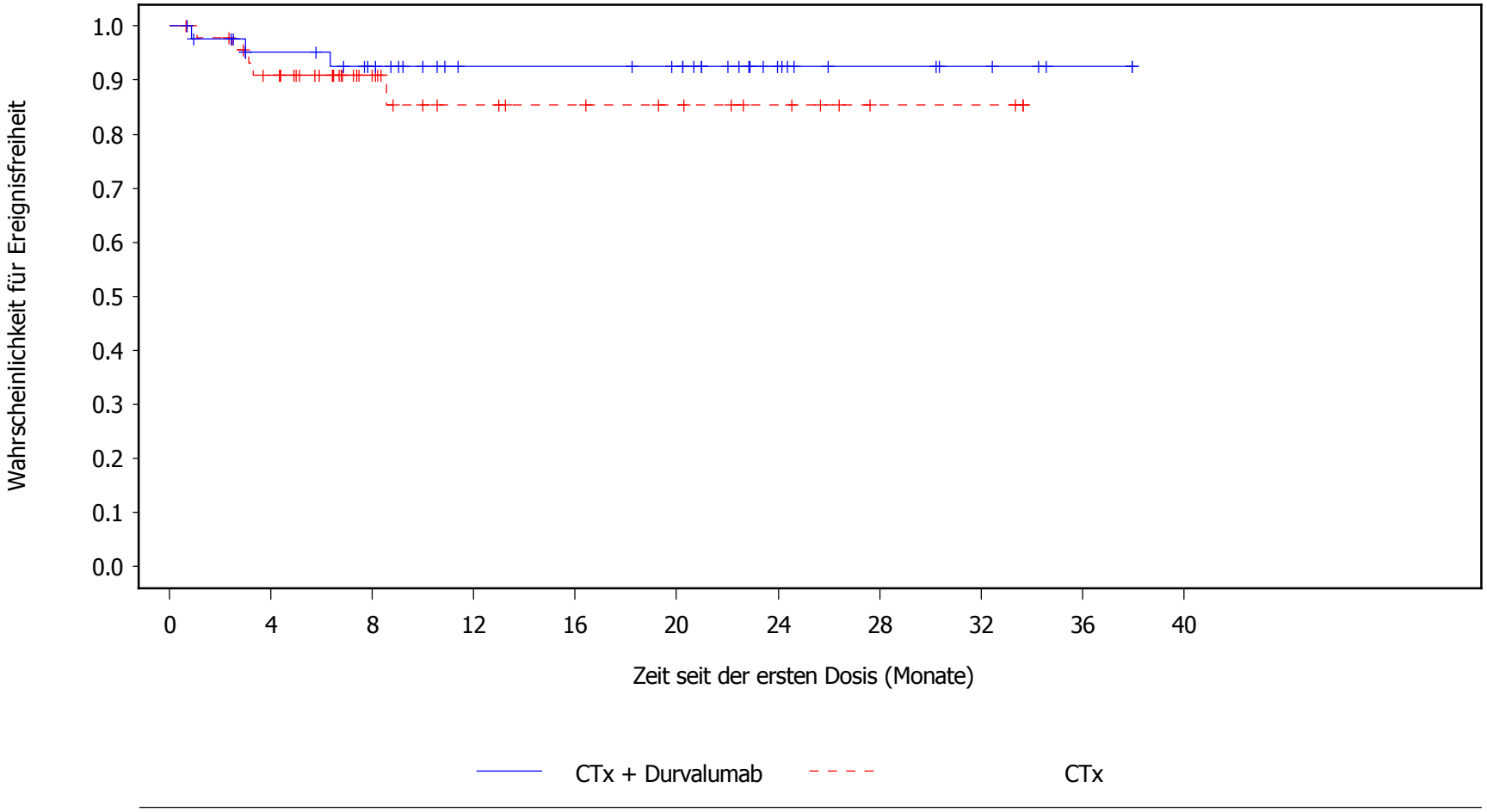
Figure 3.3.1.2D.38 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Schwindelgefuehl
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	29	23	22	20	9	5	4	1	0	CTx + Durvalumab
46	39	20	13	11	9	6	2	1	0	0	CTx

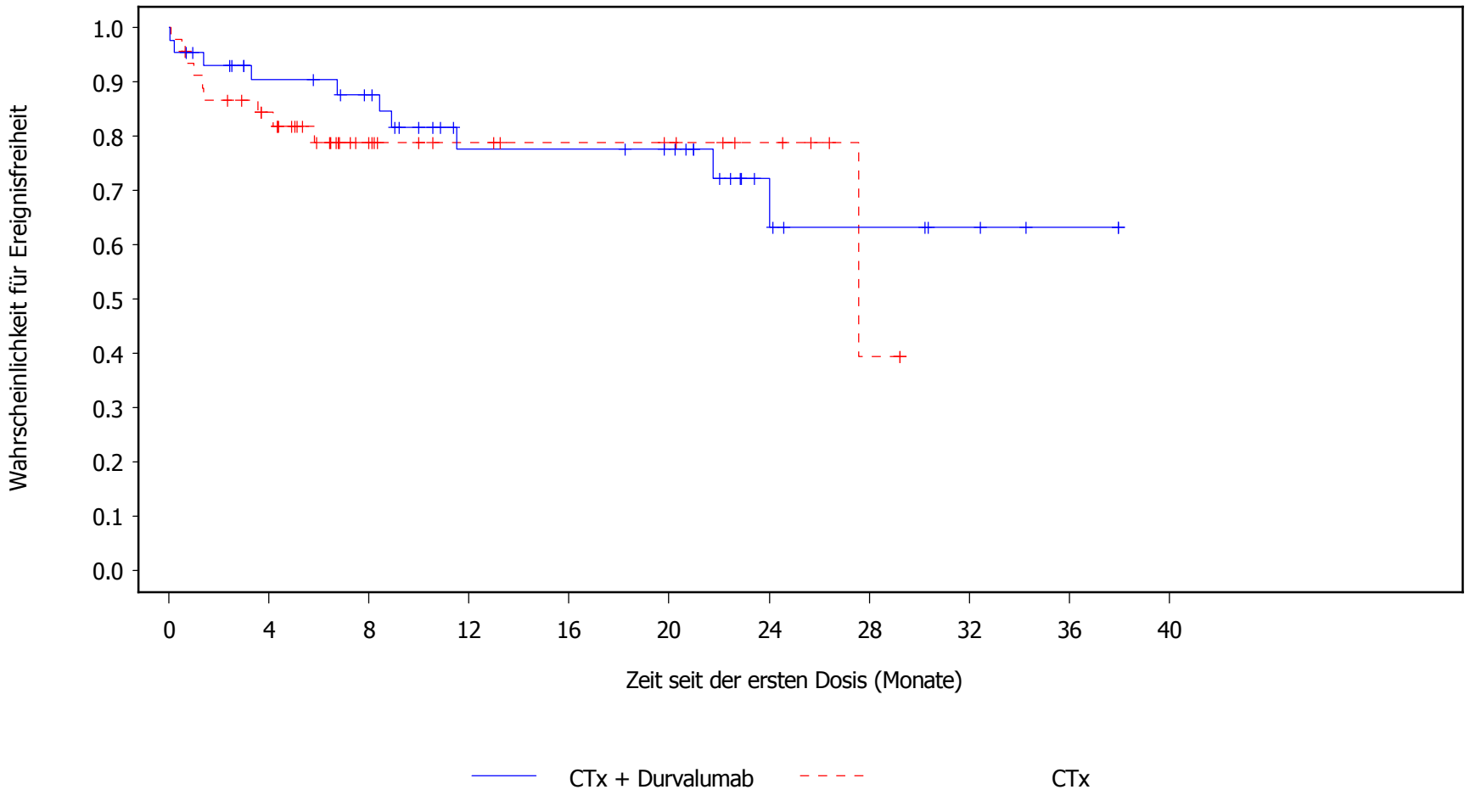
Figure 3.3.1.2D.39 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Erkrankungen des Ohrs und des Labyrinths
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	31	23	23	21	10	6	4	1	0	CTx + Durvalumab
46	38	21	13	11	9	6	2	2	0	0	CTx

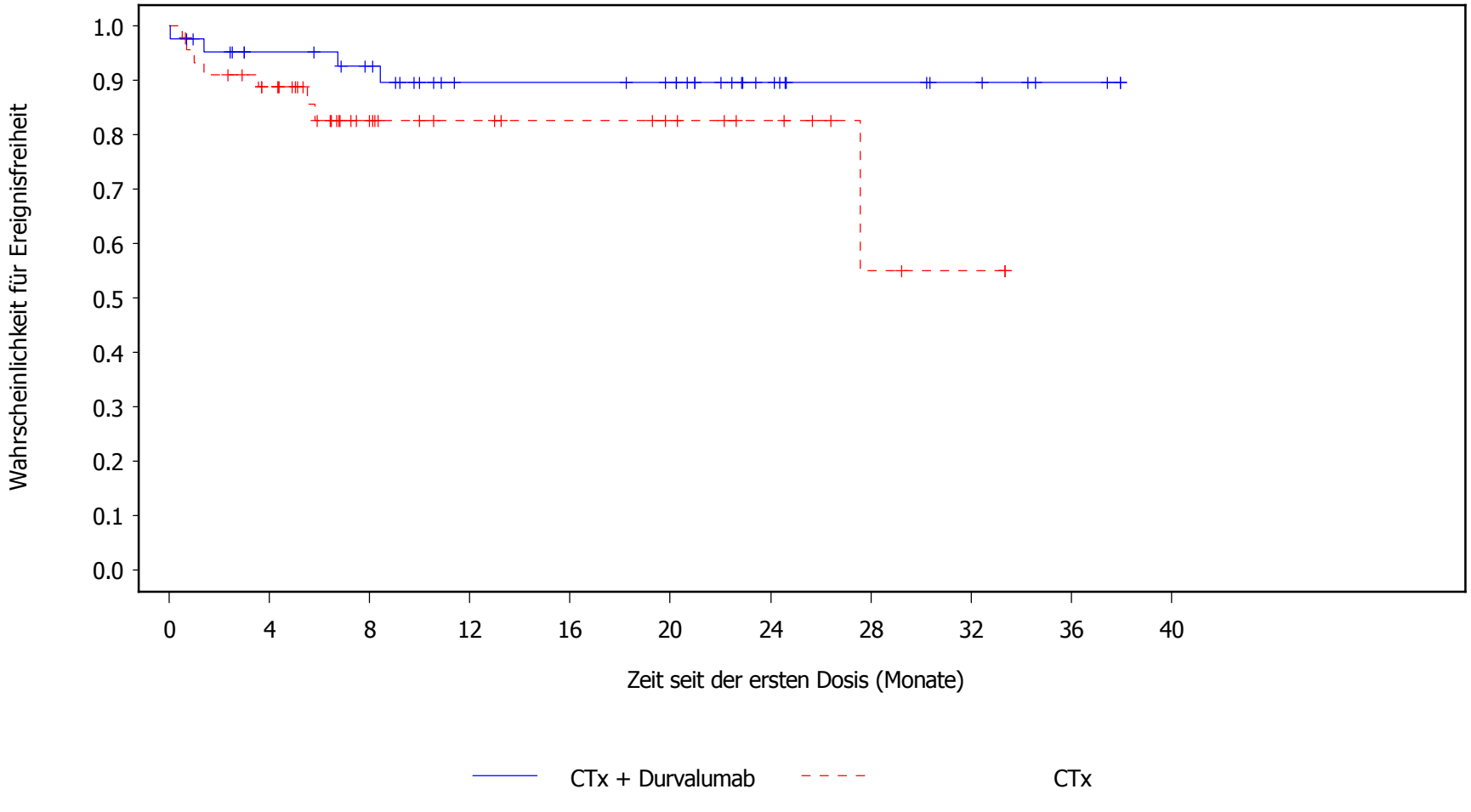
Figure 3.3.1.2D.40 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Gefaesserkrankungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	30	20	20	18	8	5	3	1	0	CTx + Durvalumab
46	34	17	11	9	8	5	1	0	0	0	CTx

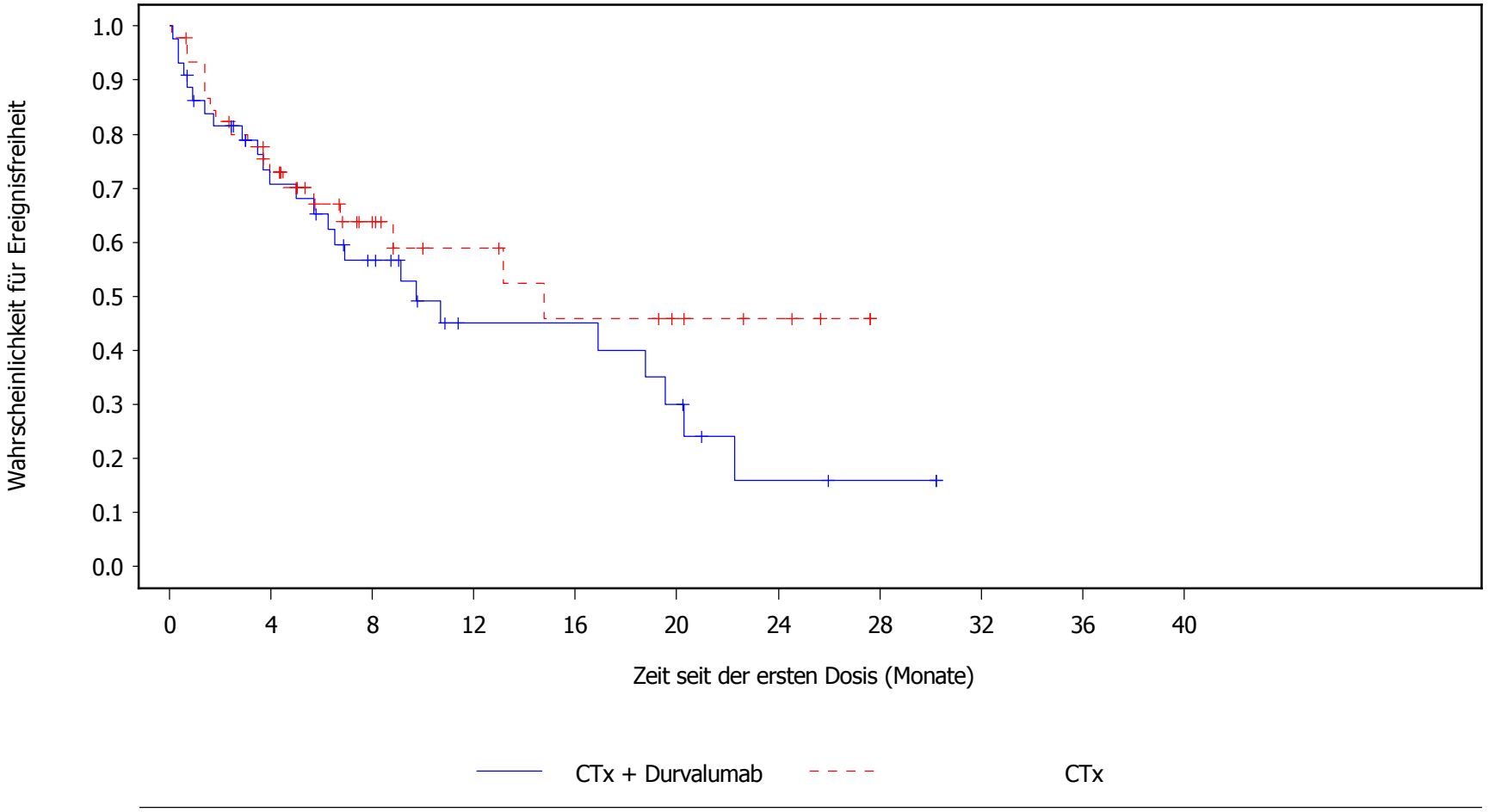
Figure 3.3.1.2D.41 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Hypertonie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	32	23	23	21	11	7	5	2	0	CTx + Durvalumab
46	36	19	13	11	9	6	2	1	0	0	CTx

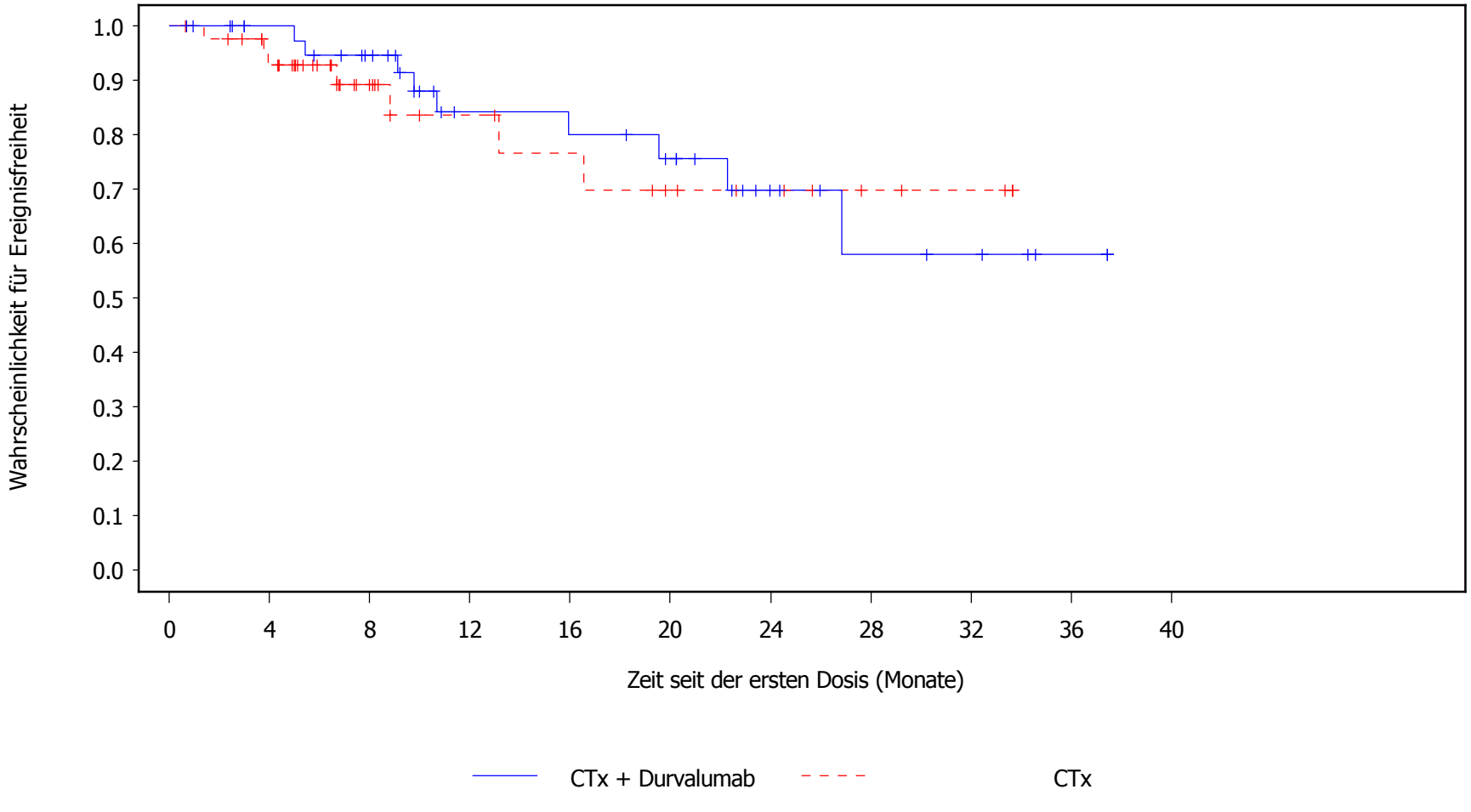
Figure 3.3.1.2D.42 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Infektionen und parasitaere Erkrankungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	26	18	9	9	6	2	1	0	0	0	CTx + Durvalumab
46	30	16	10	7	5	3	0	0	0	0	CTx

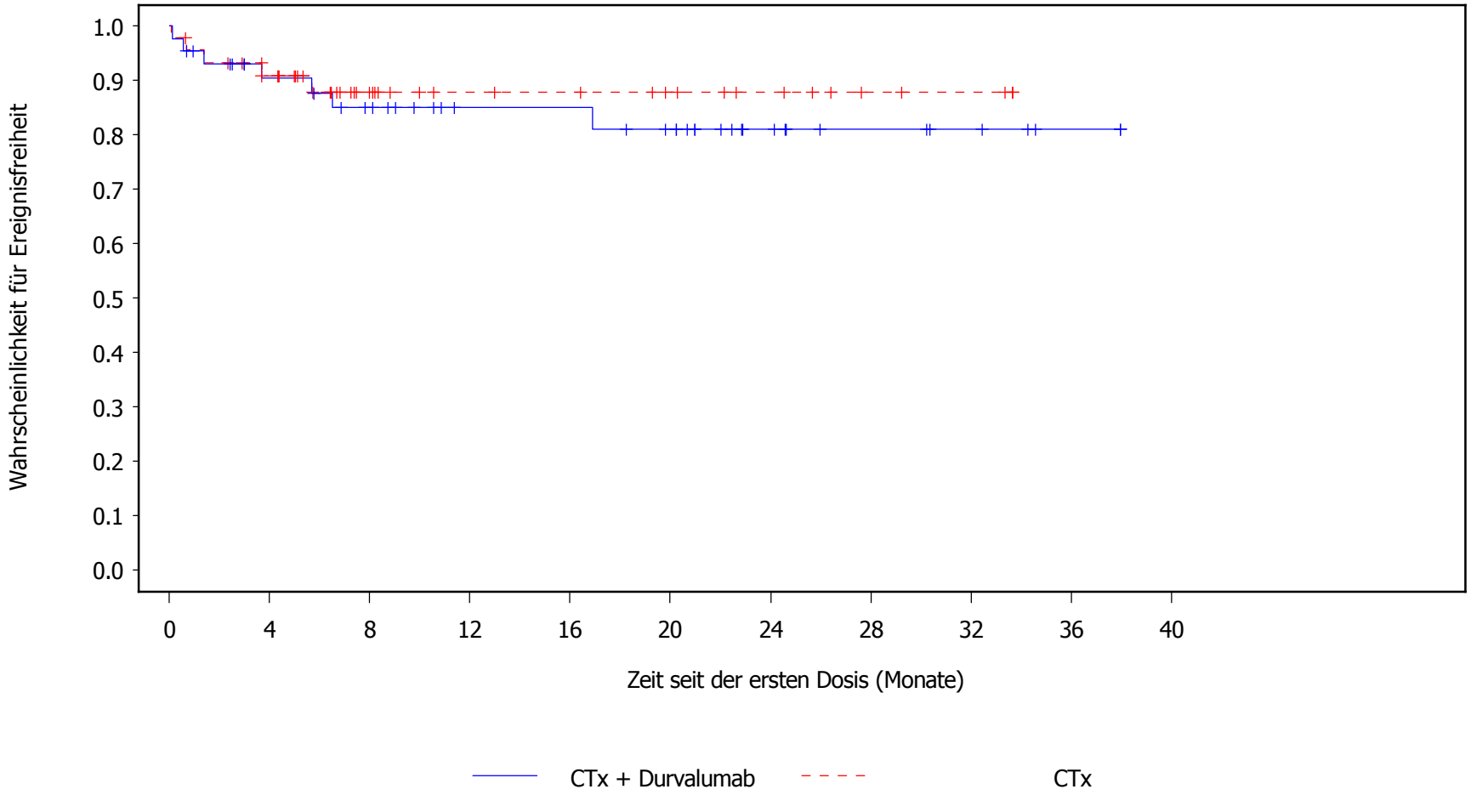
Figure 3.3.1.2D.43 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: COVID-19
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	32	20	19	16	8	5	4	1	0	CTx + Durvalumab
46	38	20	13	11	8	6	3	2	0	0	CTx

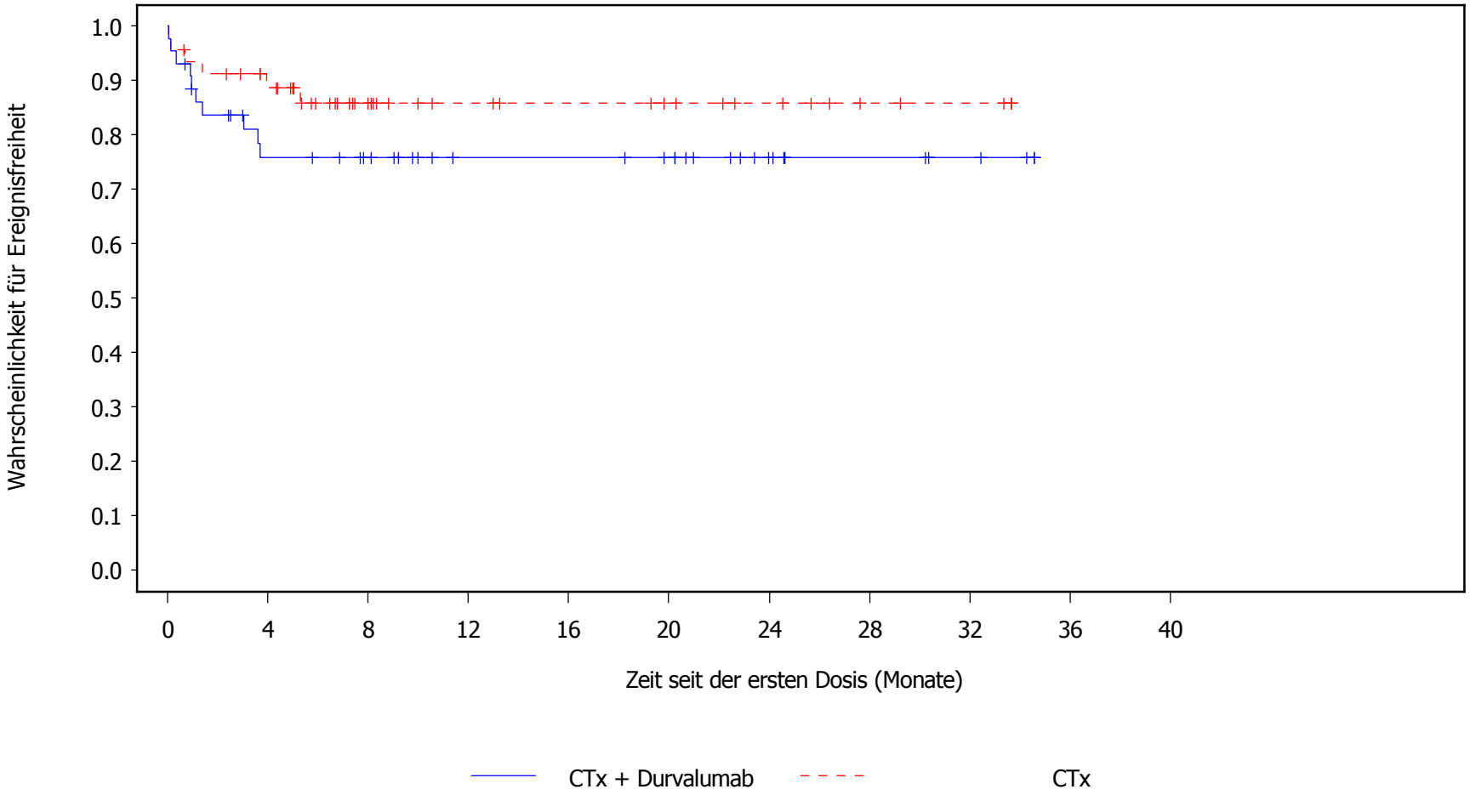
Figure 3.3.1.2D.44 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Harnwegsinfektion
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	29	22	22	19	10	6	4	1	0	CTx + Durvalumab
46	37	21	14	13	10	7	3	2	0	0	CTx

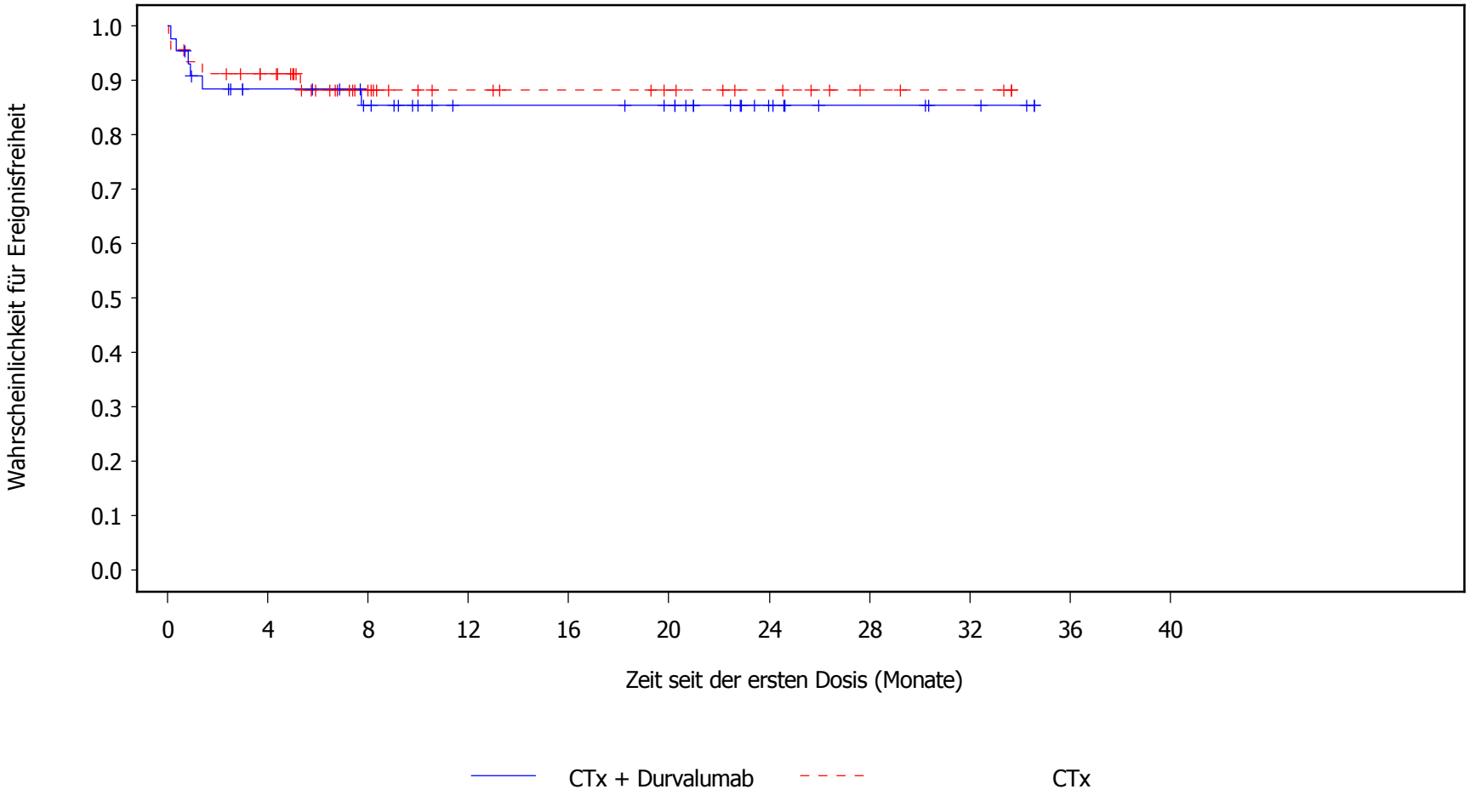
Figure 3.3.1.2D.45 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Psychiatrische Erkrankungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	29	25	18	18	16	8	5	3	0	0	CTx + Durvalumab
46	36	21	14	12	10	7	3	2	0	0	CTx

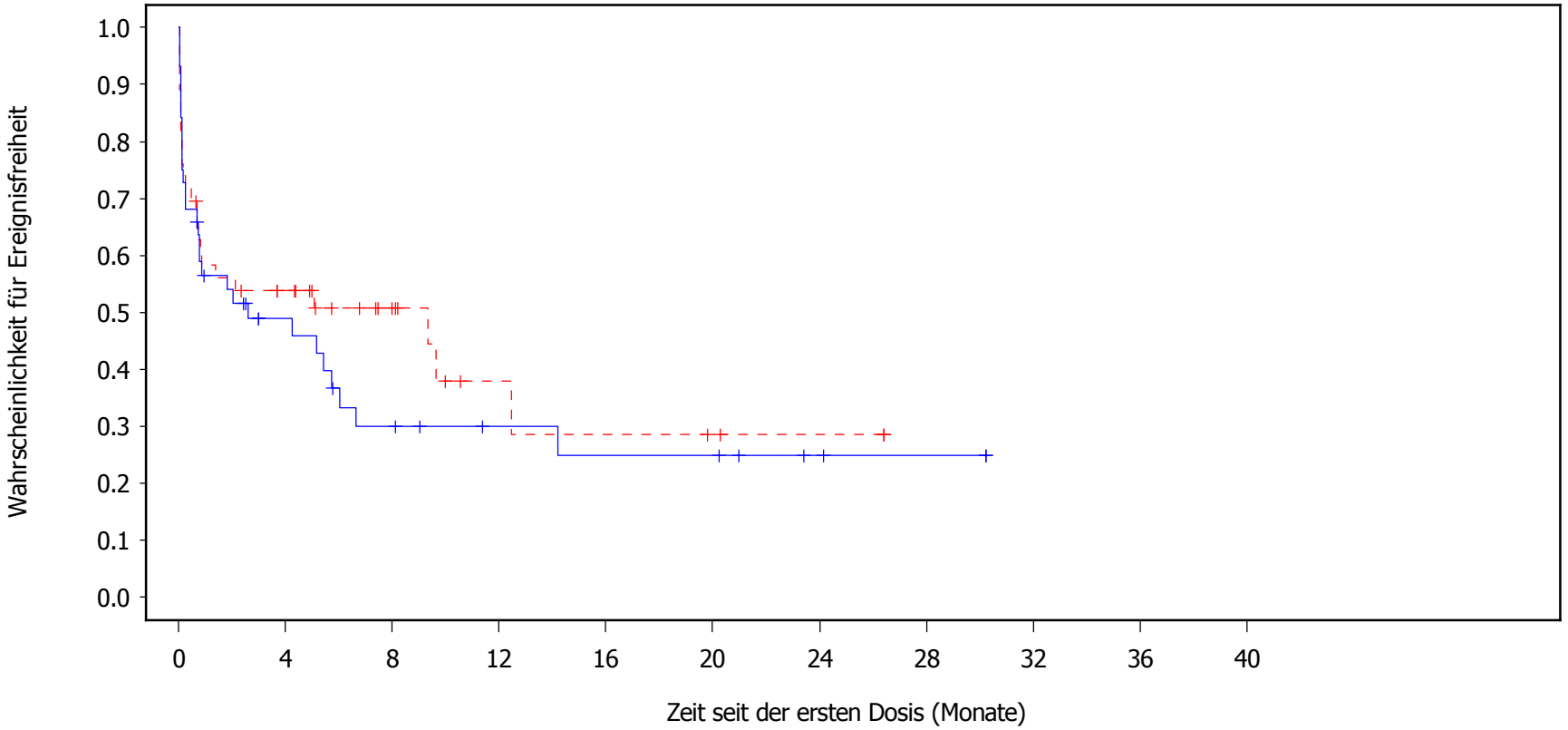
Figure 3.3.1.2D.46 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Schlaflosigkeit
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	33	28	21	21	19	9	5	3	0	0	CTx + Durvalumab
46	37	21	14	12	10	7	3	2	0	0	CTx

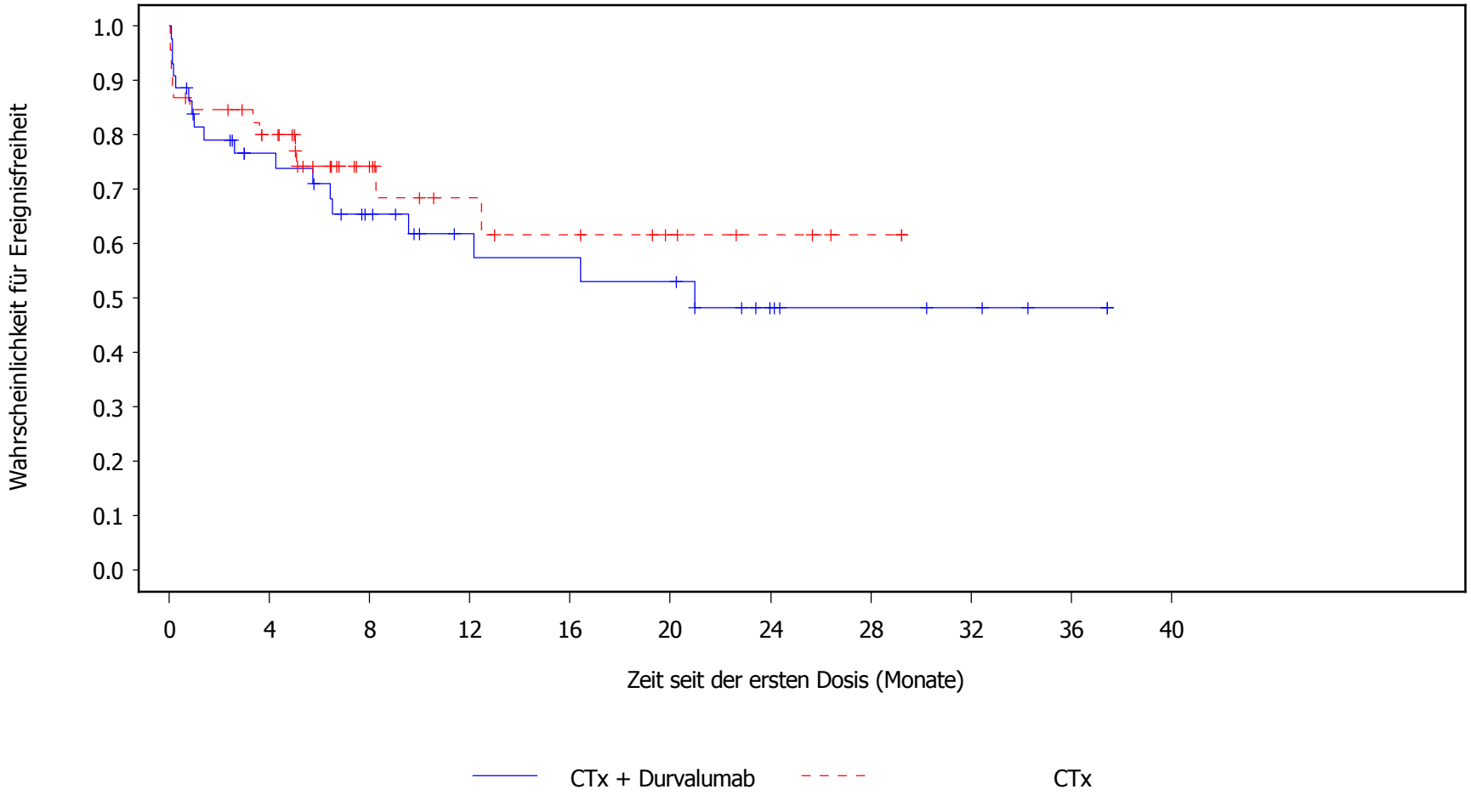
Figure 3.3.1.2D.47 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	16	9	6	5	5	2	1	0	0	0	CTx + Durvalumab
46	21	11	4	3	2	1	0	0	0	0	CTx

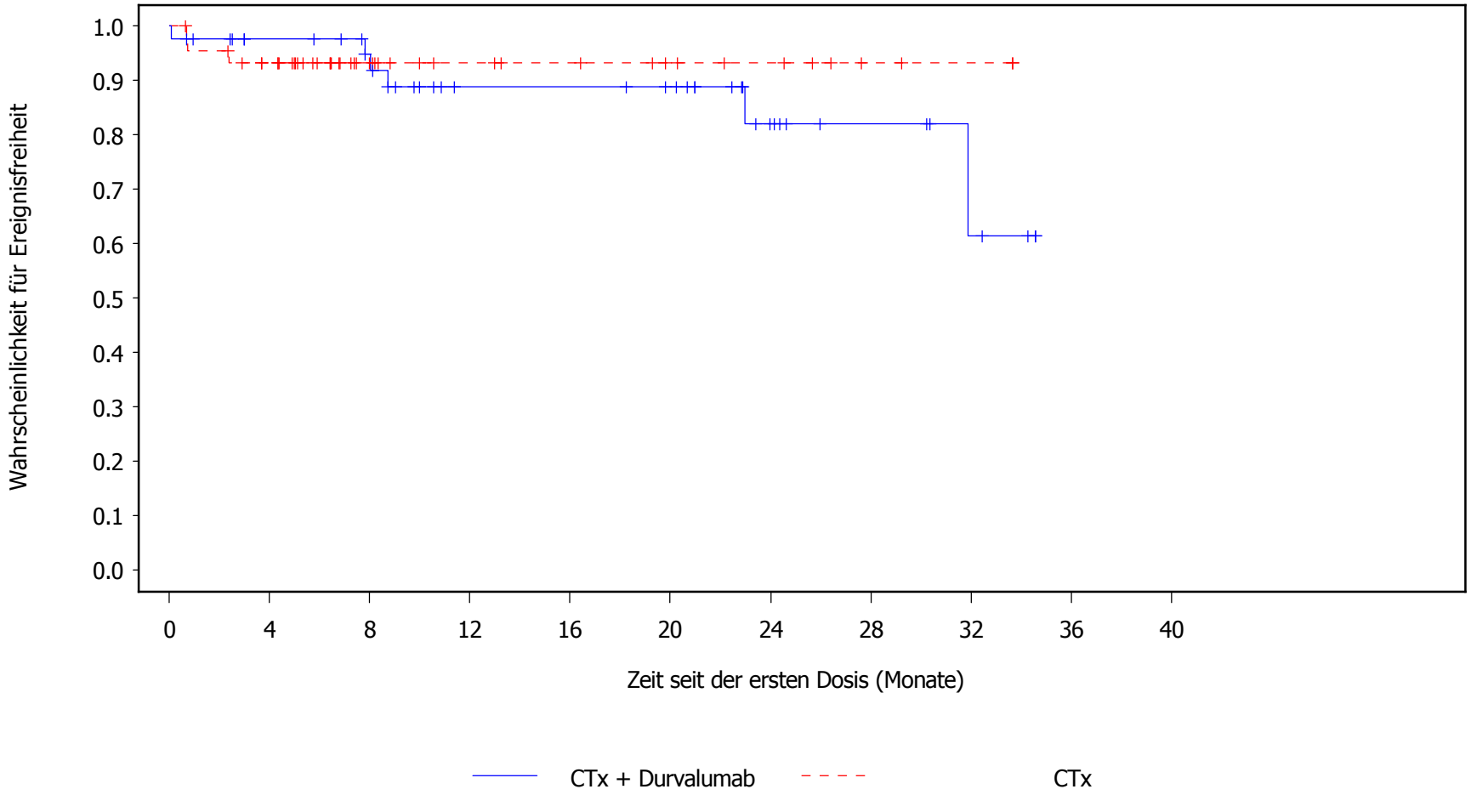
Figure 3.3.1.2D.48 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Arthralgie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	28	20	14	13	12	6	4	3	1	0	CTx + Durvalumab
46	32	16	10	8	5	3	1	0	0	0	CTx

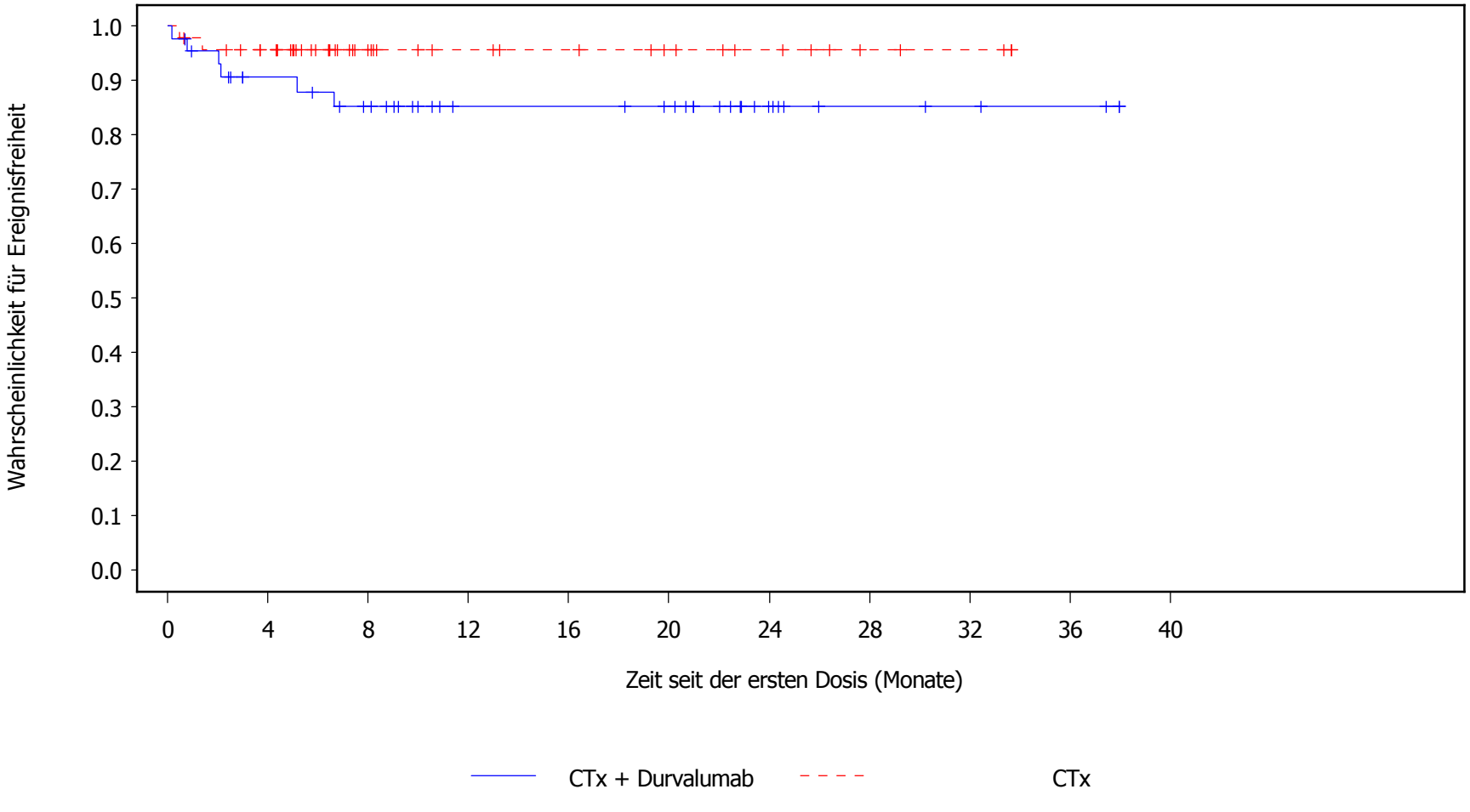
Figure 3.3.1.2D.49 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Muskelspasmen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	37	32	22	22	20	10	6	3	0	0	CTx + Durvalumab
46	38	20	13	11	8	6	2	1	0	0	CTx

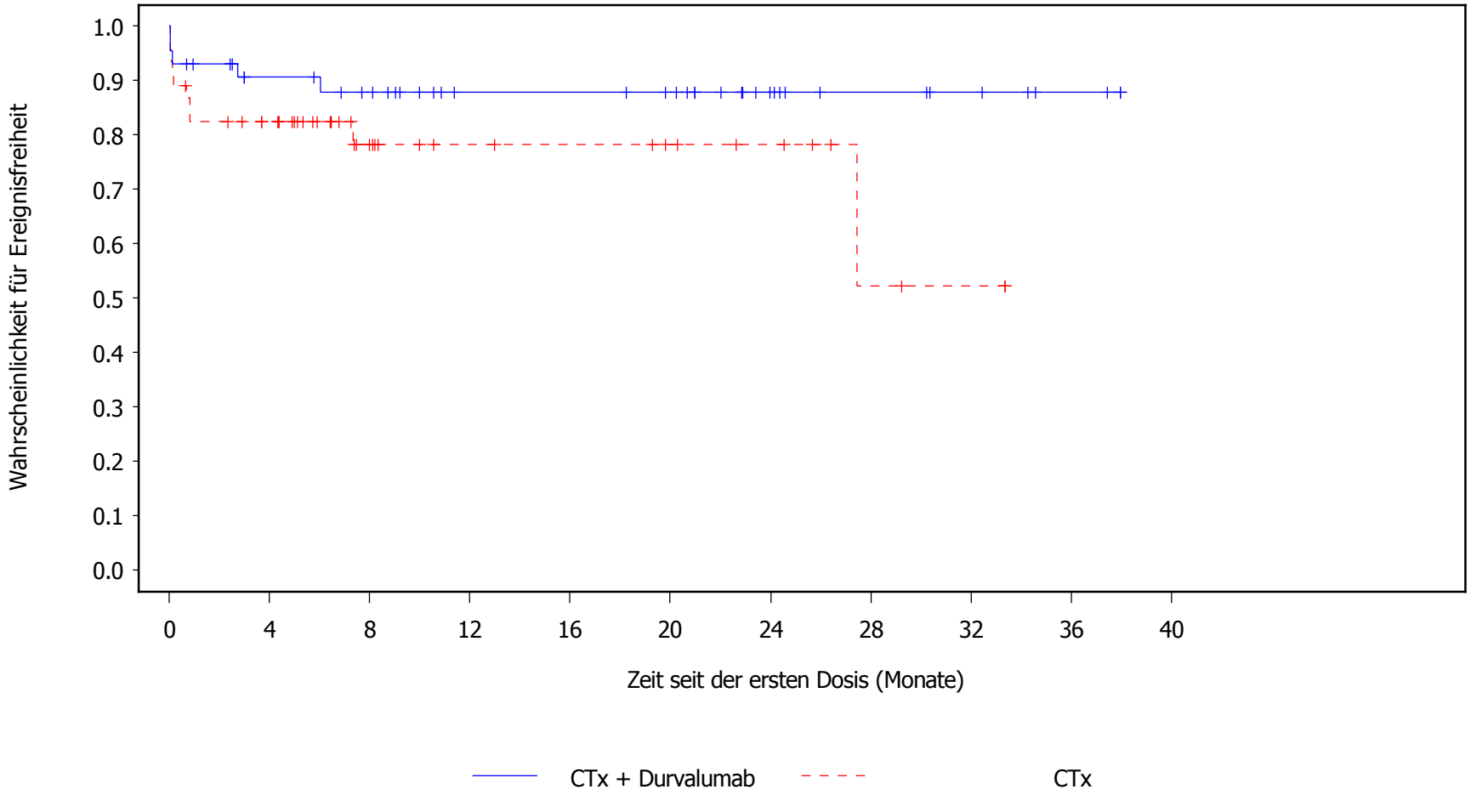
Figure 3.3.1.2D.50 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Muskulaere Schwaeche
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	29	20	20	18	8	4	3	2	0	CTx + Durvalumab
46	39	21	15	13	10	7	3	2	0	0	CTx

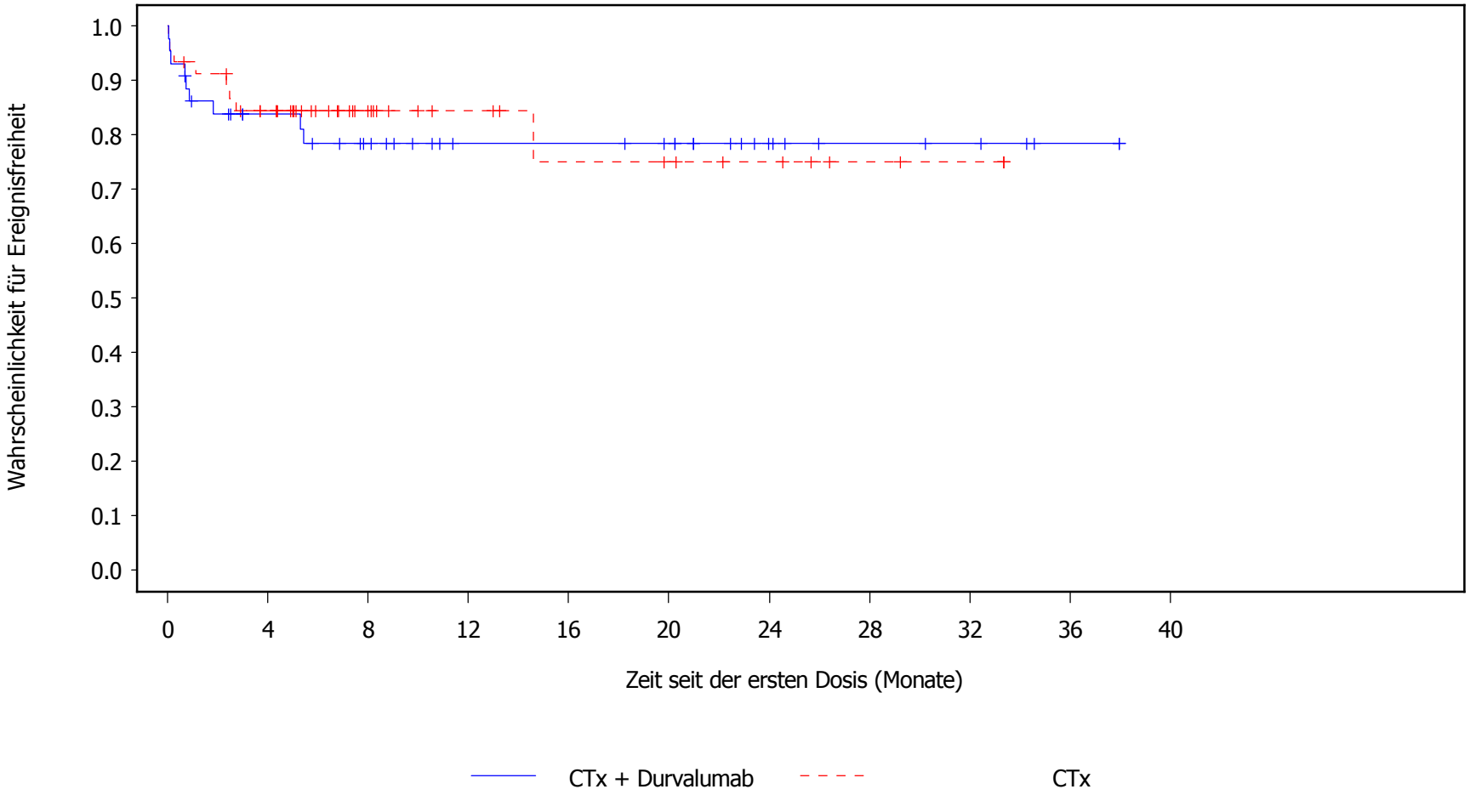
Figure 3.3.1.2D.51 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Myalgie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	30	22	22	20	11	7	5	2	0	CTx + Durvalumab
46	33	17	11	10	8	6	2	1	0	0	CTx

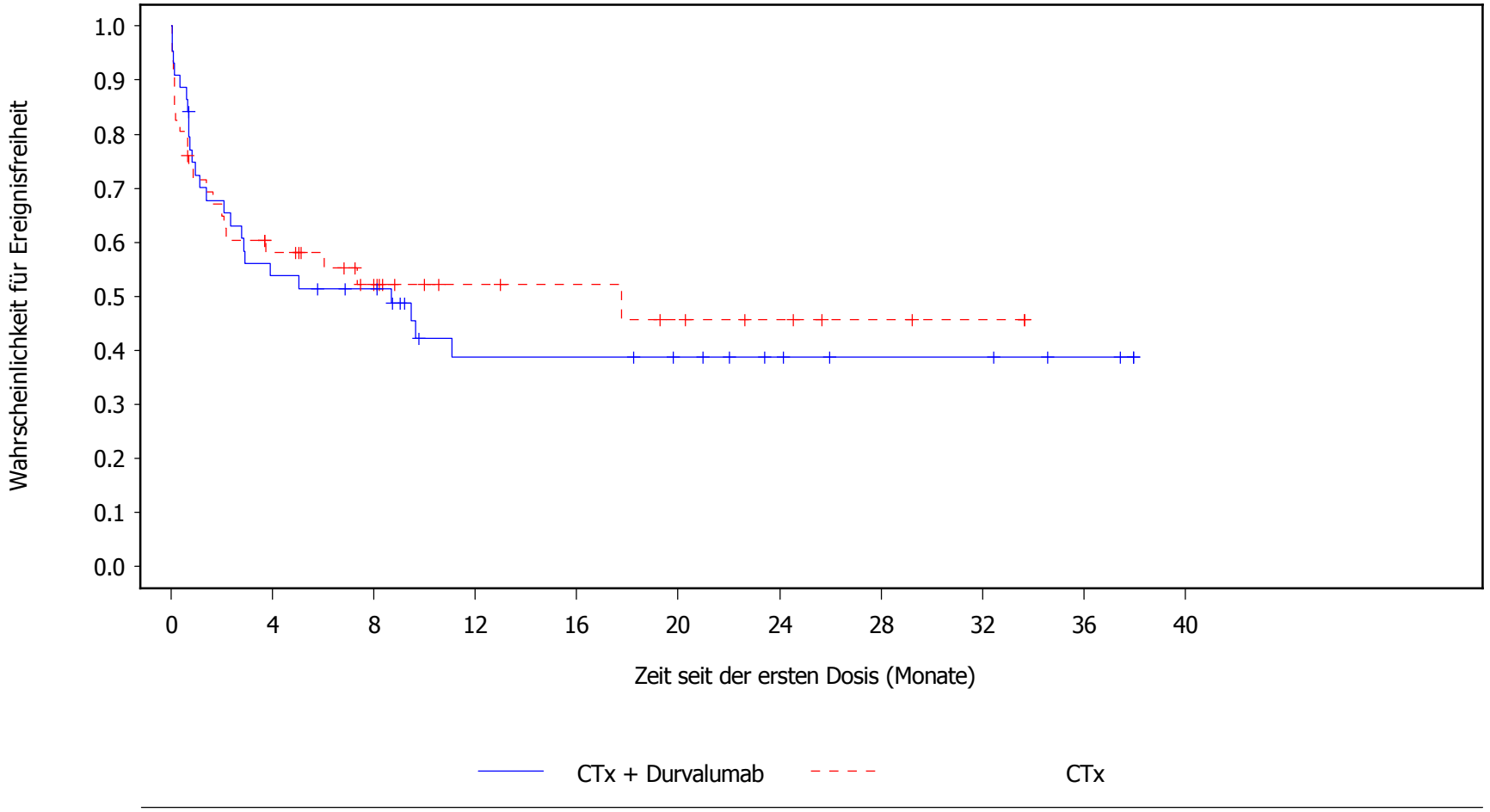
Figure 3.3.1.2D.52 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Schmerz in einer Extremitaet
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	31	25	18	18	16	8	5	4	1	0	CTx + Durvalumab
46	34	18	11	8	7	5	2	1	0	0	CTx

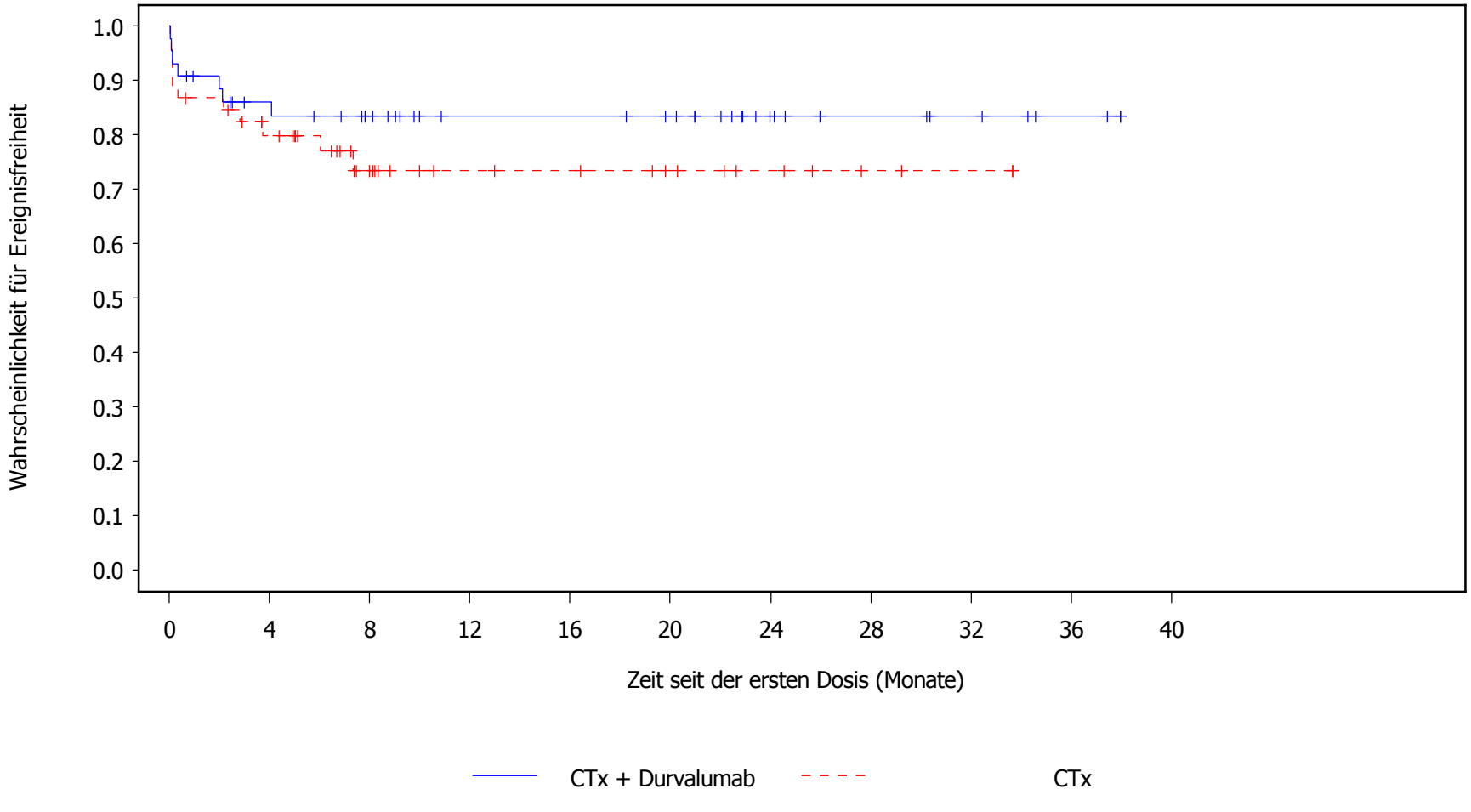
Figure 3.3.1.2D.53 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Stoffwechsel- und Ernaehrungsstoerungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	23	20	11	11	9	6	4	4	2	0	CTx + Durvalumab
46	24	16	9	8	6	4	2	1	0	0	CTx

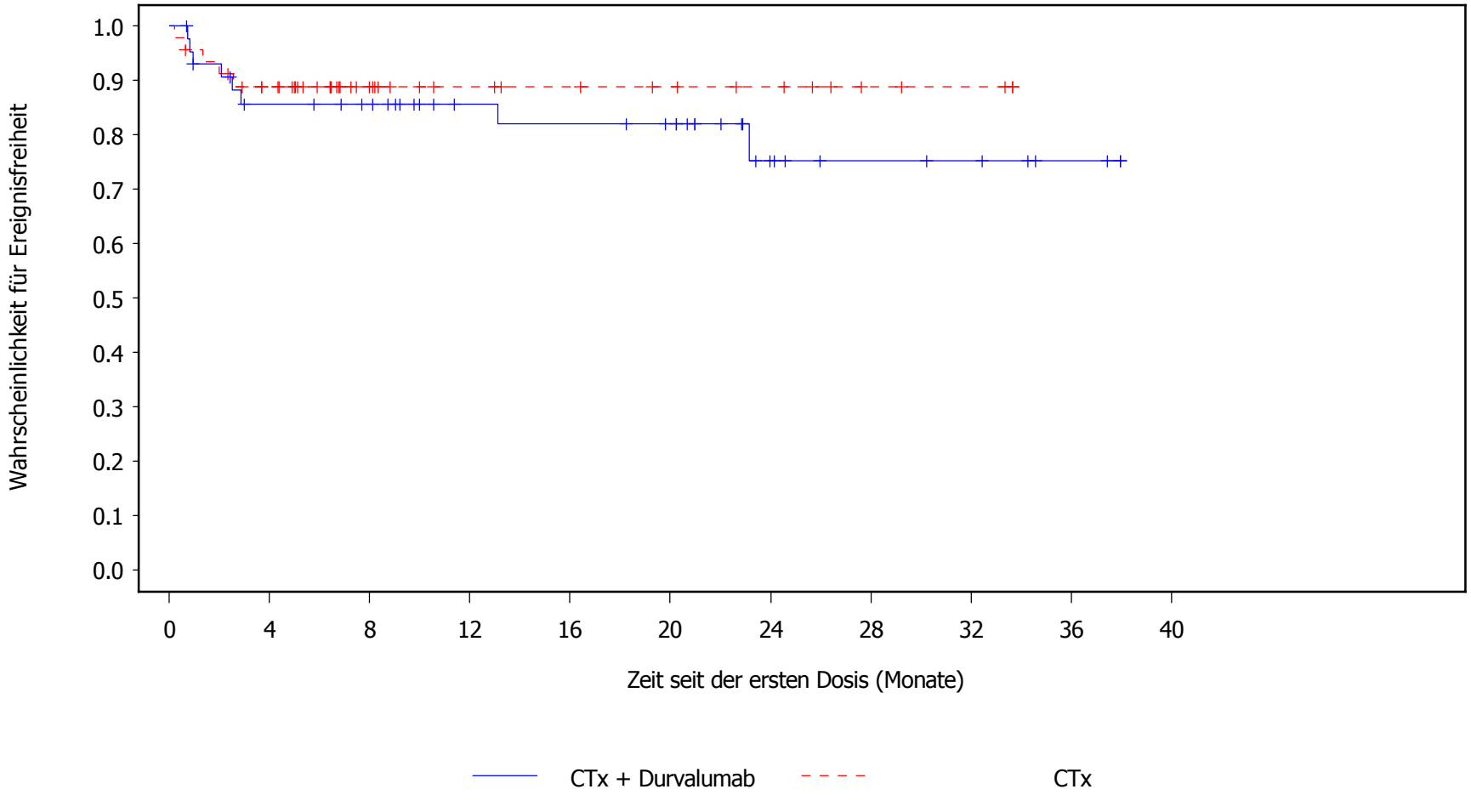
Figure 3.3.1.2D.54 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Appetit vermindert
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	33	28	21	21	19	10	7	5	2	0	CTx + Durvalumab
46	32	19	12	11	8	5	2	1	0	0	CTx

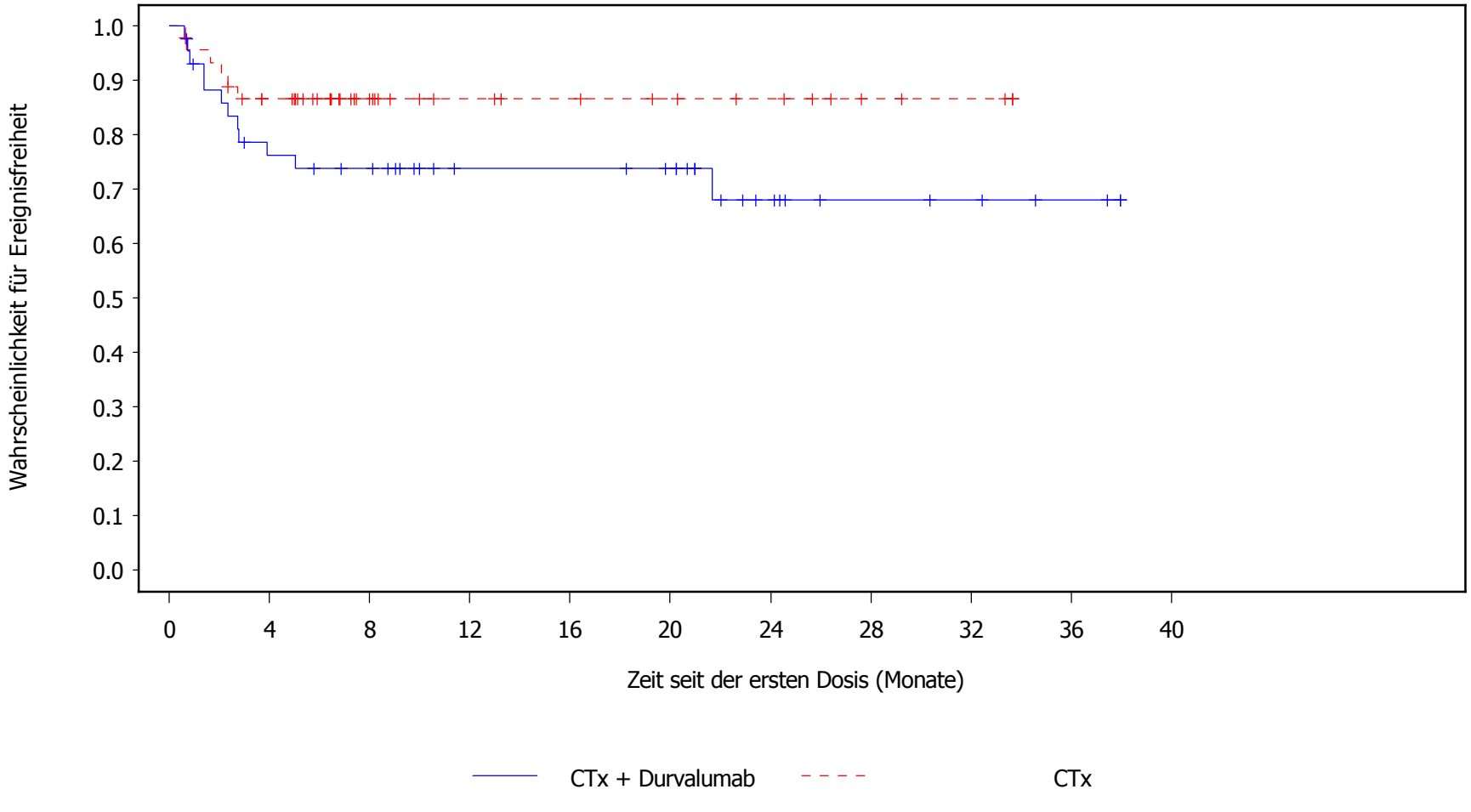
Figure 3.3.1.2D.55 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Hypokaliaemie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	31	23	22	20	9	6	5	2	0	CTx + Durvalumab
46	36	20	13	11	9	7	3	2	0	0	CTx

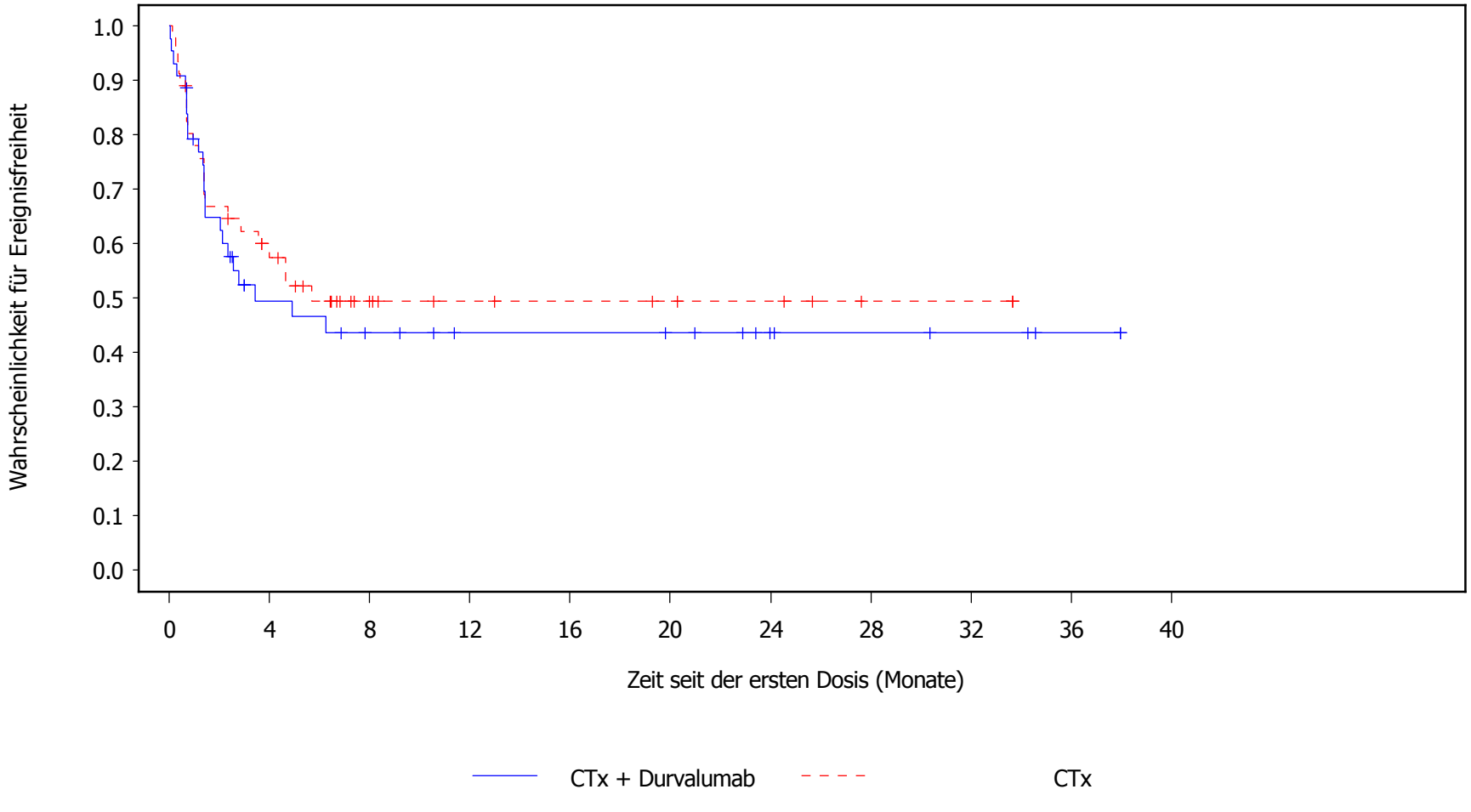
Figure 3.3.1.2D.56 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Hypomagnesiaemie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	31	28	20	20	18	9	5	4	2	0	CTx + Durvalumab
46	35	20	13	11	9	7	3	2	0	0	CTx

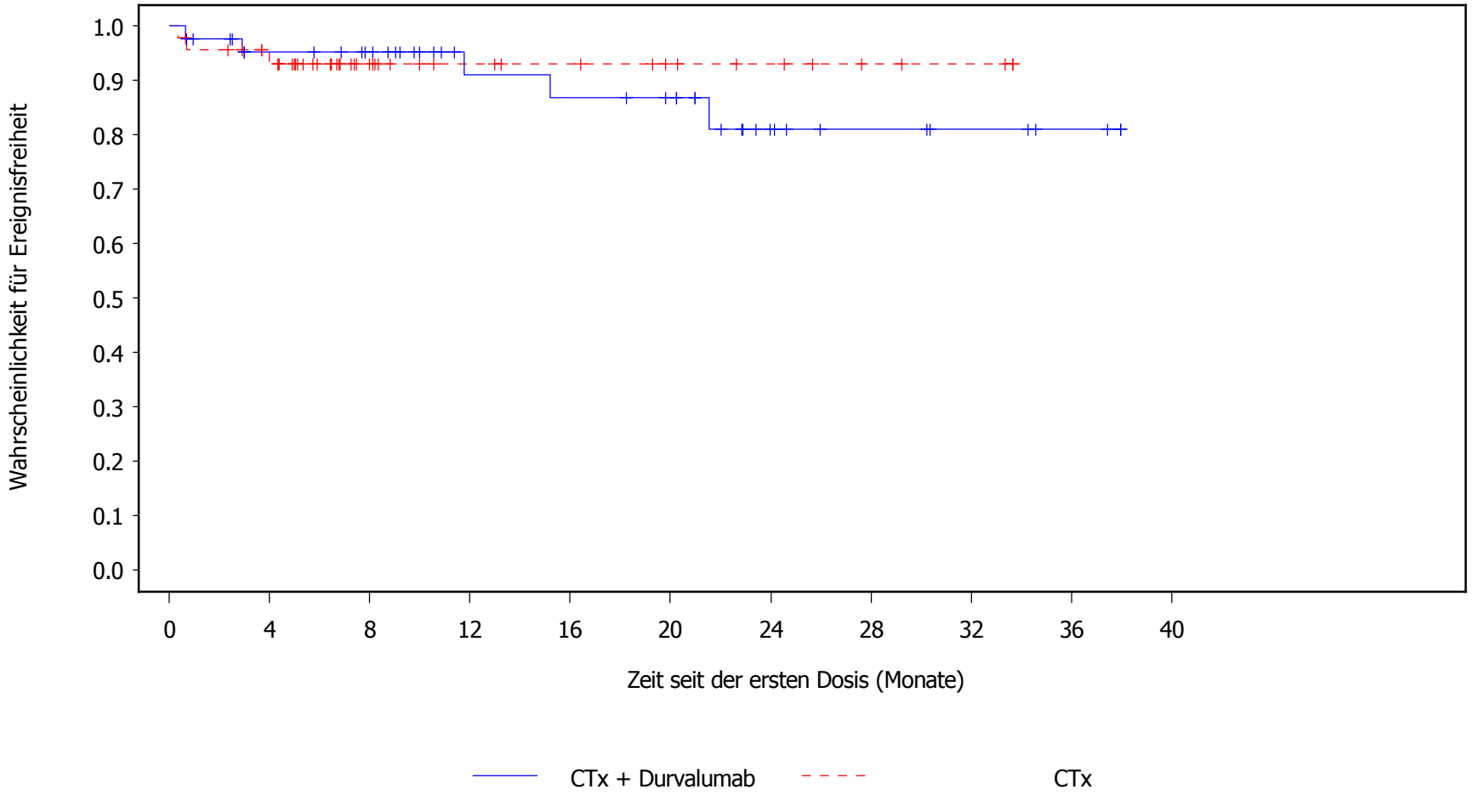
Figure 3.3.1.2D.57 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Untersuchungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	17	13	10	10	9	5	4	3	1	0	CTx + Durvalumab
46	24	11	7	6	5	4	1	1	0	0	CTx

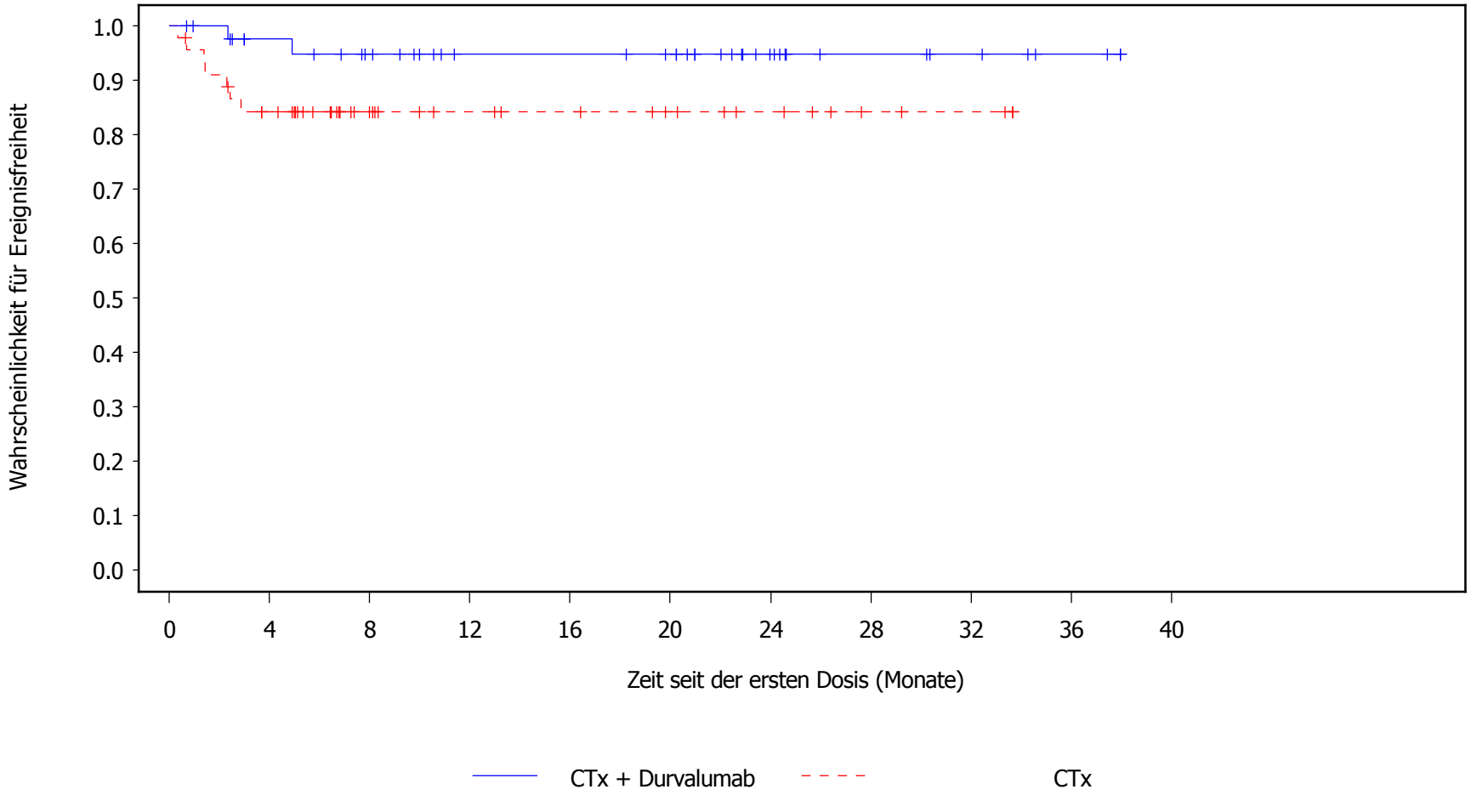
Figure 3.3.1.2D.58 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Alaninaminotransferase erhoeht
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	32	22	21	19	9	6	4	2	0	CTx + Durvalumab
46	39	20	13	11	8	6	3	2	0	0	CTx

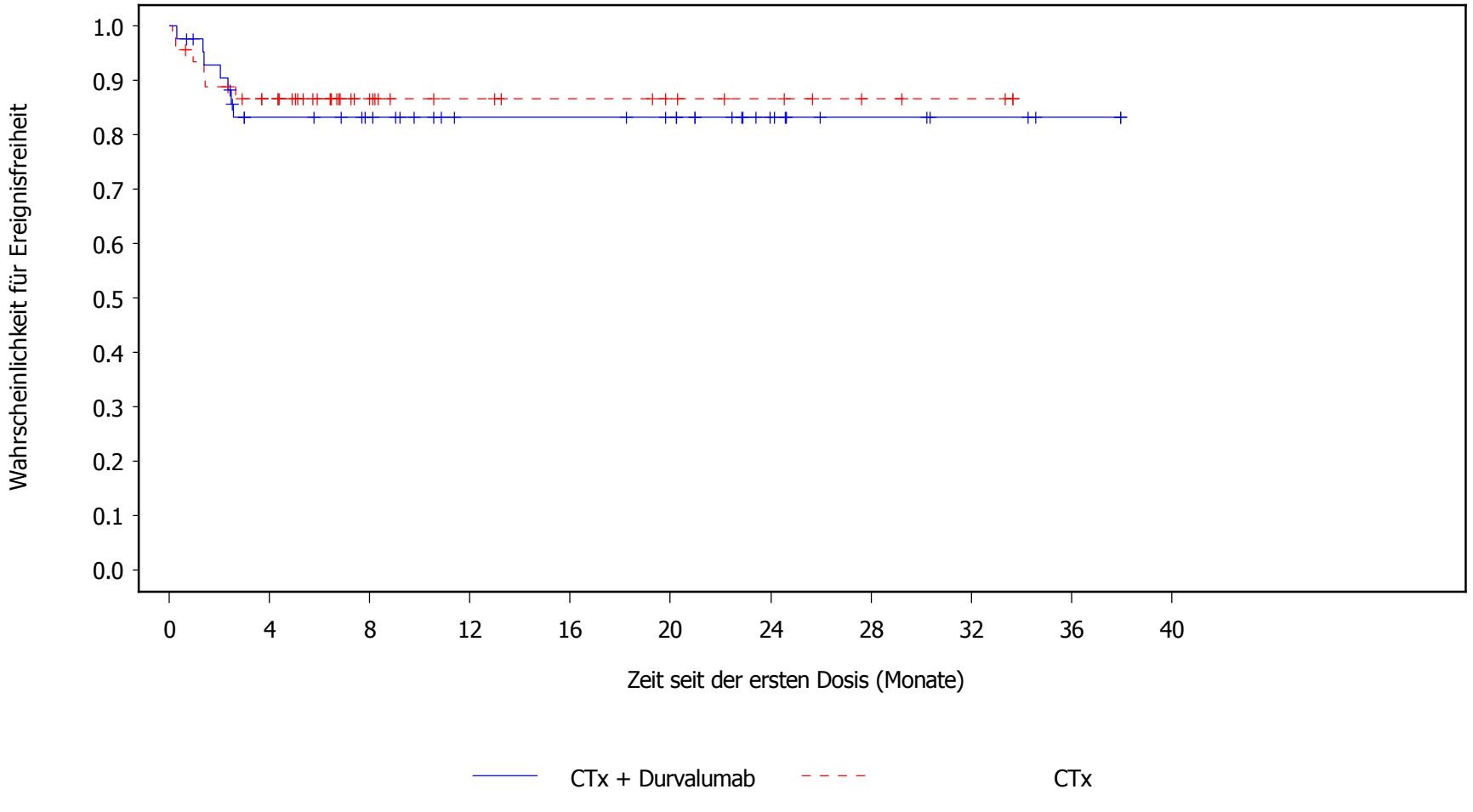
Figure 3.3.1.2D.59 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Gewicht erniedrigt
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	37	32	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	35	21	15	13	10	7	3	2	0	0	CTx

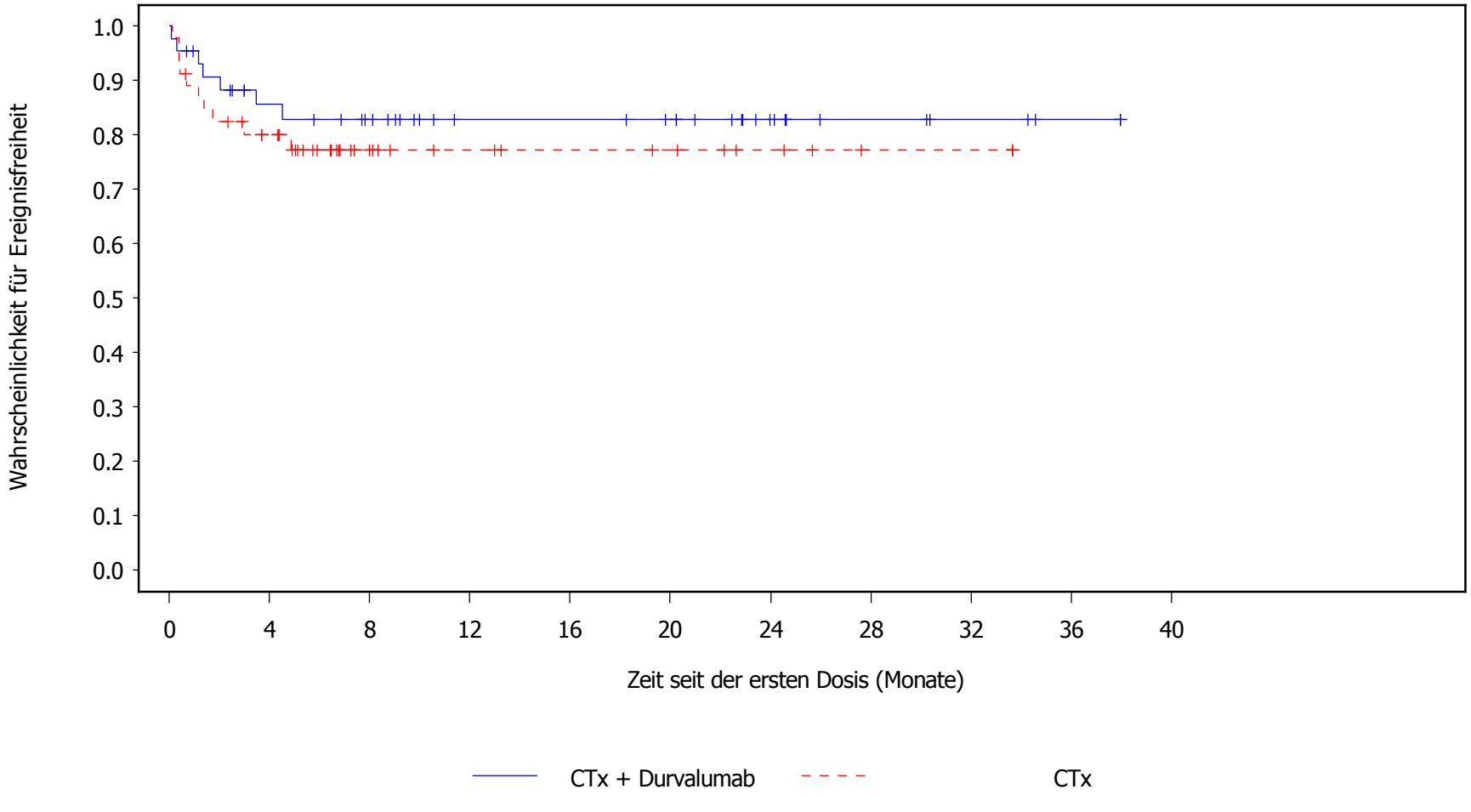
Figure 3.3.1.2D.60 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Leukozytenzahl erniedrigt
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	31	27	20	20	18	9	5	3	1	0	CTx + Durvalumab
46	35	18	12	10	8	6	3	2	0	0	CTx

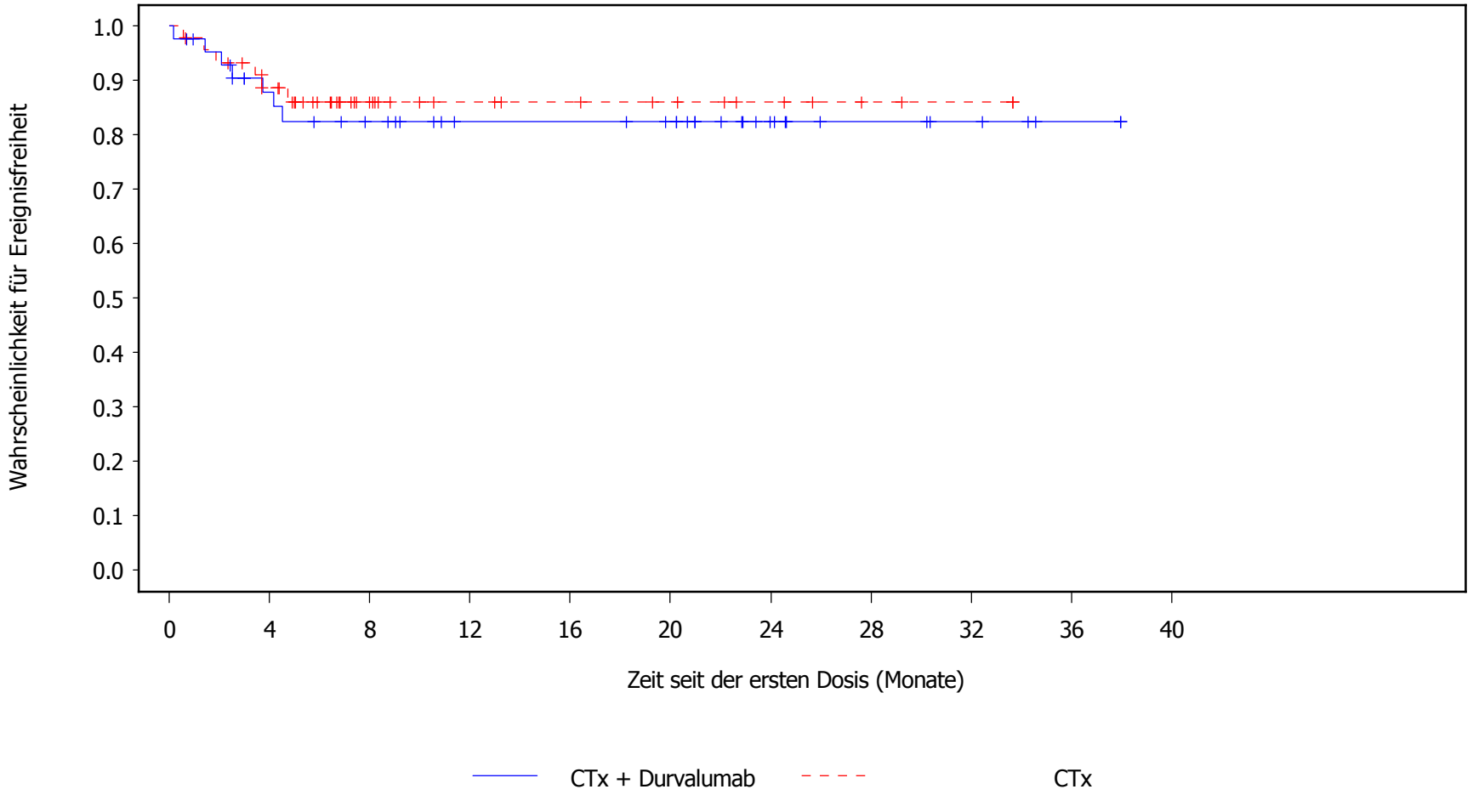
Figure 3.3.1.2D.61 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Neutrophilenzahl erniedrigt
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	32	27	19	19	17	9	5	3	1	0	CTx + Durvalumab
46	32	15	10	8	7	4	1	1	0	0	CTx

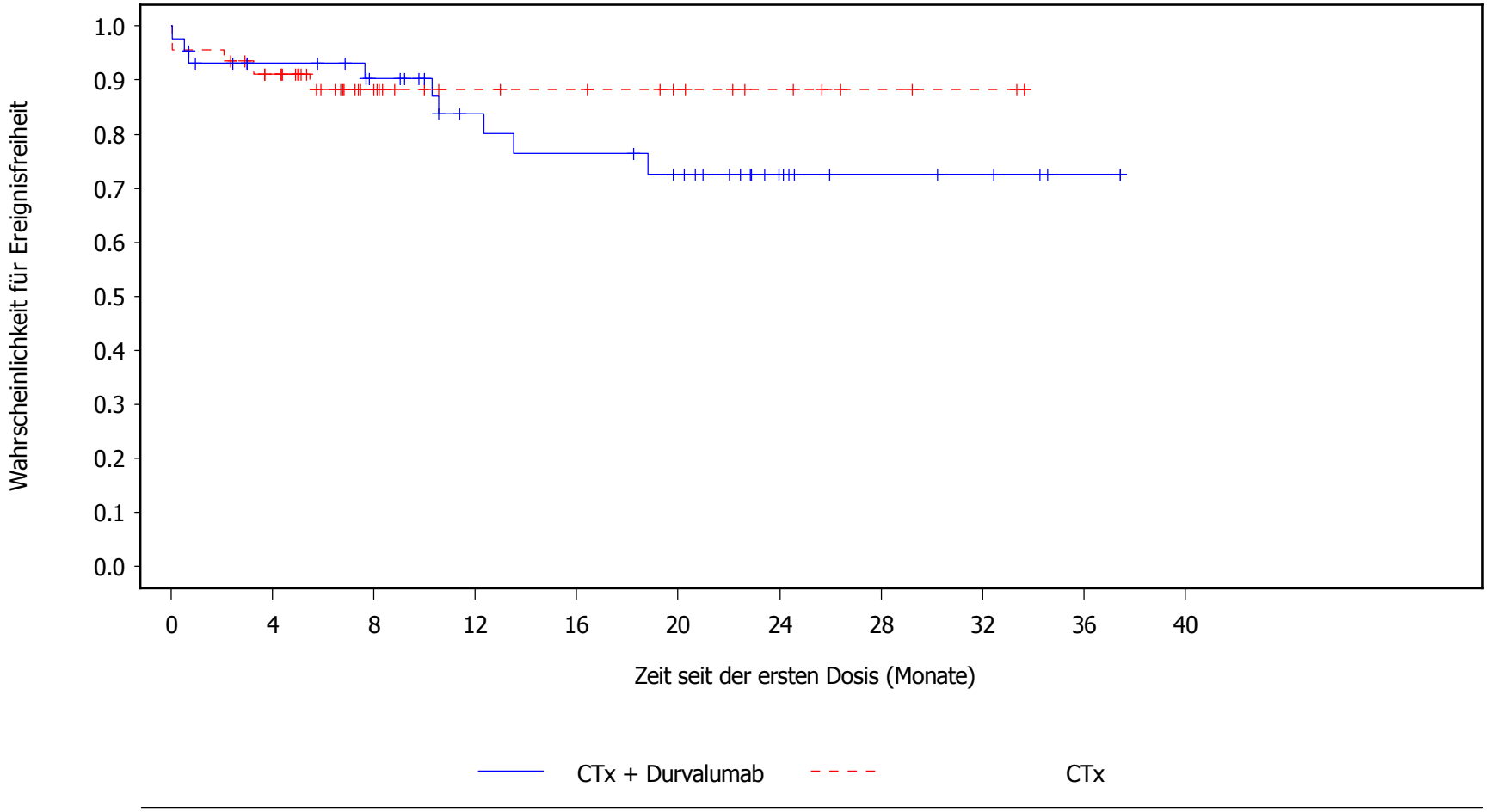
Figure 3.3.1.2D.62 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of PT: Thrombozytenzahl vermindert
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	33	28	22	22	20	10	6	4	1	0	CTx + Durvalumab
46	36	19	12	10	8	5	2	1	0	0	CTx

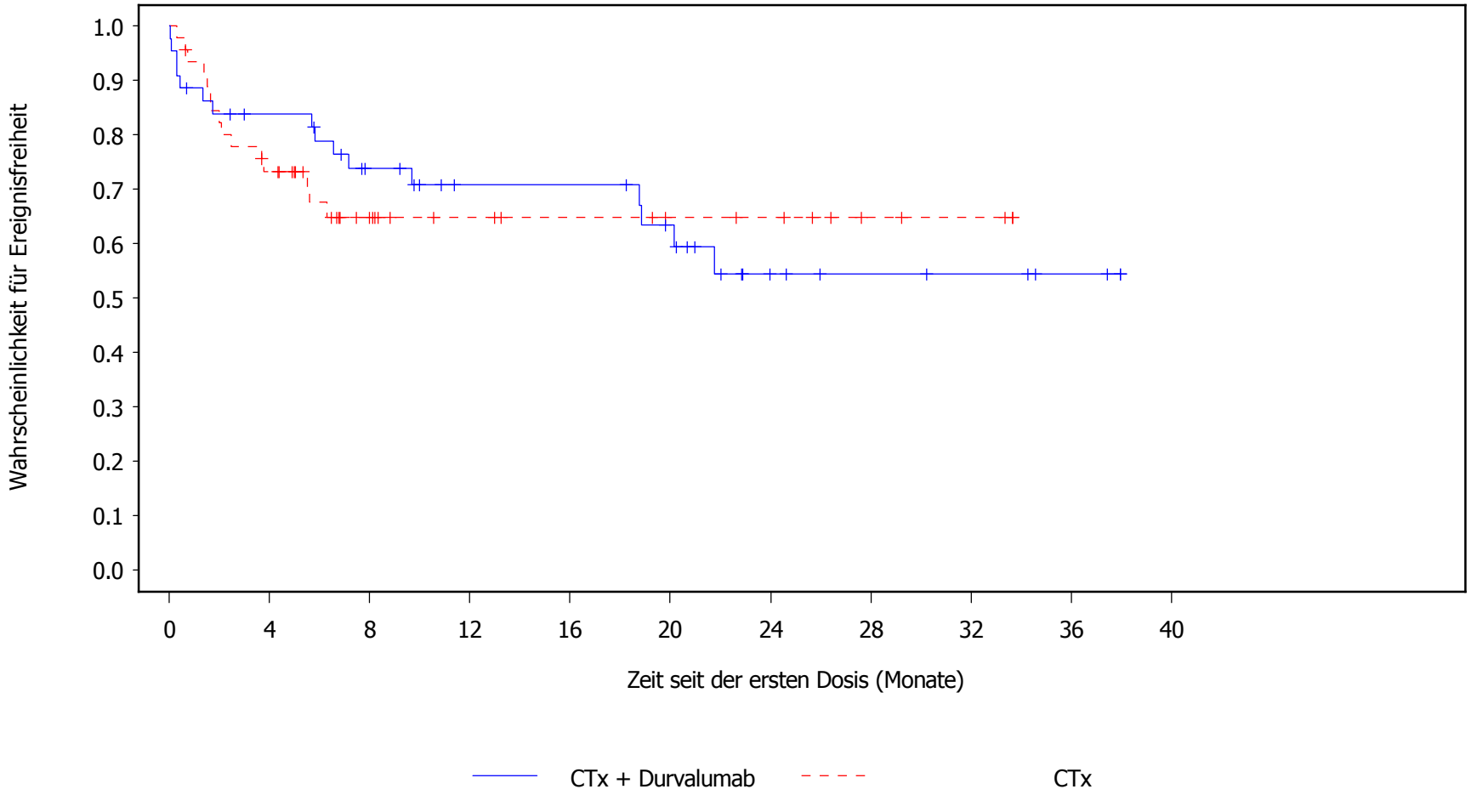
Figure 3.3.1.2D.63 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	31	23	21	18	9	5	4	1	0	CTx + Durvalumab
46	38	20	13	12	9	6	3	2	0	0	CTx

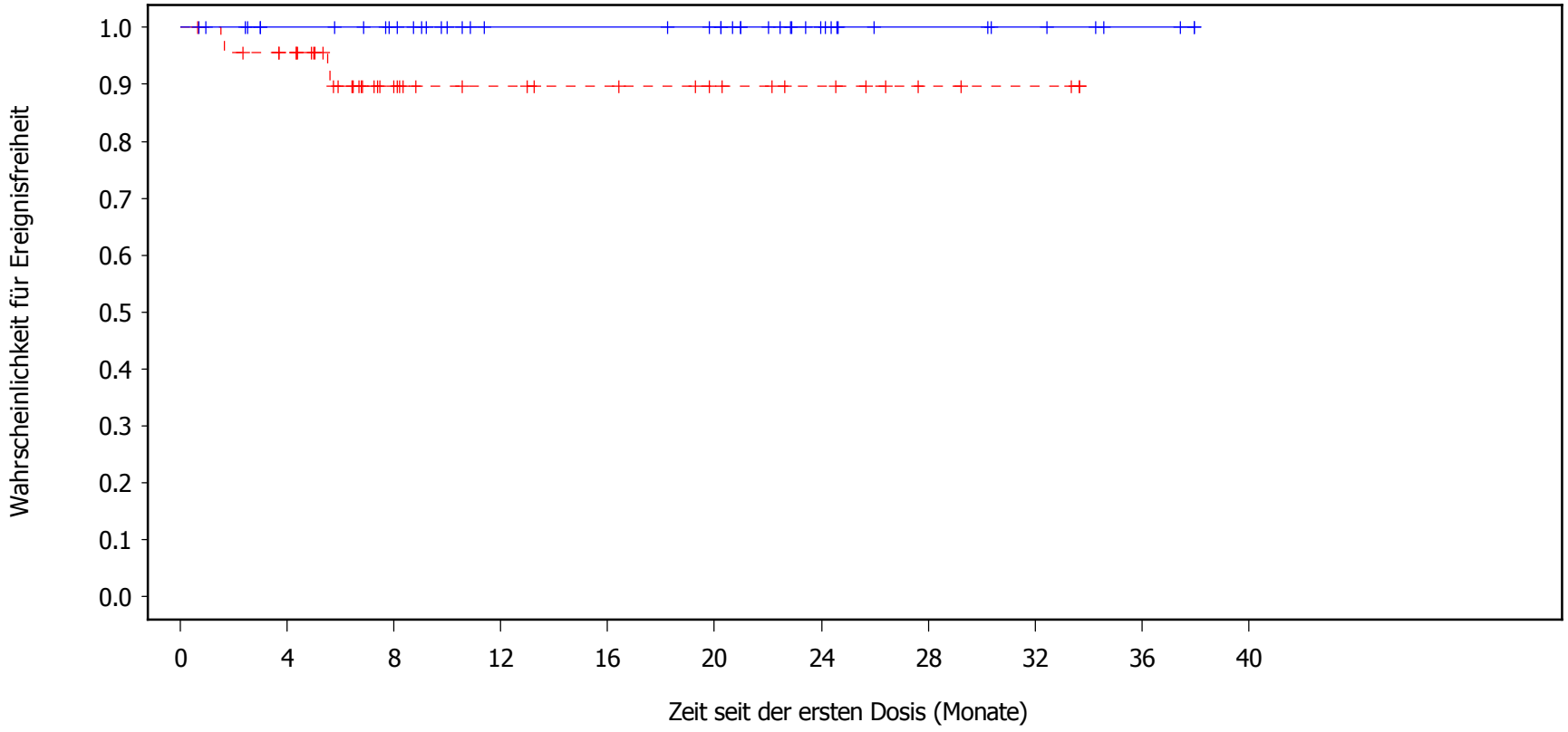
Figure 3.3.1.2D.64 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	26	20	20	16	7	5	4	2	0	CTx + Durvalumab
46	32	18	12	10	8	7	3	2	0	0	CTx

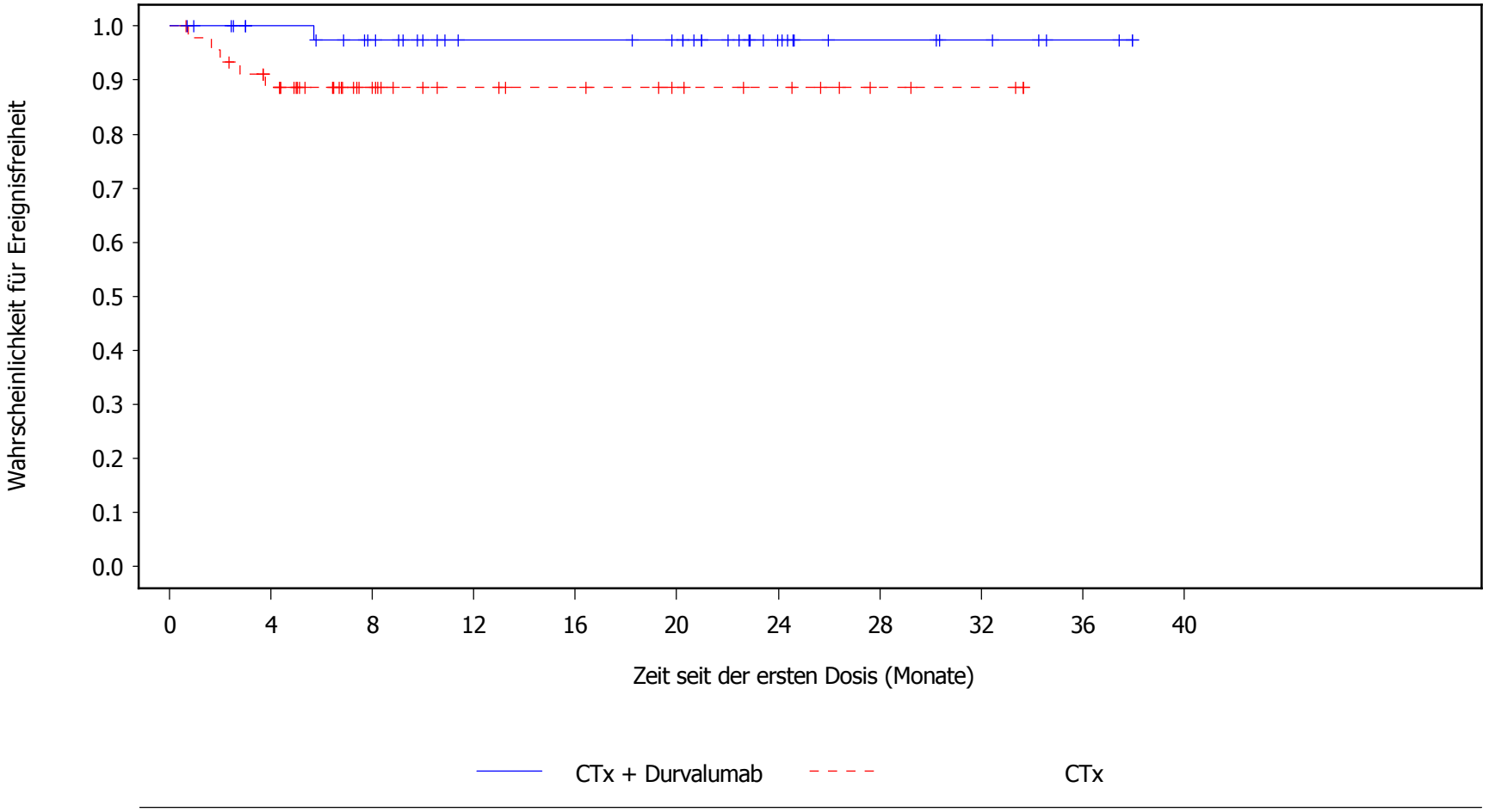
Figure 3.3.1.2D.65 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen der Nieren und Harnwege
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	40	21	15	13	10	7	3	2	0	0	CTx

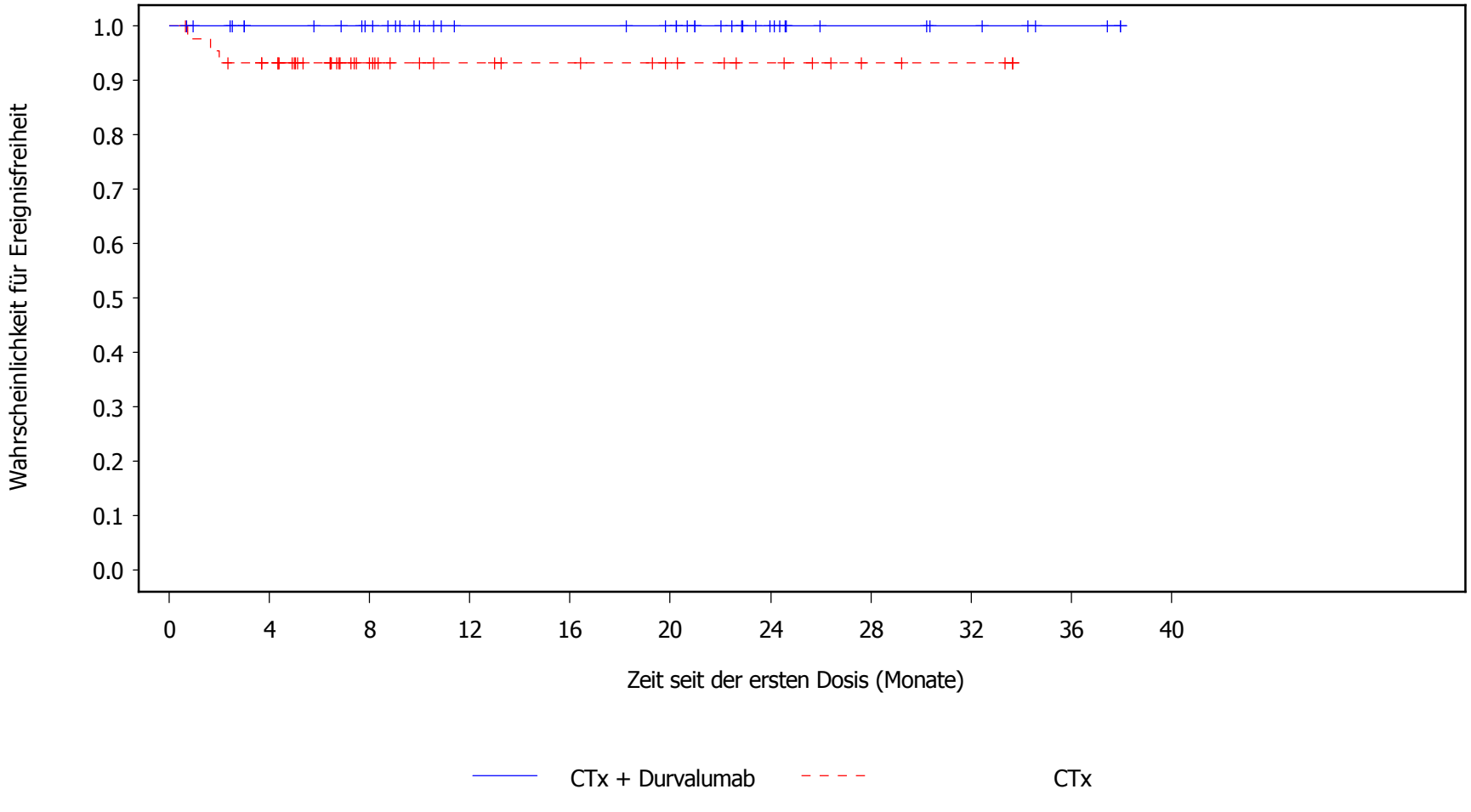
Figure 3.3.1.2D.66 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	33	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	37	21	14	12	9	7	3	2	0	0	CTx

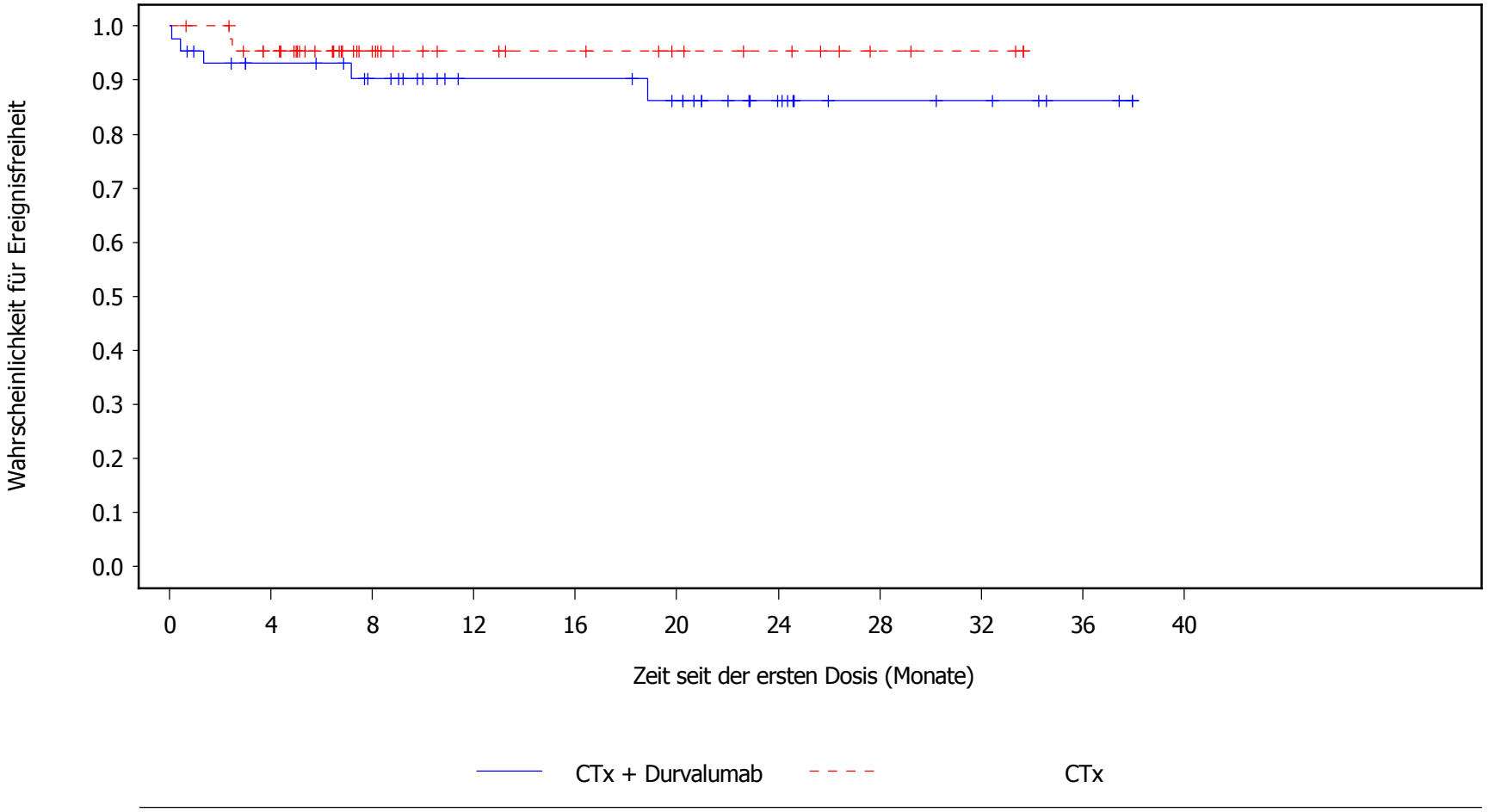
Figure 3.3.1.2D.67 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE PT: Anaemie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	39	22	15	13	10	7	3	2	0	0	CTx

Figure 3.3.1.2D.68 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Gastrointestinaltrakts
Patients with dMMR tumour status, DCO 18OCT2023

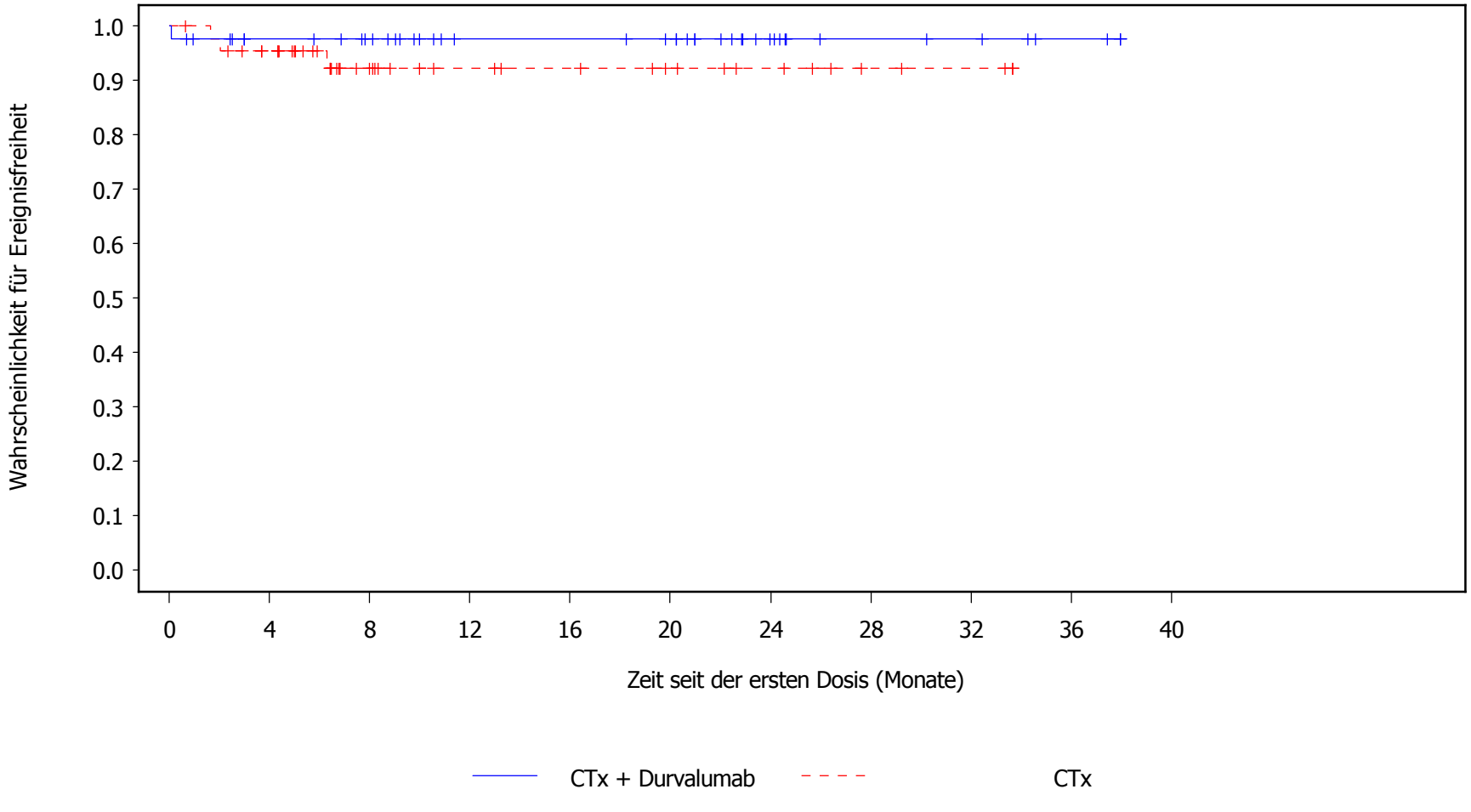


Anzahl an Patienten unter Risiko:

44	36	31	23	23	20	11	6	5	2	0	CTx + Durvalumab
46	39	21	14	12	9	7	3	2	0	0	CTx

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.1.2D.69 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Erkrankungen des Nervensystems
Patients with dMMR tumour status, DCO 18OCT2023

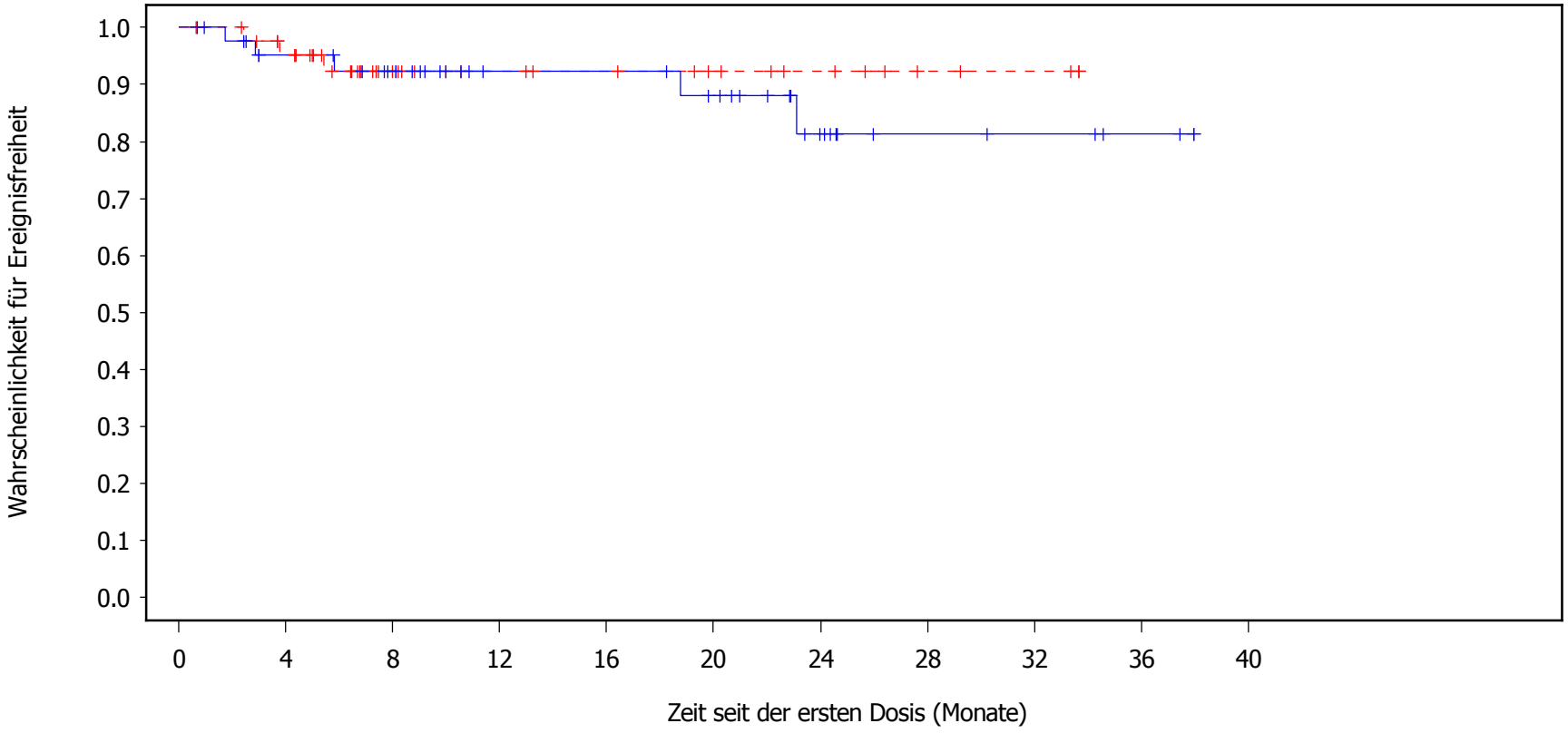


Anzahl an Patienten unter Risiko:

44	37	33	24	24	22	11	6	5	2	0	CTx + Durvalumab
46	39	22	15	13	10	7	3	2	0	0	CTx

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 3.3.1.2D.70 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Infektionen und parasitaere Erkrankungen
Patients with dMMR tumour status, DCO 18OCT2023

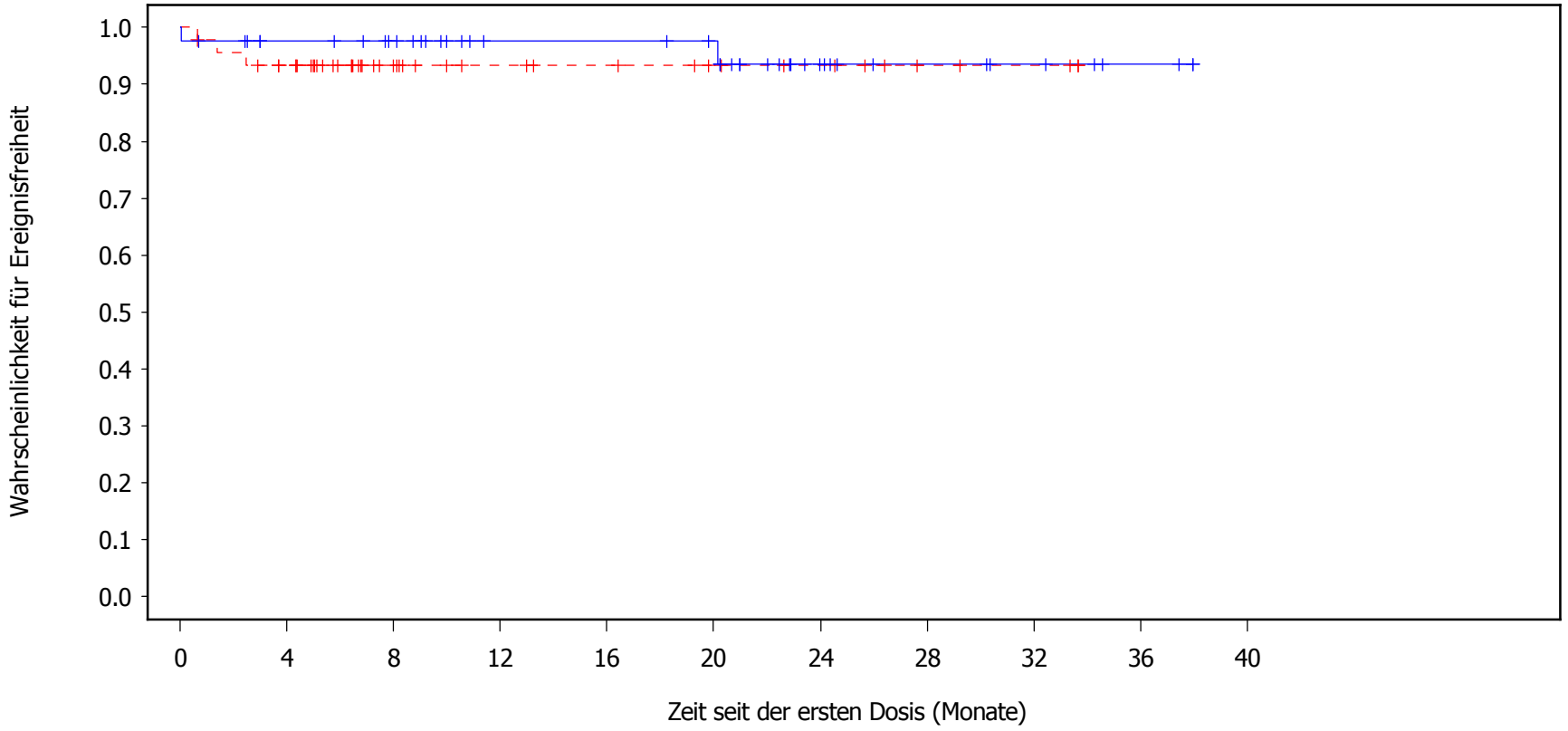


Anzahl an Patienten unter Risiko:

44	36	31	22	22	19	10	5	4	2	0	CTx + Durvalumab
46	39	22	15	13	10	7	3	2	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaeacr 15APR2024:10:33

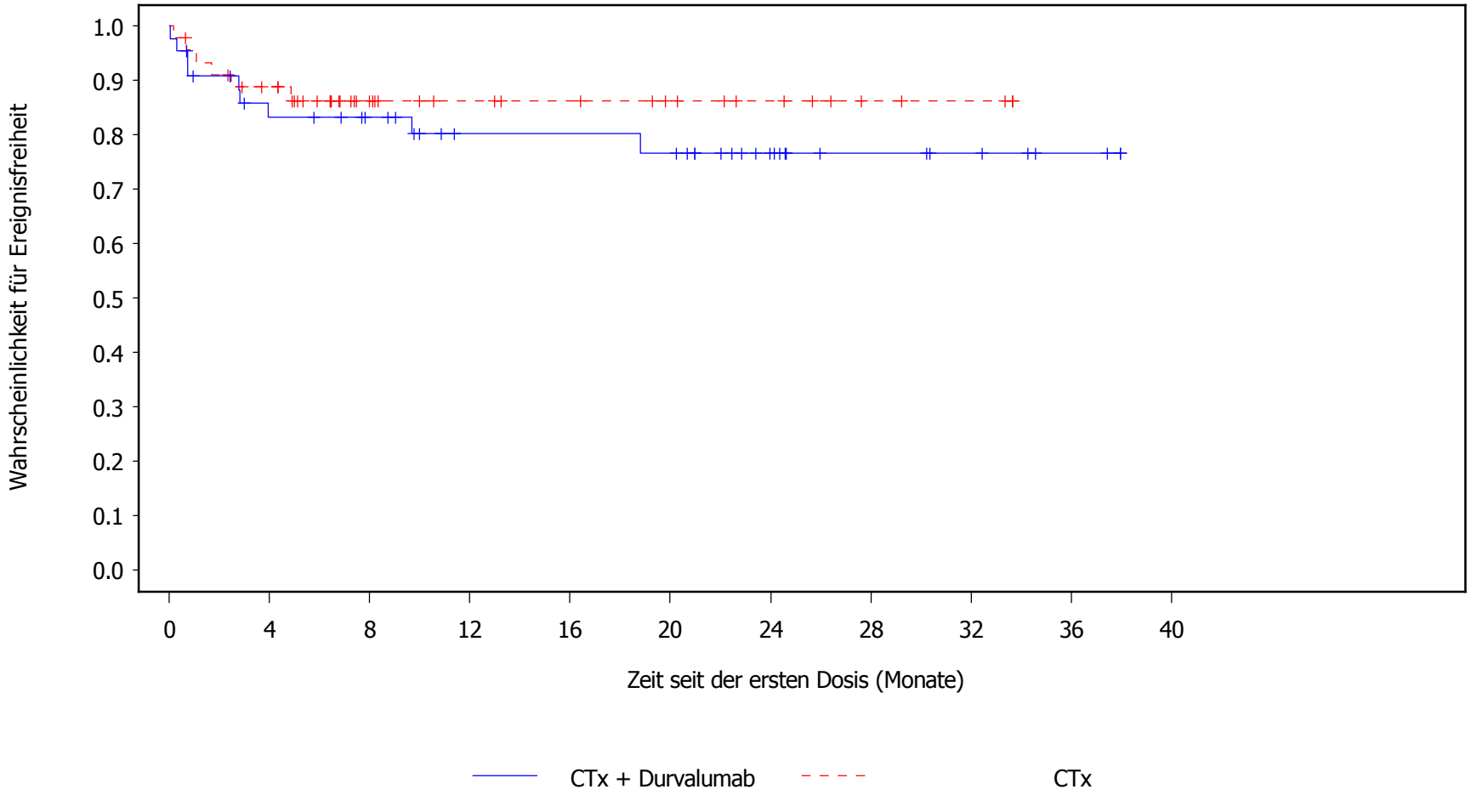
Figure 3.3.1.2D.71 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUE SOC: Stoffwechsel- und Ernaehrungsstoerungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	11	7	5	2	0	CTx + Durvalumab
46	39	21	14	12	9	7	3	2	0	0	CTx

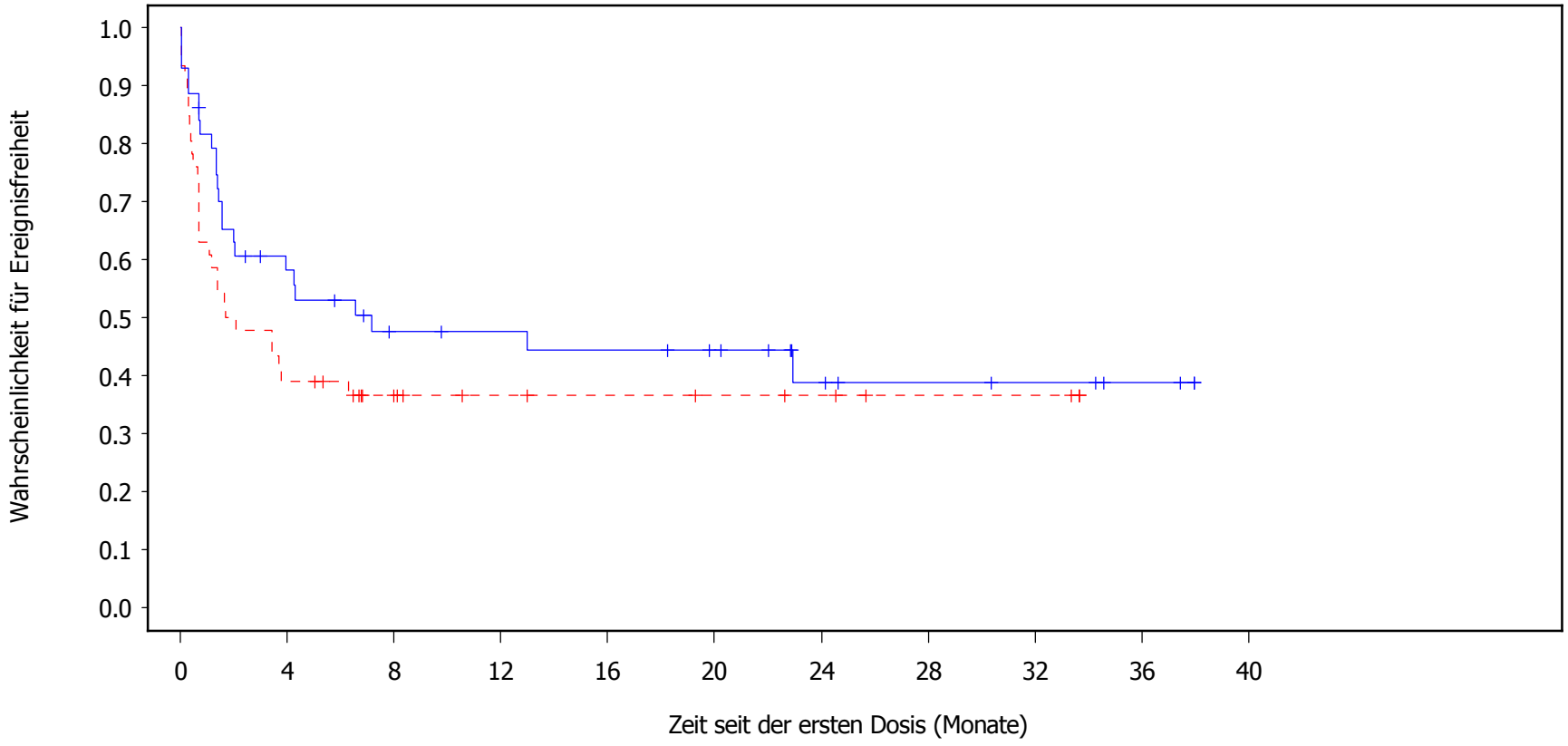
Figure 3.3.1.2D.72 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of Therapieabbruch aufgrund von UE
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	33	29	22	22	21	12	7	5	2	0	CTx + Durvalumab
46	37	21	15	13	10	7	3	2	0	0	CTx

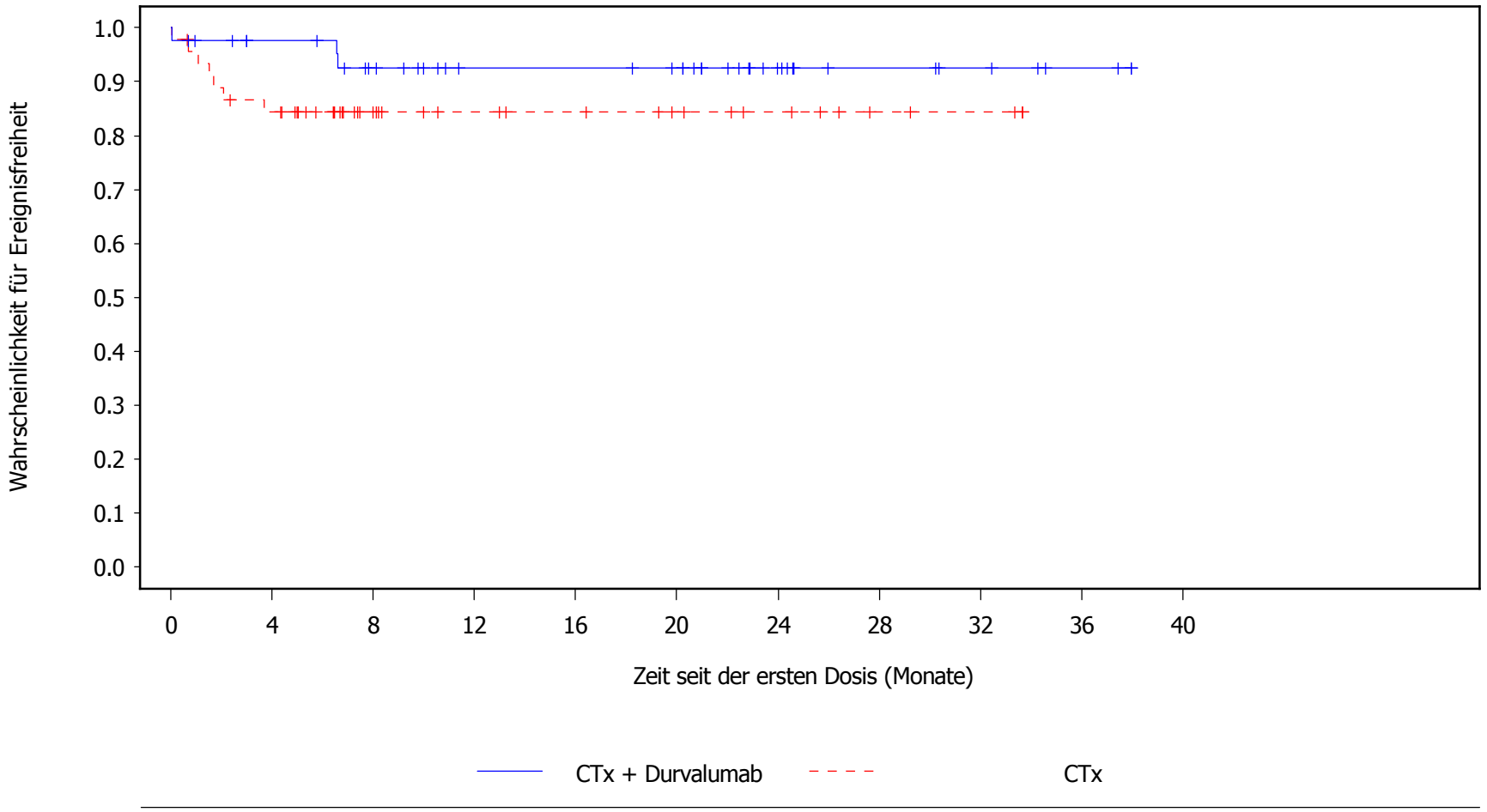
Figure 3.3.1.2D.73 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UE mit CTCAE Grad >=3
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	23	16	15	14	12	7	5	4	2	0	CTx + Durvalumab
46	18	11	7	6	5	4	2	2	0	0	CTx

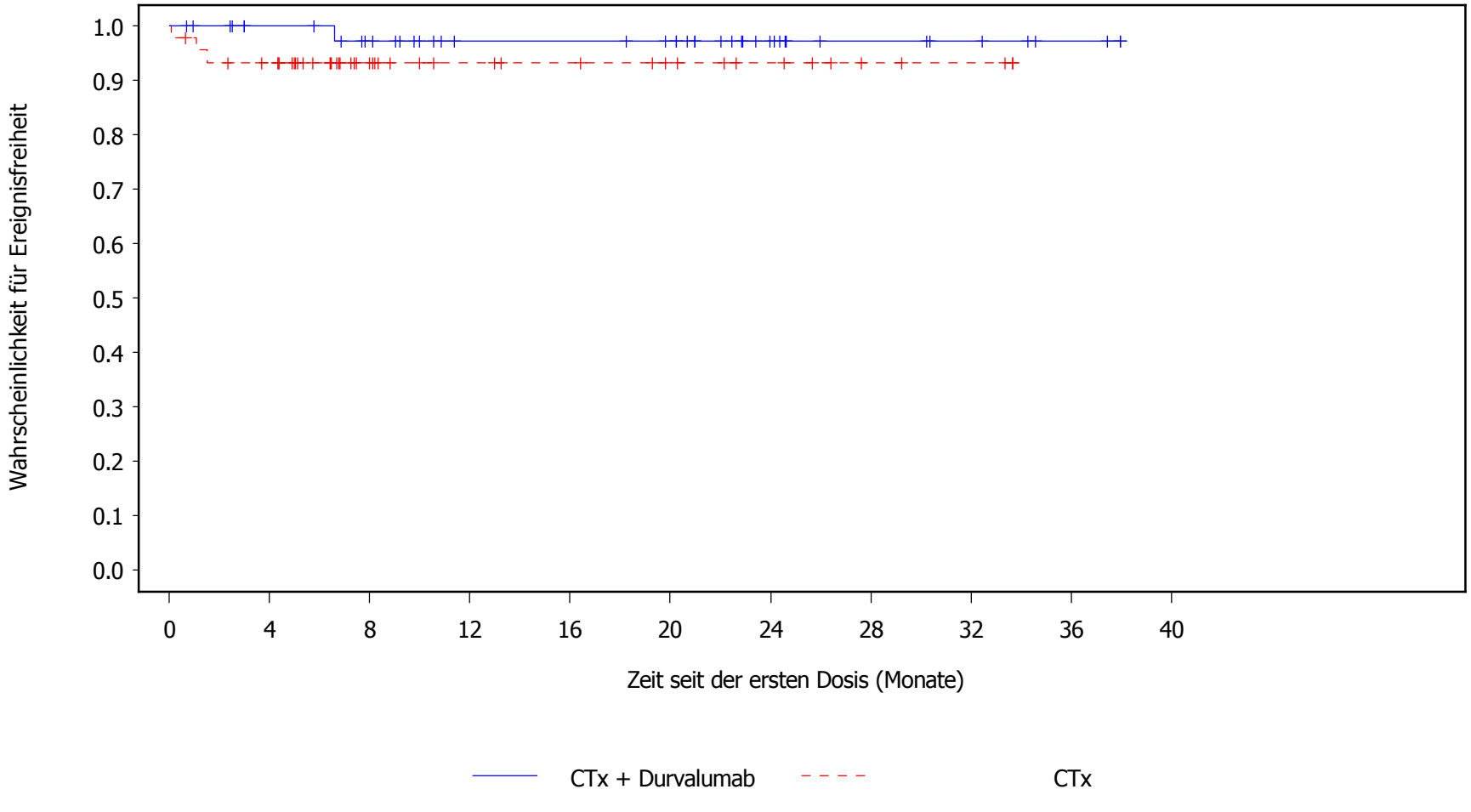
Figure 3.3.1.2D.74 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	32	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	37	21	15	13	10	7	3	2	0	0	CTx

Figure 3.3.1.2D.75 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Asthenie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	33	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	40	22	15	13	10	7	3	2	0	0	CTx

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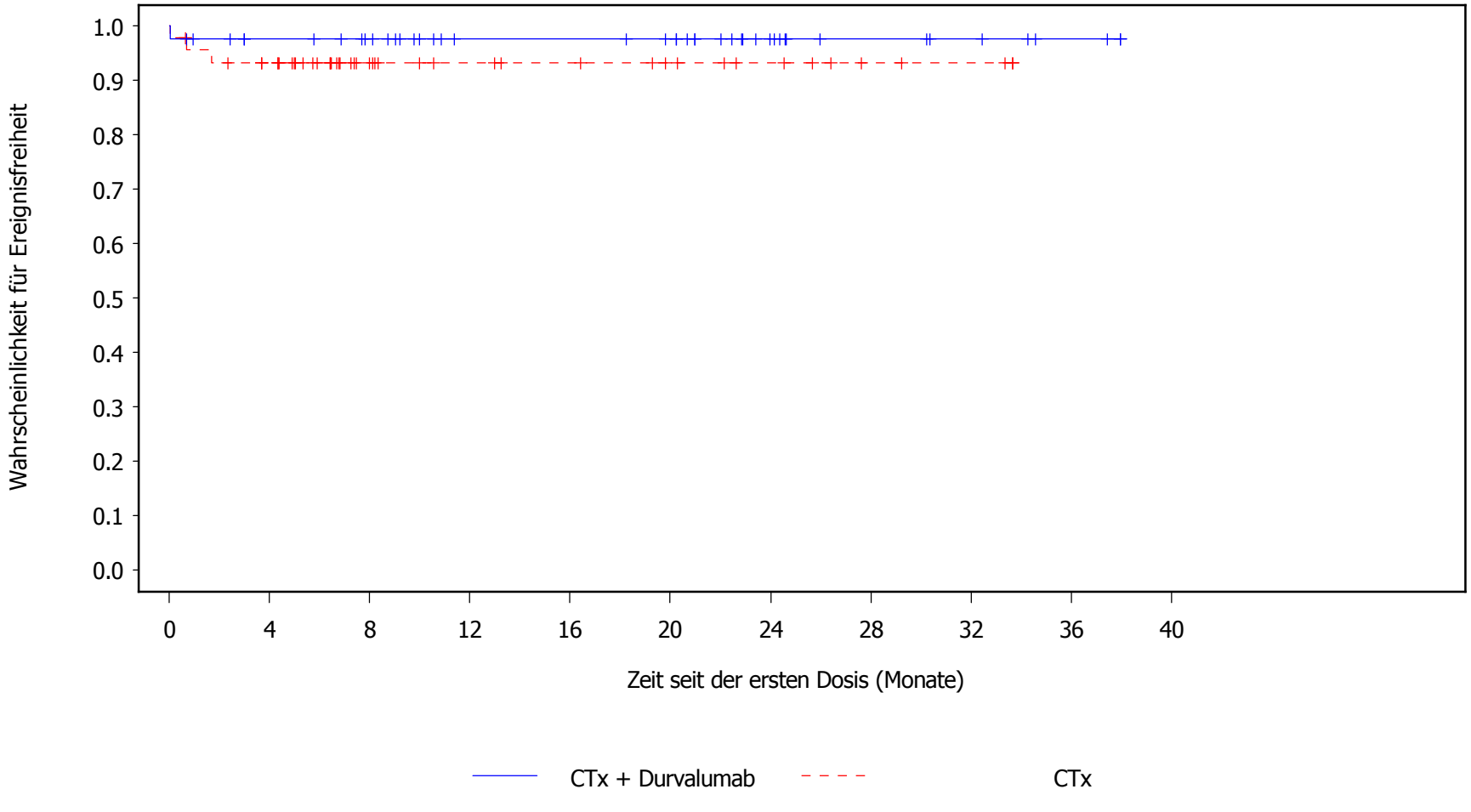
Figure 3.3.1.2D.76 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Ermuedung
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	39	21	15	13	10	7	3	2	0	0	CTx

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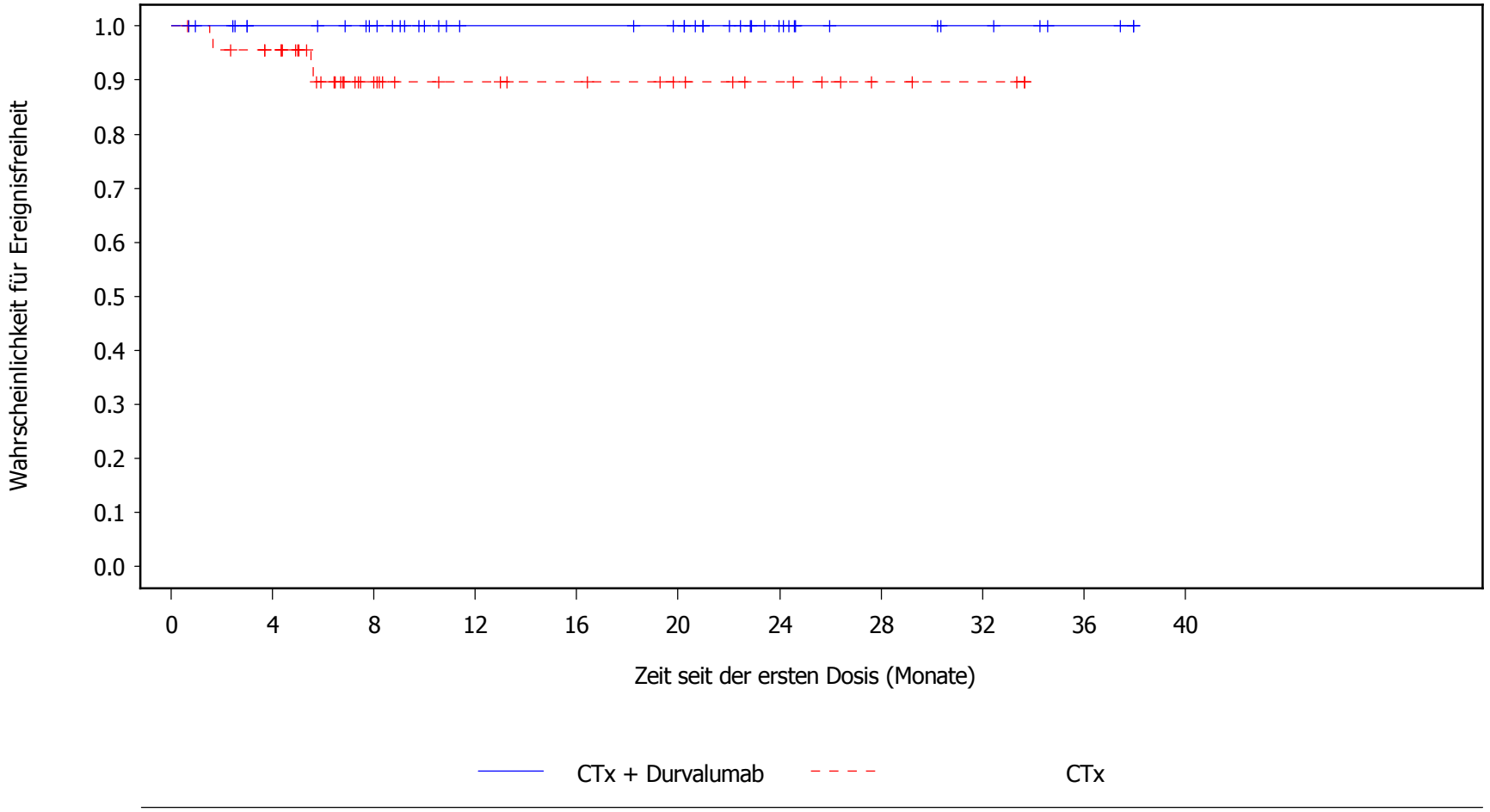
Figure 3.3.1.2D.77 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen der Nieren und Harnwege
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	40	21	15	13	10	7	3	2	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaeacy 15APR2024:10:33

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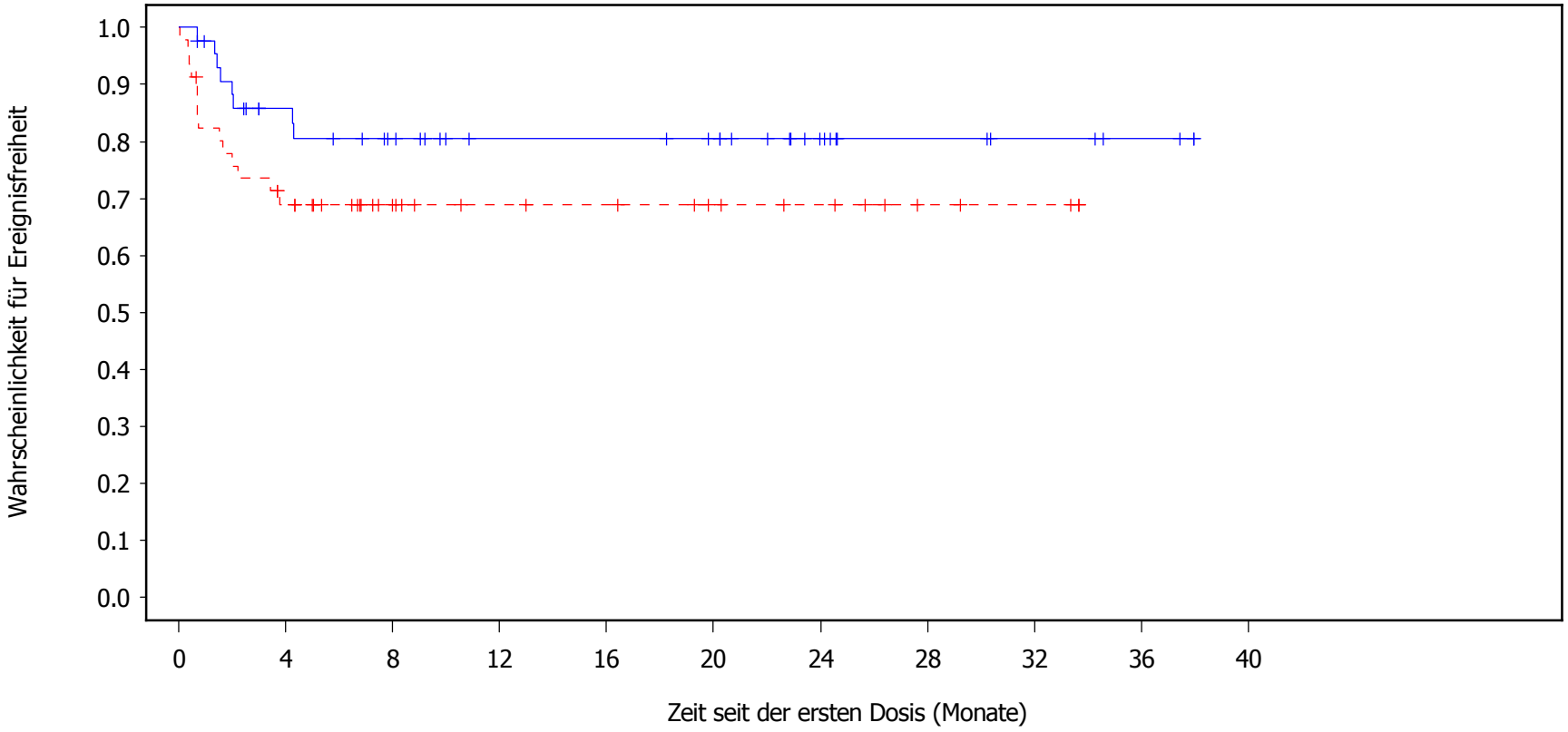
Figure 3.3.1.2D.78 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Patients with dMMR tumour status, DCO 18OCT2023

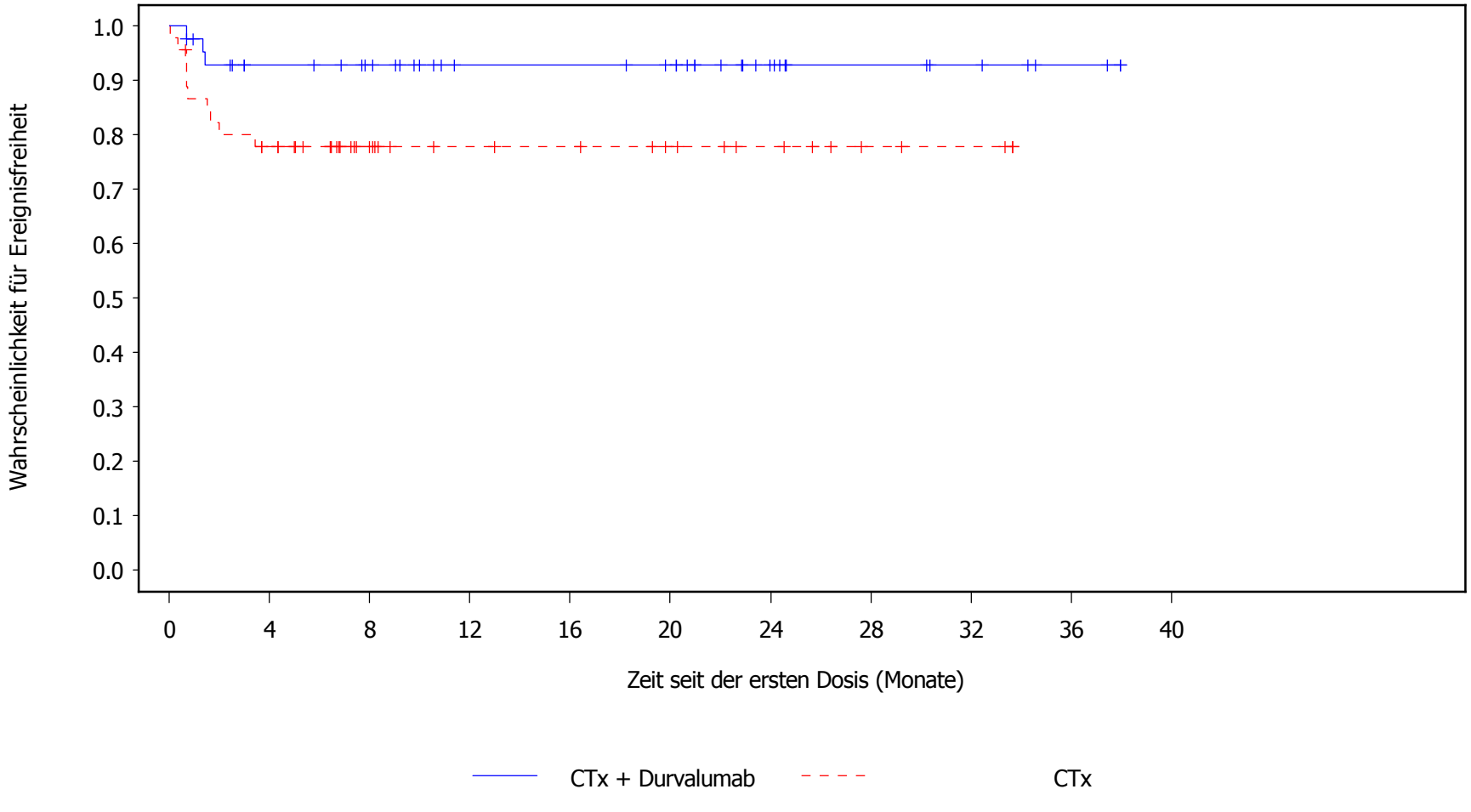


Anzahl an Patienten unter Risiko:

44	32	26	20	20	18	10	6	4	2	0	CTx + Durvalumab
46	29	18	13	12	9	7	3	2	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaeacz 15APR2024:10:33

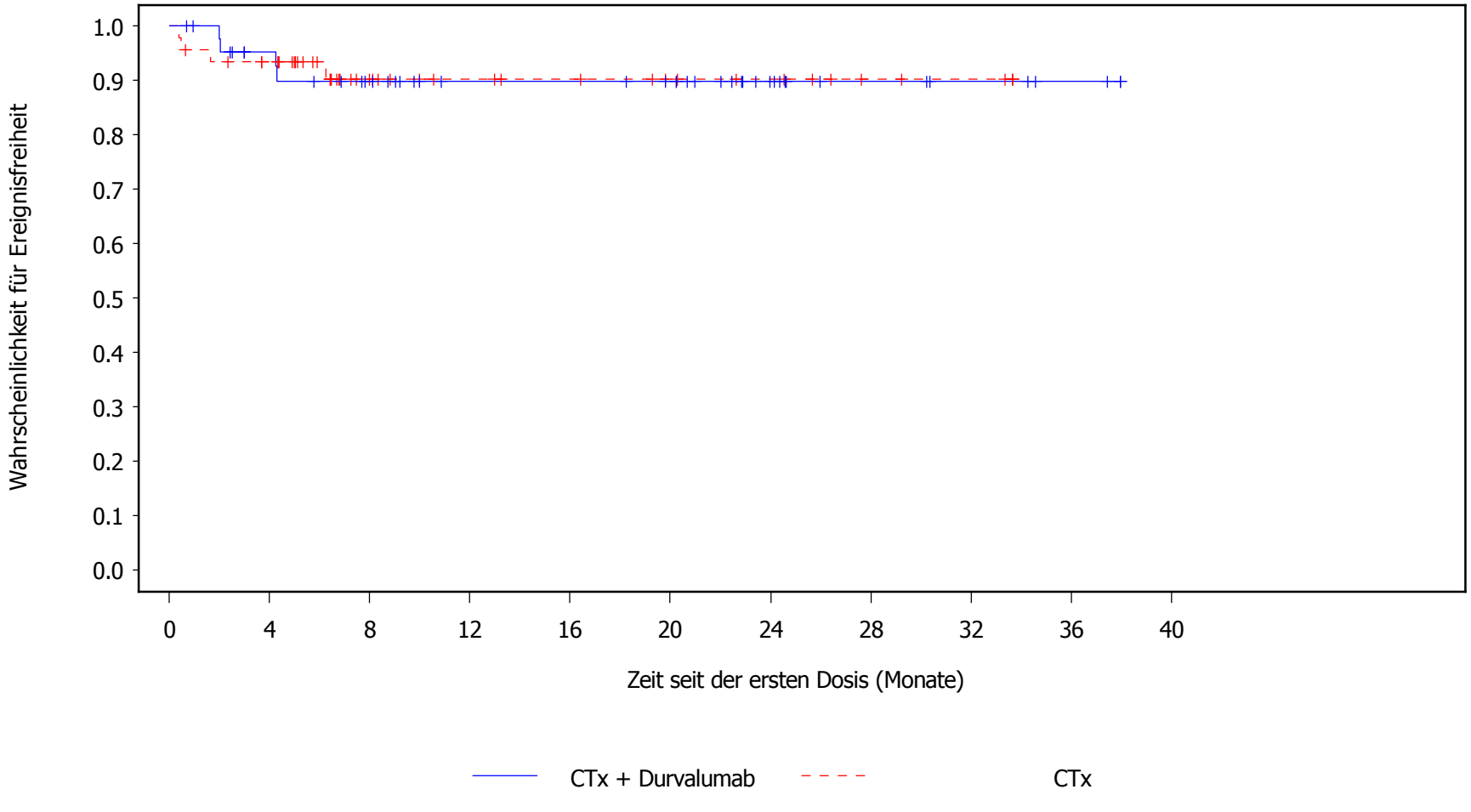
Figure 3.3.1.2D.79 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Anaemie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	35	31	23	23	21	11	7	5	2	0	CTx + Durvalumab
46	33	20	14	13	10	7	3	2	0	0	CTx

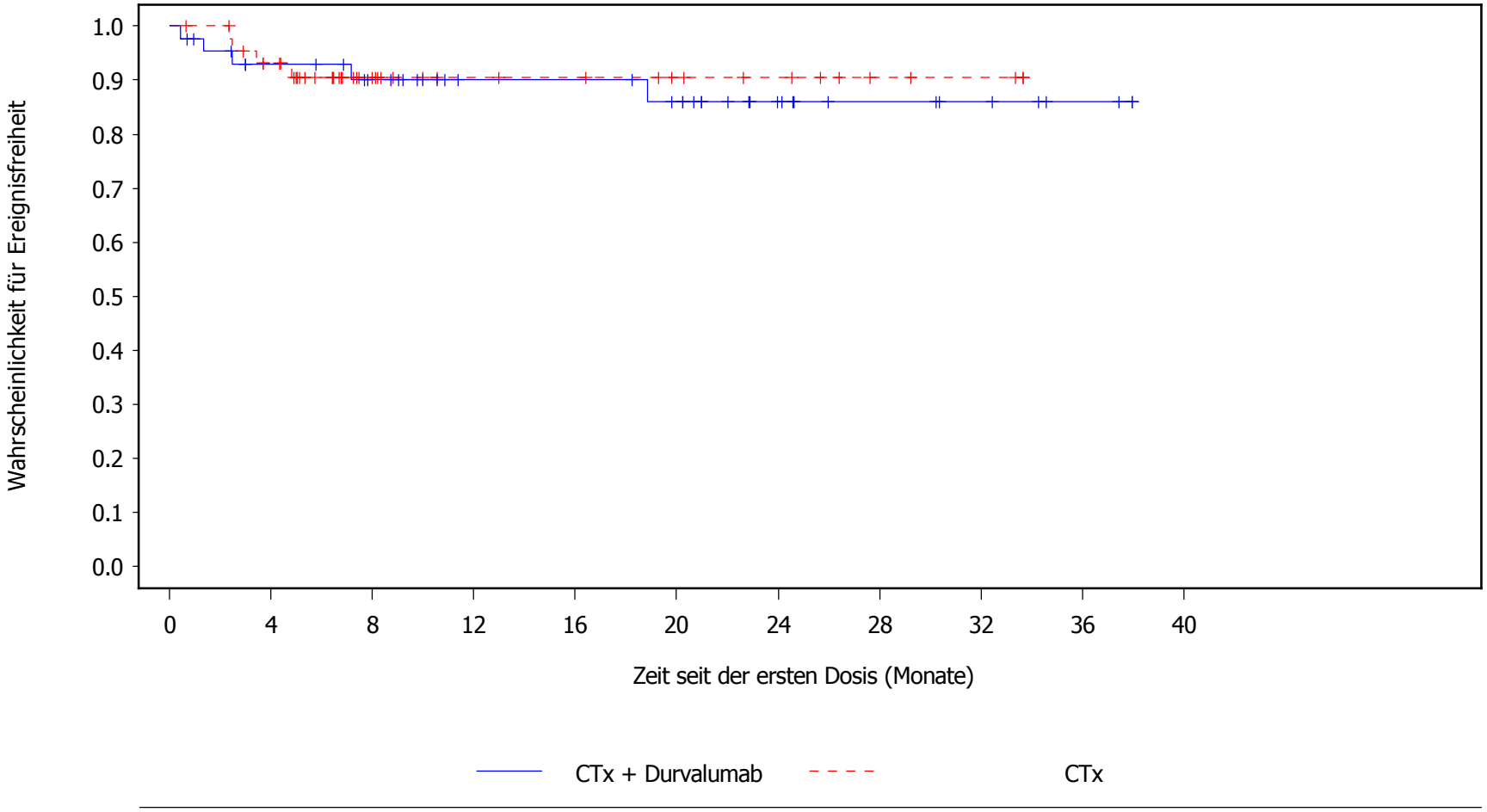
Figure 3.3.1.2D.80 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Neutropenie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	30	23	23	21	11	6	4	2	0	CTx + Durvalumab
46	39	20	14	12	9	7	3	2	0	0	CTx

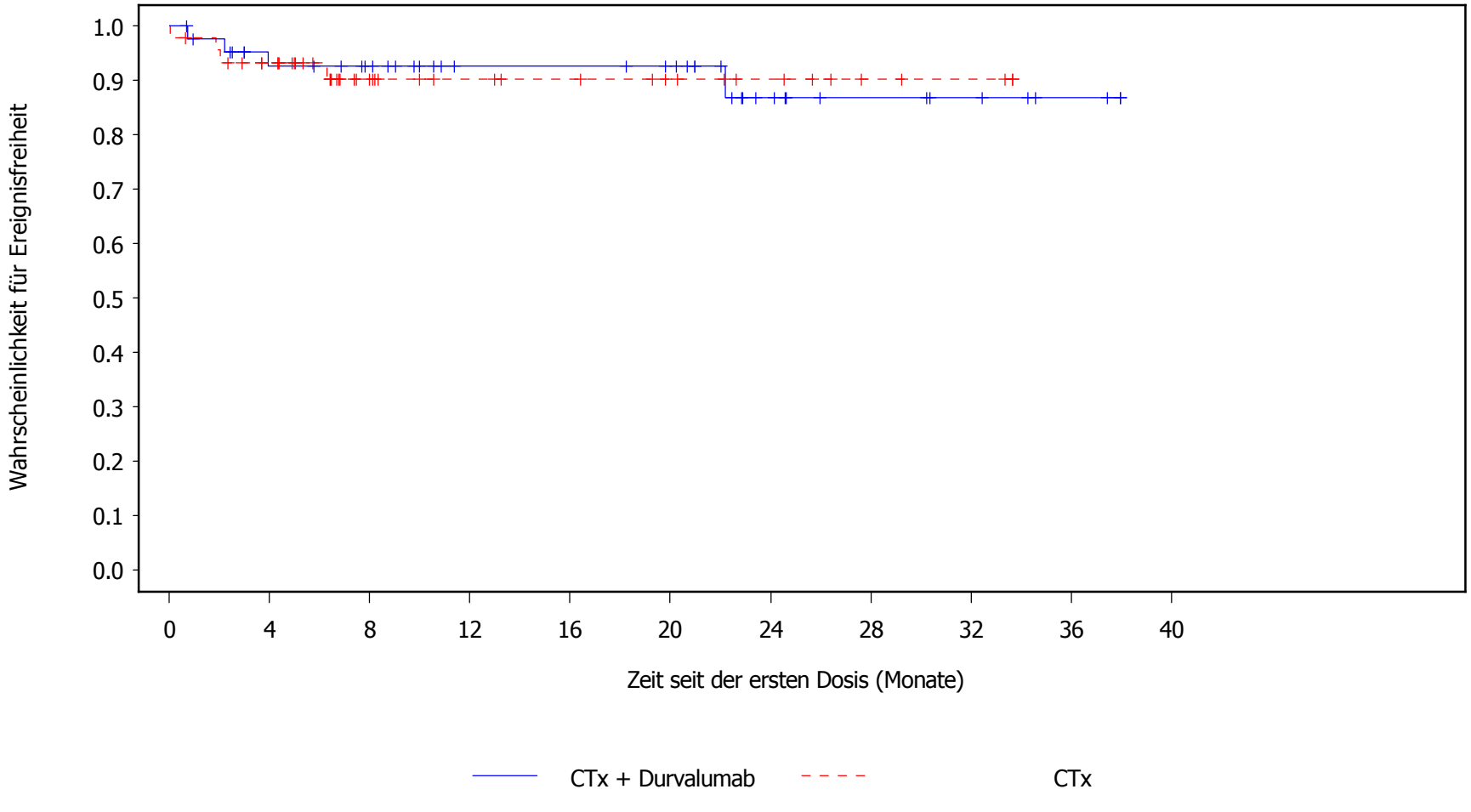
Figure 3.3.1.2D.81 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Gastrointestinaltrakts
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	31	23	23	20	11	7	5	2	0	CTx + Durvalumab
46	38	20	13	12	9	7	3	2	0	0	CTx

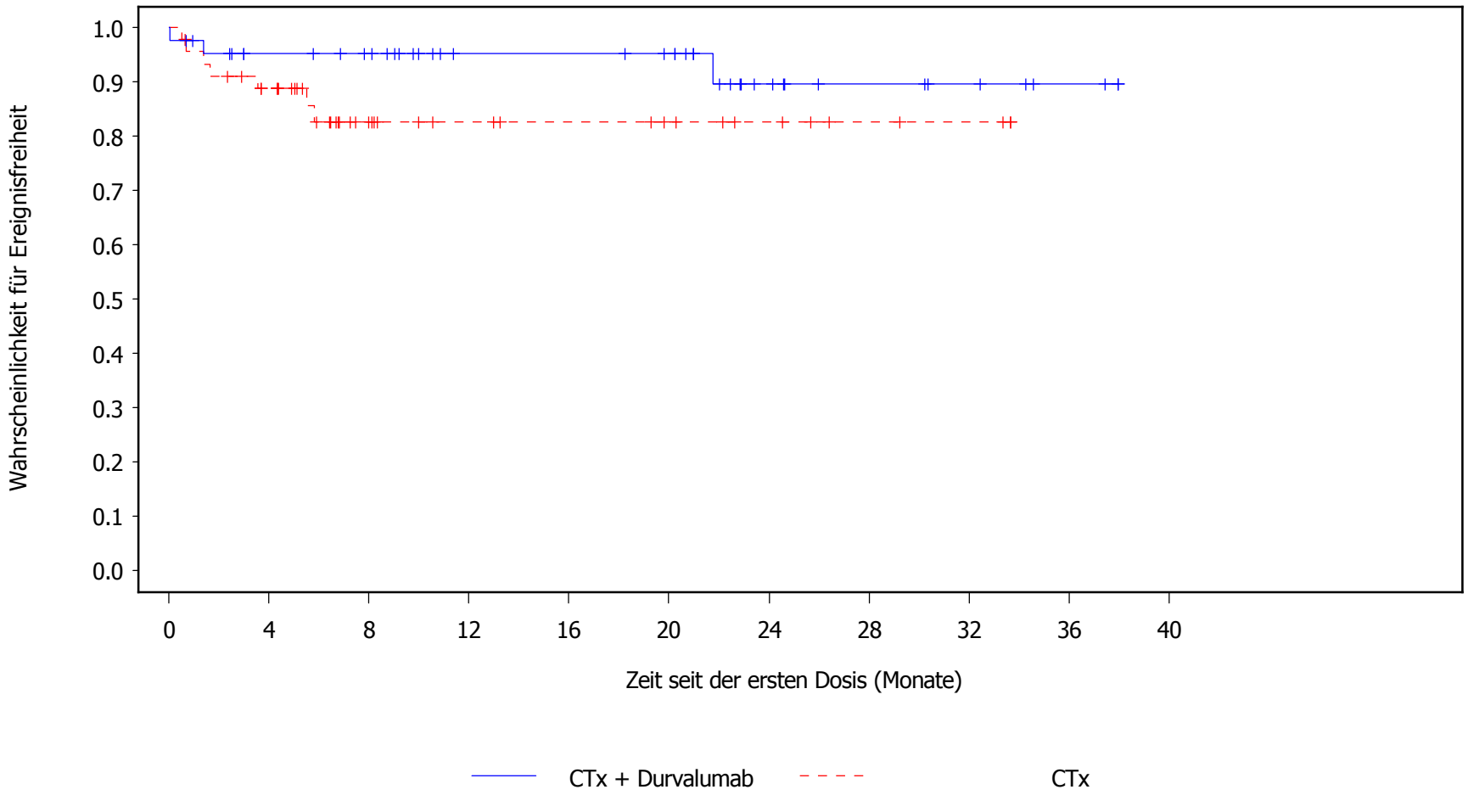
Figure 3.3.1.2D.82 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Erkrankungen des Nervensystems
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	35	31	23	23	21	11	7	5	2	0	CTx + Durvalumab
46	38	21	15	13	10	7	3	2	0	0	CTx

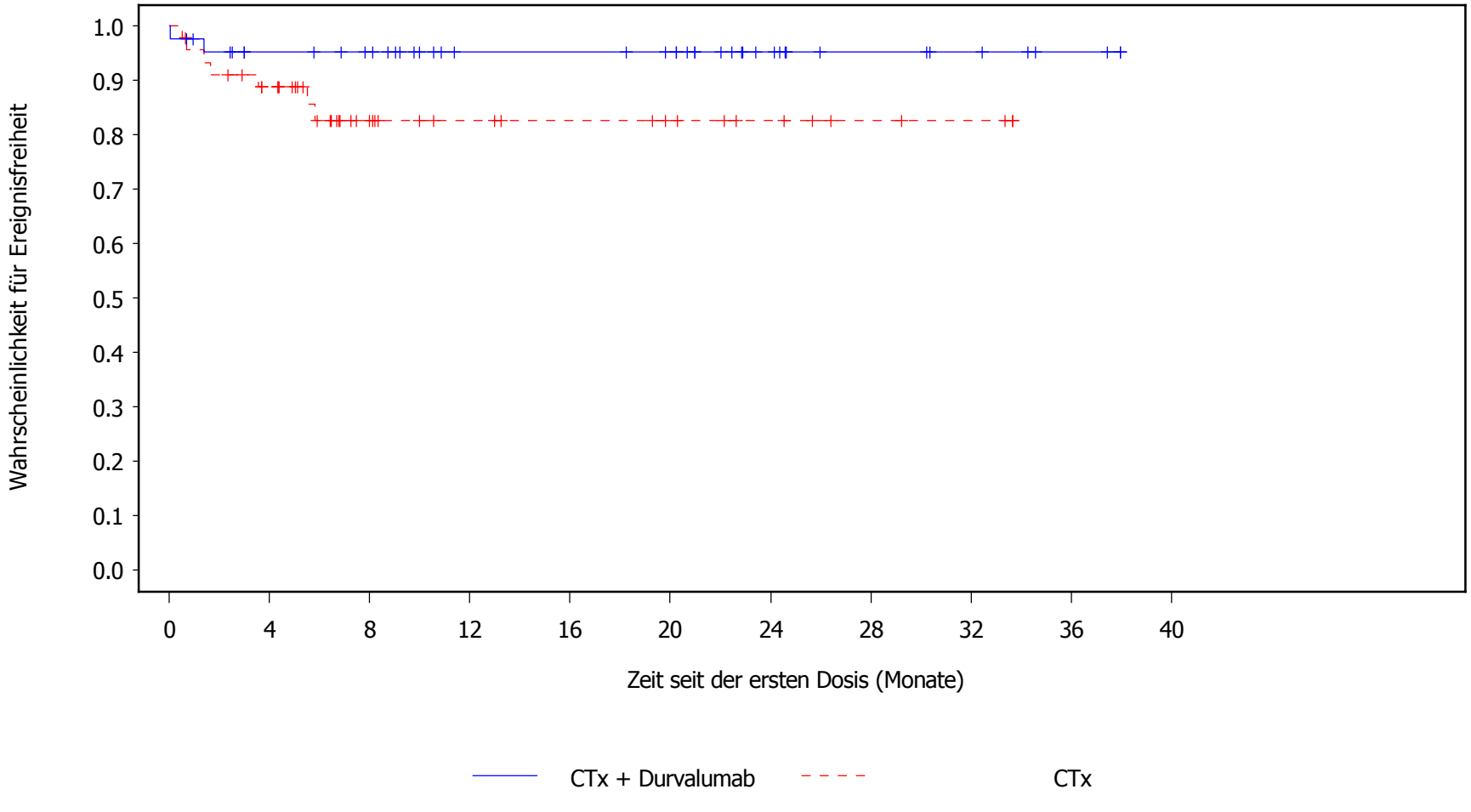
Figure 3.3.1.2D.83 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Gefaesserkrankungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	33	24	24	22	11	7	5	2	0	CTx + Durvalumab
46	36	19	13	11	9	6	3	2	0	0	CTx

Figure 3.3.1.2D.84 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Hypertonie
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	33	24	24	22	12	7	5	2	0	CTx + Durvalumab
46	36	19	13	11	9	6	3	2	0	0	CTx

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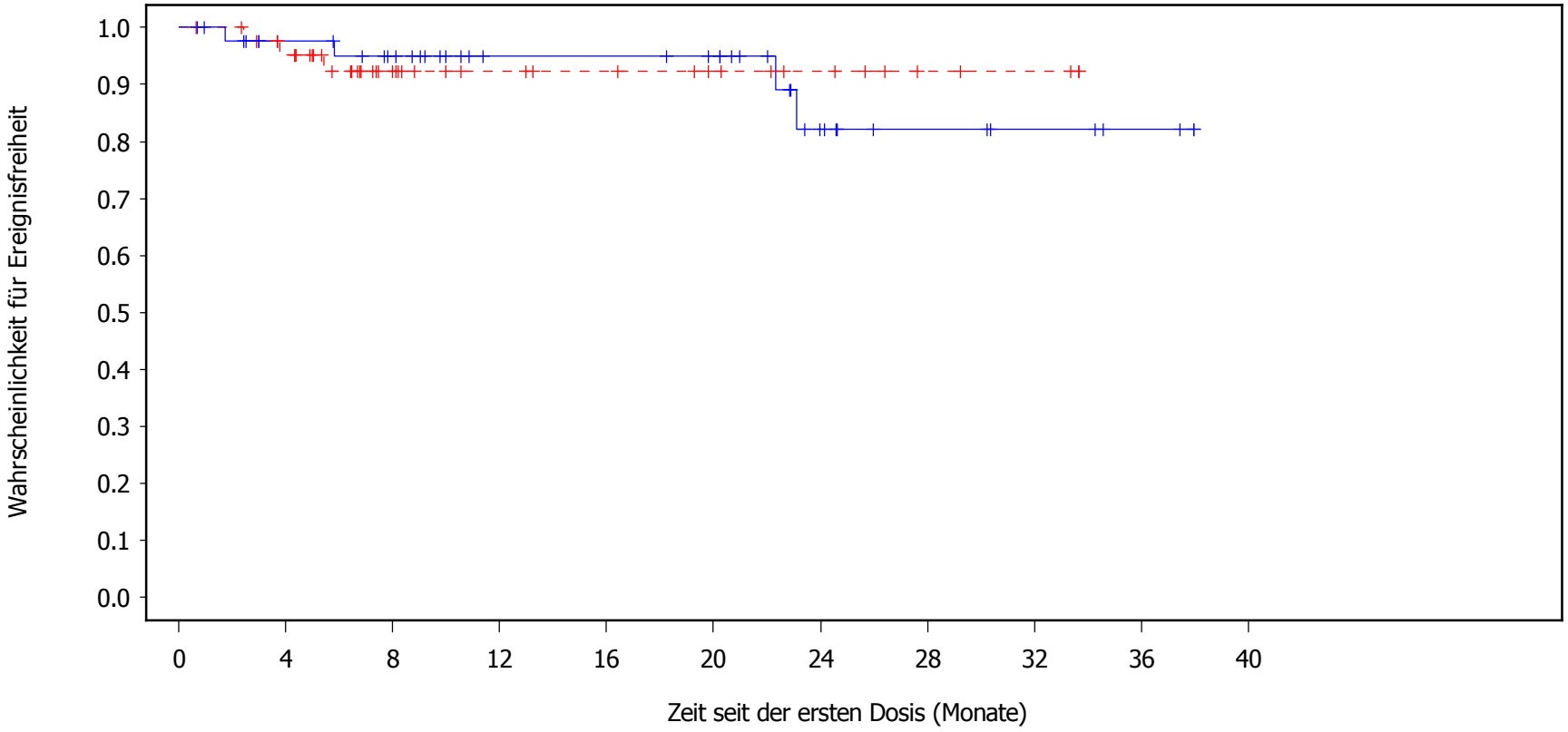
Figure 3.3.1.2D.85 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Infektionen und parasitaere Erkrankungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	37	32	23	23	21	10	6	4	2	0	CTx + Durvalumab
46	39	22	15	13	10	7	3	2	0	0	CTx

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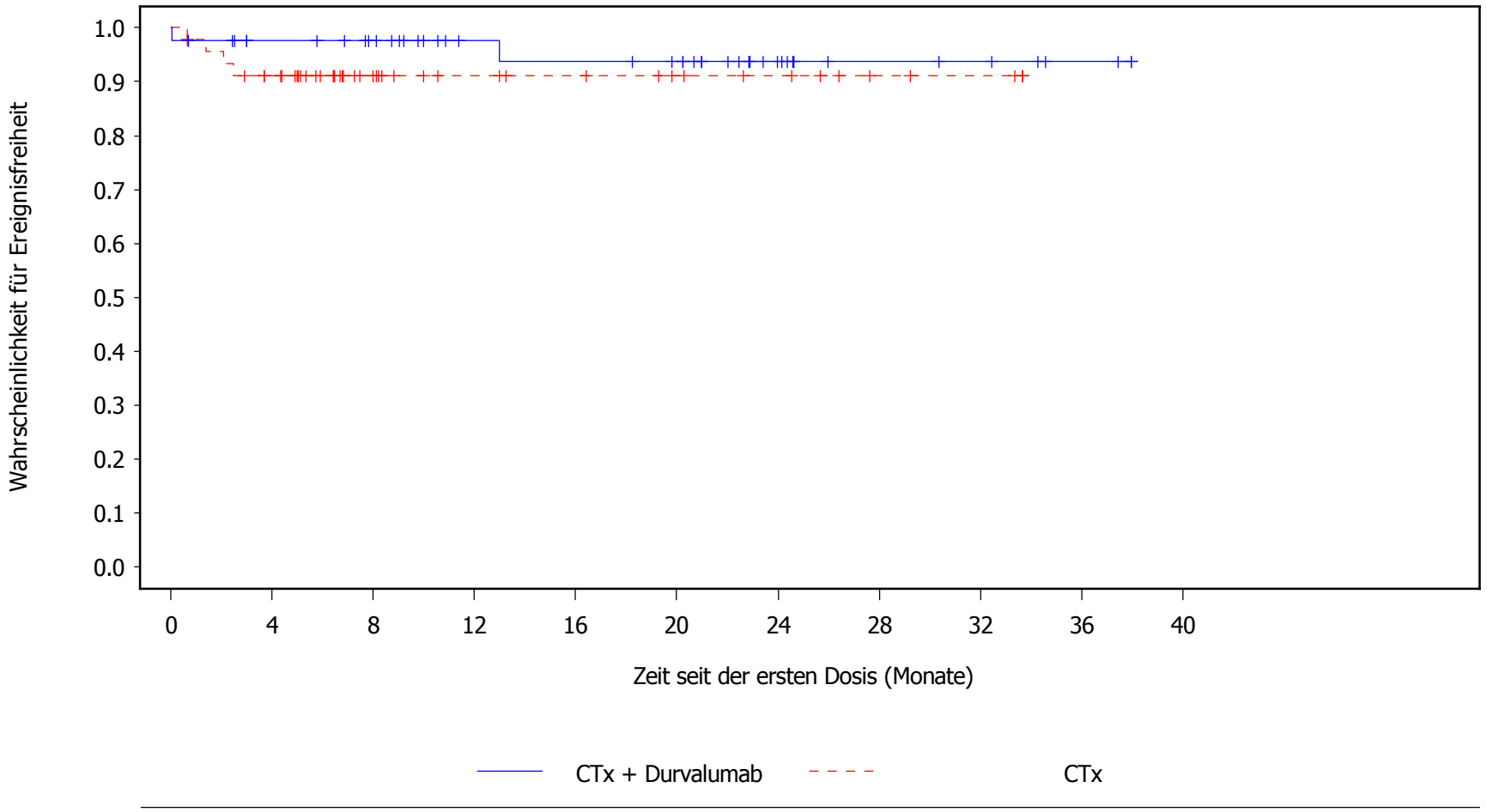
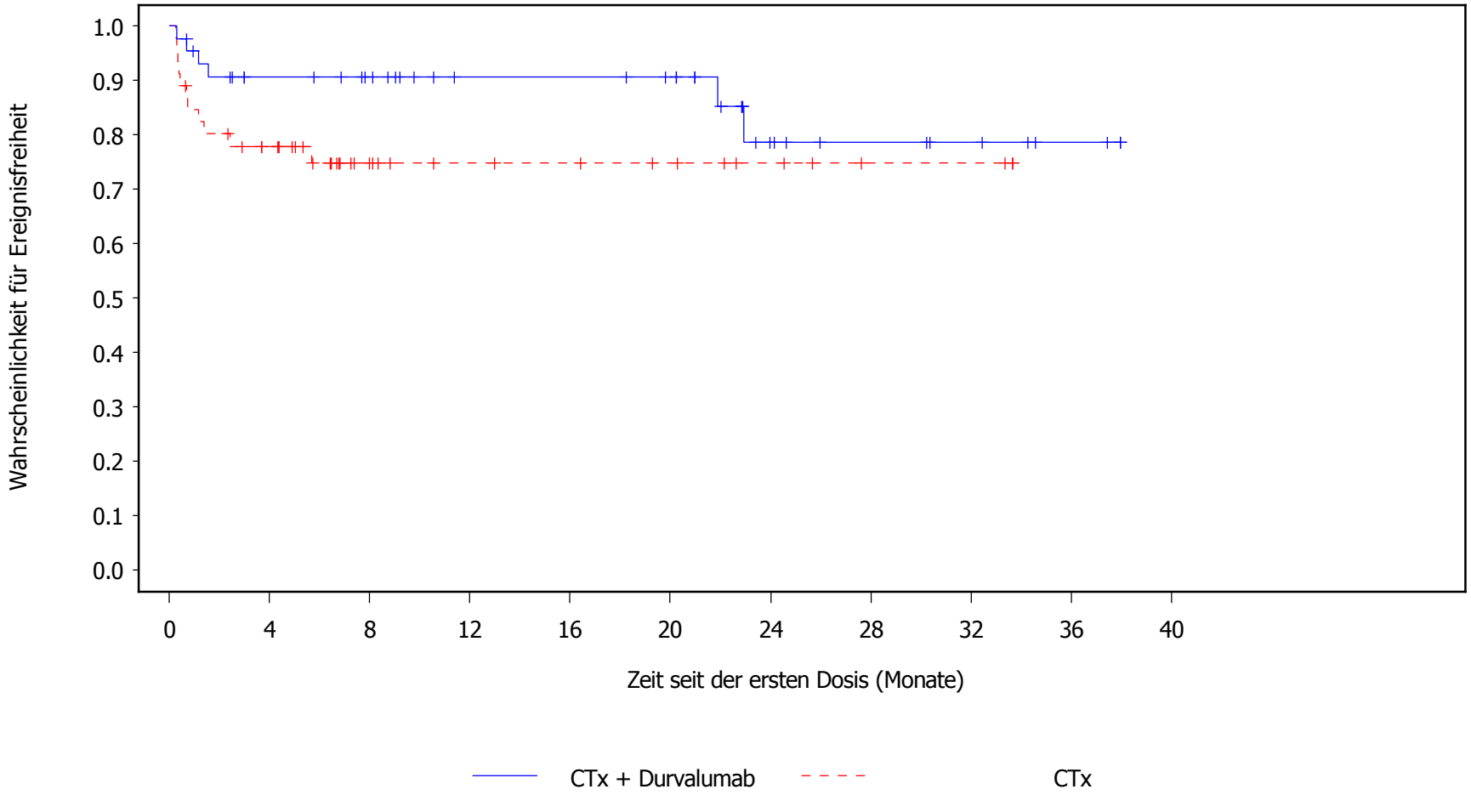
Figure 3.3.1.2D.86 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Stoffwechsel- und Ernaehrungsstoerungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	24	22	11	6	5	2	0	CTx + Durvalumab
46	38	21	14	12	9	7	3	2	0	0	CTx

Figure 3.3.1.2D.87 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Untersuchungen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	30	23	23	21	10	7	5	2	0	CTx + Durvalumab
46	31	16	11	10	8	5	2	2	0	0	CTx

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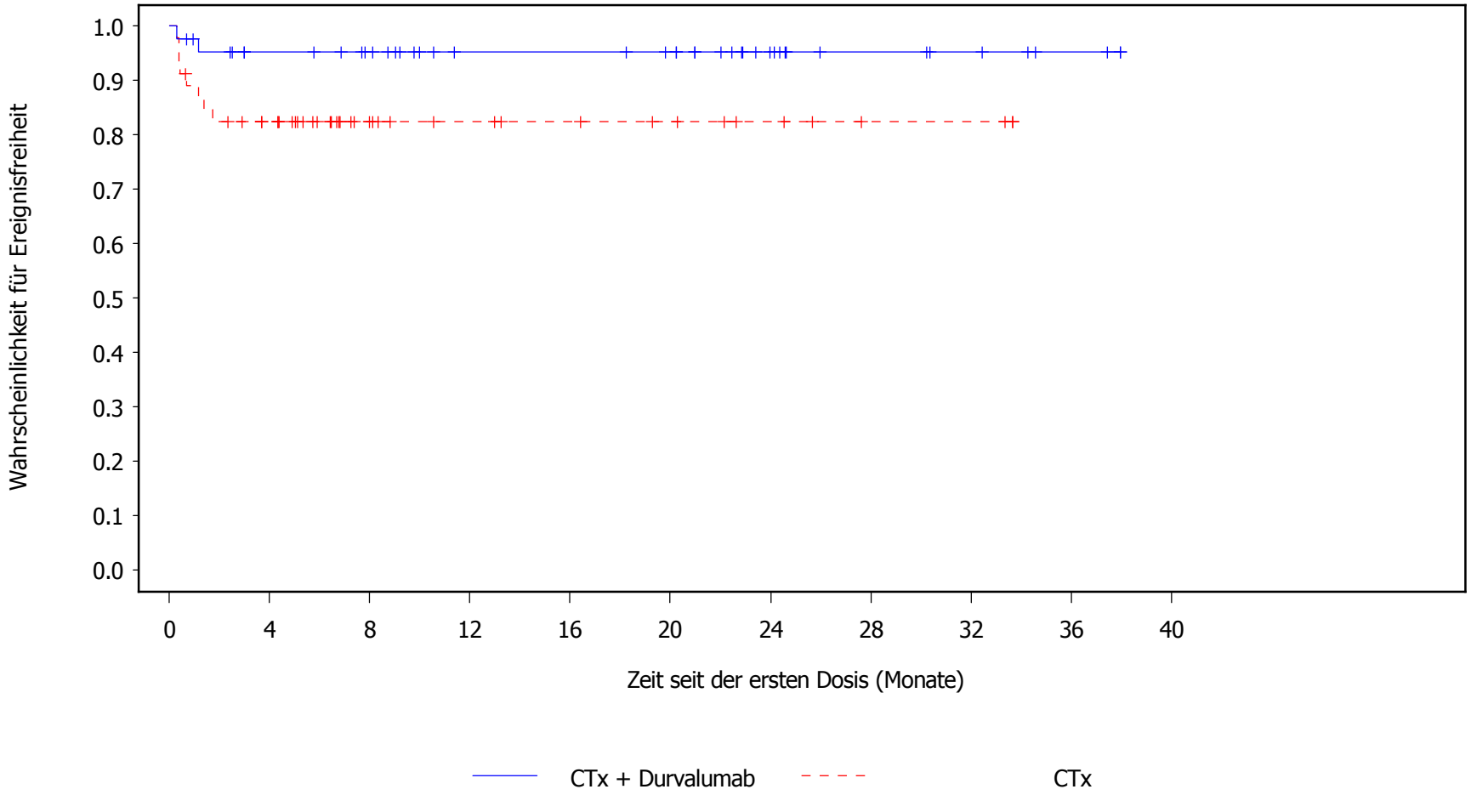
Figure 3.3.1.2D.88 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 PT: Neutrophilenzahl erniedrigt
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	32	24	24	22	12	7	5	2	0	CTx + Durvalumab
46	33	17	12	10	8	5	2	2	0	0	CTx

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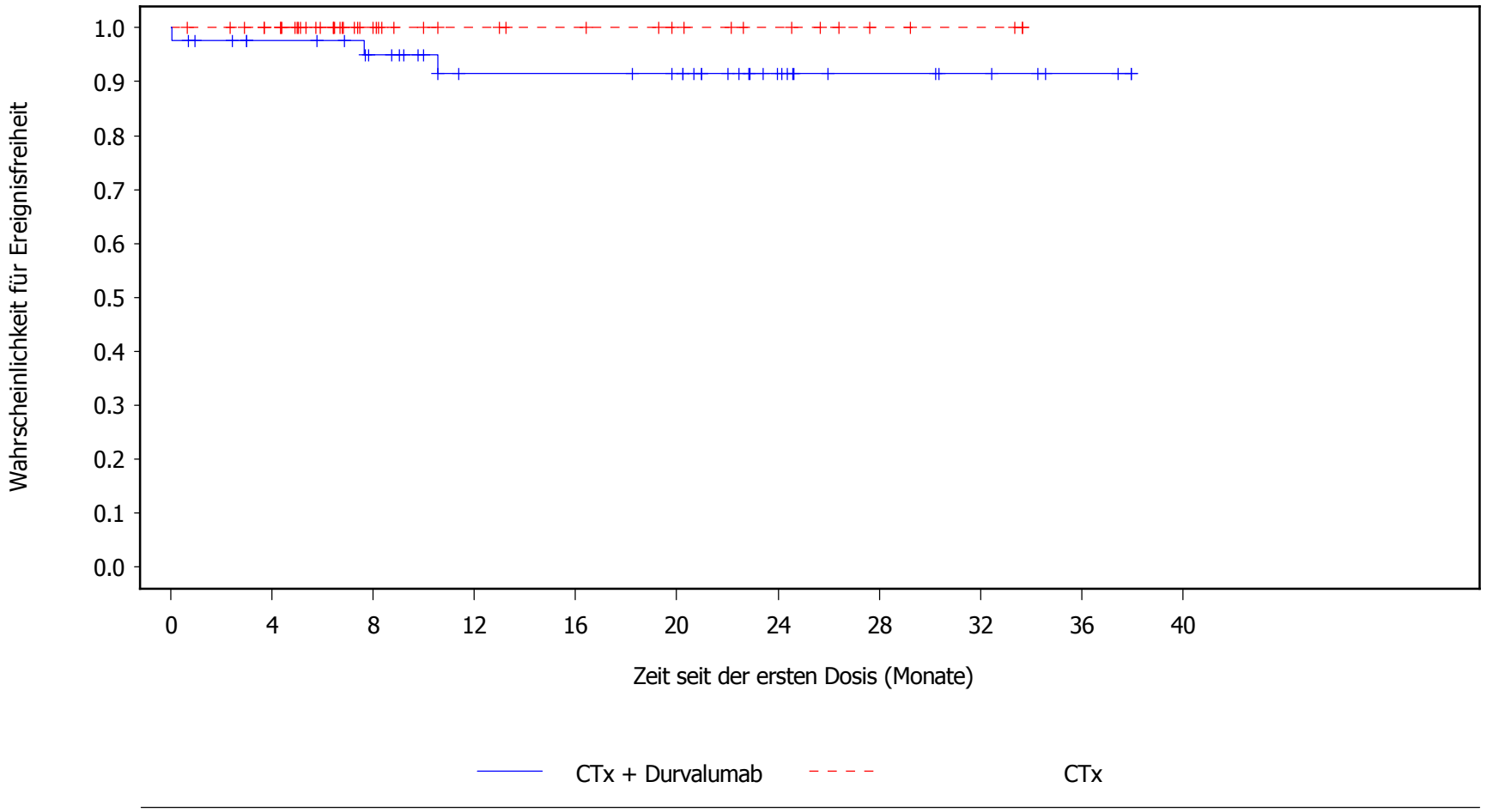
Figure 3.3.1.2D.89 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of G>=3 SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen
Patients with dMMR tumour status, DCO 18OCT2023

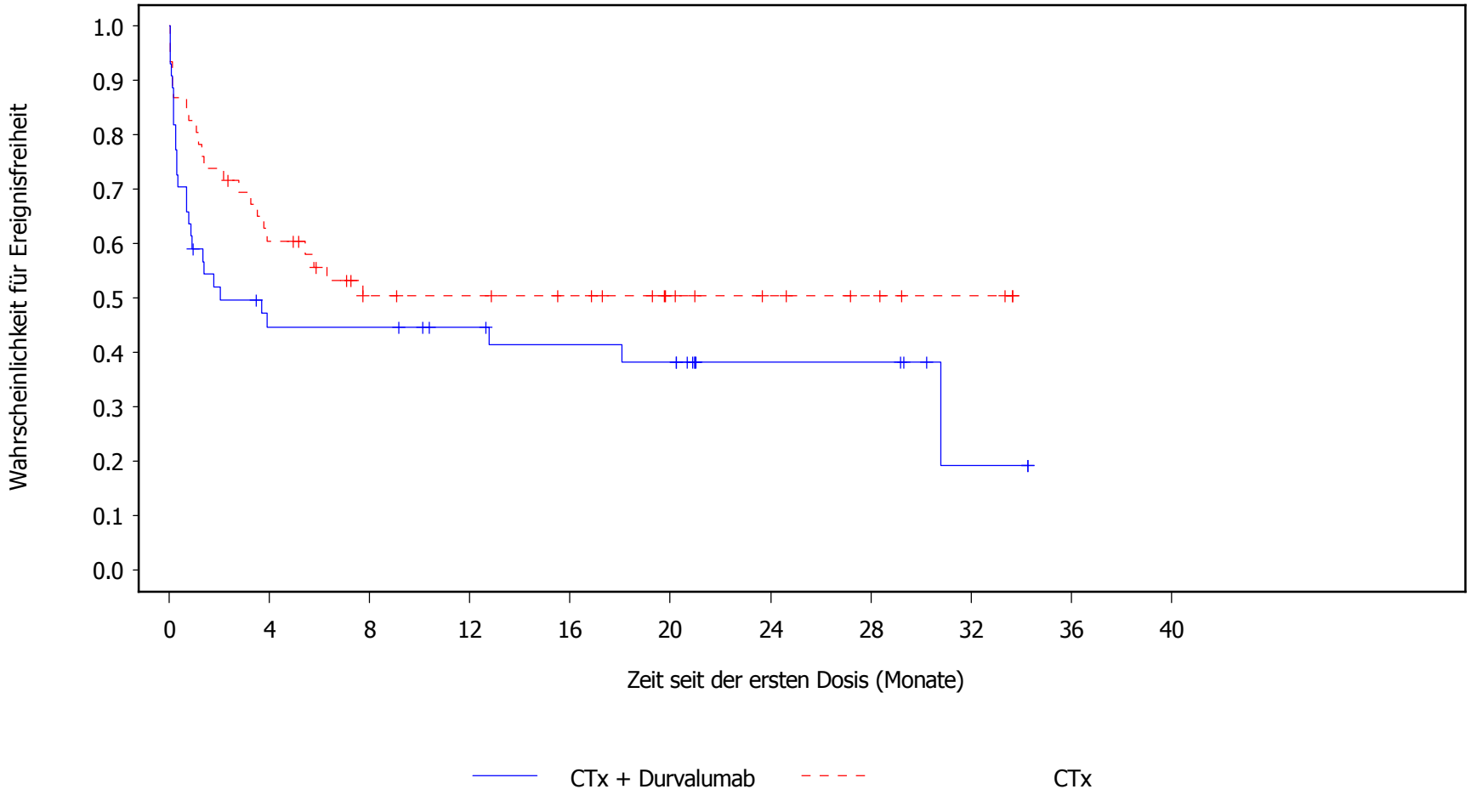


Anzahl an Patienten unter Risiko:

44	38	33	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttemainae.sas gttemainaeadk 15APR2024:10:33

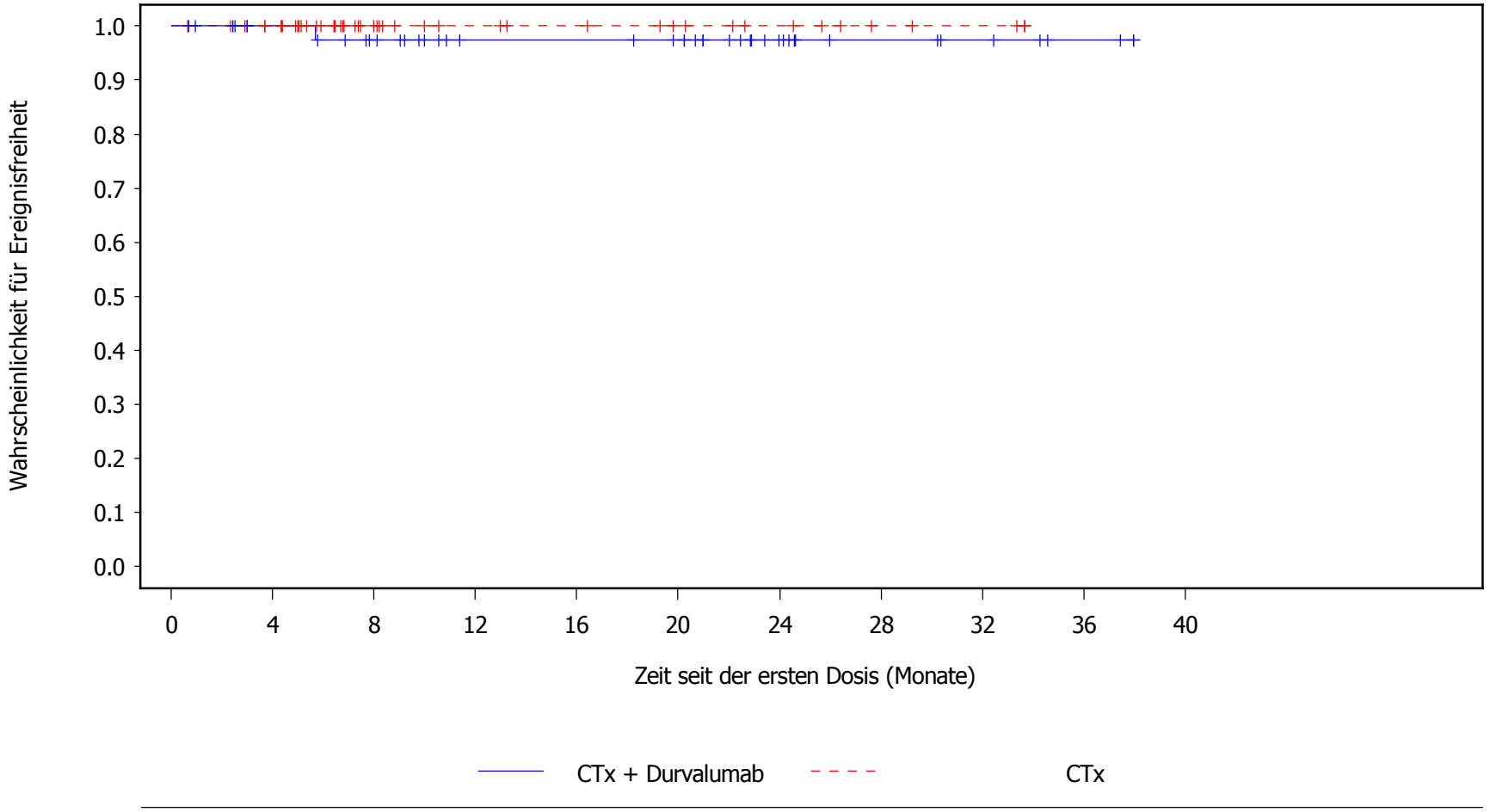
Figure 3.3.1.2D.90 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	18	18	15	13	12	5	5	1	0	0	CTx + Durvalumab
46	27	17	16	14	9	6	4	2	0	0	CTx

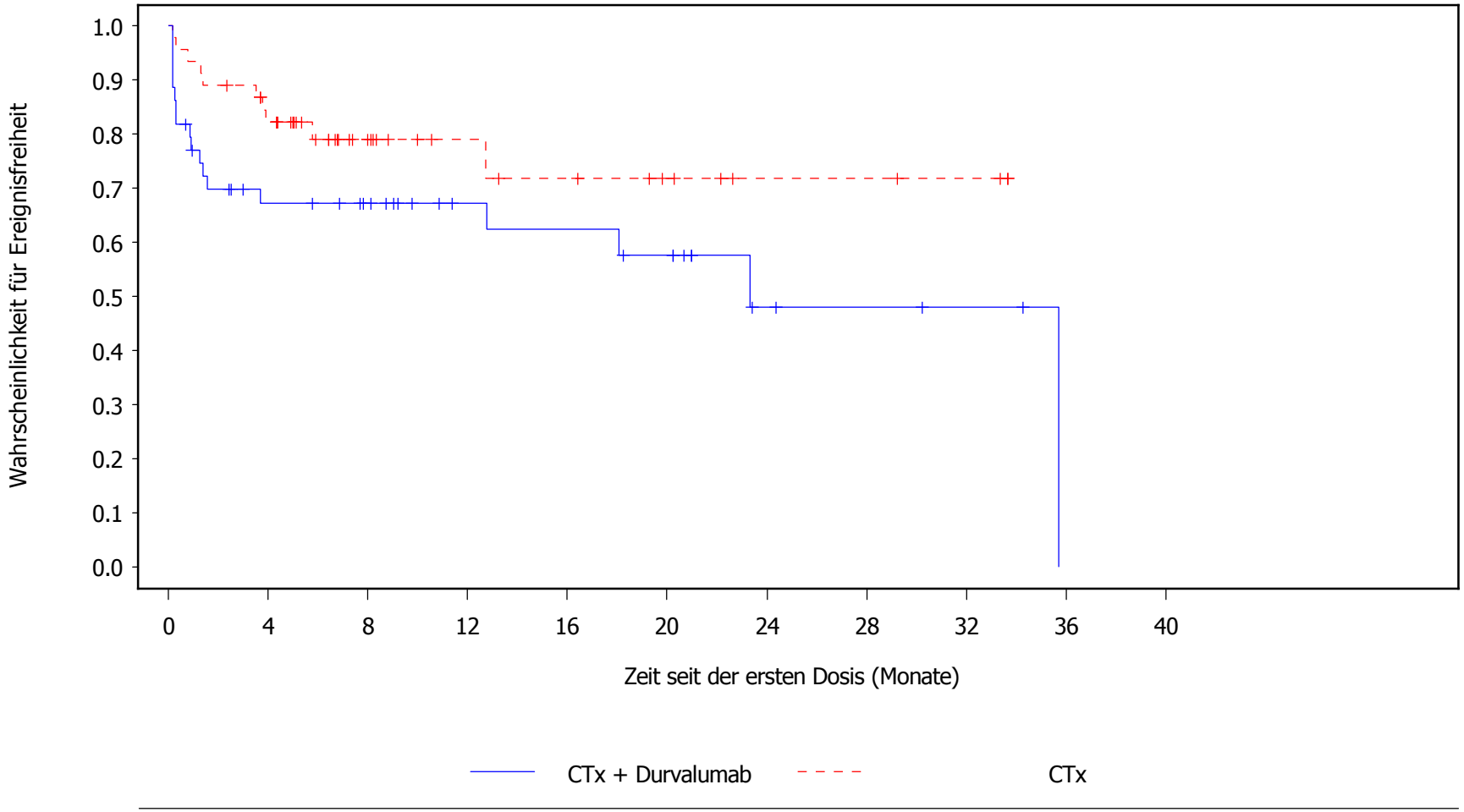
Figure 3.3.1.2D.91 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Andere seltene/sonstige Ereignisse
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	33	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

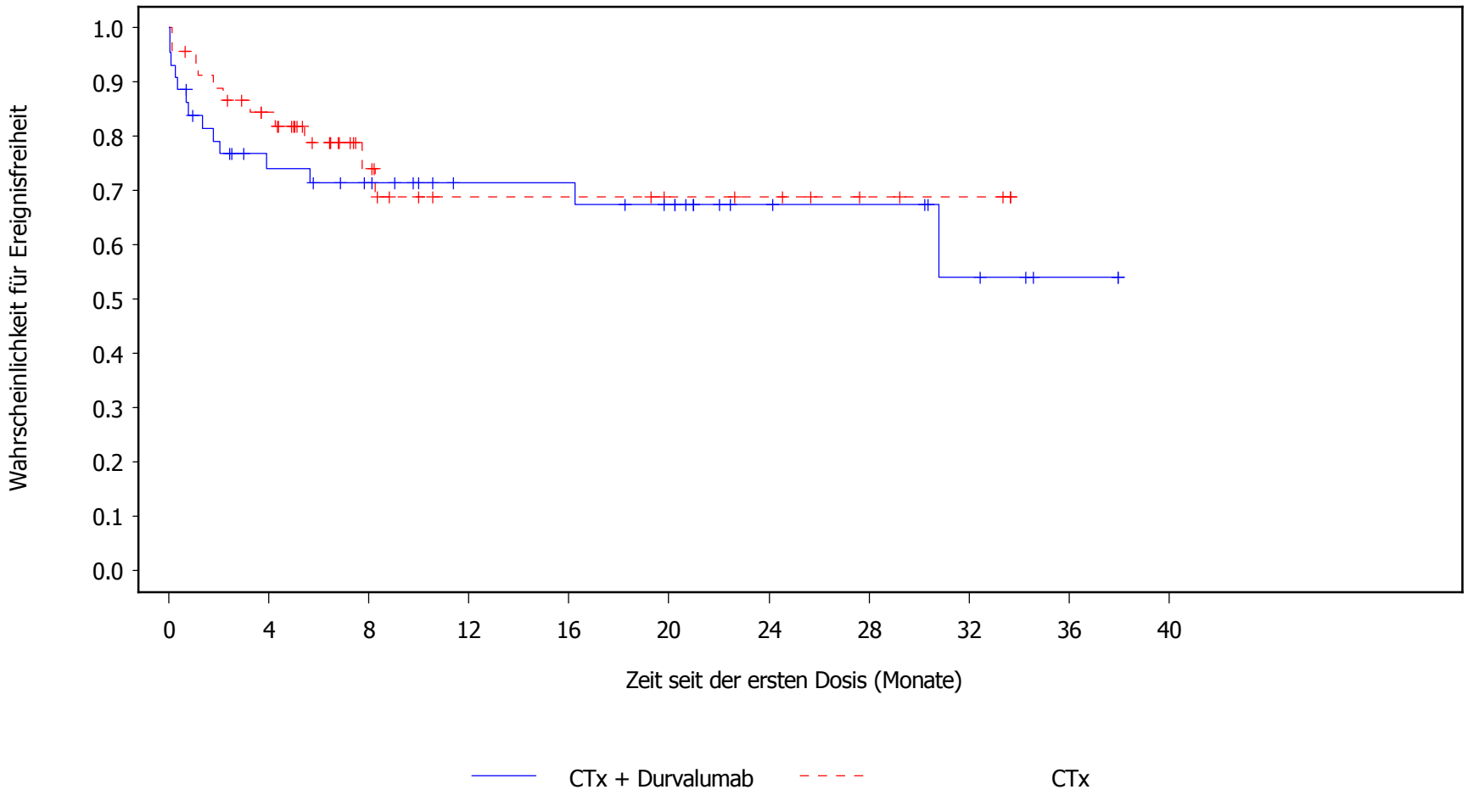
Figure 3.3.1.2D.92 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Dermatitis/Hautausschlag
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	25	21	14	13	11	4	3	2	0	0	CTx + Durvalumab
46	35	18	11	9	6	3	3	2	0	0	CTx

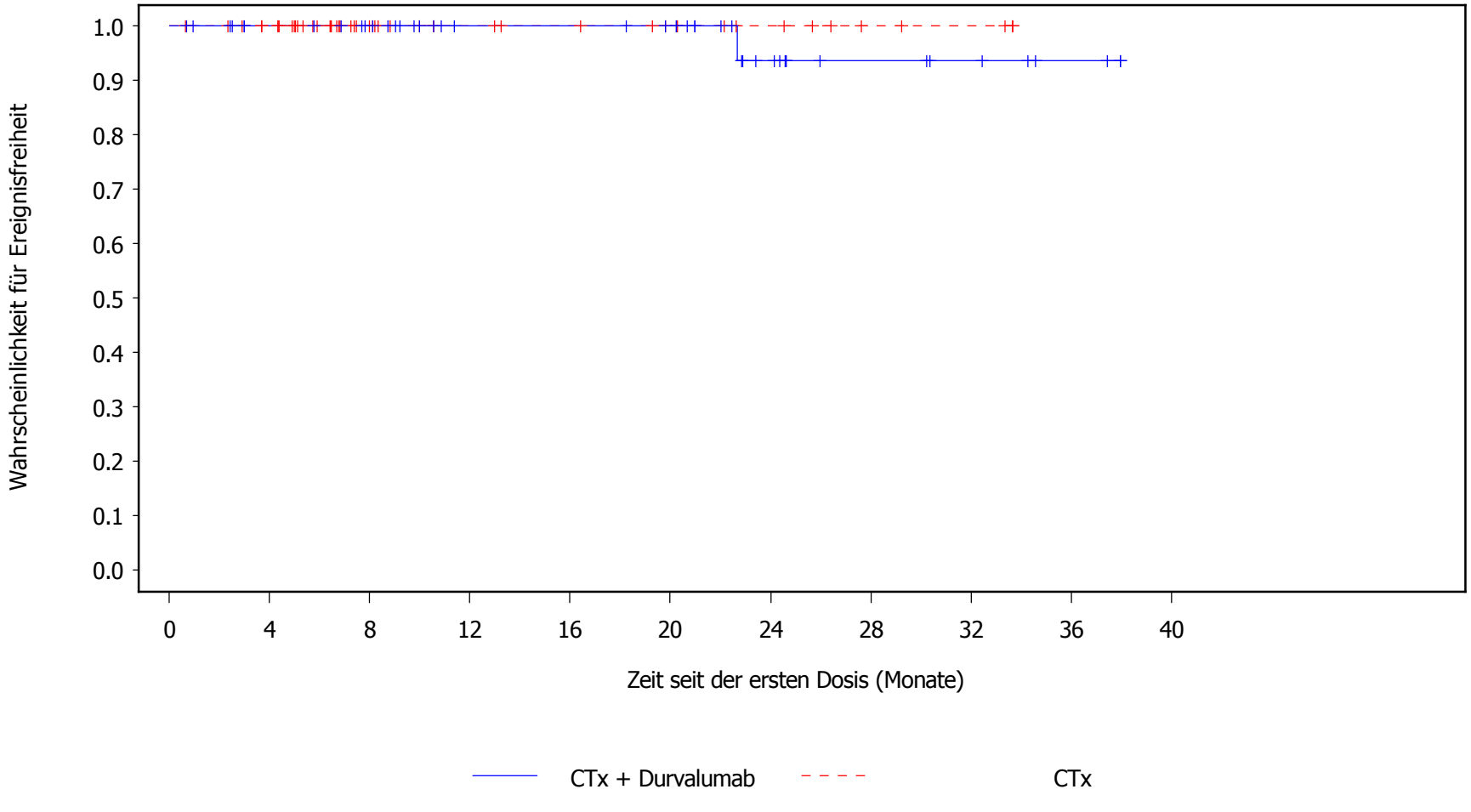
Figure 3.3.1.2D.93 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Diarrhö/Kolitis
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	28	24	18	18	15	8	7	4	1	0	CTx + Durvalumab
46	34	16	9	9	7	6	3	2	0	0	CTx

Figure 3.3.1.2D.94 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Hepatische Ereignisse
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

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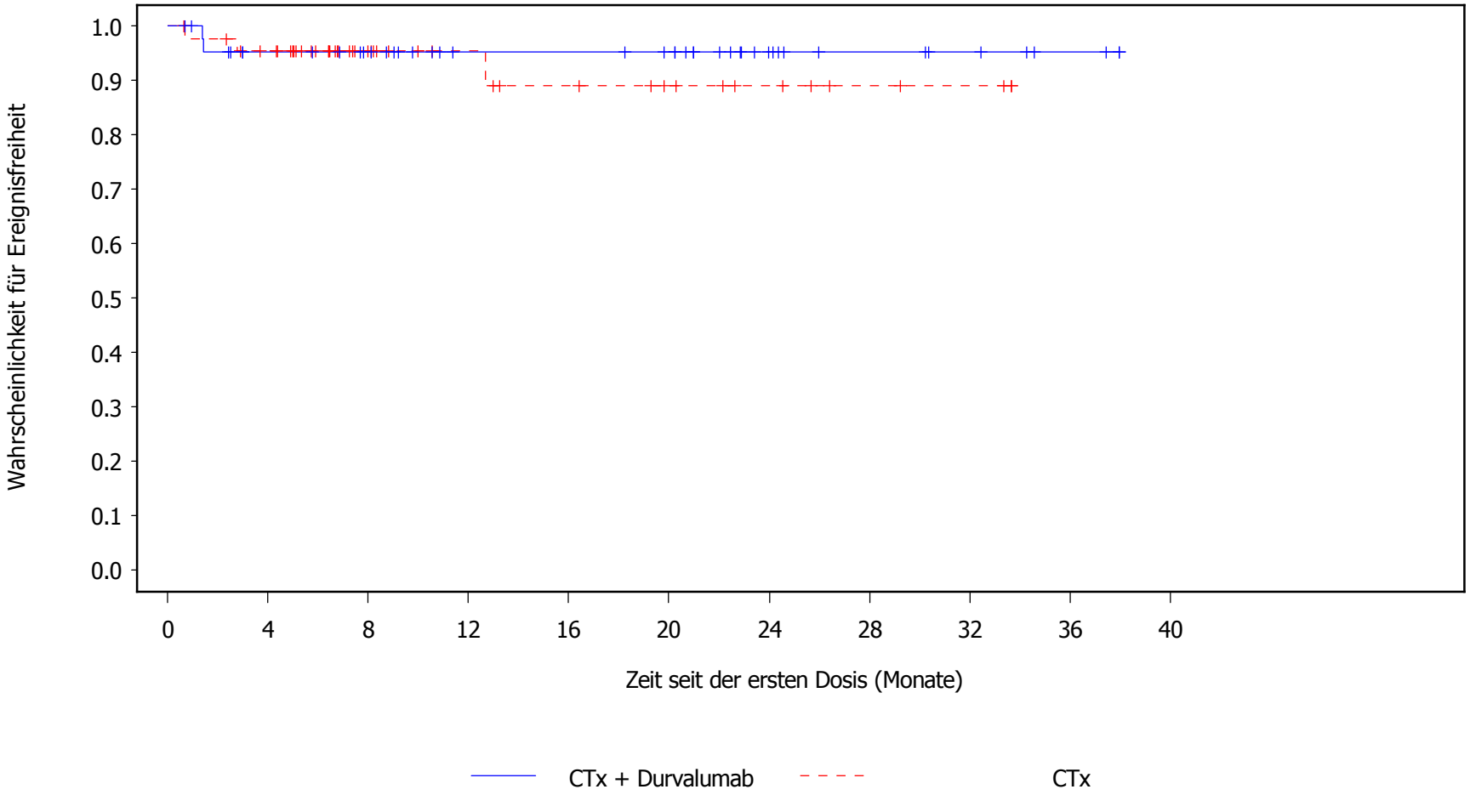
Figure 3.3.1.2D.95 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Hyperthyreose Ereignisse
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	32	24	24	22	11	7	5	2	0	CTx + Durvalumab
46	40	22	15	12	9	6	3	2	0	0	CTx

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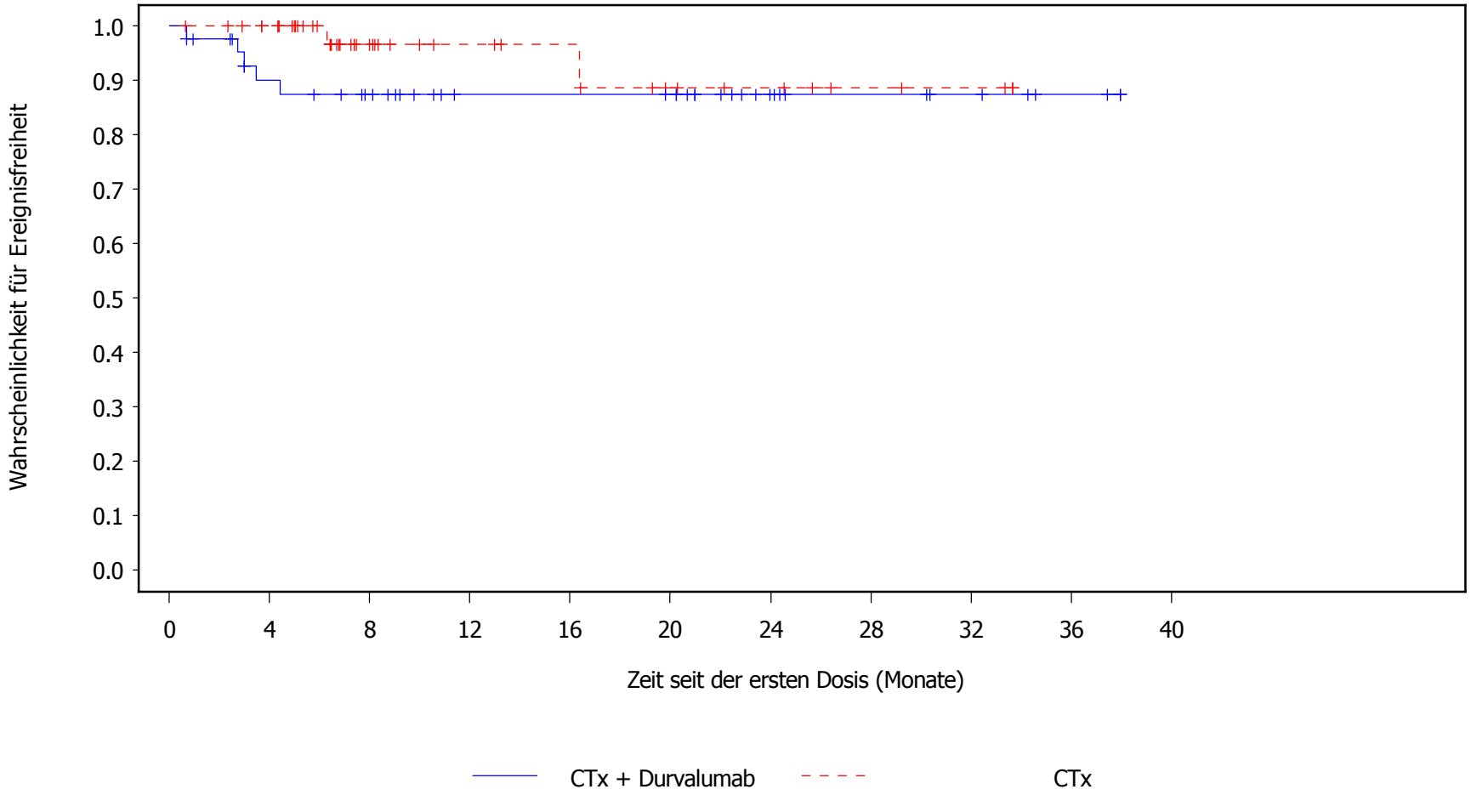
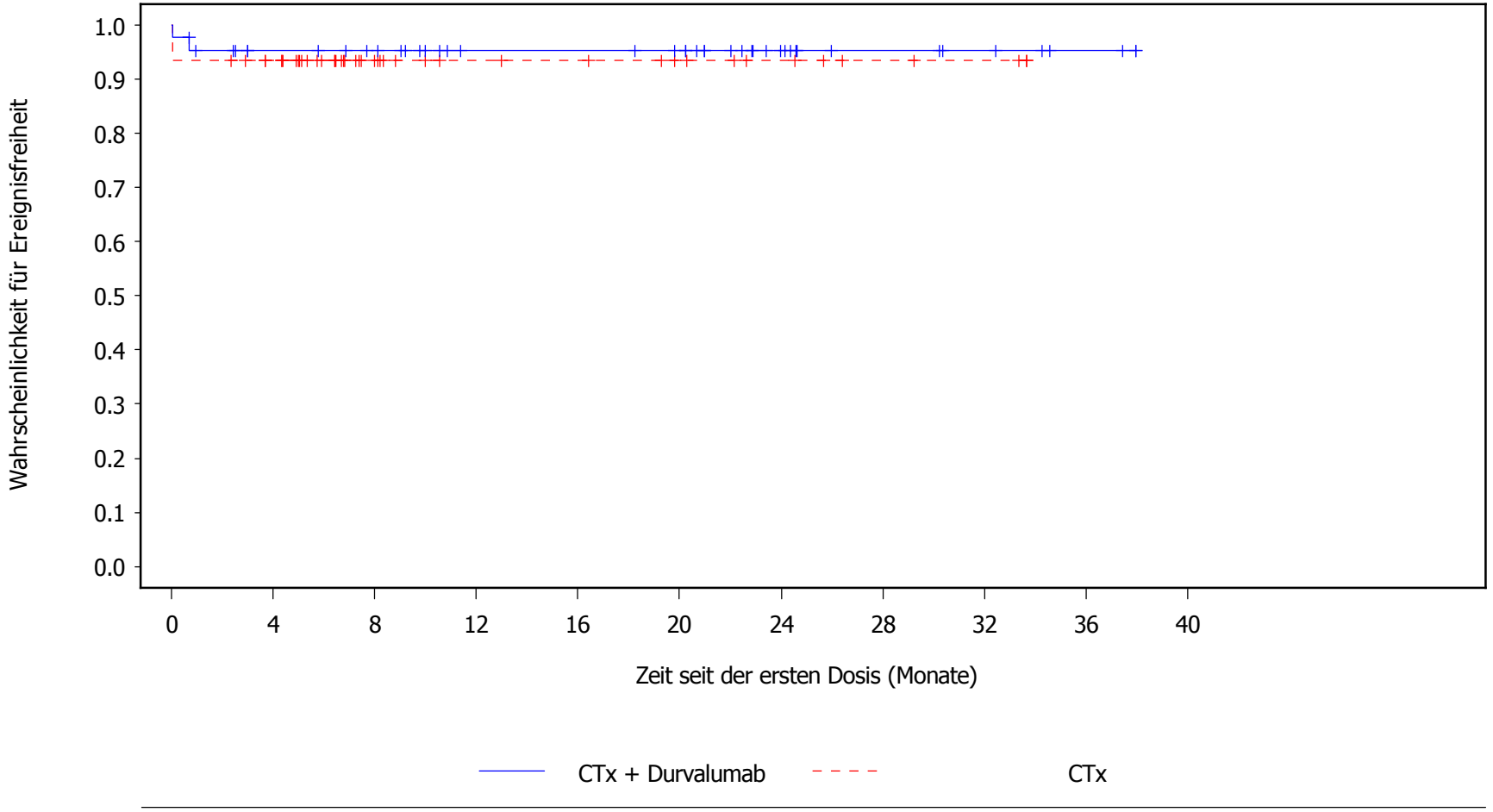
Figure 3.3.1.2D.96 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Hypothyreose Ereignisse
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	34	29	21	21	20	10	7	5	2	0	CTx + Durvalumab
46	41	21	14	12	8	6	3	2	0	0	CTx

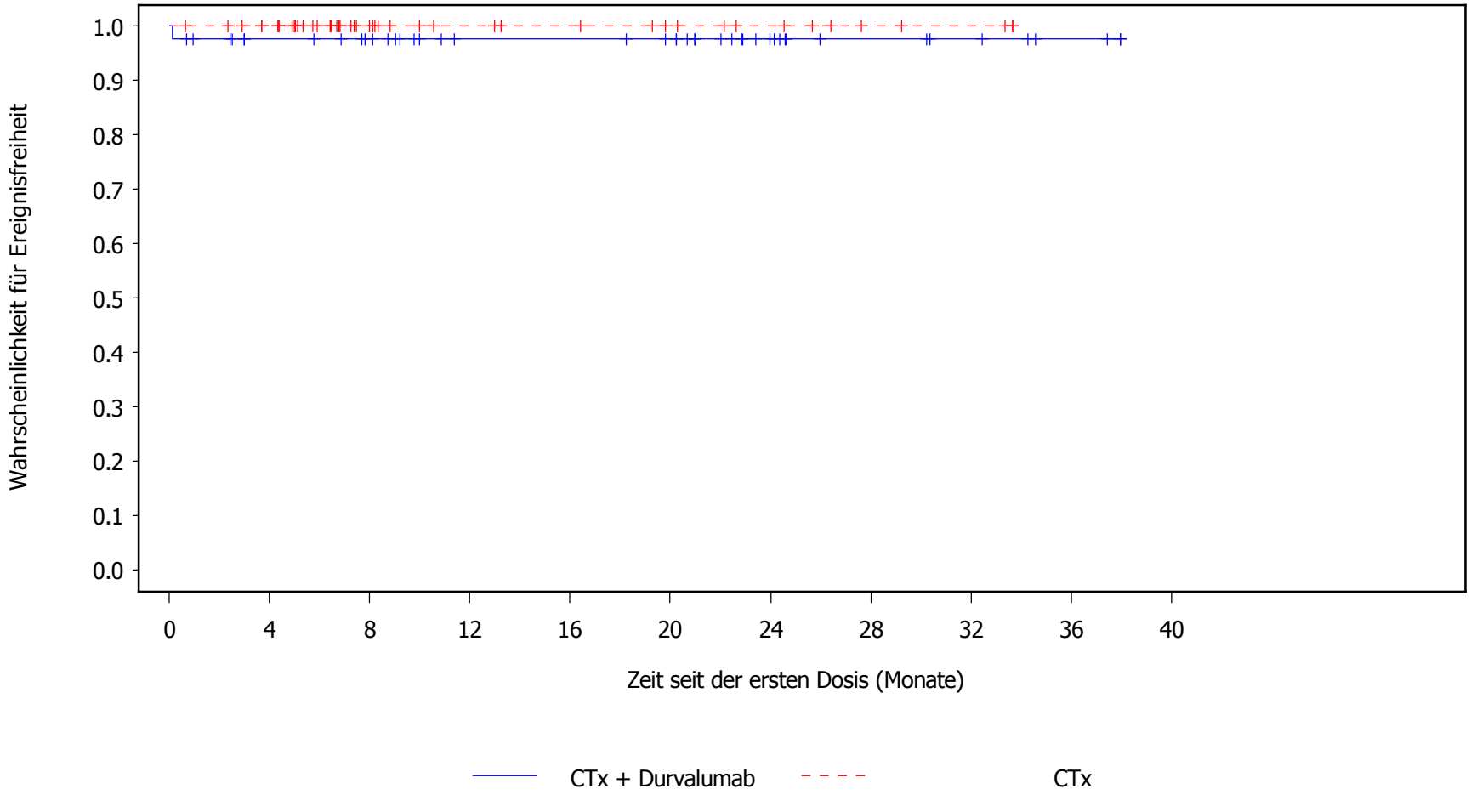
Figure 3.3.1.2D.97 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	33	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	39	20	13	12	9	6	3	2	0	0	CTx

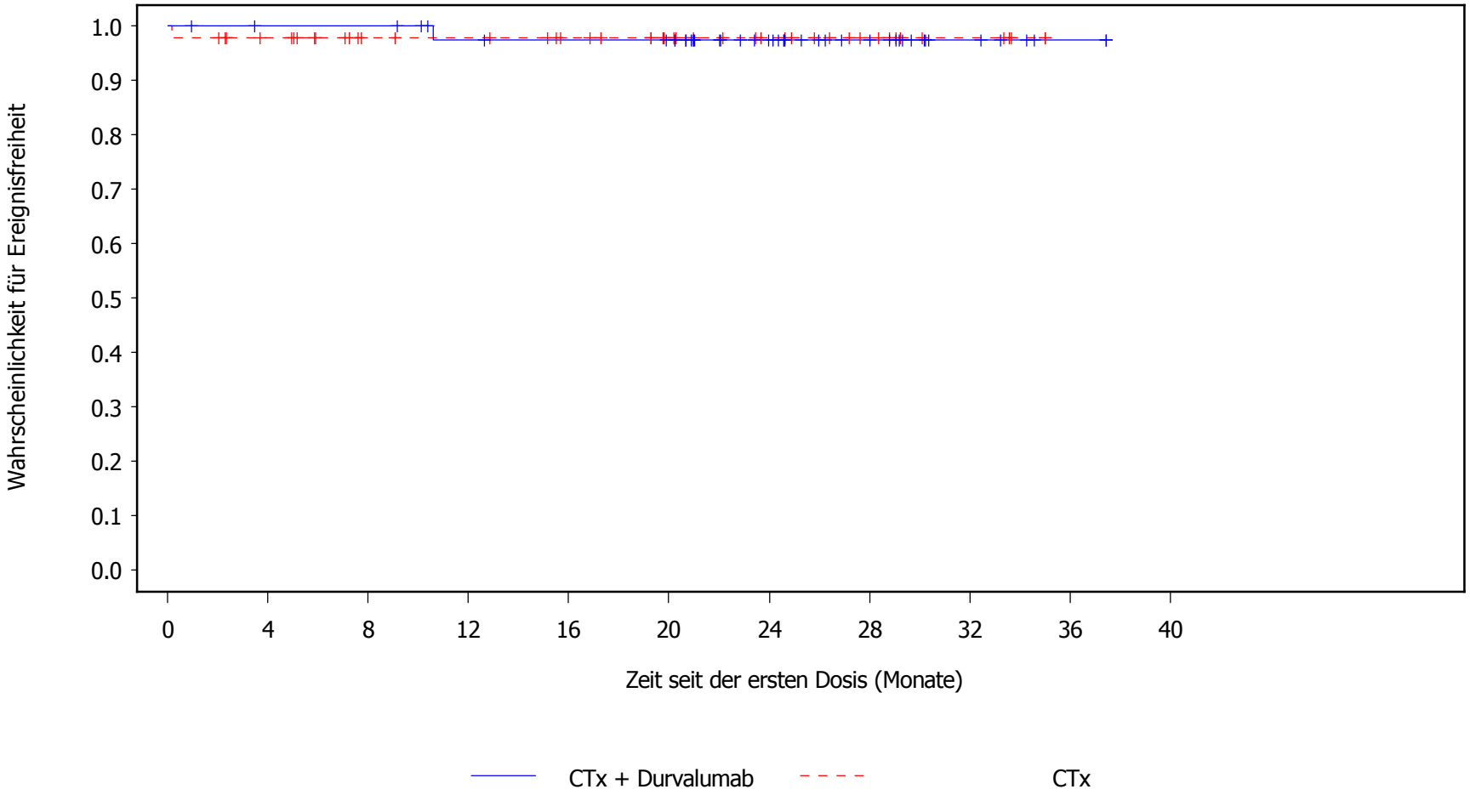
Figure 3.3.1.2D.98 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Myositis
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	37	33	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

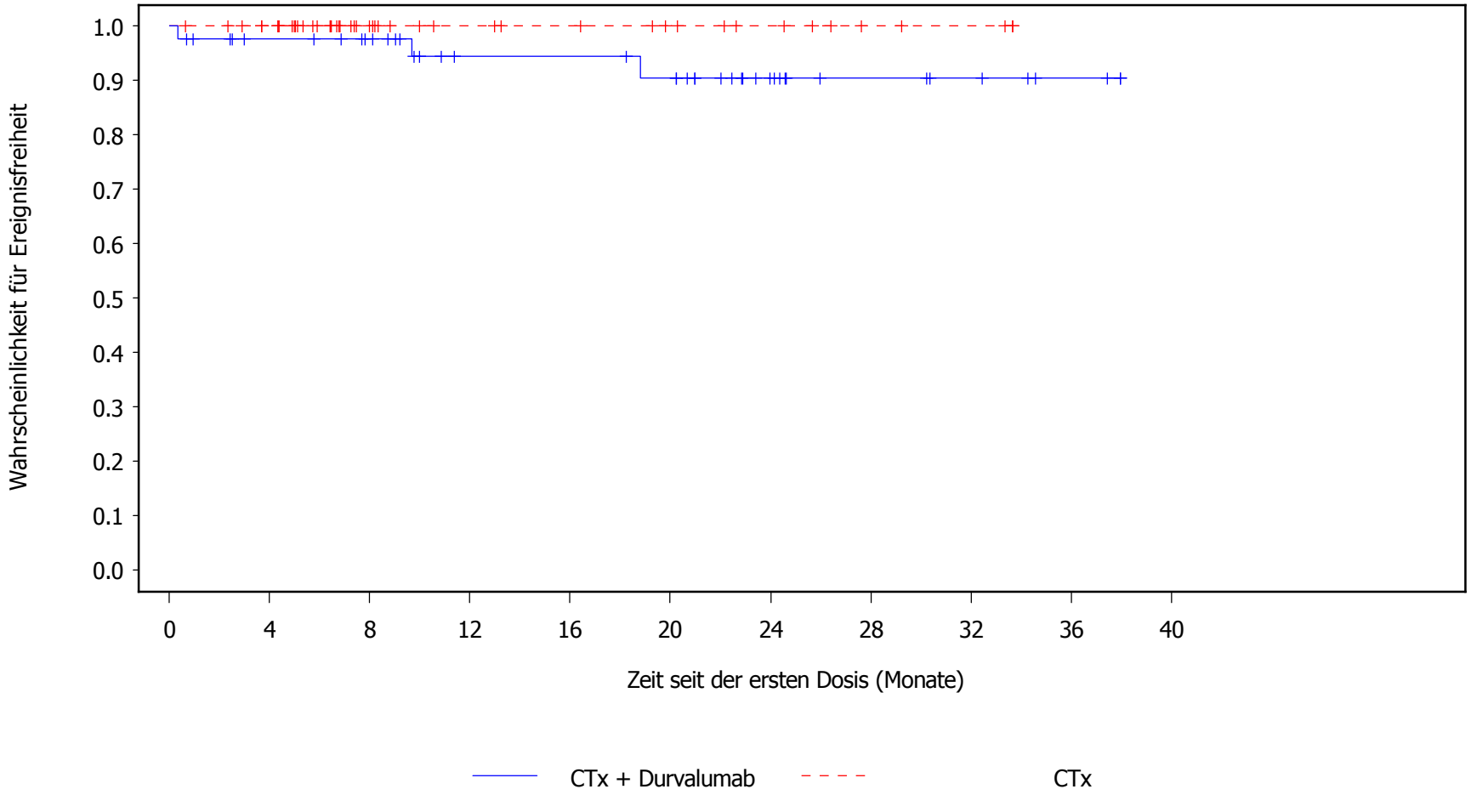
Figure 3.3.1.2D.99 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Neue primäre Malignität
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	42	42	38	37	36	23	14	5	1	0	CTx + Durvalumab
46	41	32	31	27	21	15	9	4	0	0	CTx

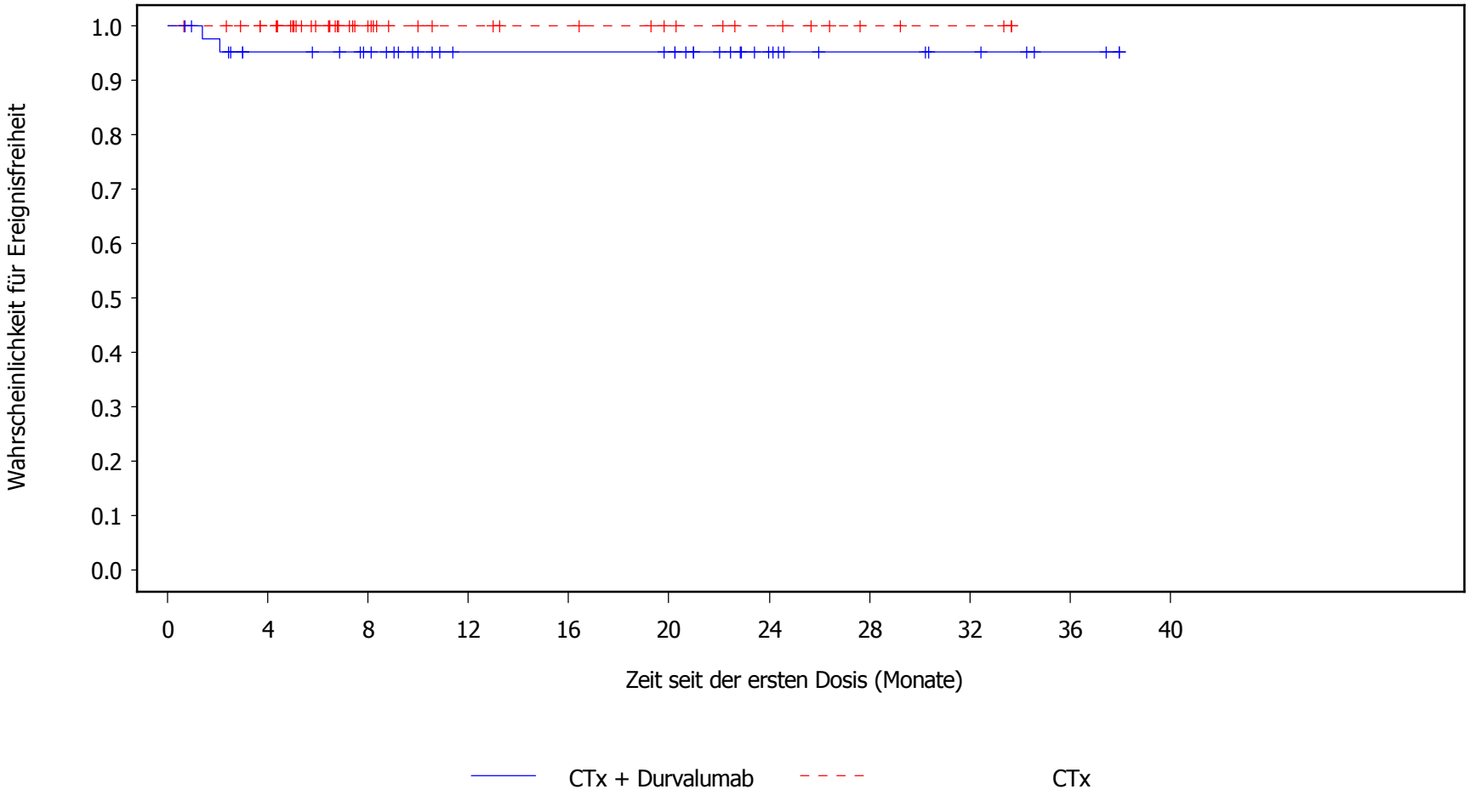
Figure 3.3.1.2D.100 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Pneumonitis
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

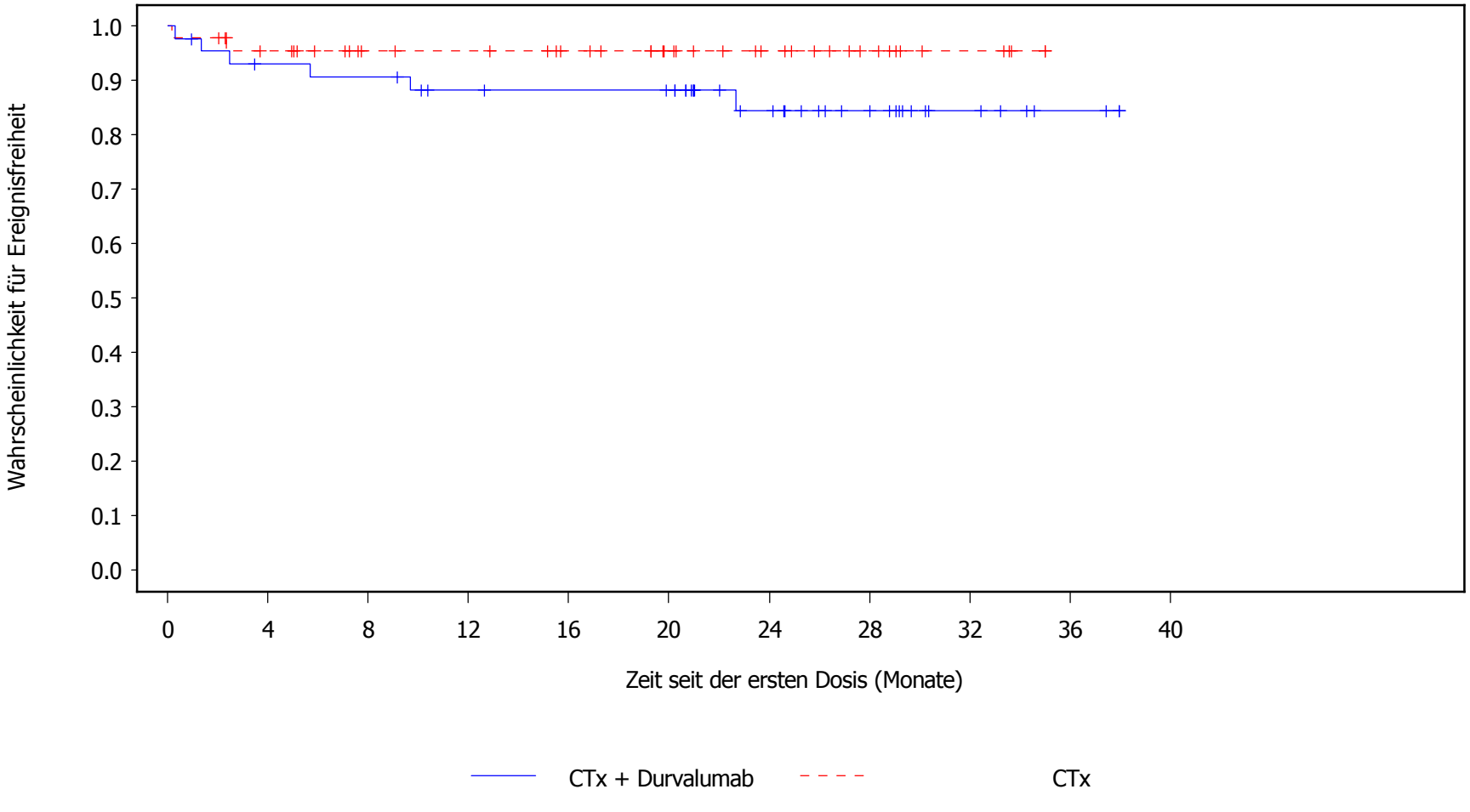
Figure 3.3.1.2D.101 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI GT: Thyreoiditis
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	32	23	23	22	11	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

Figure 3.3.1.2D.102 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	39	38	34	33	32	21	14	6	2	0	CTx + Durvalumab
46	40	32	31	27	21	15	9	4	0	0	CTx

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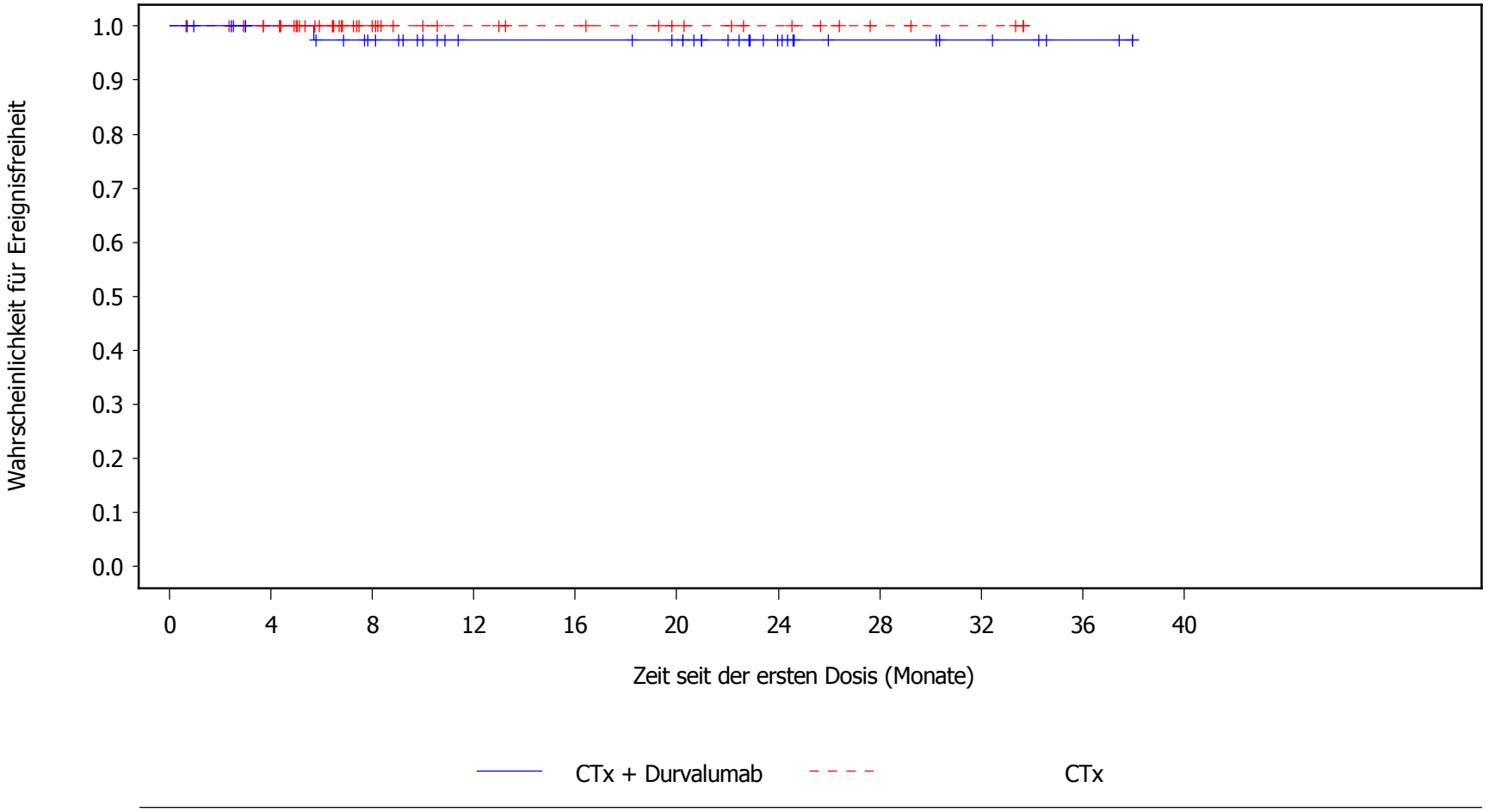
Figure 3.3.1.2D.103 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	33	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

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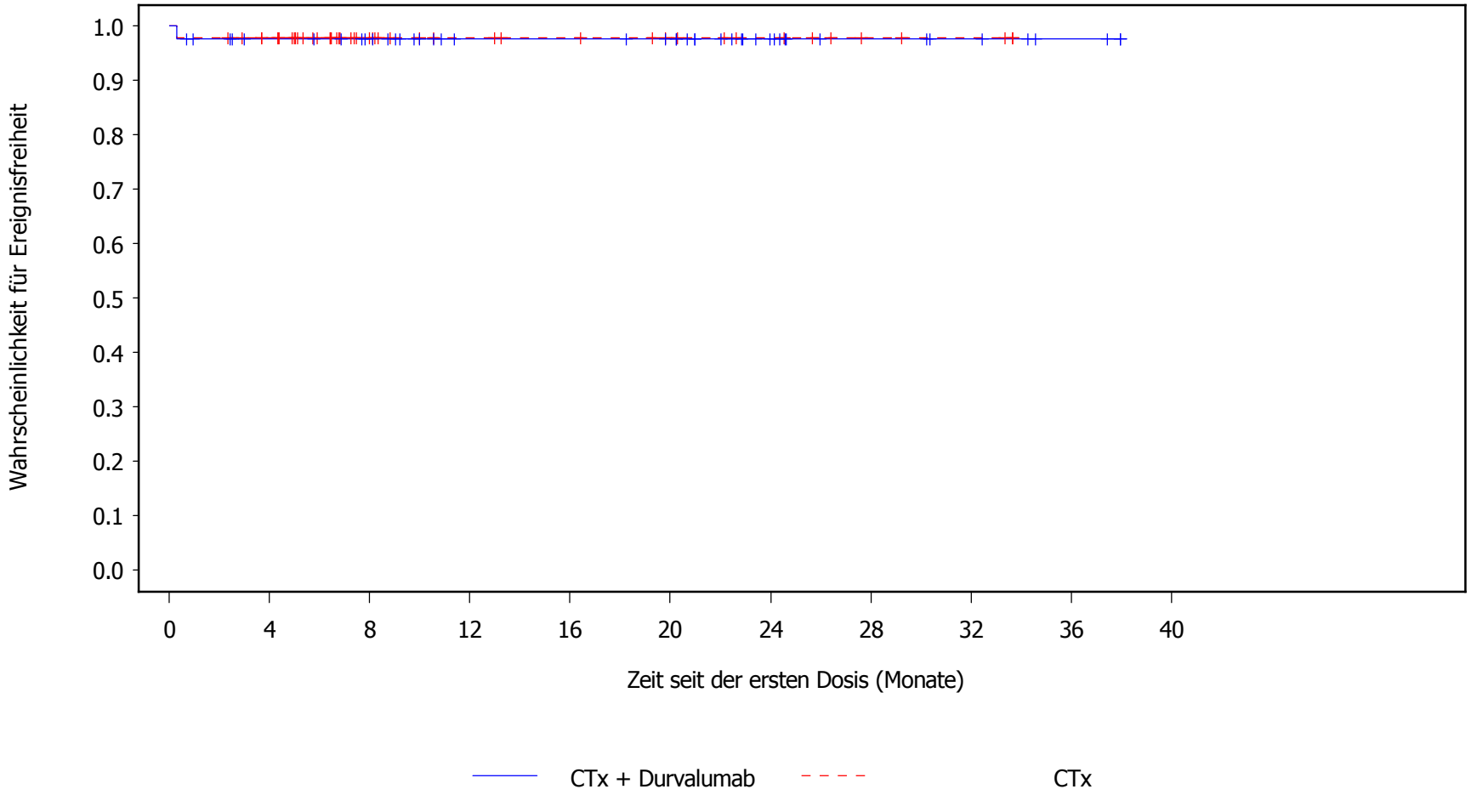
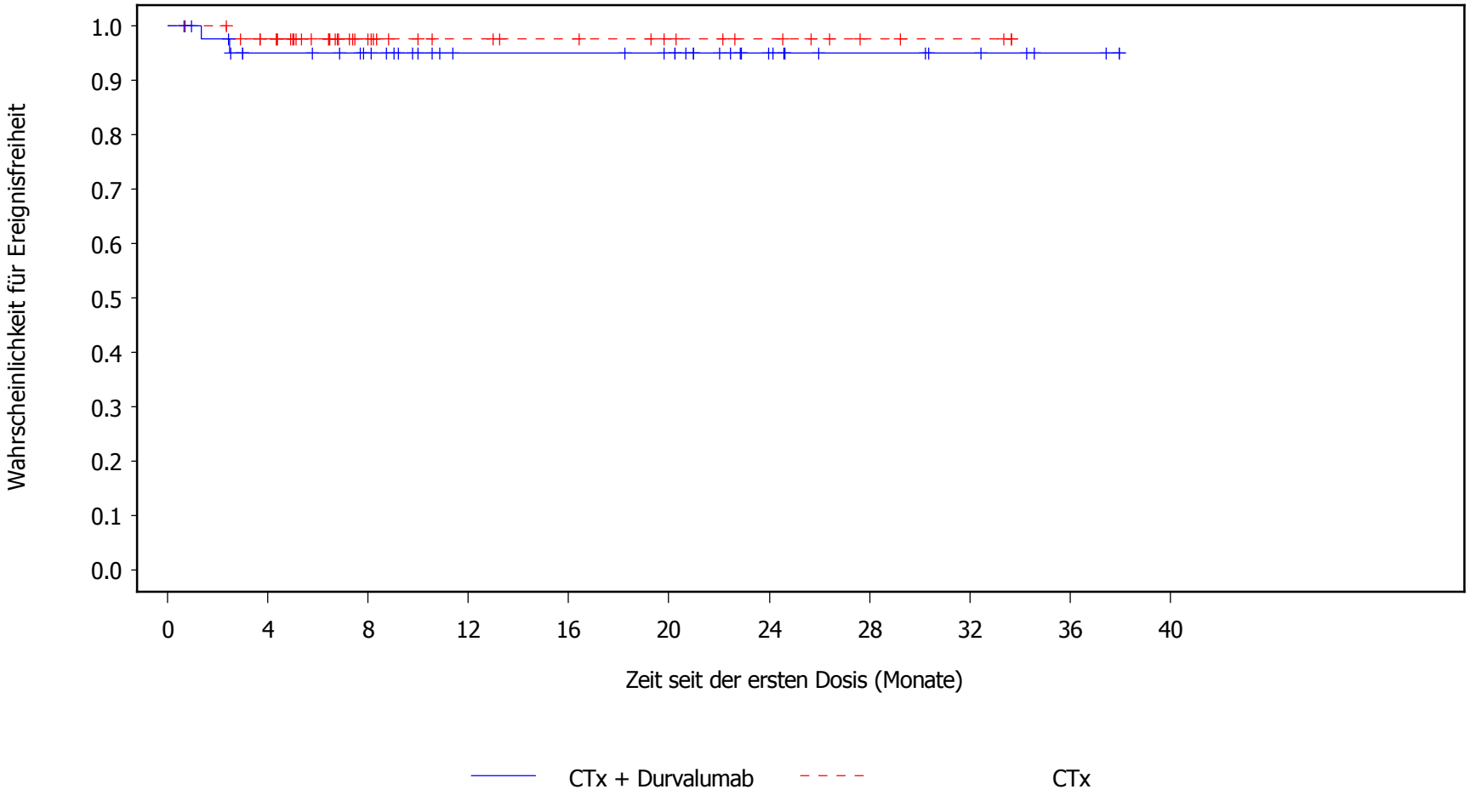
Figure 3.3.1.2D.104 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Dermatitis/Hautausschlag
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

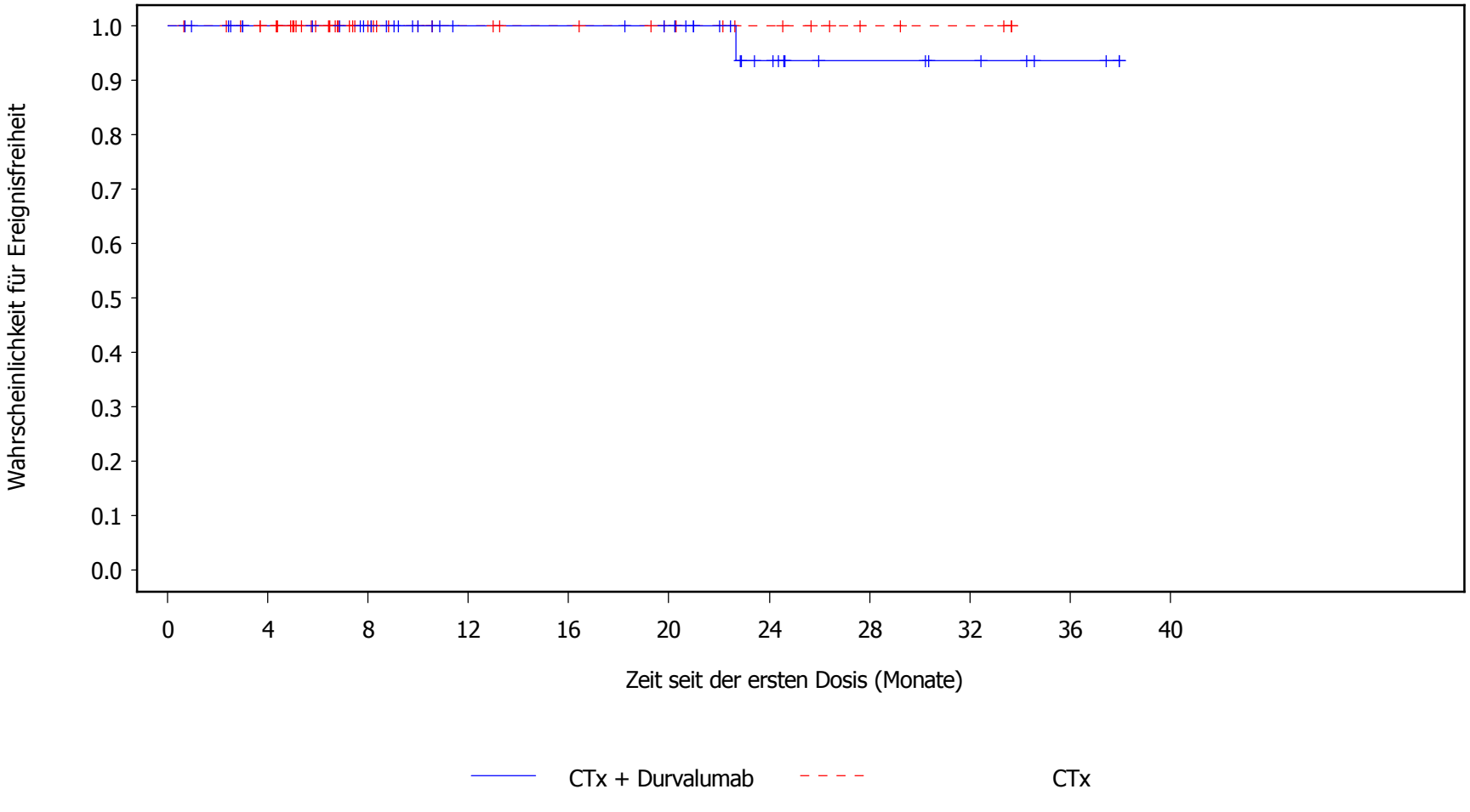
Figure 3.3.1.2D.105 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Diarrhö/Kolitis
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	36	32	23	23	21	11	7	5	2	0	CTx + Durvalumab
46	40	22	15	13	10	7	3	2	0	0	CTx

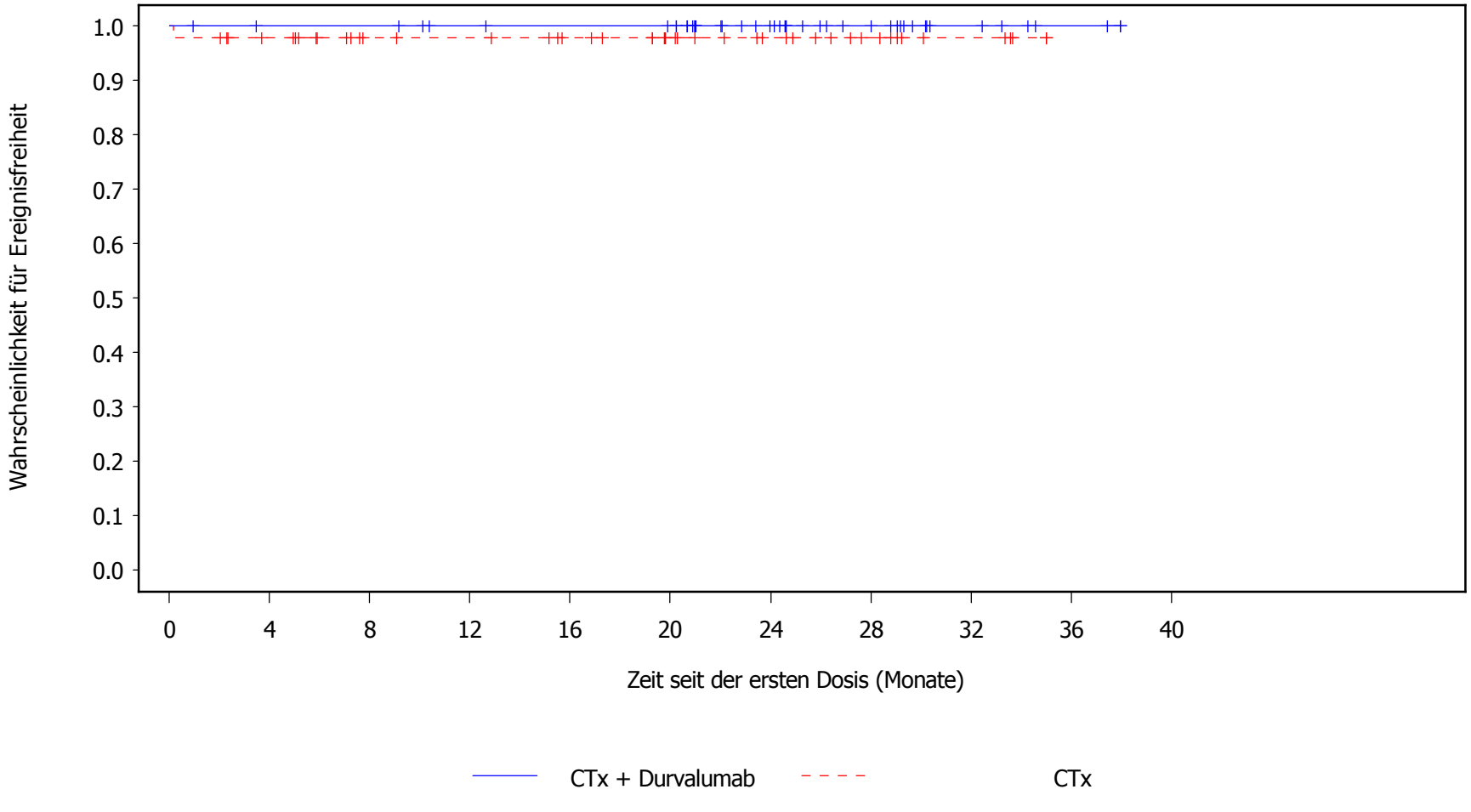
Figure 3.3.1.2D.106 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Hepatische Ereignisse
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

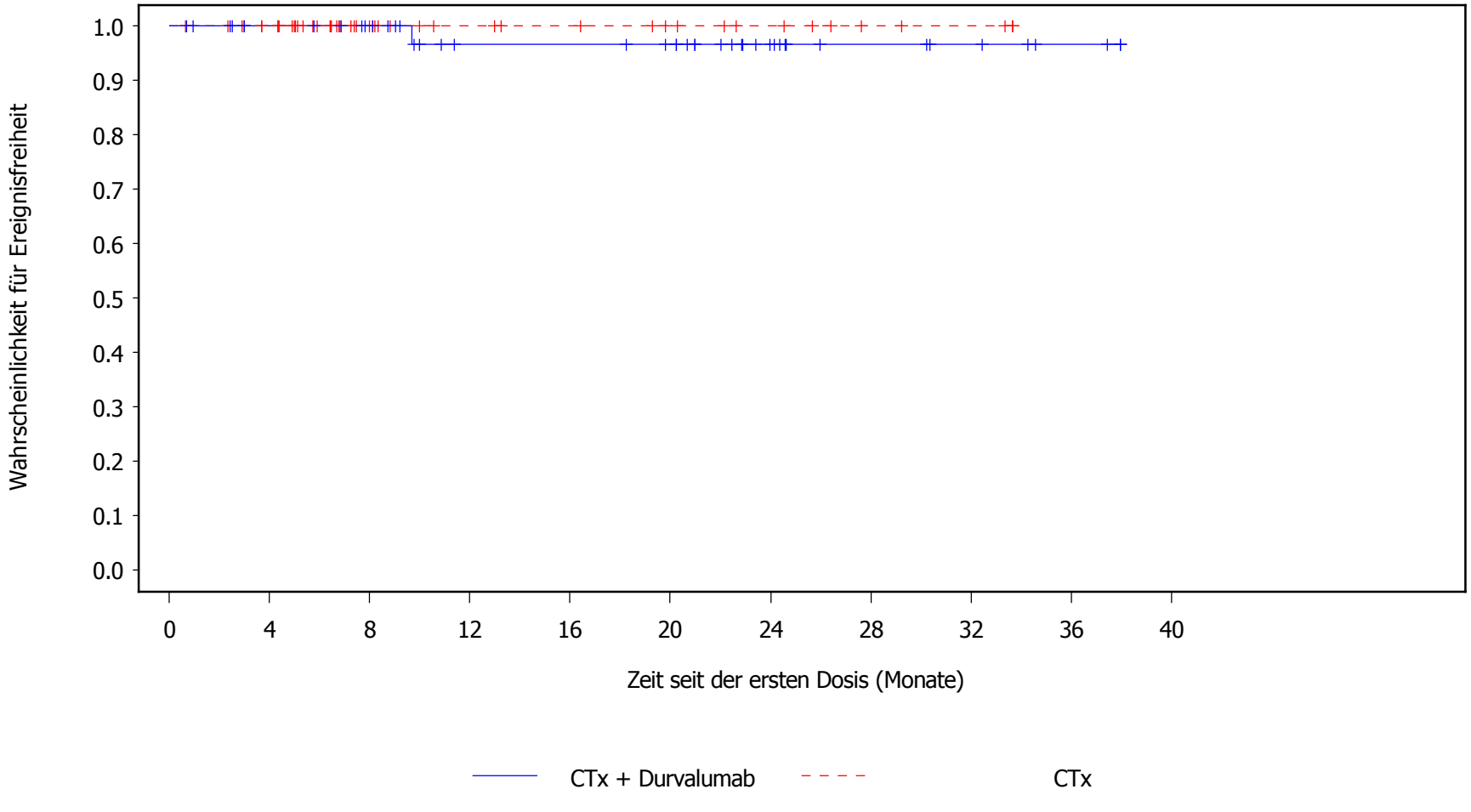
Figure 3.3.1.2D.107 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Neue primäre Malignität
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	42	42	39	38	37	24	15	6	2	0	CTx + Durvalumab
46	41	32	31	27	21	15	9	4	0	0	CTx

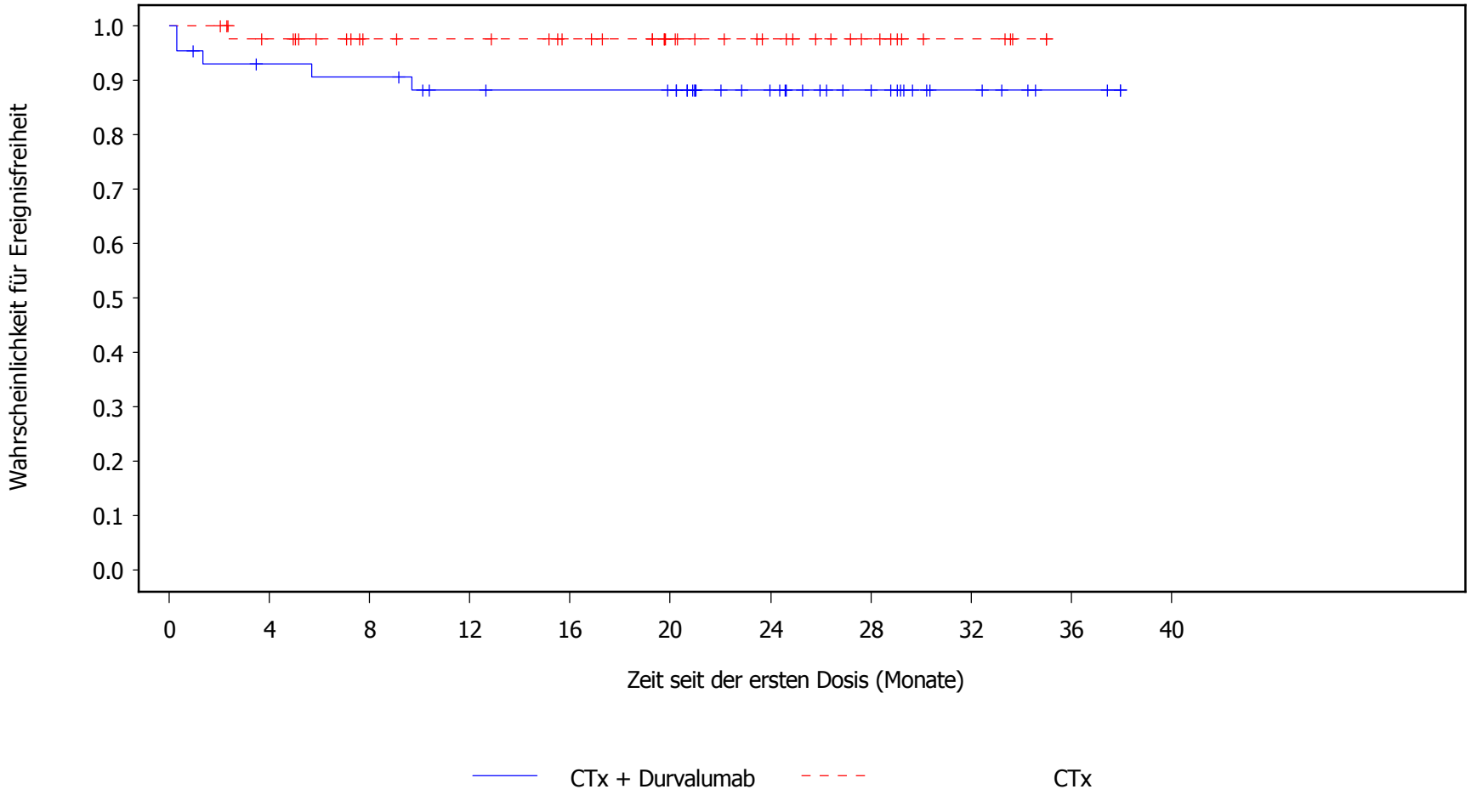
Figure 3.3.1.2D.108 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of UESI G>=3 GT: Pneumonitis
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

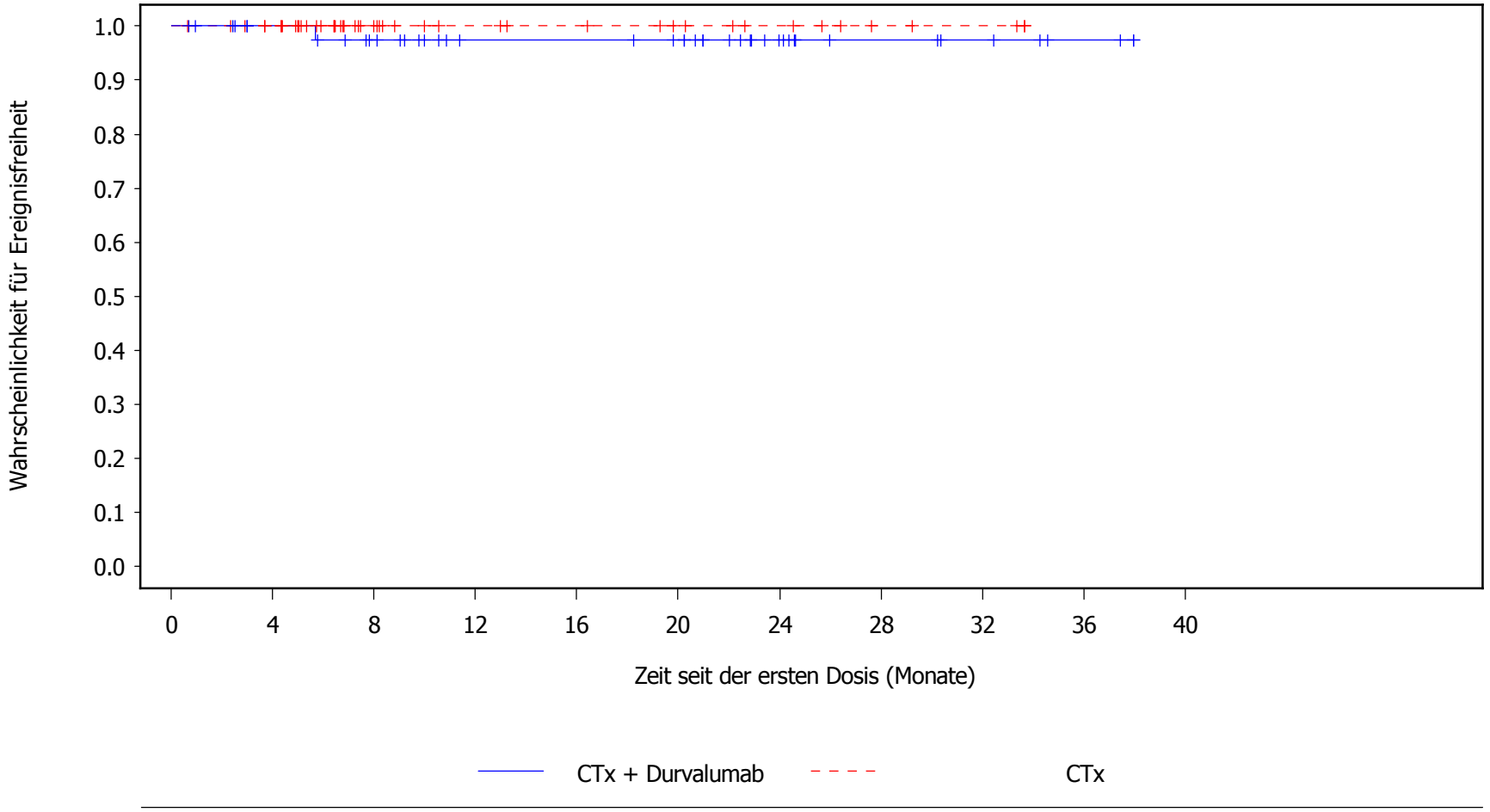
Figure 3.3.1.2D.109 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUESI
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	39	38	34	33	32	21	14	6	2	0	CTx + Durvalumab
46	41	33	32	28	21	15	9	4	0	0	CTx

Figure 3.3.1.2D.110 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUESI GT: Andere seltene/sonstige Ereignisse
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	33	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

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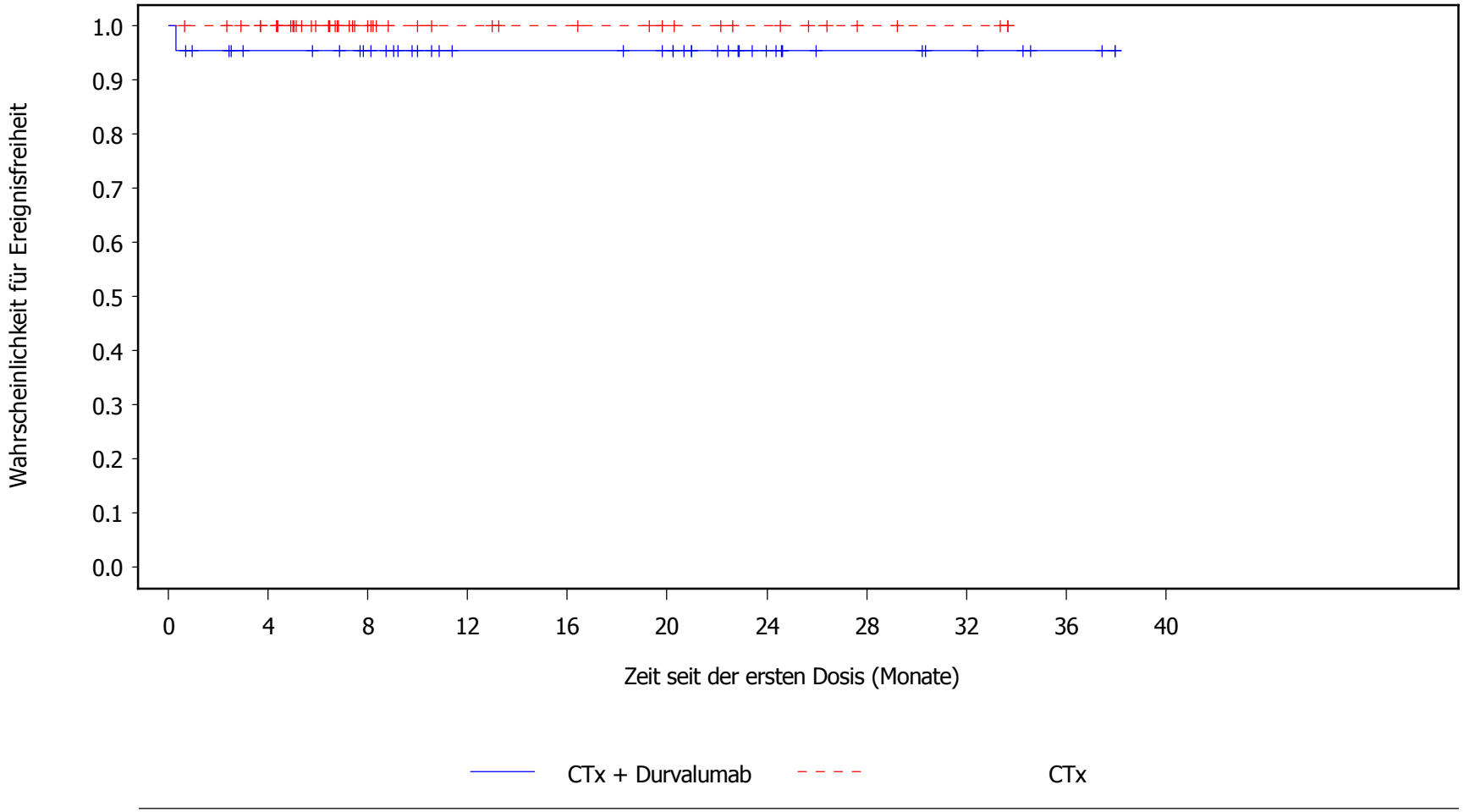
Figure 3.3.1.2D.111 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUESI GT: Dermatitis/Hautausschlag
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	37	33	24	24	22	11	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

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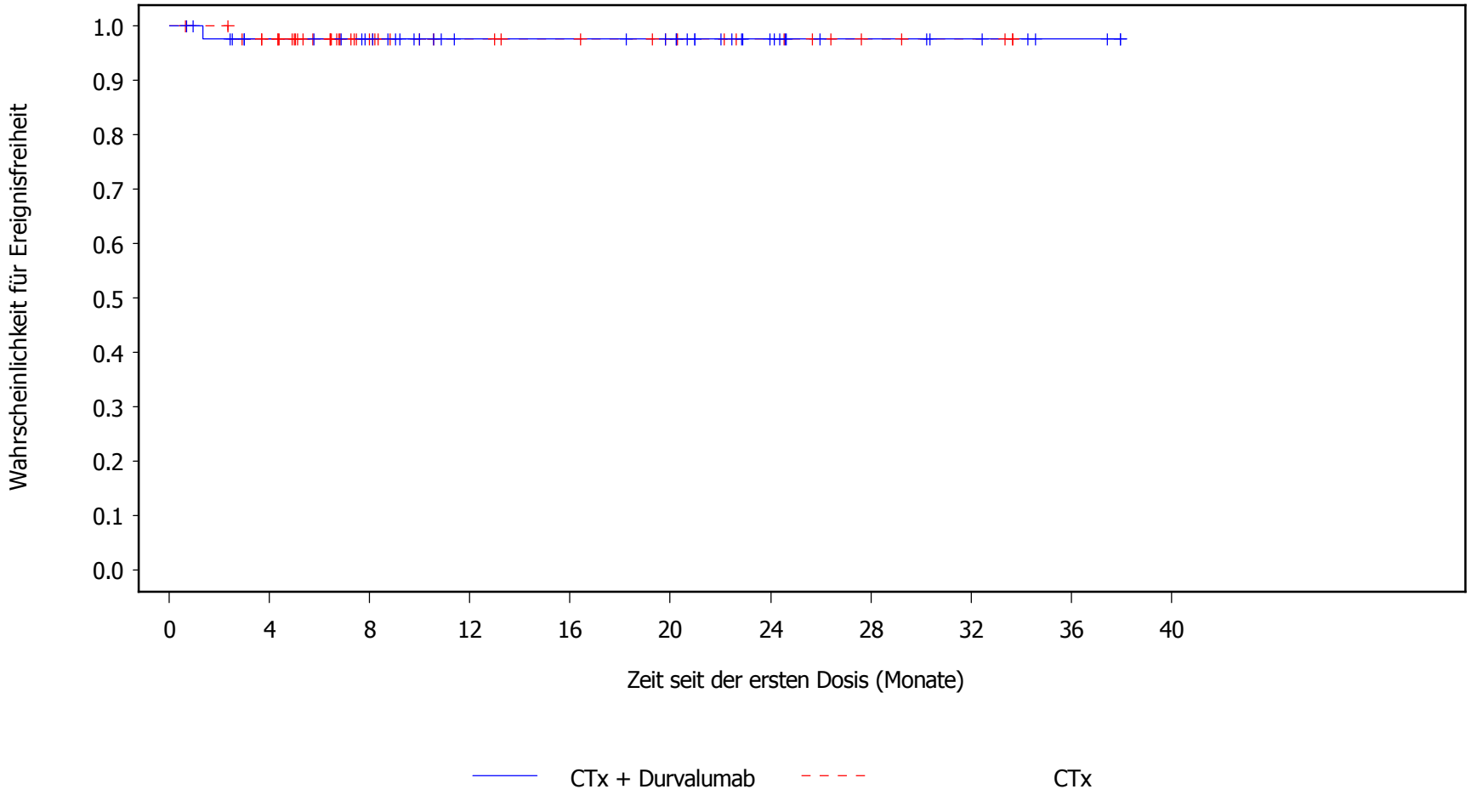
Figure 3.3.1.2D.112 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUESI GT: Diarrhö/Kolitis
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	37	33	24	24	22	12	7	5	2	0	CTx + Durvalumab
46	40	22	15	13	10	7	3	2	0	0	CTx

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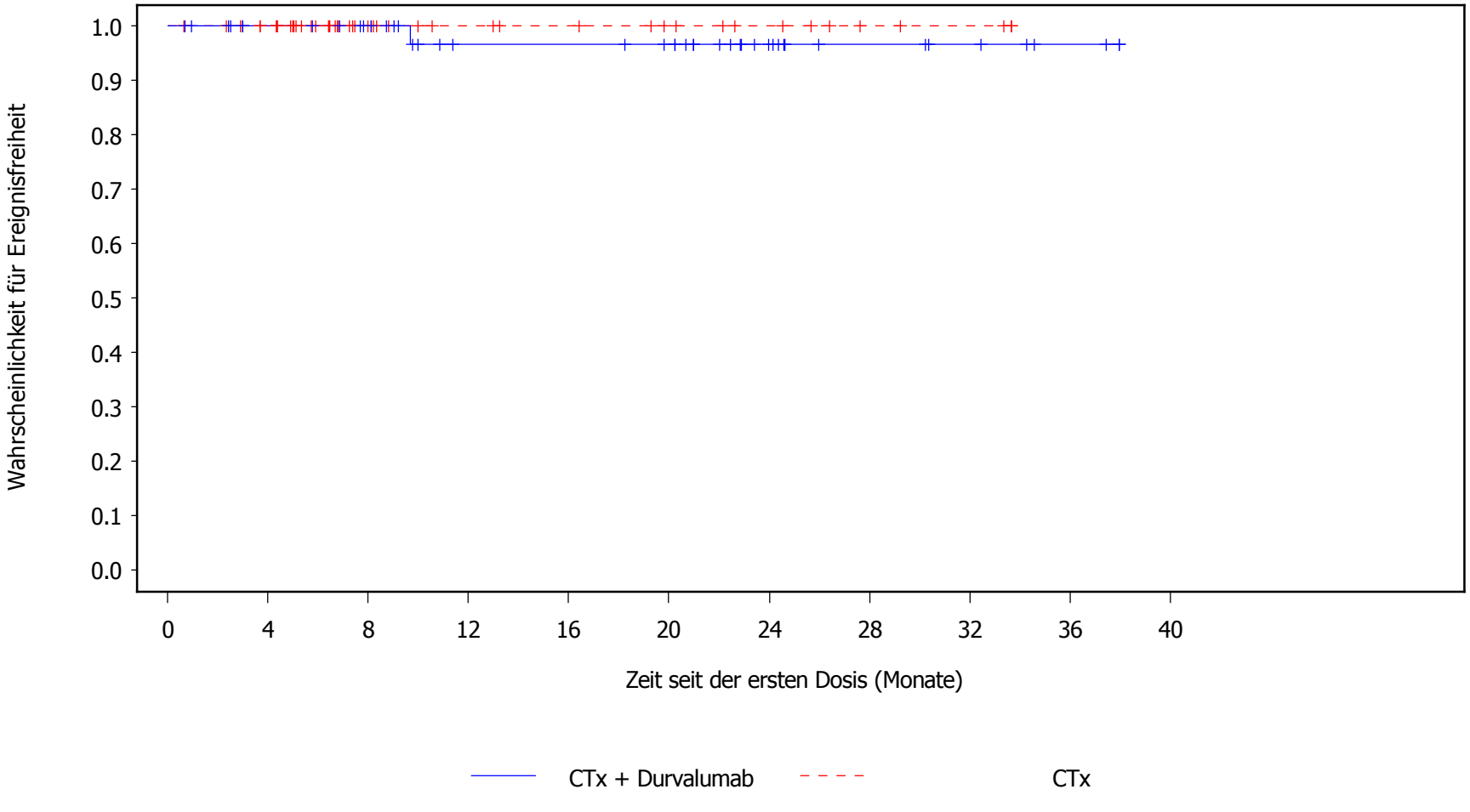
Figure 3.3.1.2D.113 DUO-E (dMMR Durva): Kaplan-Meier plot of time to first occurrence of SUESI GT: Pneumonitis
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

44	38	34	25	25	23	12	7	5	2	0	CTx + Durvalumab
46	41	22	15	13	10	7	3	2	0	0	CTx

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Table 4.1.1.1.1D DUO-E (dMMR Durva): Summary of subgroup analysis of overall survival (OS)
Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	3 (12,5)	NE [NE; NE]	25	11 (44,0)	23,7 [15,5; NE]	0,25	[0,06; 0,80]	0,0185*
Neu diagnostiziert	22	4 (18,2)	NE [NE; NE]	24	7 (29,2)	NE [NE; NE]	0,48	[0,13; 1,59]	0,2314
Interaktion p-Wert									0,4717
Region									
Asien	14	0	NE [NE; NE]	14	3 (21,4)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	32	7 (21,9)	NE [NE; NE]	35	15 (42,9)	21,0 [9,1; NE]	0,43	[0,16; 1,02]	0,0550
Interaktion p-Wert									NC
Alter									
<65	25	4 (16,0)	NE [NE; NE]	25	7 (28,0)	NE [NE; NE]	0,49	[0,13; 1,61]	0,2388
>=65	21	3 (14,3)	NE [NE; NE]	24	11 (45,8)	23,7 [7,6; NE]	0,25	[0,06; 0,80]	0,0178*
Interaktion p-Wert									0,4563
Abstammung									
Weiß	29	7 (24,1)	NE [NE; NE]	30	12 (40,0)	NE [NE; NE]	0,53	[0,20; 1,31]	0,1689
Schwarz/Afroamerikanisch	0	0	NE	2	2 (100)	10,1 [9,1; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	3 (20,0)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	12	3 (25,0)	NE [NE; NE]	15	3 (20,0)	NE [NE; NE]	1,57	[0,29; 8,58]	0,5831
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	21	10 (47,6)	20,3 [7,6; NE]	0,08	[0,00; 0,42]	0,0012*
Unbekannt	17	3 (17,6)	NE [NE; NE]	13	5 (38,5)	NE [NE; NE]	0,32	[0,06; 1,31]	0,1128
Interaktion p-Wert									0,0530
PD-L1 Expression									
Positiv	37	5 (13,5)	NE [NE; NE]	39	16 (41,0)	23,7 [15,5; NE]	0,26	[0,08; 0,66]	0,0039*
Negativ	8	2 (25,0)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	2,26	[0,22; 48,69]	0,4911

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. * 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 4.1.1.1.1D DUO-E (dMMR Durva): Summary of subgroup analysis of overall survival (OS)
Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0910
Histologie									
Endometrioid	33	4 (12,1)	NE [NE; NE]	41	15 (36,6)	23,7 [16,9; NE]	0,28	[0,08; 0,78]	0,0136*
Serös	2	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Andere	11	3 (27,3)	NE [NE; NE]	6	2 (33,3)	NE [NE; NE]	0,64	[0,11; 4,85]	0,6287
Interaktion p-Wert									0,4449
Histologischer Grad									
High grade (G3)	14	2 (14,3)	NE [NE; NE]	12	5 (41,7)	20,3 [5,2; NE]	0,24	[0,03; 1,11]	0,0681
Low grade (G1+G2)	28	4 (14,3)	NE [NE; NE]	33	12 (36,4)	23,7 [16,9; NE]	0,35	[0,10; 1,01]	0,0513
Interaktion p-Wert									0,7016
ECOG Performance Status zu Baseline									
0	23	3 (13,0)	NE [NE; NE]	29	7 (24,1)	NE [NE; NE]	0,50	[0,11; 1,81]	0,3012
1	23	4 (17,4)	NE [NE; NE]	20	11 (55,0)	15,2 [7,1; NE]	0,19	[0,05; 0,57]	0,0024*
Interaktion p-Wert									0,2923
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	3	1 (33,3)	NE [NE; NE]	NC	[NC]	NC
IV	15	3 (20,0)	NE [NE; NE]	21	6 (28,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC

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. * 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 4.1.1.1.2D DUO-E (dMMR Durva): Summary of subgroup analysis of overall survival (OS)
Patients with dMMR tumour status, DCO 18OCT2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	4 (16,7)	NE [NE; NE]	25	11 (44,0)	NE [NE; NE]	0,31	[0,08; 0,90]	0,0300*
Neu diagnostiziert	22	5 (22,7)	NE [NE; NE]	24	8 (33,3)	NE [NE; NE]	0,53	[0,16; 1,59]	0,2587
Interaktion p-Wert									0,4973
Region									
Asien	14	2 (14,3)	NE [NE; NE]	14	3 (21,4)	NE [NE; NE]	0,53	[0,07; 3,19]	0,4784
Rest der Welt	32	7 (21,9)	NE [NE; NE]	35	16 (45,7)	NE [NE; NE]	0,38	[0,15; 0,89]	0,0260*
Interaktion p-Wert									0,7504
Alter									
<65	25	4 (16,0)	NE [NE; NE]	25	8 (32,0)	NE [NE; NE]	0,42	[0,11; 1,33]	0,1430
>=65	21	5 (23,8)	NE [NE; NE]	24	11 (45,8)	23,7 [7,6; NE]	0,39	[0,12; 1,06]	0,0664
Interaktion p-Wert									0,9208
Abstammung									
Weiß	29	7 (24,1)	NE [NE; NE]	30	13 (43,3)	NE [NE; NE]	0,46	[0,17; 1,12]	0,0858
Schwarz/Afroamerikanisch	0	0	NE	2	2 (100)	10,1 [9,1; NE]	NC	[NC]	NC
Asiatisch	14	2 (14,3)	NE [NE; NE]	15	3 (20,0)	NE [NE; NE]	0,57	[0,08; 3,45]	0,5353
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,8265
HRR Mutationsstatus									
HRRm	12	3 (25,0)	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	1,04	[0,20; 4,71]	0,9620
Nicht-HRRm	17	2 (11,8)	NE [NE; NE]	21	10 (47,6)	21,0 [7,6; NE]	0,16	[0,02; 0,61]	0,0056*
Unbekannt	17	4 (23,5)	NE [NE; NE]	13	5 (38,5)	NE [NE; NE]	0,44	[0,11; 1,67]	0,2215
Interaktion p-Wert									0,2109
PD-L1 Expression									
Positiv	37	5 (13,5)	NE [NE; NE]	39	16 (41,0)	NE [NE; NE]	0,25	[0,08; 0,63]	0,0028*
Negativ	8	4 (50,0)	26,9 [1,2; NE]	8	2 (25,0)	NE [NE; NE]	2,16	[0,42; 15,60]	0,3578

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. * 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 4.1.1.1.2D DUO-E (dMMR Durva): Summary of subgroup analysis of overall survival (OS)
Patients with dMMR tumour status, DCO 18OCT2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0248*
Histologie									
Endometrioid	33	6 (18,2)	NE [NE; NE]	41	16 (39,0)	NE [NE; NE]	0,37	[0,13; 0,91]	0,0295*
Serös	2	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Andere	11	3 (27,3)	NE [NE; NE]	6	2 (33,3)	NE [NE; NE]	0,64	[0,11; 4,85]	0,6304
Interaktion p-Wert									0,5983
Histologischer Grad									
High grade (G3)	14	2 (14,3)	NE [NE; NE]	12	6 (50,0)	20,3 [5,2; NE]	0,20	[0,03; 0,88]	0,0331*
Low grade (G1+G2)	28	6 (21,4)	NE [NE; NE]	33	12 (36,4)	NE [NE; NE]	0,48	[0,17; 1,24]	0,1307
Interaktion p-Wert									0,3558
ECOG Performance Status zu Baseline									
0	23	3 (13,0)	NE [NE; NE]	29	8 (27,6)	NE [NE; NE]	0,43	[0,09; 1,50]	0,1923
1	23	6 (26,1)	NE [NE; NE]	20	11 (55,0)	15,5 [7,1; NE]	0,28	[0,10; 0,76]	0,0117*
Interaktion p-Wert									0,6261
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	3	1 (33,3)	NE [NE; NE]	0,25	[0,01; 6,33]	0,3446
IV	15	4 (26,7)	NE [NE; NE]	21	7 (33,3)	NE [NE; NE]	0,67	[0,17; 2,21]	0,5111
Interaktion p-Wert									0,5307

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. * 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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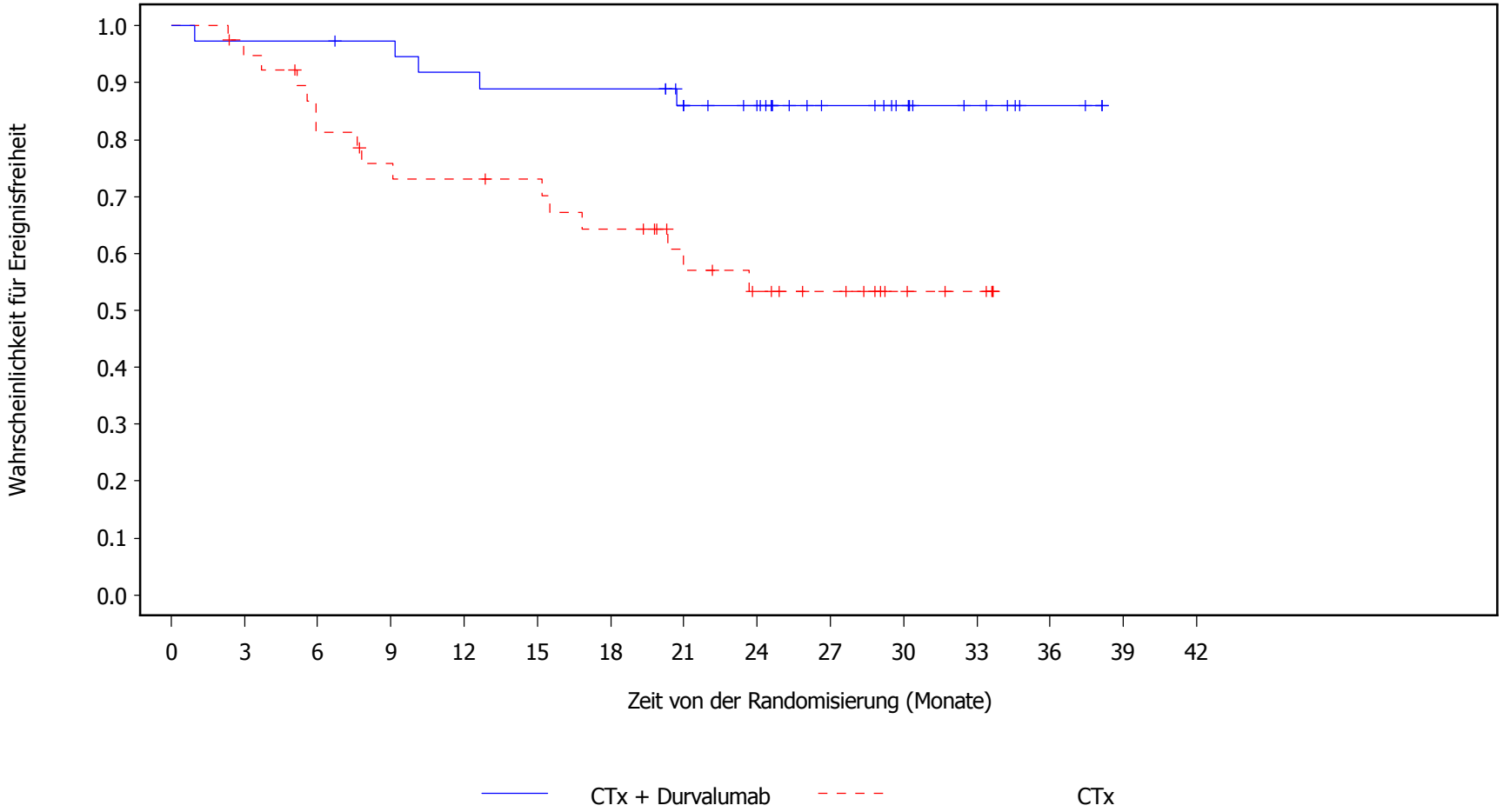
Figure 4.1.1.1.2D.1 DUO-E (dMMR Durva): Kaplan-Meier plot of Gesamtüberleben for PD-L1 Expression = Positiv
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

37	36	36	35	33	32	32	25	22	14	10	6	2	0	0	CTx + Durvalumab
39	36	30	27	26	25	22	16	13	10	5	3	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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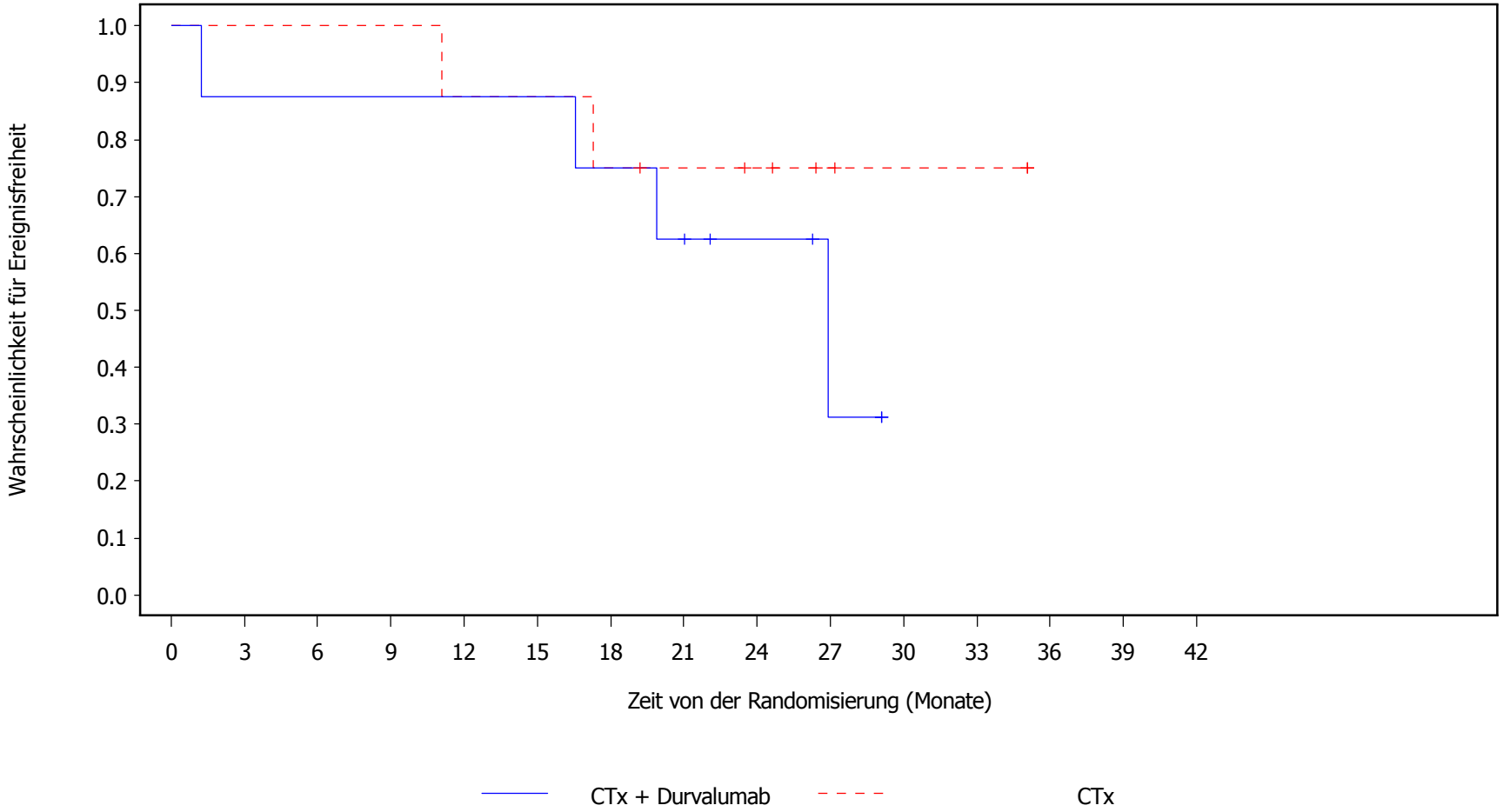
Figure 4.1.1.1.2D.2 DUO-E (dMMR Durva): Kaplan-Meier plot of Gesamtüberleben for PD-L1 Expression = Negativ
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

8	7	7	7	7	7	6	5	3	1	0	0	0	0	0	CTx + Durvalumab
8	8	8	8	7	7	6	5	4	2	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.
CTx = Carboplatin + Paclitaxel.

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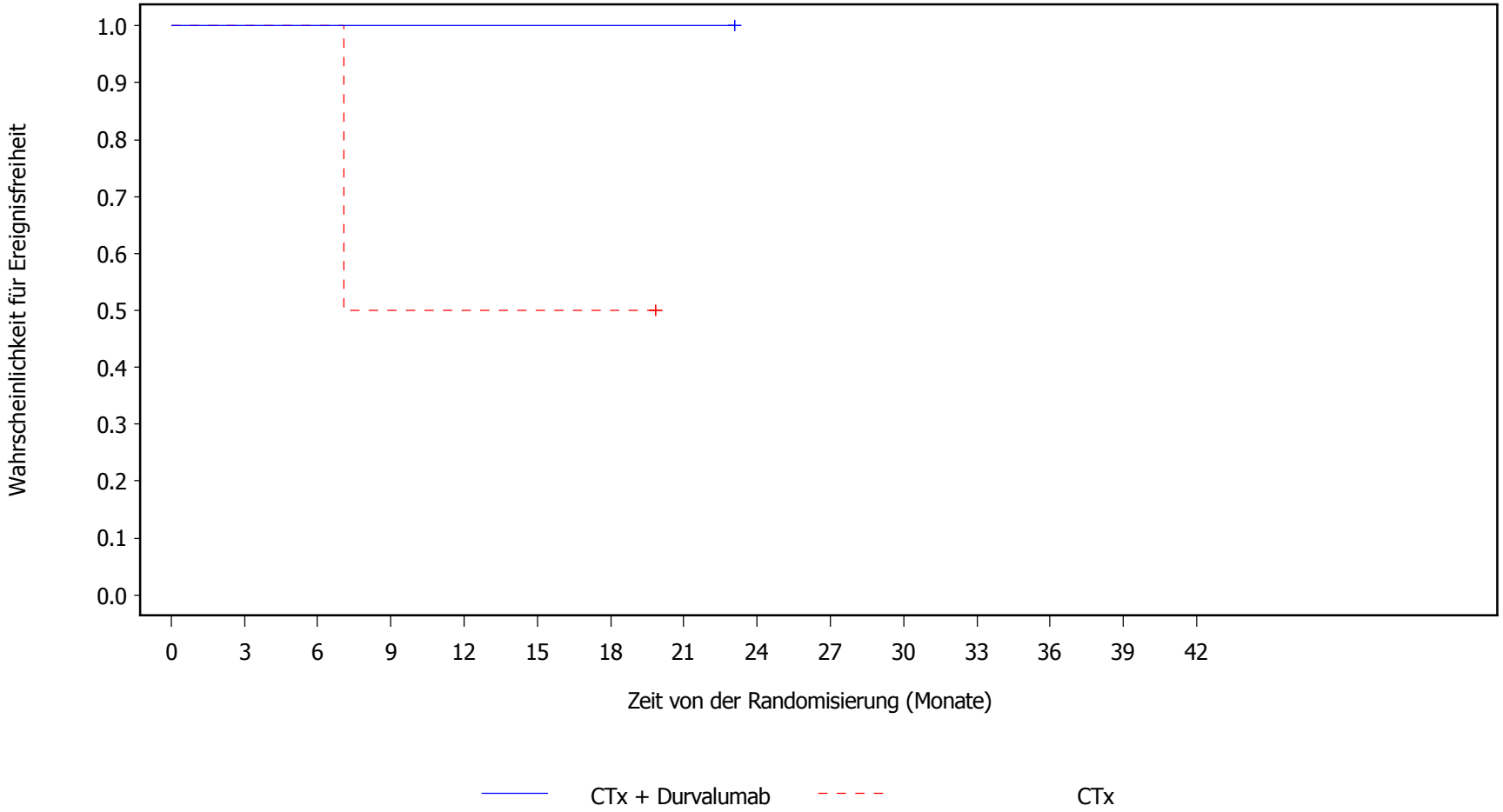
Figure 4.1.1.1.2D.3 DUO-E (dMMR Durva): Kaplan-Meier plot of Gesamtüberleben for PD-L1 Expression = Unbekannt
Patients with dMMR tumour status, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

1	1	1	1	1	1	1	1	0	0	0	0	0	0	0	CTx + Durvalumab
2	2	2	1	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.
CTx = Carboplatin + Paclitaxel.

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Table 4.1.2.1 DUO-E (dMMR Durva): Summary of subgroup analysis of progression-free survival (PFS)
Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	7 (29,2)	NE [NE; NE]	25	13 (52,0)	7,0 [4,7; NE]	0,41	[0,15; 0,996]	0,0490*
Neu diagnostiziert	22	8 (36,4)	26,0 [10,2; NE]	24	12 (50,0)	12,0 [6,3; NE]	0,44	[0,17; 1,07]	0,0716
Interaktion p-Wert									0,8974
Region									
Asien	14	5 (35,7)	18,4 [6,7; NE]	14	9 (64,3)	6,9 [6,7; NE]	0,45	[0,14; 1,31]	0,1455
Rest der Welt	32	10 (31,3)	NE [NE; NE]	35	16 (45,7)	12,0 [5,7; NE]	0,41	[0,18; 0,90]	0,0267*
Interaktion p-Wert									0,8993
Alter									
<65	25	7 (28,0)	NE [NE; NE]	25	13 (52,0)	7,2 [6,7; NE]	0,40	[0,15; 0,98]	0,0451*
>=65	21	8 (38,1)	26,0 [8,8; NE]	24	12 (50,0)	6,8 [4,2;14,8]	0,43	[0,17; 1,05]	0,0640
Interaktion p-Wert									0,9066
Abstammung									
Weiß	29	9 (31,0)	NE [NE; NE]	30	13 (43,3)	7,2 [5,7; NE]	0,43	[0,18; 1,01]	0,0531
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	4,2 [NE; NE]	NC	[NC]	NC
Asiatisch	14	5 (35,7)	18,4 [6,7; NE]	15	10 (66,7)	6,9 [6,7;14,8]	0,45	[0,14; 1,27]	0,1331
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,9597
HRR Mutationsstatus									
HRRm	12	4 (33,3)	NE [NE; NE]	15	8 (53,3)	13,5 [6,3; NE]	0,82	[0,22; 2,62]	0,7458
Nicht-HRRm	17	7 (41,2)	26,0 [7,5; NE]	21	11 (52,4)	6,8 [4,4; NE]	0,42	[0,15; 1,07]	0,0698
Unbekannt	17	4 (23,5)	NE [NE; NE]	13	6 (46,2)	6,8 [4,2; NE]	0,26	[0,07; 0,92]	0,0367*
Interaktion p-Wert									0,4430
PD-L1 Expression									
Positiv	37	12 (32,4)	NE [NE; NE]	39	20 (51,3)	7,0 [6,7; NE]	0,41	[0,19; 0,83]	0,0133*
Negativ	8	3 (37,5)	NE [NE; NE]	8	4 (50,0)	12,5 [5,7; NE]	0,56	[0,11; 2,54]	0,4444

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. * 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 4.1.2.1 DUO-E (dMMR Durva): Summary of subgroup analysis of progression-free survival (PFS)
Patients with dMMR tumour status, DCO 12ARP2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7135
Histologie									
Endometrioid	33	10 (30,3)	26,0 [10,2; NE]	41	21 (51,2)	7,2 [6,7; NE]	0,41	[0,18; 0,85]	0,0165*
Serös	2	1 (50,0)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	4 (36,4)	NE [NE; NE]	6	4 (66,7)	6,7 [1,7; NE]	0,40	[0,09; 1,70]	0,2051
Interaktion p-Wert									0,9783
Histologischer Grad									
High grade (G3)	14	3 (21,4)	NE [NE; NE]	12	8 (66,7)	6,3 [3,7;14,8]	0,15	[0,03; 0,54]	0,0032*
Low grade (G1+G2)	28	10 (35,7)	26,0 [9,7; NE]	33	16 (48,5)	12,0 [6,8; NE]	0,53	[0,23; 1,16]	0,1147
Interaktion p-Wert									0,1030
ECOG Performance Status zu Baseline									
0	23	5 (21,7)	NE [NE; NE]	29	16 (55,2)	12,0 [6,7; NE]	0,31	[0,10; 0,79]	0,0135*
1	23	10 (43,5)	26,0 [8,8; NE]	20	9 (45,0)	6,7 [4,2; NE]	0,42	[0,17; 1,06]	0,0663
Interaktion p-Wert									0,6630
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	3	2 (66,7)	8,2 [4,4; NE]	0,08	[0,00; 0,87]	0,0385*
IV	15	7 (46,7)	26,0 [7,1; NE]	21	10 (47,6)	12,5 [6,3; NE]	0,61	[0,22; 1,62]	0,3248
Interaktion p-Wert									0,1175

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. * 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 4.2.1.1.1 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Allgemeine Lebensqualität/Gesundheitsszustand
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	9 (37,5)	2,7 [1,4; NE]	25	14 (56,0)	2,2 [1,3;10,5]	0,75	[0,31; 1,71]	0,4997
Neu diagnostiziert	22	15 (68,2)	1,2 [0,7; 4,3]	24	14 (58,3)	0,8 [0,7; 7,8]	0,79	[0,37; 1,66]	0,5242
Interaktion p-Wert									0,9355
Region									
Asien	14	9 (64,3)	1,1 [0,6; NE]	14	10 (71,4)	2,0 [0,7; NE]	1,28	[0,51; 3,20]	0,5891
Rest der Welt	32	15 (46,9)	2,8 [0,9; NE]	35	18 (51,4)	2,2 [0,8; 3,5]	0,66	[0,32; 1,31]	0,2311
Interaktion p-Wert									0,2499
Alter									
<65	25	12 (48,0)	2,5 [0,7; NE]	25	14 (56,0)	2,2 [0,7; 7,8]	0,78	[0,35; 1,69]	0,5233
>=65	21	12 (57,1)	2,1 [0,7; 4,3]	24	14 (58,3)	2,0 [0,7; 3,5]	0,88	[0,40; 1,90]	0,7351
Interaktion p-Wert									0,8312
Abstammung									
Weiß	29	13 (44,8)	3,4 [0,9; NE]	30	17 (56,7)	2,2 [0,8; 3,5]	0,65	[0,31; 1,35]	0,2515
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	0,6 [NE; NE]	NC	[NC]	NC
Asiatisch	14	9 (64,3)	1,1 [0,6; NE]	15	10 (66,7)	2,0 [0,7; NE]	1,29	[0,51; 3,20]	0,5864
Andere	2	2 (100)	1,4 [0,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,2555
HRR Mutationsstatus									
HRRm	12	6 (50,0)	2,7 [0,7; NE]	15	8 (53,3)	2,0 [0,6;10,5]	0,66	[0,22; 1,91]	0,4474
Nicht-HRRm	17	11 (64,7)	2,7 [0,6;11,4]	21	13 (61,9)	2,2 [1,3; 9,7]	0,95	[0,42; 2,13]	0,8991
Unbekannt	17	7 (41,2)	1,1 [0,6; NE]	13	7 (53,8)	2,0 [0,6; NE]	0,78	[0,26; 2,28]	0,6400
Interaktion p-Wert									0,8662
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 4.2.1.1.1 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Allgemeine Lebensqualität/Gesundheitsszustand
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	20 (54,1)	2,2 [0,8;11,4]	39	23 (59,0)	2,0 [0,8; 3,5]	0,86	[0,46; 1,57]	0,6165
Negativ	8	4 (50,0)	2,4 [0,6; NE]	8	4 (50,0)	1,3 [0,7; NE]	0,87	[0,21; 3,71]	0,8478
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	2,2 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9816
Histologie									
Endometrioid	33	17 (51,5)	2,7 [0,8;11,4]	41	24 (58,5)	2,2 [1,3; 3,5]	0,90	[0,47; 1,66]	0,7343
Serös	2	1 (50,0)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	6 (54,5)	2,2 [0,6; NE]	6	4 (66,7)	1,3 [0,7; NE]	0,34	[0,10; 1,37]	0,1220
Interaktion p-Wert									0,1993
Histologischer Grad									
High grade (G3)	14	8 (57,1)	0,9 [0,6; NE]	12	6 (50,0)	1,4 [0,6; 2,0]	0,66	[0,22; 2,06]	0,4639
Low grade (G1+G2)	28	14 (50,0)	2,7 [0,8; NE]	33	19 (57,6)	2,2 [0,8; 7,8]	0,86	[0,42; 1,70]	0,6609
Interaktion p-Wert									0,6978
ECOG Performance Status zu Baseline									
0	23	10 (43,5)	1,4 [0,7; NE]	29	20 (69,0)	1,5 [0,7; 2,3]	0,74	[0,33; 1,55]	0,4287
1	23	14 (60,9)	2,7 [0,9;11,4]	20	8 (40,0)	2,2 [0,7; NE]	1,06	[0,45; 2,66]	0,8946
Interaktion p-Wert									0,5347
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	5 (71,4)	0,7 [0,6; NE]	3	2 (66,7)	5,6 [1,4; NE]	1,27	[0,27; 8,91]	0,7696
IV	15	10 (66,7)	1,8 [0,7; 4,3]	21	12 (57,1)	0,8 [0,7; 3,4]	0,74	[0,31; 1,73]	0,4847
Interaktion p-Wert									0,5567

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 4.2.1.1.2 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Körper
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	9 (37,5)	3,8 [2,0; NE]	25	15 (60,0)	1,5 [1,3;11,4]	0,60	[0,25; 1,36]	0,2272
Neu diagnostiziert	22	12 (54,5)	5,0 [1,3; NE]	24	15 (62,5)	1,4 [0,7; 8,7]	0,46	[0,21; 0,99]	0,0466*
Interaktion p-Wert									0,6347
Region									
Asien	14	6 (42,9)	9,7 [0,7; NE]	14	10 (71,4)	6,4 [1,3;13,3]	0,73	[0,25; 1,96]	0,5339
Rest der Welt	32	15 (46,9)	3,8 [2,1; NE]	35	20 (57,1)	1,4 [0,8; 2,2]	0,41	[0,20; 0,81]	0,0102*
Interaktion p-Wert									0,3632
Alter									
<65	25	12 (48,0)	3,8 [2,1; NE]	25	16 (64,0)	2,2 [0,9;11,4]	0,62	[0,29; 1,32]	0,2166
>=65	21	9 (42,9)	5,6 [0,8; NE]	24	14 (58,3)	1,5 [0,8; 6,0]	0,43	[0,17; 0,98]	0,0460*
Interaktion p-Wert									0,5062
Abstammung									
Weiß	29	13 (44,8)	3,8 [2,0; NE]	30	19 (63,3)	1,4 [0,8; 2,2]	0,40	[0,19; 0,82]	0,0118*
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	6,0 [NE; NE]	NC	[NC]	NC
Asiatisch	14	6 (42,9)	9,7 [0,7; NE]	15	10 (66,7)	6,4 [1,3;13,3]	0,74	[0,25; 1,99]	0,5527
Andere	2	2 (100)	3,9 [2,9; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,3382
HRR Mutationsstatus									
HRRm	12	5 (41,7)	2,1 [0,7; NE]	15	9 (60,0)	1,3 [0,7; 1,5]	0,21	[0,06; 0,64]	0,0059*
Nicht-HRRm	17	8 (47,1)	18,9 [1,3; NE]	21	15 (71,4)	2,2 [0,9; 4,2]	0,39	[0,16; 0,91]	0,0287*
Unbekannt	17	8 (47,1)	3,7 [0,7; NE]	13	6 (46,2)	8,7 [0,7; NE]	1,25	[0,43; 3,80]	0,6832
Interaktion p-Wert									0,0675
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 4.2.1.1.2 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Körper
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	16 (43,2)	6,1 [2,1; NE]	39	25 (64,1)	1,5 [0,9; 4,2]	0,49	[0,26; 0,92]	0,0273*
Negativ	8	4 (50,0)	2,8 [0,7; NE]	8	4 (50,0)	1,4 [0,6; NE]	0,77	[0,18; 3,26]	0,7097
Unbekannt	1	1 (100)	3,8 [NE; NE]	2	1 (50,0)	2,2 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5727
Histologie									
Endometrioid	33	15 (45,5)	3,8 [2,1; NE]	41	27 (65,9)	1,5 [0,9; 4,2]	0,58	[0,30; 1,07]	0,0812
Serös	2	2 (100)	14,3 [9,7; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	4 (36,4)	NE [NE; NE]	6	3 (50,0)	2,1 [0,7; NE]	0,38	[0,08; 1,97]	0,2312
Interaktion p-Wert									0,6305
Histologischer Grad									
High grade (G3)	14	6 (42,9)	2,9 [0,7; NE]	12	6 (50,0)	2,1 [0,8; NE]	0,56	[0,17; 1,82]	0,3243
Low grade (G1+G2)	28	14 (50,0)	3,8 [2,1; NE]	33	22 (66,7)	1,4 [0,8; 2,9]	0,48	[0,24; 0,94]	0,0314*
Interaktion p-Wert									0,8249
ECOG Performance Status zu Baseline									
0	23	9 (39,1)	9,7 [2,1; NE]	29	21 (72,4)	1,5 [0,8; 4,2]	0,39	[0,17; 0,84]	0,0158*
1	23	12 (52,2)	3,8 [0,9; NE]	20	9 (45,0)	1,8 [0,8; NE]	0,83	[0,35; 2,03]	0,6699
Interaktion p-Wert									0,2080
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	5 (71,4)	3,5 [1,3; NE]	3	2 (66,7)	6,9 [4,2; NE]	1,05	[0,22; 7,41]	0,9500
IV	15	7 (46,7)	9,7 [0,8; NE]	21	13 (61,9)	1,3 [0,7; 2,8]	0,36	[0,13; 0,90]	0,0284*
Interaktion p-Wert									0,2553

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 4.2.1.1.3 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Rolle
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	13 (54,2)	2,1 [1,0; 2,8]	25	17 (68,0)	2,0 [0,8; 2,9]	0,94	[0,45; 1,93]	0,8666
Neu diagnostiziert	22	16 (72,7)	1,8 [1,3; 3,5]	24	12 (50,0)	0,8 [0,7; NE]	0,81	[0,38; 1,76]	0,5897
Interaktion p-Wert									0,7847
Region									
Asien	14	11 (78,6)	1,8 [0,7; 3,5]	14	10 (71,4)	1,1 [0,7; NE]	1,13	[0,47; 2,72]	0,7831
Rest der Welt	32	18 (56,3)	2,1 [1,4; 3,5]	35	19 (54,3)	2,0 [0,8; 2,2]	0,77	[0,40; 1,48]	0,4300
Interaktion p-Wert									0,4878
Alter									
<65	25	16 (64,0)	2,7 [1,4; 3,5]	25	13 (52,0)	2,2 [0,7; NE]	1,06	[0,51; 2,24]	0,8823
>=65	21	13 (61,9)	1,5 [0,7; 2,1]	24	16 (66,7)	1,5 [0,7; 2,2]	0,74	[0,35; 1,55]	0,4289
Interaktion p-Wert									0,5069
Abstammung									
Weiß	29	16 (55,2)	2,1 [1,3; 3,5]	30	18 (60,0)	2,2 [0,8; 2,8]	0,81	[0,41; 1,59]	0,5409
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	0,6 [NE; NE]	NC	[NC]	NC
Asiatisch	14	11 (78,6)	1,8 [0,7; 3,5]	15	10 (66,7)	1,1 [0,7; NE]	1,12	[0,47; 2,70]	0,7915
Andere	2	2 (100)	1,8 [1,4; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,5589
HRR Mutationsstatus									
HRRm	12	5 (41,7)	2,8 [0,7; NE]	15	9 (60,0)	0,8 [0,6; 2,8]	0,32	[0,10; 0,92]	0,0341*
Nicht-HRRm	17	14 (82,4)	2,0 [0,9; 2,2]	21	14 (66,7)	2,0 [0,7; 2,2]	1,17	[0,55; 2,48]	0,6746
Unbekannt	17	10 (58,8)	2,4 [0,7; 6,0]	13	6 (46,2)	5,1 [0,6; NE]	1,39	[0,52; 4,10]	0,5157
Interaktion p-Wert									0,0858
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 4.2.1.1.3 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Rolle
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	22 (59,5)	2,2 [1,4; 3,5]	39	24 (61,5)	1,5 [0,7; 2,8]	0,81	[0,45; 1,45]	0,4756
Negativ	8	6 (75,0)	1,8 [0,7; NE]	8	4 (50,0)	0,8 [0,7; NE]	1,10	[0,31; 4,35]	0,8817
Unbekannt	1	1 (100)	1,0 [NE; NE]	2	1 (50,0)	2,2 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6657
Histologie									
Endometrioid	33	21 (63,6)	2,0 [1,4; 2,7]	41	26 (63,4)	1,5 [0,7; 2,2]	0,98	[0,54; 1,74]	0,9365
Serös	2	2 (100)	3,8 [3,5; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	6 (54,5)	2,7 [0,6; NE]	6	3 (50,0)	2,9 [0,7; NE]	0,60	[0,16; 2,86]	0,4890
Interaktion p-Wert									0,5386
Histologischer Grad									
High grade (G3)	14	9 (64,3)	1,3 [0,7; 2,2]	12	6 (50,0)	1,3 [0,6; NE]	1,19	[0,43; 3,56]	0,7433
Low grade (G1+G2)	28	18 (64,3)	2,1 [1,5; 2,8]	33	22 (66,7)	1,5 [0,7; 2,2]	0,71	[0,37; 1,32]	0,2751
Interaktion p-Wert									0,3979
ECOG Performance Status zu Baseline									
0	23	12 (52,2)	2,7 [1,3; 3,5]	29	20 (69,0)	1,4 [0,7; 2,8]	0,67	[0,32; 1,35]	0,2626
1	23	17 (73,9)	2,1 [1,0; 2,7]	20	9 (45,0)	2,2 [0,7; NE]	1,29	[0,59; 3,03]	0,5375
Interaktion p-Wert									0,2288
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	7 (100)	1,4 [0,7; 2,1]	3	1 (33,3)	NE [NE; NE]	2,41	[0,42; 45,36]	0,3636
IV	15	9 (60,0)	2,7 [0,9; NE]	21	11 (52,4)	0,8 [0,7; 2,8]	0,57	[0,23; 1,39]	0,2145
Interaktion p-Wert									0,1678

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 4.2.1.1.4 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Emotionalität
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	6 (25,0)	NE [NE; NE]	25	11 (44,0)	3,5 [2,0; NE]	0,56	[0,19; 1,49]	0,2506
Neu diagnostiziert	22	12 (54,5)	5,9 [2,1; NE]	24	9 (37,5)	4,2 [1,3; NE]	0,92	[0,39; 2,26]	0,8483
Interaktion p-Wert									0,4635
Region									
Asien	14	5 (35,7)	NE [NE; NE]	14	6 (42,9)	NE [NE; NE]	0,83	[0,24; 2,74]	0,7513
Rest der Welt	32	13 (40,6)	8,7 [2,1; NE]	35	14 (40,0)	3,5 [2,0; 6,0]	0,71	[0,32; 1,53]	0,3739
Interaktion p-Wert									0,8289
Alter									
<65	25	10 (40,0)	17,0 [1,3; NE]	25	10 (40,0)	4,2 [1,4; NE]	0,97	[0,40; 2,37]	0,9453
>=65	21	8 (38,1)	8,7 [4,3; NE]	24	10 (41,7)	3,5 [1,5; NE]	0,58	[0,22; 1,48]	0,2500
Interaktion p-Wert									0,4275
Abstammung									
Weiß	29	11 (37,9)	8,7 [2,1; NE]	30	13 (43,3)	3,5 [1,5; NE]	0,67	[0,29; 1,51]	0,3303
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	6,0 [NE; NE]	NC	[NC]	NC
Asiatisch	14	5 (35,7)	NE [NE; NE]	15	6 (40,0)	NE [NE; NE]	0,83	[0,24; 2,76]	0,7564
Andere	2	2 (100)	3,3 [0,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,7680
HRR Mutationsstatus									
HRRm	12	5 (41,7)	3,4 [0,7; NE]	15	8 (53,3)	1,4 [0,7; 5,2]	0,50	[0,15; 1,52]	0,2211
Nicht-HRRm	17	7 (41,2)	8,7 [4,3; NE]	21	9 (42,9)	3,5 [2,0; NE]	0,61	[0,22; 1,66]	0,3314
Unbekannt	17	6 (35,3)	5,9 [0,7; NE]	13	3 (23,1)	NE [NE; NE]	1,87	[0,49; 8,86]	0,3649
Interaktion p-Wert									0,2930
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 4.2.1.1.4 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Emotionalität
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	14 (37,8)	17,0 [3,4; NE]	39	17 (43,6)	3,5 [2,0; NE]	0,67	[0,32; 1,38]	0,2754
Negativ	8	4 (50,0)	5,9 [0,7; NE]	8	2 (25,0)	NE [NE; NE]	2,14	[0,42; 15,44]	0,3669
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2065
Histologie									
Endometrioid	33	12 (36,4)	8,7 [3,4; NE]	41	17 (41,5)	4,2 [2,1; NE]	0,75	[0,35; 1,56]	0,4436
Serös	2	2 (100)	10,6 [4,2; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	4 (36,4)	NE [NE; NE]	6	3 (50,0)	1,4 [0,7; NE]	0,39	[0,08; 2,00]	0,2382
Interaktion p-Wert									0,4495
Histologischer Grad									
High grade (G3)	14	7 (50,0)	3,4 [0,7; NE]	12	4 (33,3)	3,4 [0,7; NE]	1,03	[0,30; 3,98]	0,9657
Low grade (G1+G2)	28	10 (35,7)	17,0 [4,3; NE]	33	15 (45,5)	4,2 [2,0; NE]	0,55	[0,24; 1,23]	0,1477
Interaktion p-Wert									0,4053
ECOG Performance Status zu Baseline									
0	23	9 (39,1)	8,7 [0,7; NE]	29	16 (55,2)	3,4 [1,4; 6,0]	0,68	[0,28; 1,53]	0,3553
1	23	9 (39,1)	8,7 [3,4; NE]	20	4 (20,0)	NE [NE; NE]	1,32	[0,43; 4,89]	0,6366
Interaktion p-Wert									0,3555
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	5 (71,4)	5,9 [0,7; NE]	3	0	NE [NE; NE]	NC	[NC]	NC
IV	15	7 (46,7)	5,9 [3,4; NE]	21	9 (42,9)	4,2 [0,7; NE]	0,64	[0,23; 1,74]	0,3800
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 4.2.1.1.5 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Kognition
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	11 (45,8)	2,1 [0,8; 5,0]	25	15 (60,0)	2,2 [2,0; 4,4]	1,08	[0,48; 2,35]	0,8421
Neu diagnostiziert	22	14 (63,6)	2,1 [0,7; 6,1]	24	13 (54,2)	1,3 [0,7; 4,1]	0,69	[0,32; 1,49]	0,3345
Interaktion p-Wert									0,4137
Region									
Asien	14	7 (50,0)	2,7 [0,7; NE]	14	11 (78,6)	2,1 [0,7; 4,1]	0,66	[0,24; 1,68]	0,3877
Rest der Welt	32	18 (56,3)	2,1 [0,8; 4,1]	35	17 (48,6)	2,1 [1,3; 4,4]	1,04	[0,53; 2,04]	0,9027
Interaktion p-Wert									0,4377
Alter									
<65	25	14 (56,0)	2,1 [0,8; 5,0]	25	14 (56,0)	2,1 [1,3; 4,1]	1,02	[0,48; 2,16]	0,9607
>=65	21	11 (52,4)	2,2 [0,8; NE]	24	14 (58,3)	2,1 [0,8; 4,2]	0,78	[0,34; 1,71]	0,5297
Interaktion p-Wert									0,6224
Abstammung									
Weiß	29	16 (55,2)	2,0 [0,8; 3,8]	30	16 (53,3)	2,1 [1,3; 4,4]	1,08	[0,53; 2,17]	0,8324
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	2,0 [NE; NE]	NC	[NC]	NC
Asiatisch	14	7 (50,0)	2,7 [0,7; NE]	15	11 (73,3)	2,1 [0,7; 4,1]	0,67	[0,25; 1,71]	0,4061
Andere	2	2 (100)	2,4 [0,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,4269
HRR Mutationsstatus									
HRRm	12	5 (41,7)	3,4 [0,7; NE]	15	9 (60,0)	1,3 [0,7; 4,4]	0,46	[0,14; 1,34]	0,1565
Nicht-HRRm	17	12 (70,6)	1,4 [0,7; 4,1]	21	12 (57,1)	2,1 [1,4; 4,2]	1,33	[0,59; 3,01]	0,4823
Unbekannt	17	8 (47,1)	2,4 [0,7; NE]	13	7 (53,8)	3,4 [0,7; NE]	0,89	[0,32; 2,56]	0,8289
Interaktion p-Wert									0,2995
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 4.2.1.1.5 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Kognition
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	18 (48,6)	3,4 [0,9; NE]	39	23 (59,0)	2,1 [1,3; 4,2]	0,74	[0,39; 1,38]	0,3519
Negativ	8	6 (75,0)	1,1 [0,6; NE]	8	4 (50,0)	2,0 [0,8; NE]	2,37	[0,67; 9,39]	0,1789
Unbekannt	1	1 (100)	3,8 [NE; NE]	2	1 (50,0)	2,2 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1081
Histologie									
Endometrioid	33	18 (54,5)	2,7 [0,8; 5,0]	41	24 (58,5)	2,1 [1,4; 4,1]	0,90	[0,48; 1,66]	0,7469
Serös	2	2 (100)	1,1 [0,7; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	5 (45,5)	1,3 [0,6; NE]	6	4 (66,7)	1,4 [0,7; NE]	0,36	[0,09; 1,47]	0,1455
Interaktion p-Wert									0,2239
Histologischer Grad									
High grade (G3)	14	8 (57,1)	2,1 [0,7; 2,7]	12	6 (50,0)	1,3 [0,7; NE]	0,86	[0,30; 2,63]	0,7825
Low grade (G1+G2)	28	16 (57,1)	2,8 [0,8; 5,0]	33	21 (63,6)	2,0 [1,4; 4,1]	0,79	[0,41; 1,52]	0,4888
Interaktion p-Wert									0,9013
ECOG Performance Status zu Baseline									
0	23	11 (47,8)	2,0 [0,7; 5,0]	29	21 (72,4)	2,0 [1,3; 2,2]	0,85	[0,39; 1,73]	0,6605
1	23	14 (60,9)	2,7 [0,8; NE]	20	7 (35,0)	4,2 [1,3; NE]	1,33	[0,55; 3,50]	0,5371
Interaktion p-Wert									0,4491
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	6 (85,7)	1,3 [0,6; 4,1]	3	1 (33,3)	NE [NE; NE]	3,15	[0,53; 59,64]	0,2299
IV	15	8 (53,3)	2,7 [0,7; NE]	21	12 (57,1)	0,8 [0,7; 1,4]	0,53	[0,20; 1,29]	0,1599
Interaktion p-Wert									0,0865

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 4.2.1.1.6 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Sozial
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	13 (54,2)	1,7 [0,8; 4,1]	25	10 (40,0)	3,5 [1,4; NE]	2,00	[0,88; 4,68]	0,0987
Neu diagnostiziert	22	13 (59,1)	1,5 [0,8; NE]	24	12 (50,0)	1,4 [0,7; 5,0]	0,84	[0,38; 1,86]	0,6581
Interaktion p-Wert									0,1349
Region									
Asien	14	11 (78,6)	0,8 [0,6; 1,5]	14	8 (57,1)	4,6 [0,7; NE]	3,05	[1,22; 7,98]	0,0176*
Rest der Welt	32	15 (46,9)	2,4 [1,3; NE]	35	14 (40,0)	2,3 [0,8; NE]	0,90	[0,43; 1,89]	0,7726
Interaktion p-Wert									0,0425*
Alter									
<65	25	16 (64,0)	1,5 [0,8; 2,8]	25	12 (48,0)	4,1 [1,3; NE]	1,56	[0,74; 3,38]	0,2435
>=65	21	10 (47,6)	1,7 [0,7; NE]	24	10 (41,7)	2,7 [0,7; NE]	1,05	[0,43; 2,57]	0,9106
Interaktion p-Wert									0,5054
Abstammung									
Weiß	29	13 (44,8)	2,1 [1,3; NE]	30	13 (43,3)	2,1 [0,8; NE]	0,94	[0,43; 2,04]	0,8669
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	2,7 [NE; NE]	NC	[NC]	NC
Asiatisch	14	11 (78,6)	0,8 [0,6; 1,5]	15	8 (53,3)	4,6 [0,7; NE]	2,95	[1,18; 7,71]	0,0213*
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,0620
HRR Mutationsstatus									
HRRm	12	8 (66,7)	2,0 [0,7; 2,8]	15	7 (46,7)	1,3 [0,7; NE]	1,12	[0,40; 3,20]	0,8327
Nicht-HRRm	17	10 (58,8)	2,1 [0,6; NE]	21	9 (42,9)	3,5 [0,7; NE]	1,28	[0,52; 3,24]	0,5879
Unbekannt	17	8 (47,1)	1,4 [0,7; NE]	13	6 (46,2)	4,1 [1,4; NE]	1,56	[0,54; 4,75]	0,4091
Interaktion p-Wert									0,9047
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 4.2.1.1.6 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Funktionsskala: Sozial
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	21 (56,8)	2,0 [1,3; 4,1]	39	17 (43,6)	3,5 [1,3; NE]	1,36	[0,72; 2,60]	0,3510
Negativ	8	4 (50,0)	0,8 [0,6; NE]	8	4 (50,0)	2,0 [0,8; NE]	1,35	[0,32; 5,75]	0,6700
Unbekannt	1	1 (100)	1,0 [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9991
Histologie									
Endometrioid	33	17 (51,5)	2,0 [1,0; 5,1]	41	19 (46,3)	2,7 [1,4; NE]	1,17	[0,60; 2,26]	0,6376
Serös	2	2 (100)	1,4 [1,4; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	7 (63,6)	1,3 [0,6; 4,1]	6	3 (50,0)	1,4 [0,7; NE]	1,07	[0,29; 4,96]	0,9268
Interaktion p-Wert									0,9026
Histologischer Grad									
High grade (G3)	14	8 (57,1)	1,4 [0,6; NE]	12	3 (25,0)	5,0 [0,7; NE]	2,50	[0,72; 11,41]	0,1537
Low grade (G1+G2)	28	15 (53,6)	2,1 [1,0; NE]	33	17 (51,5)	2,1 [0,8; 4,1]	1,00	[0,49; 2,01]	0,9994
Interaktion p-Wert									0,2150
ECOG Performance Status zu Baseline									
0	23	11 (47,8)	2,1 [0,8; 5,1]	29	15 (51,7)	2,1 [0,8; NE]	1,09	[0,49; 2,37]	0,8264
1	23	15 (65,2)	1,4 [0,8; 4,1]	20	7 (35,0)	5,0 [0,7; NE]	1,70	[0,71; 4,45]	0,2359
Interaktion p-Wert									0,4624
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	4 (57,1)	2,1 [0,6; NE]	3	1 (33,3)	NE [NE; NE]	0,99	[0,14; 19,32]	0,9894
IV	15	9 (60,0)	1,4 [0,7; NE]	21	11 (52,4)	1,4 [0,7; 5,0]	0,91	[0,37; 2,20]	0,8339
Interaktion p-Wert									0,9473

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 4.2.1.1.7 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Fatigue
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	14 (58,3)	1,7 [0,7; 3,4]	25	19 (76,0)	1,4 [0,8; 2,1]	0,94	[0,46; 1,86]	0,8554
Neu diagnostiziert	22	16 (72,7)	1,7 [0,7; 3,5]	24	15 (62,5)	0,8 [0,7; 2,2]	0,69	[0,34; 1,40]	0,2980
Interaktion p-Wert									0,5358
Region									
Asien	14	10 (71,4)	1,1 [0,7; 3,5]	14	12 (85,7)	1,0 [0,7; 2,0]	0,90	[0,38; 2,10]	0,8123
Rest der Welt	32	20 (62,5)	2,0 [0,9; 3,4]	35	22 (62,9)	1,4 [0,8; 2,2]	0,76	[0,41; 1,41]	0,3840
Interaktion p-Wert									0,7505
Alter									
<65	25	15 (60,0)	2,4 [1,0; 4,2]	25	17 (68,0)	2,0 [0,7; 2,2]	0,73	[0,36; 1,47]	0,3754
>=65	21	15 (71,4)	0,8 [0,7; 2,1]	24	17 (70,8)	0,8 [0,7; 1,5]	0,97	[0,48; 1,96]	0,9374
Interaktion p-Wert									0,5678
Abstammung									
Weiß	29	18 (62,1)	2,0 [0,9; 3,4]	30	21 (70,0)	1,3 [0,8; 2,1]	0,71	[0,37; 1,34]	0,2889
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	6,0 [NE; NE]	NC	[NC]	NC
Asiatisch	14	10 (71,4)	1,1 [0,7; 3,5]	15	12 (80,0)	1,0 [0,7; 2,0]	0,89	[0,37; 2,07]	0,7852
Andere	2	2 (100)	1,0 [0,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6732
HRR Mutationsstatus									
HRRm	12	5 (41,7)	2,7 [0,7; NE]	15	9 (60,0)	0,8 [0,7; 1,5]	0,21	[0,06; 0,63]	0,0053*
Nicht-HRRm	17	14 (82,4)	1,3 [0,7; 3,0]	21	16 (76,2)	2,1 [0,8; 2,2]	1,11	[0,53; 2,30]	0,7736
Unbekannt	17	11 (64,7)	1,7 [0,7; 3,5]	13	9 (69,2)	0,8 [0,7; NE]	1,18	[0,48; 2,95]	0,7178
Interaktion p-Wert									0,0270*
PD-L1 Expression									
Positiv	37	23 (62,2)	2,1 [0,8; 3,4]	39	28 (71,8)	1,3 [0,8; 2,1]	0,78	[0,45; 1,36]	0,3867

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 4.2.1.1.7 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Fatigue
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	8	6 (75,0)	1,1 [0,6; NE]	8	5 (62,5)	0,7 [0,6; NE]	0,48	[0,14; 1,68]	0,2378
Unbekannt	1	1 (100)	1,0 [NE; NE]	2	1 (50,0)	2,2 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4660
Histologie									
Endometrioid	33	23 (69,7)	1,4 [0,8; 2,7]	41	30 (73,2)	1,3 [0,8; 2,1]	1,03	[0,59; 1,78]	0,9131
Serös	2	2 (100)	3,8 [3,5; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	5 (45,5)	1,3 [0,6; NE]	6	4 (66,7)	1,0 [0,7; NE]	0,19	[0,05; 0,78]	0,0236*
Interaktion p-Wert									0,0299*
Histologischer Grad									
High grade (G3)	14	10 (71,4)	1,3 [0,7; 2,1]	12	7 (58,3)	1,3 [0,7; NE]	1,00	[0,38; 2,76]	0,9967
Low grade (G1+G2)	28	19 (67,9)	2,0 [0,7; 3,4]	33	24 (72,7)	0,8 [0,7; 2,0]	0,75	[0,40; 1,37]	0,3519
Interaktion p-Wert									0,6248
ECOG Performance Status zu Baseline									
0	23	13 (56,5)	1,3 [0,7; 3,5]	29	24 (82,8)	0,8 [0,7; 1,5]	0,60	[0,29; 1,16]	0,1316
1	23	17 (73,9)	2,0 [0,9; 2,7]	20	10 (50,0)	2,1 [0,8;13,3]	1,35	[0,62; 3,07]	0,4508
Interaktion p-Wert									0,1205
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	7 (100)	0,8 [0,6; 2,1]	3	2 (66,7)	2,4 [0,7; NE]	1,66	[0,39; 11,26]	0,5156
IV	15	9 (60,0)	2,7 [0,8; NE]	21	13 (61,9)	0,8 [0,7; 2,0]	0,49	[0,20; 1,14]	0,0986
Interaktion p-Wert									0,1640

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 4.2.1.1.8 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Übelkeit und Erbrechen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	11 (45,8)	5,0 [1,4; 6,9]	25	10 (40,0)	9,6 [1,5; NE]	1,54	[0,65; 3,69]	0,3259
Neu diagnostiziert	22	13 (59,1)	3,8 [1,3; NE]	24	13 (54,2)	2,1 [0,7; 3,5]	0,60	[0,27; 1,31]	0,1942
Interaktion p-Wert									0,1098
Region									
Asien	14	9 (64,3)	1,5 [0,7; 5,0]	14	10 (71,4)	5,4 [1,4;12,4]	1,64	[0,65; 4,09]	0,2909
Rest der Welt	32	15 (46,9)	6,1 [2,0; 7,8]	35	13 (37,1)	3,5 [0,8; NE]	0,79	[0,37; 1,70]	0,5437
Interaktion p-Wert									0,2322
Alter									
<65	25	15 (60,0)	2,8 [1,3; 6,1]	25	14 (56,0)	3,4 [1,4; 9,6]	1,16	[0,56; 2,44]	0,6878
>=65	21	9 (42,9)	6,9 [0,8; NE]	24	9 (37,5)	3,5 [0,8; NE]	0,82	[0,32; 2,11]	0,6735
Interaktion p-Wert									0,5636
Abstammung									
Weiß	29	13 (44,8)	4,3 [2,0; 7,8]	30	12 (40,0)	2,8 [0,8; NE]	0,83	[0,37; 1,85]	0,6357
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	6,0 [NE; NE]	NC	[NC]	NC
Asiatisch	14	9 (64,3)	1,5 [0,7; 5,0]	15	10 (66,7)	5,4 [1,4;12,4]	1,60	[0,63; 4,00]	0,3106
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,2840
HRR Mutationsstatus									
HRRm	12	5 (41,7)	2,8 [0,7; NE]	15	8 (53,3)	2,0 [0,6; 3,5]	0,62	[0,19; 1,85]	0,3885
Nicht-HRRm	17	12 (70,6)	5,0 [1,3; 6,9]	21	8 (38,1)	9,6 [1,5; NE]	1,61	[0,66; 4,11]	0,2943
Unbekannt	17	7 (41,2)	3,3 [0,8; NE]	13	7 (53,8)	6,0 [0,7; NE]	0,77	[0,26; 2,25]	0,6227
Interaktion p-Wert									0,3518
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 4.2.1.1.8 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Übelkeit und Erbrechen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	18 (48,6)	4,3 [2,0; 7,8]	39	18 (46,2)	6,0 [1,5; 9,6]	0,92	[0,47; 1,78]	0,7962
Negativ	8	5 (62,5)	1,4 [0,7; NE]	8	4 (50,0)	3,5 [0,7; NE]	1,71	[0,45; 6,99]	0,4273
Unbekannt	1	1 (100)	3,1 [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4113
Histologie									
Endometrioid	33	17 (51,5)	4,1 [1,4; 6,9]	41	20 (48,8)	3,5 [1,4; 9,6]	1,08	[0,56; 2,06]	0,8157
Serös	2	2 (100)	2,5 [1,4; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	5 (45,5)	6,9 [0,7; NE]	6	3 (50,0)	2,1 [0,7; NE]	0,44	[0,11; 2,20]	0,2933
Interaktion p-Wert									0,2888
Histologischer Grad									
High grade (G3)	14	7 (50,0)	1,5 [0,7; NE]	12	3 (25,0)	NE [NE; NE]	1,90	[0,52; 8,85]	0,3401
Low grade (G1+G2)	28	15 (53,6)	4,3 [1,4; 7,8]	33	17 (51,5)	3,4 [1,4; 9,6]	0,88	[0,43; 1,76]	0,7124
Interaktion p-Wert									0,3102
ECOG Performance Status zu Baseline									
0	23	9 (39,1)	4,1 [1,3; NE]	29	16 (55,2)	2,8 [1,5; 9,6]	0,78	[0,33; 1,73]	0,5444
1	23	15 (65,2)	4,3 [1,4; 6,9]	20	7 (35,0)	7,4 [0,7; NE]	1,33	[0,56; 3,48]	0,5287
Interaktion p-Wert									0,3829
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	4 (57,1)	7,8 [0,7; NE]	3	0	NE [NE; NE]	NC	[NC]	NC
IV	15	9 (60,0)	2,8 [0,8; NE]	21	13 (61,9)	1,4 [0,7; 3,4]	0,56	[0,23; 1,31]	0,1776
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 4.2.1.1.9 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	10 (41,7)	2,8 [0,8; NE]	25	13 (52,0)	4,2 [1,3; 7,9]	0,99	[0,42; 2,25]	0,9808
Neu diagnostiziert	22	14 (63,6)	2,3 [0,7; 6,9]	24	11 (45,8)	4,2 [0,7; 9,7]	1,08	[0,49; 2,44]	0,8486
Interaktion p-Wert									0,8811
Region									
Asien	14	10 (71,4)	1,1 [0,6; 3,5]	14	8 (57,1)	6,1 [0,7; NE]	2,63	[1,02; 6,96]	0,0445*
Rest der Welt	32	14 (43,8)	3,5 [1,3; NE]	35	16 (45,7)	3,5 [0,8; 4,2]	0,63	[0,30; 1,30]	0,2113
Interaktion p-Wert									0,0194*
Alter									
<65	25	11 (44,0)	3,5 [1,4; NE]	25	11 (44,0)	7,9 [2,0; NE]	0,94	[0,40; 2,19]	0,8780
>=65	21	13 (61,9)	0,9 [0,7; 6,9]	24	13 (54,2)	2,9 [0,7; 6,1]	1,25	[0,57; 2,72]	0,5782
Interaktion p-Wert									0,6242
Abstammung									
Weiß	29	12 (41,4)	6,9 [1,3; NE]	30	15 (50,0)	2,9 [0,8; 7,9]	0,58	[0,26; 1,24]	0,1586
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	4,1 [NE; NE]	NC	[NC]	NC
Asiatisch	14	10 (71,4)	1,1 [0,6; 3,5]	15	8 (53,3)	6,1 [0,7; NE]	2,60	[1,01; 6,89]	0,0469*
Andere	2	2 (100)	1,0 [0,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,0159*
HRR Mutationsstatus									
HRRm	12	3 (25,0)	NE [NE; NE]	15	9 (60,0)	0,8 [0,6; 4,2]	0,16	[0,04; 0,55]	0,0031*
Nicht-HRRm	17	13 (76,5)	1,3 [0,6; 3,5]	21	12 (57,1)	4,2 [0,8; 7,9]	1,50	[0,68; 3,35]	0,3114
Unbekannt	17	8 (47,1)	3,1 [0,8; NE]	13	3 (23,1)	NE [NE; NE]	3,22	[0,93; 14,73]	0,0660
Interaktion p-Wert									0,0015*
PD-L1 Expression									
Positiv	37	19 (51,4)	2,0 [0,9; 7,8]	39	21 (53,8)	4,2 [0,8; 6,1]	0,90	[0,48; 1,68]	0,7353

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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 4.2.1.1.9 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	8	5 (62,5)	2,8 [0,6; NE]	8	3 (37,5)	9,6 [1,3; NE]	2,27	[0,55; 11,18]	0,2543
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2410
Histologie									
Endometrioid	33	17 (51,5)	2,1 [0,8; 7,8]	41	22 (53,7)	4,2 [1,3; 7,9]	1,07	[0,56; 2,00]	0,8441
Serös	2	2 (100)	3,5 [3,5; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	5 (45,5)	2,0 [0,6; NE]	6	2 (33,3)	NE [NE; NE]	0,85	[0,18; 6,01]	0,8509
Interaktion p-Wert									0,8065
Histologischer Grad									
High grade (G3)	14	9 (64,3)	1,3 [0,7; 6,9]	12	3 (25,0)	NE [NE; NE]	2,08	[0,61; 9,40]	0,2506
Low grade (G1+G2)	28	14 (50,0)	2,8 [0,8; NE]	33	20 (60,6)	4,1 [0,8; 6,1]	0,77	[0,38; 1,52]	0,4480
Interaktion p-Wert									0,1675
ECOG Performance Status zu Baseline									
0	23	10 (43,5)	3,5 [0,7; NE]	29	18 (62,1)	2,9 [0,8; 6,1]	0,73	[0,32; 1,57]	0,4324
1	23	14 (60,9)	1,6 [0,8; NE]	20	6 (30,0)	7,9 [0,8; NE]	1,88	[0,75; 5,32]	0,1806
Interaktion p-Wert									0,1264
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	5 (71,4)	2,0 [0,6; NE]	3	1 (33,3)	9,7 [NE; NE]	2,81	[0,45; 54,01]	0,2978
IV	15	9 (60,0)	2,7 [0,8; NE]	21	10 (47,6)	2,9 [0,7; 9,6]	0,86	[0,34; 2,14]	0,7410
Interaktion p-Wert									0,2822

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 4.2.1.1.10 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Dyspnoe
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	9 (37,5)	4,1 [1,0; NE]	25	12 (48,0)	2,8 [1,3; NE]	0,83	[0,34; 1,96]	0,6688
Neu diagnostiziert	22	13 (59,1)	2,8 [1,4; NE]	24	11 (45,8)	4,1 [0,9; NE]	0,87	[0,39; 1,98]	0,7272
Interaktion p-Wert									0,9413
Region									
Asien	14	8 (57,1)	1,8 [0,7; NE]	14	10 (71,4)	1,4 [0,7; NE]	0,83	[0,32; 2,12]	0,6997
Rest der Welt	32	14 (43,8)	4,1 [2,0; NE]	35	13 (37,1)	4,3 [2,1; NE]	0,92	[0,43; 1,98]	0,8188
Interaktion p-Wert									0,8774
Alter									
<65	25	13 (52,0)	3,5 [1,3;17,0]	25	12 (48,0)	4,1 [1,3; NE]	0,93	[0,42; 2,08]	0,8665
>=65	21	9 (42,9)	3,8 [1,4; NE]	24	11 (45,8)	3,4 [1,4; 6,0]	0,78	[0,31; 1,89]	0,5787
Interaktion p-Wert									0,7623
Abstammung									
Weiß	29	13 (44,8)	3,5 [1,4; NE]	30	12 (40,0)	4,3 [2,1; NE]	1,03	[0,47; 2,29]	0,9446
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	6,0 [NE; NE]	NC	[NC]	NC
Asiatisch	14	8 (57,1)	1,8 [0,7; NE]	15	10 (66,7)	1,4 [0,7; NE]	0,84	[0,32; 2,14]	0,7154
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,7463
HRR Mutationsstatus									
HRRm	12	6 (50,0)	2,1 [0,7; NE]	15	6 (40,0)	1,4 [0,7; NE]	1,00	[0,31; 3,21]	0,9988
Nicht-HRRm	17	8 (47,1)	17,0 [1,4; NE]	21	12 (57,1)	2,2 [0,9; 6,0]	0,54	[0,21; 1,32]	0,1798
Unbekannt	17	8 (47,1)	2,5 [0,8; NE]	13	5 (38,5)	6,0 [1,4; NE]	1,55	[0,51; 5,15]	0,4371
Interaktion p-Wert									0,3367
PD-L1 Expression									
Positiv	37	17 (45,9)	4,1 [2,0; NE]	39	19 (48,7)	3,7 [2,1; 6,0]	0,84	[0,43; 1,62]	0,5976

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 4.2.1.1.10 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Dyspnoe
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	8	4 (50,0)	2,5 [1,4; NE]	8	4 (50,0)	1,4 [0,6; NE]	0,56	[0,13; 2,37]	0,4152
Unbekannt	1	1 (100)	1,0 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6065
Histologie									
Endometrioid	33	15 (45,5)	3,4 [1,4; NE]	41	20 (48,8)	2,8 [1,4; 6,0]	0,95	[0,48; 1,86]	0,8912
Serös	2	2 (100)	12,9 [8,8; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	5 (45,5)	4,1 [1,3; NE]	6	3 (50,0)	2,3 [0,7; NE]	0,43	[0,10; 2,12]	0,2744
Interaktion p-Wert									0,3408
Histologischer Grad									
High grade (G3)	14	9 (64,3)	1,4 [0,7; 4,1]	12	7 (58,3)	1,3 [0,7; 3,4]	0,80	[0,30; 2,25]	0,6634
Low grade (G1+G2)	28	11 (39,3)	17,0 [2,1; NE]	33	14 (42,4)	6,0 [2,1; NE]	0,74	[0,33; 1,62]	0,4488
Interaktion p-Wert									0,8970
ECOG Performance Status zu Baseline									
0	23	12 (52,2)	3,4 [1,3; 8,8]	29	17 (58,6)	2,1 [1,3; 6,0]	0,86	[0,40; 1,79]	0,6871
1	23	10 (43,5)	NE [NE; NE]	20	6 (30,0)	4,1 [2,1; NE]	1,12	[0,41; 3,29]	0,8313
Interaktion p-Wert									0,6815
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	5 (71,4)	3,5 [0,7; NE]	3	2 (66,7)	3,4 [0,7; NE]	0,64	[0,14; 4,55]	0,6149
IV	15	8 (53,3)	2,1 [1,4; NE]	21	9 (42,9)	4,1 [0,9; NE]	0,86	[0,32; 2,26]	0,7545
Interaktion p-Wert									0,7728

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 4.2.1.1.11 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schlaflosigkeit
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	12 (50,0)	1,7 [1,0; 3,1]	25	12 (48,0)	4,0 [2,1; NE]	1,74	[0,77; 3,94]	0,1778
Neu diagnostiziert	22	14 (63,6)	3,8 [0,8;22,6]	24	10 (41,7)	2,2 [0,7; NE]	0,86	[0,38; 2,03]	0,7281
Interaktion p-Wert									0,2352
Region									
Asien	14	8 (57,1)	2,3 [0,7; NE]	14	8 (57,1)	11,6 [0,7; NE]	1,41	[0,52; 3,85]	0,4936
Rest der Welt	32	18 (56,3)	2,7 [1,3;10,6]	35	14 (40,0)	2,9 [2,0; NE]	1,11	[0,55; 2,30]	0,7621
Interaktion p-Wert									0,7019
Alter									
<65	25	16 (64,0)	1,9 [0,8; 3,1]	25	11 (44,0)	9,6 [2,0; NE]	1,76	[0,82; 3,93]	0,1497
>=65	21	10 (47,6)	4,1 [1,4; NE]	24	11 (45,8)	3,4 [1,3;11,6]	0,80	[0,33; 1,91]	0,6116
Interaktion p-Wert									0,1811
Abstammung									
Weiß	29	15 (51,7)	3,1 [1,4;22,6]	30	14 (46,7)	2,2 [1,3; 9,6]	0,90	[0,43; 1,89]	0,7710
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	8 (57,1)	2,3 [0,7; NE]	15	8 (53,3)	11,6 [0,7; NE]	1,42	[0,52; 3,88]	0,4883
Andere	2	2 (100)	1,0 [0,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,4642
HRR Mutationsstatus									
HRRm	12	8 (66,7)	1,0 [0,7; 9,6]	15	6 (40,0)	2,9 [0,6; NE]	2,12	[0,73; 6,50]	0,1638
Nicht-HRRm	17	11 (64,7)	2,7 [1,3; NE]	21	11 (52,4)	2,2 [2,0; NE]	1,08	[0,46; 2,54]	0,8590
Unbekannt	17	7 (41,2)	3,5 [0,8; NE]	13	5 (38,5)	12,8 [0,7; NE]	1,08	[0,34; 3,70]	0,8910
Interaktion p-Wert									0,5784
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 4.2.1.1.11 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schlaflosigkeit
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	21 (56,8)	2,7 [1,3; 9,6]	39	19 (48,7)	3,4 [2,0;11,6]	1,11	[0,59; 2,09]	0,7472
Negativ	8	4 (50,0)	12,0 [0,6; NE]	8	2 (25,0)	12,8 [2,0; NE]	2,53	[0,49; 18,37]	0,2700
Unbekannt	1	1 (100)	3,1 [NE; NE]	2	1 (50,0)	2,2 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3596
Histologie									
Endometrioid	33	18 (54,5)	2,0 [1,0; 4,1]	41	19 (46,3)	3,4 [2,1;12,8]	1,35	[0,70; 2,59]	0,3653
Serös	2	2 (100)	3,1 [2,8; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	6 (54,5)	9,6 [0,7; NE]	6	3 (50,0)	2,4 [0,7; NE]	0,57	[0,15; 2,73]	0,4476
Interaktion p-Wert									0,2903
Histologischer Grad									
High grade (G3)	14	8 (57,1)	9,6 [0,8; NE]	12	4 (33,3)	4,0 [0,6; NE]	1,06	[0,33; 3,99]	0,9294
Low grade (G1+G2)	28	16 (57,1)	2,0 [1,0; 4,1]	33	18 (54,5)	2,2 [2,0;11,6]	1,07	[0,54; 2,11]	0,8474
Interaktion p-Wert									0,9864
ECOG Performance Status zu Baseline									
0	23	13 (56,5)	1,4 [0,7; 3,5]	29	17 (58,6)	2,9 [2,0;11,6]	1,49	[0,71; 3,08]	0,2864
1	23	13 (56,5)	3,1 [1,4; NE]	20	5 (25,0)	NE [NE; NE]	1,55	[0,58; 4,86]	0,3895
Interaktion p-Wert									0,9494
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	6 (85,7)	0,8 [0,7; 4,1]	3	1 (33,3)	NE [NE; NE]	2,68	[0,45; 50,90]	0,3099
IV	15	8 (53,3)	10,6 [2,0; NE]	21	9 (42,9)	2,2 [0,7; NE]	0,54	[0,19; 1,48]	0,2303
Interaktion p-Wert									0,1385

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 4.2.1.1.12 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Appetitverlust
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	9 (37,5)	4,1 [0,8; NE]	25	14 (56,0)	2,8 [1,3; 6,1]	0,74	[0,31; 1,70]	0,4842
Neu diagnostiziert	22	13 (59,1)	3,5 [1,3; NE]	24	14 (58,3)	2,1 [0,8; 3,5]	0,57	[0,26; 1,23]	0,1511
Interaktion p-Wert									0,6496
Region									
Asien	14	9 (64,3)	2,4 [0,7; NE]	14	12 (85,7)	3,5 [1,3; 6,9]	1,04	[0,42; 2,45]	0,9371
Rest der Welt	32	13 (40,6)	5,9 [2,0; NE]	35	16 (45,7)	2,1 [1,3; 3,5]	0,53	[0,25; 1,11]	0,0899
Interaktion p-Wert									0,2499
Alter									
<65	25	14 (56,0)	3,5 [1,4;18,9]	25	14 (56,0)	3,5 [1,4; 9,6]	0,86	[0,40; 1,82]	0,6861
>=65	21	8 (38,1)	NE [NE; NE]	24	14 (58,3)	2,8 [0,8; 5,1]	0,48	[0,19; 1,14]	0,0958
Interaktion p-Wert									0,3243
Abstammung									
Weiß	29	12 (41,4)	5,9 [1,4; NE]	30	15 (50,0)	2,1 [0,8; 3,5]	0,57	[0,26; 1,22]	0,1479
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	6,0 [NE; NE]	NC	[NC]	NC
Asiatisch	14	9 (64,3)	2,4 [0,7; NE]	15	12 (80,0)	3,5 [1,3; 6,9]	1,03	[0,42; 2,44]	0,9451
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,3161
HRR Mutationsstatus									
HRRm	12	6 (50,0)	2,1 [0,7; NE]	15	9 (60,0)	1,4 [0,6; 3,5]	0,58	[0,19; 1,62]	0,3022
Nicht-HRRm	17	7 (41,2)	18,9 [1,3; NE]	21	11 (52,4)	2,1 [1,3; NE]	0,49	[0,18; 1,25]	0,1338
Unbekannt	17	9 (52,9)	3,1 [0,8; 3,5]	13	8 (61,5)	5,1 [0,8; 6,9]	1,08	[0,41; 2,89]	0,8782
Interaktion p-Wert									0,4865
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 4.2.1.1.12 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Appetitverlust
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	18 (48,6)	3,5 [2,0; NE]	39	24 (61,5)	2,8 [1,4; 5,1]	0,63	[0,34; 1,17]	0,1471
Negativ	8	3 (37,5)	3,5 [0,8; NE]	8	4 (50,0)	2,0 [0,7; NE]	0,60	[0,12; 2,74]	0,4984
Unbekannt	1	1 (100)	1,0 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9389
Histologie									
Endometrioid	33	15 (45,5)	2,7 [1,3; NE]	41	24 (58,5)	2,8 [1,4; 6,0]	0,76	[0,39; 1,43]	0,3924
Serös	2	2 (100)	11,2 [3,5; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	5 (45,5)	5,9 [0,6; NE]	6	4 (66,7)	1,0 [0,7; NE]	0,24	[0,06; 0,99]	0,0478*
Interaktion p-Wert									0,1400
Histologischer Grad									
High grade (G3)	14	9 (64,3)	2,7 [0,8; 5,9]	12	6 (50,0)	1,3 [0,6; NE]	0,72	[0,26; 2,15]	0,5364
Low grade (G1+G2)	28	12 (42,9)	3,5 [1,3; NE]	33	21 (63,6)	2,1 [1,4; 3,5]	0,48	[0,22; 0,99]	0,0456*
Interaktion p-Wert									0,5355
ECOG Performance Status zu Baseline									
0	23	11 (47,8)	3,5 [1,3;18,9]	29	21 (72,4)	2,1 [1,4; 3,5]	0,60	[0,28; 1,23]	0,1684
1	23	11 (47,8)	4,1 [0,8; NE]	20	7 (35,0)	6,9 [0,7; NE]	0,94	[0,37; 2,56]	0,9031
Interaktion p-Wert									0,4604
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	5 (71,4)	3,4 [1,3; NE]	3	1 (33,3)	NE [NE; NE]	2,21	[0,36; 42,40]	0,4323
IV	15	8 (53,3)	3,5 [0,8; NE]	21	13 (61,9)	1,4 [0,7; 3,5]	0,46	[0,18; 1,10]	0,0823
Interaktion p-Wert									0,1429

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 4.2.1.1.13 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Verstopfung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	11 (45,8)	2,4 [0,8; NE]	25	16 (64,0)	3,4 [1,5; 5,8]	0,92	[0,41; 1,98]	0,8308
Neu diagnostiziert	22	16 (72,7)	3,4 [0,9; 7,0]	24	13 (54,2)	1,4 [0,7; 3,4]	0,73	[0,35; 1,56]	0,4113
Interaktion p-Wert									0,6757
Region									
Asien	14	10 (71,4)	1,3 [0,7; 7,0]	14	11 (78,6)	3,4 [1,4; 6,8]	1,41	[0,58; 3,38]	0,4353
Rest der Welt	32	17 (53,1)	3,4 [1,3;10,5]	35	18 (51,4)	2,1 [1,4; 3,5]	0,59	[0,30; 1,17]	0,1331
Interaktion p-Wert									0,1208
Alter									
<65	25	15 (60,0)	2,5 [1,3; 3,8]	25	16 (64,0)	2,2 [1,3; 4,2]	0,92	[0,45; 1,87]	0,8151
>=65	21	12 (57,1)	3,2 [0,7;10,6]	24	13 (54,2)	2,8 [1,4; 3,5]	0,72	[0,31; 1,64]	0,4336
Interaktion p-Wert									0,6608
Abstammung									
Weiß	29	15 (51,7)	3,7 [2,1;10,5]	30	17 (56,7)	1,5 [0,8; 3,4]	0,52	[0,25; 1,06]	0,0726
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	6,0 [NE; NE]	NC	[NC]	NC
Asiatisch	14	10 (71,4)	1,3 [0,7; 7,0]	15	11 (73,3)	3,4 [1,4; 6,8]	1,43	[0,59; 3,42]	0,4220
Andere	2	2 (100)	1,0 [0,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,0761
HRR Mutationsstatus									
HRRm	12	5 (41,7)	5,9 [0,7; NE]	15	7 (46,7)	1,5 [0,7; NE]	0,54	[0,16; 1,71]	0,2945
Nicht-HRRm	17	14 (82,4)	1,3 [0,7; 2,7]	21	14 (66,7)	2,8 [1,4; 3,5]	1,66	[0,78; 3,54]	0,1843
Unbekannt	17	8 (47,1)	3,8 [2,1; NE]	13	8 (61,5)	3,4 [0,7; 6,0]	0,53	[0,19; 1,45]	0,2084
Interaktion p-Wert									0,1103
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 4.2.1.1.13 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Verstopfung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	22 (59,5)	2,7 [1,3; 5,9]	39	25 (64,1)	2,2 [1,4; 3,4]	0,80	[0,44; 1,44]	0,4626
Negativ	8	4 (50,0)	4,6 [0,6; NE]	8	3 (37,5)	5,8 [1,4; NE]	1,29	[0,28; 6,58]	0,7362
Unbekannt	1	1 (100)	3,8 [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5595
Histologie									
Endometrioid	33	19 (57,6)	2,1 [0,8; 3,8]	41	25 (61,0)	2,2 [1,4; 3,5]	0,95	[0,51; 1,73]	0,8666
Serös	2	2 (100)	3,1 [2,8; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	6 (54,5)	5,9 [0,9; NE]	6	4 (66,7)	2,1 [0,7; NE]	0,31	[0,08; 1,24]	0,0928
Interaktion p-Wert									0,1335
Histologischer Grad									
High grade (G3)	14	10 (71,4)	1,3 [0,7; 5,9]	12	5 (41,7)	3,4 [1,3; NE]	1,70	[0,59; 5,58]	0,3327
Low grade (G1+G2)	28	16 (57,1)	2,8 [1,3; 7,0]	33	22 (66,7)	1,5 [1,4; 3,4]	0,59	[0,30; 1,13]	0,1108
Interaktion p-Wert									0,0912
ECOG Performance Status zu Baseline									
0	23	12 (52,2)	2,7 [0,7; 5,9]	29	21 (72,4)	2,2 [1,4; 3,4]	0,75	[0,35; 1,50]	0,4180
1	23	15 (65,2)	3,4 [0,9;10,6]	20	8 (40,0)	3,5 [1,4; NE]	1,14	[0,49; 2,84]	0,7703
Interaktion p-Wert									0,4548
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	6 (85,7)	2,1 [0,7; NE]	3	2 (66,7)	2,1 [0,7; NE]	0,78	[0,18; 5,38]	0,7686
IV	15	10 (66,7)	3,7 [0,9;10,6]	21	11 (52,4)	1,4 [0,7; 3,4]	0,65	[0,27; 1,58]	0,3408
Interaktion p-Wert									0,8476

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 4.2.1.1.14 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Diarrhö
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	12 (50,0)	3,4 [1,4; 5,9]	25	10 (40,0)	7,0 [2,1; NE]	1,88	[0,81; 4,46]	0,1411
Neu diagnostiziert	22	11 (50,0)	9,6 [1,4; NE]	24	14 (58,3)	2,8 [1,4; 4,2]	0,43	[0,19; 0,96]	0,0402*
Interaktion p-Wert									0,0134*
Region									
Asien	14	6 (42,9)	9,6 [0,6; NE]	14	10 (71,4)	4,6 [1,3; 8,7]	0,65	[0,22; 1,75]	0,3954
Rest der Welt	32	17 (53,1)	3,4 [2,1;13,3]	35	14 (40,0)	3,5 [1,5; 7,0]	1,03	[0,50; 2,13]	0,9382
Interaktion p-Wert									0,4596
Alter									
<65	25	15 (60,0)	2,7 [1,4; 9,6]	25	13 (52,0)	5,8 [1,5; 8,7]	1,25	[0,59; 2,68]	0,5511
>=65	21	8 (38,1)	14,2 [2,1; NE]	24	11 (45,8)	3,5 [1,3; NE]	0,55	[0,21; 1,38]	0,2027
Interaktion p-Wert									0,1717
Abstammung									
Weiß	29	14 (48,3)	3,4 [2,0;14,2]	30	14 (46,7)	3,5 [1,5; 7,0]	0,96	[0,45; 2,04]	0,9162
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	6 (42,9)	9,6 [0,6; NE]	15	10 (66,7)	4,6 [1,3; 8,7]	0,66	[0,22; 1,78]	0,4134
Andere	2	2 (100)	8,7 [4,1; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,5525
HRR Mutationsstatus									
HRRm	12	5 (41,7)	2,3 [0,7; NE]	15	7 (46,7)	3,5 [0,7; 8,7]	1,18	[0,35; 3,73]	0,7788
Nicht-HRRm	17	11 (64,7)	4,1 [1,3;14,2]	21	10 (47,6)	3,5 [1,4; NE]	1,05	[0,44; 2,54]	0,9089
Unbekannt	17	7 (41,2)	6,2 [0,7; NE]	13	7 (53,8)	1,8 [1,3; NE]	0,56	[0,19; 1,68]	0,2959
Interaktion p-Wert									0,5876
PD-L1 Expression									
Positiv	37	17 (45,9)	4,2 [2,7; NE]	39	20 (51,3)	3,5 [1,5; 8,7]	0,82	[0,42; 1,56]	0,5403

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 4.2.1.1.14 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Diarrhö
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	8	5 (62,5)	2,4 [0,6; NE]	8	4 (50,0)	2,7 [1,4; NE]	0,90	[0,24; 3,69]	0,8809
Unbekannt	1	1 (100)	1,7 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8928
Histologie									
Endometrioid	33	16 (48,5)	4,1 [2,3;14,2]	41	20 (48,8)	3,5 [2,7; 8,7]	0,97	[0,49; 1,87]	0,9174
Serös	2	2 (100)	2,1 [0,7; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	5 (45,5)	13,3 [0,6; NE]	6	4 (66,7)	1,0 [0,7; NE]	0,08	[0,02; 0,37]	0,0019*
Interaktion p-Wert									0,0039*
Histologischer Grad									
High grade (G3)	14	6 (42,9)	13,3 [1,3; NE]	12	5 (41,7)	1,4 [0,7; NE]	0,32	[0,09; 1,14]	0,0761
Low grade (G1+G2)	28	16 (57,1)	2,7 [1,7; 4,2]	33	16 (48,5)	4,2 [2,1; 8,7]	1,29	[0,64; 2,61]	0,4682
Interaktion p-Wert									0,0566
ECOG Performance Status zu Baseline									
0	23	9 (39,1)	3,8 [1,4; NE]	29	16 (55,2)	2,8 [1,4; 8,7]	0,82	[0,35; 1,82]	0,6271
1	23	14 (60,9)	4,2 [1,7;14,2]	20	8 (40,0)	3,5 [2,0; NE]	1,00	[0,43; 2,53]	0,9912
Interaktion p-Wert									0,7347
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	4 (57,1)	4,1 [1,3; NE]	3	2 (66,7)	2,8 [1,4; NE]	0,41	[0,08; 2,99]	0,3350
IV	15	7 (46,7)	14,2 [0,7; NE]	21	12 (57,1)	2,8 [1,4; 7,9]	0,39	[0,13; 1,04]	0,0589
Interaktion p-Wert									0,9638

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 4.2.1.1.15 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30
Finanzielle Schwierigkeiten
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	10 (41,7)	6,1 [1,0;13,4]	25	8 (32,0)	11,6 [2,8; NE]	1,71	[0,68; 4,49]	0,2546
Neu diagnostiziert	22	9 (40,9)	NE [NE; NE]	24	7 (29,2)	10,7 [2,2; NE]	1,09	[0,40; 3,06]	0,8708
Interaktion p-Wert									0,5128
Region									
Asien	14	7 (50,0)	2,7 [0,6; NE]	14	6 (42,9)	11,6 [3,4; NE]	2,02	[0,67; 6,28]	0,2095
Rest der Welt	32	12 (37,5)	13,3 [1,4; NE]	35	9 (25,7)	NE [NE; NE]	1,10	[0,46; 2,72]	0,8248
Interaktion p-Wert									0,3989
Alter									
<65	25	11 (44,0)	6,1 [0,8; NE]	25	7 (28,0)	NE [NE; NE]	1,69	[0,66; 4,61]	0,2758
>=65	21	8 (38,1)	11,5 [0,7; NE]	24	8 (33,3)	11,6 [1,3; NE]	1,07	[0,39; 2,91]	0,8921
Interaktion p-Wert									0,5136
Abstammung									
Weiß	29	10 (34,5)	13,3 [1,4; NE]	30	8 (26,7)	NE [NE; NE]	1,18	[0,46; 3,11]	0,7248
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	0,6 [NE; NE]	NC	[NC]	NC
Asiatisch	14	7 (50,0)	2,7 [0,6; NE]	15	6 (40,0)	11,6 [3,4; NE]	2,02	[0,67; 6,29]	0,2082
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,4667
HRR Mutationsstatus									
HRRm	12	6 (50,0)	2,8 [0,7; NE]	15	6 (40,0)	10,7 [2,2; NE]	1,49	[0,46; 4,80]	0,4928
Nicht-HRRm	17	8 (47,1)	13,3 [0,6; NE]	21	7 (33,3)	NE [NE; NE]	1,17	[0,42; 3,38]	0,7591
Unbekannt	17	5 (29,4)	NE [NE; NE]	13	2 (15,4)	NE [NE; NE]	2,14	[0,46; 14,98]	0,3412
Interaktion p-Wert									0,8212
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 4.2.1.1.15 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Finanzielle Schwierigkeiten
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	16 (43,2)	11,5 [1,0; NE]	39	14 (35,9)	11,6 [3,4; NE]	1,19	[0,58; 2,49]	0,6328
Negativ	8	3 (37,5)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	3,92	[0,50; 79,54]	0,2001
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2984
Histologie									
Endometrioid	33	15 (45,5)	11,5 [1,0;13,4]	41	12 (29,3)	NE [NE; NE]	1,86	[0,87; 4,06]	0,1082
Serös	2	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	4 (36,4)	NE [NE; NE]	6	3 (50,0)	2,1 [0,7; NE]	0,37	[0,08; 1,93]	0,2220
Interaktion p-Wert									0,0772
Histologischer Grad									
High grade (G3)	14	8 (57,1)	0,8 [0,6; NE]	12	3 (25,0)	6,8 [0,7; NE]	2,51	[0,72; 11,51]	0,1521
Low grade (G1+G2)	28	11 (39,3)	13,3 [1,4; NE]	33	11 (33,3)	11,6 [2,8; NE]	1,06	[0,45; 2,48]	0,8978
Interaktion p-Wert									0,2667
ECOG Performance Status zu Baseline									
0	23	8 (34,8)	13,3 [0,7; NE]	29	10 (34,5)	11,6 [3,4; NE]	1,28	[0,49; 3,28]	0,6059
1	23	11 (47,8)	11,5 [1,0; NE]	20	5 (25,0)	NE [NE; NE]	1,51	[0,55; 4,80]	0,4327
Interaktion p-Wert									0,8181
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	5 (71,4)	1,4 [0,6; NE]	3	0	NE [NE; NE]	NC	[NC]	NC
IV	15	4 (26,7)	NE [NE; NE]	21	7 (33,3)	10,7 [0,8; NE]	0,66	[0,17; 2,21]	0,5095
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 4.2.2.1.1 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelles Interesse
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	5 (20,8)	6,1 [2,4; NE]	25	6 (24,0)	NE [NE; NE]	1,17	[0,34; 3,91]	0,7916
Neu diagnostiziert	22	6 (27,3)	NE [NE; NE]	24	6 (25,0)	NE [NE; NE]	0,67	[0,21; 2,14]	0,4878
Interaktion p-Wert									0,5034
Region									
Asien	14	4 (28,6)	NE [NE; NE]	14	4 (28,6)	NE [NE; NE]	1,20	[0,28; 5,10]	0,7926
Rest der Welt	32	7 (21,9)	NE [NE; NE]	35	8 (22,9)	9,6 [2,2; NE]	0,70	[0,24; 1,96]	0,4879
Interaktion p-Wert									0,5336
Alter									
<65	25	10 (40,0)	6,1 [2,4; NE]	25	8 (32,0)	NE [NE; NE]	1,35	[0,53; 3,54]	0,5308
>=65	21	1 (4,8)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	0,21	[0,01; 1,43]	0,1160
Interaktion p-Wert									0,0924
Abstammung									
Weiß	29	6 (20,7)	NE [NE; NE]	30	8 (26,7)	9,6 [2,2; NE]	0,66	[0,22; 1,92]	0,4488
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	4 (28,6)	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	1,19	[0,28; 5,05]	0,8027
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,5109
HRR Mutationsstatus									
HRRm	12	1 (8,3)	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	0,44	[0,02; 2,95]	0,4239
Nicht-HRRm	17	6 (35,3)	12,4 [3,5; NE]	21	4 (19,0)	NE [NE; NE]	1,41	[0,40; 5,52]	0,5941
Unbekannt	17	4 (23,5)	NE [NE; NE]	13	4 (30,8)	9,6 [0,8; NE]	0,69	[0,16; 2,93]	0,6043
Interaktion p-Wert									0,5763
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 4.2.2.1.1 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelles Interesse
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	8 (21,6)	NE [NE; NE]	39	9 (23,1)	NE [NE; NE]	0,90	[0,33; 2,35]	0,8210
Negativ	8	2 (25,0)	NE [NE; NE]	8	3 (37,5)	9,6 [0,8; NE]	0,53	[0,07; 3,21]	0,4841
Unbekannt	1	1 (100)	2,4 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6127
Histologie									
Endometrioid	33	6 (18,2)	NE [NE; NE]	41	11 (26,8)	NE [NE; NE]	0,68	[0,23; 1,78]	0,4319
Serös	2	1 (50,0)	NE [NE; NE]	2	1 (50,0)	1,4 [NE; NE]	NC	[NC]	NC
Andere	11	4 (36,4)	12,4 [0,7; NE]	6	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	14	3 (21,4)	NE [NE; NE]	12	1 (8,3)	NE [NE; NE]	1,80	[0,23; 36,43]	0,5954
Low grade (G1+G2)	28	7 (25,0)	NE [NE; NE]	33	8 (24,2)	NE [NE; NE]	0,97	[0,34; 2,71]	0,9567
Interaktion p-Wert									0,6156
ECOG Performance Status zu Baseline									
0	23	4 (17,4)	NE [NE; NE]	29	9 (31,0)	NE [NE; NE]	0,74	[0,20; 2,29]	0,6144
1	23	7 (30,4)	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	1,26	[0,35; 5,84]	0,7356
Interaktion p-Wert									0,5571
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	2 (28,6)	NE [NE; NE]	3	1 (33,3)	NE [NE; NE]	NC	[NC]	NC
IV	15	4 (26,7)	NE [NE; NE]	21	5 (23,8)	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 4.2.2.1.2 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Sexuelle Aktivität
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	4 (16,7)	19,7 [2,4; NE]	25	2 (8,0)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	22	5 (22,7)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	3 (21,4)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	32	6 (18,8)	19,7 [7,8; NE]	35	6 (17,1)	NE [NE; NE]	0,64	[0,18; 2,17]	0,4707
Interaktion p-Wert									NC
Alter									
<65	25	8 (32,0)	19,7 [2,7; NE]	25	3 (12,0)	NE [NE; NE]	2,78	[0,80; 12,71]	0,1106
>=65	21	1 (4,8)	NE [NE; NE]	24	3 (12,5)	NE [NE; NE]	0,30	[0,01; 2,38]	0,2658
Interaktion p-Wert									0,0749
Abstammung									
Weiß	29	6 (20,7)	19,7 [7,0; NE]	30	6 (20,0)	NE [NE; NE]	0,72	[0,20; 2,42]	0,5891
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	3 (21,4)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	12	1 (8,3)	NE [NE; NE]	15	3 (20,0)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	4 (23,5)	NE [NE; NE]	21	2 (9,5)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	17	4 (23,5)	NE [NE; NE]	13	1 (7,7)	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 4.2.2.1.2 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Sexuelle Aktivität
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	6 (16,2)	NE [NE; NE]	39	5 (12,8)	NE [NE; NE]	1,19	[0,36; 4,15]	0,7763
Negativ	8	2 (25,0)	NE [NE; NE]	8	1 (12,5)	NE [NE; NE]	1,91	[0,18; 41,07]	0,5873
Unbekannt	1	1 (100)	2,4 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7254
Histologie									
Endometrioid	33	6 (18,2)	NE [NE; NE]	41	6 (14,6)	NE [NE; NE]	1,30	[0,41; 4,17]	0,6494
Serös	2	1 (50,0)	19,7 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	2 (18,2)	NE [NE; NE]	6	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	14	1 (7,1)	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	7 (25,0)	19,7 [7,0; NE]	33	5 (15,2)	NE [NE; NE]	1,44	[0,46; 4,88]	0,5351
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	23	3 (13,0)	NE [NE; NE]	29	5 (17,2)	NE [NE; NE]	NC	[NC]	NC
1	23	6 (26,1)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	3	0	NE [NE; NE]	NC	[NC]	NC
IV	15	4 (26,7)	NE [NE; NE]	21	4 (19,0)	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 4.2.2.1.3 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelles Vergnügen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	2 (8,3)	0,8 [0,7; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	22	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	32	2 (6,3)	1,0 [0,7; NE]	35	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	25	1 (4,0)	1,0 [NE; NE]	25	0	NE [NE; NE]	NC	[NC]	NC
>=65	21	1 (4,8)	0,7 [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	29	1 (3,4)	NE [NE; NE]	30	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	12	1 (8,3)	1,0 [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	0,7 [NE; NE]	21	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	17	0	NE [NE; NE]	13	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 4.2.2.1.3 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelles Vergnügen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	2 (5,4)	1,0 [0,7; NE]	39	0	NE [NE; NE]	NC	[NC]	NC
Negativ	8	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	33	2 (6,1)	0,8 [0,7; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	0	NE [NE; NE]	6	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	14	0	NE [NE; NE]	12	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	1,0 [0,7; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	23	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	2 (8,7)	0,8 [0,7; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	3	0	NE [NE; NE]	NC	[NC]	NC
IV	15	0	NE [NE; NE]	21	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 4.2.2.1.4 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Lymphödem
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	12 (50,0)	2,9 [0,8; 4,4]	25	16 (64,0)	1,5 [0,8; 2,9]	0,84	[0,39; 1,77]	0,6470
Neu diagnostiziert	22	16 (72,7)	2,8 [0,9; 5,2]	24	11 (45,8)	1,8 [0,7; NE]	1,12	[0,52; 2,48]	0,7778
Interaktion p-Wert									0,6017
Region									
Asien	14	12 (85,7)	1,4 [0,6; 3,4]	14	9 (64,3)	3,1 [0,7; NE]	2,80	[1,16; 7,02]	0,0219*
Rest der Welt	32	16 (50,0)	4,2 [1,3; 8,7]	35	18 (51,4)	1,5 [0,8; 2,7]	0,51	[0,25; 1,01]	0,0547
Interaktion p-Wert									0,0034*
Alter									
<65	25	15 (60,0)	2,9 [0,8; 5,2]	25	15 (60,0)	1,5 [0,7; 5,1]	1,00	[0,48; 2,06]	0,9940
>=65	21	13 (61,9)	2,2 [0,9; 4,4]	24	12 (50,0)	2,1 [0,7; 2,9]	0,88	[0,40; 1,98]	0,7621
Interaktion p-Wert									0,8264
Abstammung									
Weiß	29	14 (48,3)	2,9 [1,0; 8,7]	30	17 (56,7)	1,5 [0,8; 2,9]	0,61	[0,29; 1,26]	0,1828
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	0,6 [NE; NE]	NC	[NC]	NC
Asiatisch	14	12 (85,7)	1,4 [0,6; 3,4]	15	9 (60,0)	3,1 [0,7; NE]	2,66	[1,11; 6,65]	0,0287*
Andere	2	2 (100)	10,6 [8,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,0124*
HRR Mutationsstatus									
HRRm	12	6 (50,0)	2,2 [0,7; NE]	15	9 (60,0)	0,8 [0,7; 2,0]	0,46	[0,15; 1,31]	0,1465
Nicht-HRRm	17	12 (70,6)	2,1 [0,6; 8,7]	21	13 (61,9)	2,1 [0,8; 4,2]	0,88	[0,39; 1,96]	0,7463
Unbekannt	17	10 (58,8)	3,4 [0,7; 8,7]	13	5 (38,5)	6,8 [0,6; NE]	1,82	[0,65; 5,87]	0,2618
Interaktion p-Wert									0,1922
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 4.2.2.1.4 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Lymphödem
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	24 (64,9)	2,9 [1,3; 4,2]	39	23 (59,0)	2,0 [0,8; 2,9]	0,96	[0,54; 1,72]	0,8909
Negativ	8	3 (37,5)	NE [NE; NE]	8	4 (50,0)	1,3 [0,7; NE]	0,68	[0,13; 3,10]	0,6141
Unbekannt	1	1 (100)	1,0 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6743
Histologie									
Endometrioid	33	19 (57,6)	2,9 [1,3; 4,1]	41	25 (61,0)	1,5 [0,8; 2,9]	0,96	[0,52; 1,74]	0,8905
Serös	2	2 (100)	1,8 [0,7; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	7 (63,6)	4,7 [0,6;12,5]	6	2 (33,3)	0,7 [0,7; NE]	0,62	[0,15; 4,19]	0,5697
Interaktion p-Wert									0,6231
Histologischer Grad									
High grade (G3)	14	9 (64,3)	3,4 [0,6;11,6]	12	6 (50,0)	2,0 [0,7; 4,2]	0,74	[0,26; 2,25]	0,5811
Low grade (G1+G2)	28	16 (57,1)	2,5 [0,9; 4,4]	33	19 (57,6)	1,5 [0,8; 2,9]	0,86	[0,44; 1,68]	0,6636
Interaktion p-Wert									0,8115
ECOG Performance Status zu Baseline									
0	23	11 (47,8)	1,4 [0,7; 4,2]	29	20 (69,0)	1,3 [0,7; 2,1]	0,85	[0,39; 1,74]	0,6553
1	23	17 (73,9)	3,4 [1,0; 5,2]	20	7 (35,0)	5,1 [1,5; NE]	1,55	[0,67; 4,00]	0,3196
Interaktion p-Wert									0,2957
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	6 (85,7)	1,3 [0,6; NE]	3	1 (33,3)	NE [NE; NE]	4,55	[0,76; 86,50]	0,1032
IV	15	10 (66,7)	3,8 [0,7;11,6]	21	10 (47,6)	1,2 [0,7; NE]	0,78	[0,32; 1,91]	0,5801
Interaktion p-Wert									0,0918

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 4.2.2.1.5 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Urologische Symptome
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	9 (37,5)	2,4 [0,7; NE]	25	12 (48,0)	2,8 [1,5; 9,8]	1,10	[0,45; 2,60]	0,8274
Neu diagnostiziert	22	9 (40,9)	7,8 [1,5; NE]	24	6 (25,0)	NE [NE; NE]	1,21	[0,44; 3,63]	0,7122
Interaktion p-Wert									0,8871
Region									
Asien	14	5 (35,7)	NE [NE; NE]	14	7 (50,0)	9,8 [1,3; NE]	0,83	[0,24; 2,60]	0,7458
Rest der Welt	32	13 (40,6)	2,8 [1,4; NE]	35	11 (31,4)	3,5 [1,5; NE]	1,18	[0,52; 2,70]	0,6891
Interaktion p-Wert									0,6193
Alter									
<65	25	10 (40,0)	2,8 [1,5; NE]	25	8 (32,0)	NE [NE; NE]	1,30	[0,51; 3,41]	0,5760
>=65	21	8 (38,1)	7,8 [0,6; NE]	24	10 (41,7)	6,0 [1,4; 9,8]	0,88	[0,33; 2,25]	0,7917
Interaktion p-Wert									0,5602
Abstammung									
Weiß	29	10 (34,5)	3,6 [0,7; NE]	30	10 (33,3)	3,5 [1,5; NE]	1,10	[0,45; 2,70]	0,8332
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	6,0 [NE; NE]	NC	[NC]	NC
Asiatisch	14	5 (35,7)	NE [NE; NE]	15	7 (46,7)	9,8 [1,3; NE]	0,83	[0,25; 2,61]	0,7508
Andere	2	2 (100)	2,1 [2,0; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,7034
HRR Mutationsstatus									
HRRm	12	2 (16,7)	NE [NE; NE]	15	8 (53,3)	1,5 [0,6; NE]	0,28	[0,04; 1,14]	0,0776
Nicht-HRRm	17	10 (58,8)	2,5 [0,6; NE]	21	8 (38,1)	3,5 [1,4; NE]	1,51	[0,59; 3,97]	0,3844
Unbekannt	17	6 (35,3)	7,8 [0,7; NE]	13	2 (15,4)	NE [NE; NE]	2,66	[0,61; 18,18]	0,2004
Interaktion p-Wert									0,0665
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 4.2.2.1.5 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Urologische Symptome
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	13 (35,1)	7,0 [2,0; NE]	39	16 (41,0)	6,0 [1,5; NE]	0,89	[0,42; 1,86]	0,7588
Negativ	8	4 (50,0)	4,6 [0,6; NE]	8	2 (25,0)	NE [NE; NE]	2,13	[0,41; 15,35]	0,3690
Unbekannt	1	1 (100)	2,4 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3450
Histologie									
Endometrioid	33	12 (36,4)	7,0 [1,4; NE]	41	15 (36,6)	6,0 [2,2; NE]	1,16	[0,53; 2,49]	0,6961
Serös	2	1 (50,0)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	5 (45,5)	2,9 [0,6; NE]	6	3 (50,0)	1,3 [0,7; NE]	0,26	[0,06; 1,32]	0,0976
Interaktion p-Wert									0,0936
Histologischer Grad									
High grade (G3)	14	5 (35,7)	3,6 [0,6; NE]	12	4 (33,3)	2,0 [0,6; NE]	0,66	[0,17; 2,70]	0,5453
Low grade (G1+G2)	28	13 (46,4)	2,4 [0,7; NE]	33	13 (39,4)	6,0 [1,5; NE]	1,29	[0,59; 2,81]	0,5213
Interaktion p-Wert									0,3980
ECOG Performance Status zu Baseline									
0	23	5 (21,7)	NE [NE; NE]	29	14 (48,3)	2,8 [1,5; NE]	0,66	[0,21; 1,72]	0,4060
1	23	13 (56,5)	3,6 [1,5; NE]	20	4 (20,0)	NE [NE; NE]	2,04	[0,72; 7,26]	0,1878
Interaktion p-Wert									0,1258
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	4 (57,1)	1,4 [0,6; NE]	3	0	NE [NE; NE]	NC	[NC]	NC
IV	15	5 (33,3)	NE [NE; NE]	21	6 (28,6)	NE [NE; NE]	0,70	[0,20; 2,37]	0,5570
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 4.2.2.1.6 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Gastrointestinale Symptome
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	9 (37,5)	3,5 [1,4; NE]	25	12 (48,0)	3,4 [1,3; NE]	1,13	[0,46; 2,69]	0,7868
Neu diagnostiziert	22	9 (40,9)	8,7 [1,3; NE]	24	11 (45,8)	2,5 [0,7; NE]	0,43	[0,17; 1,06]	0,0672
Interaktion p-Wert									0,1391
Region									
Asien	14	7 (50,0)	8,7 [0,8; NE]	14	8 (57,1)	2,5 [0,7; NE]	0,93	[0,33; 2,60]	0,8919
Rest der Welt	32	11 (34,4)	5,9 [2,2; NE]	35	15 (42,9)	2,9 [0,8; 8,8]	0,61	[0,27; 1,32]	0,2055
Interaktion p-Wert									0,5116
Alter									
<65	25	10 (40,0)	6,1 [2,1; NE]	25	11 (44,0)	2,9 [0,7; NE]	0,84	[0,35; 1,99]	0,6822
>=65	21	8 (38,1)	5,9 [1,3; NE]	24	12 (50,0)	2,9 [0,8;14,2]	0,60	[0,24; 1,46]	0,2639
Interaktion p-Wert									0,6051
Abstammung									
Weiß	29	10 (34,5)	5,9 [2,1; NE]	30	14 (46,7)	3,4 [1,3;14,2]	0,69	[0,30; 1,55]	0,3721
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	0,6 [NE; NE]	NC	[NC]	NC
Asiatisch	14	7 (50,0)	8,7 [0,8; NE]	15	8 (53,3)	2,5 [0,7; NE]	0,93	[0,32; 2,59]	0,8849
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6595
HRR Mutationsstatus									
HRRm	12	3 (25,0)	NE [NE; NE]	15	8 (53,3)	2,2 [0,6;14,2]	0,63	[0,14; 2,22]	0,4881
Nicht-HRRm	17	10 (58,8)	4,2 [1,3; 8,7]	21	9 (42,9)	8,8 [1,3; NE]	1,23	[0,50; 3,11]	0,6473
Unbekannt	17	5 (29,4)	NE [NE; NE]	13	6 (46,2)	2,0 [0,6; NE]	0,40	[0,11; 1,34]	0,1335
Interaktion p-Wert									0,3154
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 4.2.2.1.6 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Gastrointestinale Symptome
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	13 (35,1)	8,7 [2,2; NE]	39	19 (48,7)	2,9 [2,0;14,2]	0,64	[0,31; 1,29]	0,2141
Negativ	8	5 (62,5)	3,2 [0,8; NE]	8	3 (37,5)	2,0 [0,8; NE]	1,50	[0,36; 7,37]	0,5764
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,2931
Histologie									
Endometrioid	33	13 (39,4)	6,0 [2,1;10,5]	41	20 (48,8)	2,9 [1,3;14,2]	0,79	[0,38; 1,57]	0,4966
Serös	2	1 (50,0)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	4 (36,4)	NE [NE; NE]	6	3 (50,0)	2,0 [0,7; NE]	0,24	[0,05; 1,26]	0,0865
Interaktion p-Wert									0,1817
Histologischer Grad									
High grade (G3)	14	6 (42,9)	8,7 [0,6; NE]	12	5 (41,7)	2,0 [0,6; NE]	0,48	[0,14; 1,70]	0,2427
Low grade (G1+G2)	28	12 (42,9)	4,1 [1,3; NE]	33	17 (51,5)	2,9 [1,3;14,2]	0,82	[0,38; 1,71]	0,6038
Interaktion p-Wert									0,4588
ECOG Performance Status zu Baseline									
0	23	5 (21,7)	8,7 [1,3; NE]	29	18 (62,1)	2,8 [1,4; 4,2]	0,43	[0,14; 1,07]	0,0712
1	23	13 (56,5)	4,2 [2,1; NE]	20	5 (25,0)	NE [NE; NE]	1,43	[0,54; 4,46]	0,4864
Interaktion p-Wert									0,0831
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	3 (42,9)	8,7 [0,6; NE]	3	1 (33,3)	8,8 [NE; NE]	1,37	[0,17; 27,87]	0,7800
IV	15	6 (40,0)	10,5 [0,8; NE]	21	10 (47,6)	1,8 [0,7; NE]	0,29	[0,08; 0,86]	0,0253*
Interaktion p-Wert									0,1992

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 4.2.2.1.7 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Eingeschränkte Körperwahrnehmung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	13 (54,2)	0,8 [0,7; 1,5]	25	14 (56,0)	1,3 [0,7; 2,9]	1,49	[0,69; 3,20]	0,3009
Neu diagnostiziert	22	15 (68,2)	1,3 [0,7; 2,8]	24	14 (58,3)	0,7 [0,7; 1,4]	0,63	[0,30; 1,33]	0,2188
Interaktion p-Wert									0,1108
Region									
Asien	14	11 (78,6)	0,8 [0,6; 1,4]	14	10 (71,4)	0,7 [0,7; NE]	1,59	[0,66; 3,86]	0,2931
Rest der Welt	32	17 (53,1)	1,4 [0,8; 3,5]	35	18 (51,4)	1,3 [0,7; 2,2]	0,81	[0,41; 1,59]	0,5406
Interaktion p-Wert									0,2303
Alter									
<65	25	15 (60,0)	1,4 [0,8; 2,1]	25	15 (60,0)	0,7 [0,7; 2,2]	0,83	[0,40; 1,71]	0,6078
>=65	21	13 (61,9)	0,8 [0,6; 1,4]	24	13 (54,2)	1,4 [0,7; 2,2]	1,27	[0,58; 2,78]	0,5381
Interaktion p-Wert									0,4240
Abstammung									
Weiß	29	15 (51,7)	1,2 [0,7; 2,1]	30	18 (60,0)	0,8 [0,7; 2,2]	0,86	[0,42; 1,71]	0,6575
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	11 (78,6)	0,8 [0,6; 1,4]	15	10 (66,7)	0,7 [0,7; NE]	1,55	[0,65; 3,76]	0,3196
Andere	2	2 (100)	3,8 [3,5; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,2929
HRR Mutationsstatus									
HRRm	12	6 (50,0)	0,8 [0,7; NE]	15	9 (60,0)	0,8 [0,6; 2,1]	0,88	[0,30; 2,46]	0,8150
Nicht-HRRm	17	12 (70,6)	1,4 [0,6; 4,1]	21	14 (66,7)	0,8 [0,7; 2,2]	0,66	[0,29; 1,45]	0,2951
Unbekannt	17	10 (58,8)	0,9 [0,7; 1,5]	13	5 (38,5)	NE [NE; NE]	2,40	[0,84; 7,77]	0,1022
Interaktion p-Wert									0,1537
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 4.2.2.1.7 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Eingeschränkte Körperwahrnehmung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	21 (56,8)	1,3 [0,8; 2,1]	39	24 (61,5)	1,3 [0,7; 2,2]	0,94	[0,52; 1,69]	0,8323
Negativ	8	6 (75,0)	0,8 [0,6; NE]	8	4 (50,0)	0,7 [0,6; NE]	1,09	[0,31; 4,28]	0,8905
Unbekannt	1	1 (100)	1,0 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8304
Histologie									
Endometrioid	33	20 (60,6)	0,8 [0,7; 1,4]	41	26 (63,4)	0,8 [0,7; 2,1]	1,01	[0,56; 1,80]	0,9805
Serös	2	2 (100)	1,4 [0,7; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	6 (54,5)	2,1 [0,6; NE]	6	2 (33,3)	1,3 [0,7; NE]	0,98	[0,23; 6,72]	0,9831
Interaktion p-Wert									0,9775
Histologischer Grad									
High grade (G3)	14	10 (71,4)	0,9 [0,6; 1,5]	12	5 (41,7)	1,3 [0,6; NE]	1,50	[0,53; 4,83]	0,4494
Low grade (G1+G2)	28	16 (57,1)	1,2 [0,7; 2,1]	33	21 (63,6)	0,8 [0,7; 1,5]	0,80	[0,41; 1,53]	0,4966
Interaktion p-Wert									0,3157
ECOG Performance Status zu Baseline									
0	23	11 (47,8)	0,8 [0,6; 2,8]	29	21 (72,4)	0,7 [0,7; 1,3]	0,94	[0,44; 1,91]	0,8618
1	23	17 (73,9)	1,3 [0,8; 1,5]	20	7 (35,0)	2,2 [0,7; NE]	1,60	[0,69; 4,15]	0,2810
Interaktion p-Wert									0,3516
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	6 (85,7)	0,8 [0,6; NE]	3	2 (66,7)	0,7 [NE; NE]	0,59	[0,13; 4,16]	0,5483
IV	15	9 (60,0)	1,4 [0,7; NE]	21	12 (57,1)	0,7 [0,7; 2,2]	0,50	[0,20; 1,21]	0,1250
Interaktion p-Wert									0,8662

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 4.2.2.1.8 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelle/vaginale Probleme
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	2 (8,3)	0,8 [0,7; NE]	25	1 (4,0)	0,7 [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	22	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	1 (7,1)	0,7 [NE; NE]	NC	[NC]	NC
Rest der Welt	32	2 (6,3)	1,0 [0,7; NE]	35	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	25	1 (4,0)	1,0 [NE; NE]	25	1 (4,0)	0,7 [NE; NE]	NC	[NC]	NC
>=65	21	1 (4,8)	0,7 [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	29	1 (3,4)	NE [NE; NE]	30	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	1 (6,7)	0,7 [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	12	1 (8,3)	1,0 [NE; NE]	15	1 (6,7)	0,7 [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	0,7 [NE; NE]	21	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	17	0	NE [NE; NE]	13	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 4.2.2.1.8 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24
Sexuelle/vaginale Probleme
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	2 (5,4)	1,0 [0,7; NE]	39	1 (2,6)	0,7 [NE; NE]	NC	[NC]	NC
Negativ	8	0	NE [NE; NE]	8	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	33	2 (6,1)	0,8 [0,7; NE]	41	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	0	NE [NE; NE]	6	1 (16,7)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	14	0	NE [NE; NE]	12	1 (8,3)	0,7 [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	1,0 [0,7; NE]	33	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	23	0	NE [NE; NE]	29	1 (3,4)	0,7 [NE; NE]	NC	[NC]	NC
1	23	2 (8,7)	0,8 [0,7; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	3	0	NE [NE; NE]	NC	[NC]	NC
IV	15	0	NE [NE; NE]	21	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 4.2.2.1.9 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Rücken- und Beckenschmerzen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	8 (33,3)	18,9 [0,8; NE]	25	11 (44,0)	6,1 [1,5;12,4]	0,90	[0,35; 2,22]	0,8169
Neu diagnostiziert	22	9 (40,9)	9,8 [2,2; NE]	24	10 (41,7)	2,2 [0,8; NE]	0,58	[0,23; 1,44]	0,2342
Interaktion p-Wert									0,5000
Region									
Asien	14	7 (50,0)	9,8 [0,7; NE]	14	7 (50,0)	6,1 [1,3; NE]	1,28	[0,43; 3,76]	0,6514
Rest der Welt	32	10 (31,3)	18,9 [2,1; NE]	35	14 (40,0)	2,9 [0,8; NE]	0,48	[0,20; 1,09]	0,0805
Interaktion p-Wert									0,1583
Alter									
<65	25	10 (40,0)	9,8 [2,1; NE]	25	10 (40,0)	2,9 [2,0; NE]	0,93	[0,38; 2,26]	0,8646
>=65	21	7 (33,3)	10,5 [0,7; NE]	24	11 (45,8)	6,1 [0,8; NE]	0,53	[0,19; 1,35]	0,1846
Interaktion p-Wert									0,3961
Abstammung									
Weiß	29	8 (27,6)	18,9 [2,1; NE]	30	13 (43,3)	2,2 [0,8; NE]	0,45	[0,18; 1,10]	0,0817
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	6,9 [NE; NE]	NC	[NC]	NC
Asiatisch	14	7 (50,0)	9,8 [0,7; NE]	15	7 (46,7)	6,1 [1,3; NE]	1,30	[0,44; 3,82]	0,6321
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,1437
HRR Mutationsstatus									
HRRm	12	6 (50,0)	1,6 [0,7; 2,8]	15	8 (53,3)	2,0 [0,7;12,4]	1,60	[0,52; 4,71]	0,4010
Nicht-HRRm	17	8 (47,1)	10,5 [1,3; NE]	21	8 (38,1)	2,9 [0,8; NE]	0,83	[0,30; 2,30]	0,7218
Unbekannt	17	3 (17,6)	NE [NE; NE]	13	5 (38,5)	6,9 [0,7; NE]	0,38	[0,08; 1,57]	0,1805
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 4.2.2.1.9 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Rücken- und Beckenschmerzen
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	16 (43,2)	7,1 [2,1; NE]	39	19 (48,7)	2,9 [1,5;12,4]	0,77	[0,39; 1,52]	0,4512
Negativ	8	1 (12,5)	NE [NE; NE]	8	2 (25,0)	NE [NE; NE]	0,43	[0,02; 4,60]	0,4824
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6461
Histologie									
Endometrioid	33	11 (33,3)	10,5 [2,2; NE]	41	18 (43,9)	2,9 [2,1; NE]	0,76	[0,35; 1,60]	0,4805
Serös	2	2 (100)	10,5 [2,1; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	4 (36,4)	9,8 [0,6; NE]	6	3 (50,0)	0,7 [0,7; NE]	0,09	[0,02; 0,50]	0,0081*
Interaktion p-Wert									0,0251*
Histologischer Grad									
High grade (G3)	14	6 (42,9)	4,1 [0,6; NE]	12	4 (33,3)	2,0 [0,7; NE]	0,66	[0,18; 2,63]	0,5344
Low grade (G1+G2)	28	8 (28,6)	18,9 [1,6; NE]	33	16 (48,5)	2,9 [1,4;12,4]	0,43	[0,17; 1,02]	0,0549
Interaktion p-Wert									0,5909
ECOG Performance Status zu Baseline									
0	23	8 (34,8)	6,6 [0,6; NE]	29	16 (55,2)	2,2 [1,3; 6,9]	0,76	[0,30; 1,76]	0,5302
1	23	9 (39,1)	9,8 [3,4; NE]	20	5 (25,0)	NE [NE; NE]	0,99	[0,34; 3,23]	0,9799
Interaktion p-Wert									0,7155
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	3 (42,9)	10,5 [0,6; NE]	3	0	NE [NE; NE]	NC	[NC]	NC
IV	15	6 (40,0)	9,8 [2,1; NE]	21	10 (47,6)	2,1 [0,8; NE]	0,40	[0,14; 1,10]	0,0759
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 4.2.2.1.10 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	12 (50,0)	1,4 [0,7; 3,5]	25	17 (68,0)	2,0 [0,8; 2,2]	0,92	[0,43; 1,91]	0,8148
Neu diagnostiziert	22	16 (72,7)	1,7 [0,7; 3,4]	24	16 (66,7)	1,1 [0,7; 1,5]	0,48	[0,23; 0,997]	0,0491*
Interaktion p-Wert									0,2255
Region									
Asien	14	9 (64,3)	0,7 [0,6; 5,9]	14	13 (92,9)	0,8 [0,7; 1,4]	0,44	[0,17; 1,04]	0,0606
Rest der Welt	32	19 (59,4)	1,7 [1,3; 3,4]	35	20 (57,1)	2,0 [0,8; 2,2]	0,87	[0,45; 1,64]	0,6584
Interaktion p-Wert									0,2104
Alter									
<65	25	14 (56,0)	1,6 [0,7; 4,2]	25	17 (68,0)	1,4 [0,7; 2,1]	0,57	[0,27; 1,17]	0,1263
>=65	21	14 (66,7)	1,4 [0,6; 3,4]	24	16 (66,7)	1,4 [0,8; 2,2]	0,85	[0,41; 1,75]	0,6590
Interaktion p-Wert									0,4382
Abstammung									
Weiß	29	17 (58,6)	1,6 [0,9; 3,4]	30	20 (66,7)	2,0 [0,8; 2,2]	0,80	[0,41; 1,55]	0,5074
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	9 (64,3)	0,7 [0,6; 5,9]	15	13 (86,7)	0,8 [0,7; 1,4]	0,43	[0,17; 1,02]	0,0565
Andere	2	2 (100)	2,1 [1,4; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,2578
HRR Mutationsstatus									
HRRm	12	6 (50,0)	1,3 [0,7; NE]	15	9 (60,0)	0,8 [0,6; 2,1]	0,53	[0,17; 1,48]	0,2227
Nicht-HRRm	17	13 (76,5)	1,9 [0,6; 3,5]	21	17 (81,0)	1,5 [0,8; 2,2]	0,73	[0,34; 1,52]	0,3997
Unbekannt	17	9 (52,9)	1,9 [0,7; NE]	13	7 (53,8)	1,4 [0,6; NE]	0,80	[0,29; 2,28]	0,6658
Interaktion p-Wert									0,8314
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 4.2.2.1.10 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Kribbeln/Taubheitsgefühl
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	22 (59,5)	1,4 [0,7; 2,9]	39	28 (71,8)	1,4 [0,8; 2,1]	0,73	[0,41; 1,29]	0,2783
Negativ	8	5 (62,5)	2,9 [0,6; NE]	8	5 (62,5)	1,4 [0,7; NE]	0,45	[0,12; 1,65]	0,2220
Unbekannt	1	1 (100)	1,7 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4981
Histologie									
Endometrioid	33	19 (57,6)	1,7 [0,8; 3,4]	41	30 (73,2)	1,4 [0,8; 2,1]	0,67	[0,37; 1,20]	0,1799
Serös	2	2 (100)	1,1 [0,7; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	7 (63,6)	1,9 [0,6; NE]	6	3 (50,0)	0,7 [0,7; NE]	0,17	[0,04; 0,84]	0,0323*
Interaktion p-Wert									0,1005
Histologischer Grad									
High grade (G3)	14	8 (57,1)	1,9 [0,6; 5,9]	12	8 (66,7)	1,0 [0,6; 1,5]	0,39	[0,14; 1,08]	0,0683
Low grade (G1+G2)	28	17 (60,7)	1,6 [0,8; 2,9]	33	22 (66,7)	2,0 [0,8; 2,1]	0,75	[0,38; 1,42]	0,3712
Interaktion p-Wert									0,2804
ECOG Performance Status zu Baseline									
0	23	11 (47,8)	1,4 [0,6; 4,2]	29	21 (72,4)	1,4 [0,8; 2,1]	0,78	[0,35; 1,63]	0,5180
1	23	17 (73,9)	2,0 [0,8; 3,4]	20	12 (60,0)	0,8 [0,7; 2,1]	0,60	[0,29; 1,30]	0,1887
Interaktion p-Wert									0,6321
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	5 (71,4)	1,4 [0,6; NE]	3	2 (66,7)	2,8 [1,4; NE]	1,18	[0,25; 8,31]	0,8407
IV	15	11 (73,3)	2,2 [0,7; 4,2]	21	14 (66,7)	0,8 [0,7; 1,5]	0,35	[0,14; 0,85]	0,0206*
Interaktion p-Wert									0,1895

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 4.2.2.1.11 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Muskulärer Schmerz
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	11 (45,8)	1,4 [0,8; 4,1]	25	16 (64,0)	1,3 [0,7; 2,7]	0,74	[0,33; 1,58]	0,4364
Neu diagnostiziert	22	12 (54,5)	2,1 [0,7; NE]	24	13 (54,2)	0,8 [0,7; 3,5]	0,64	[0,28; 1,42]	0,2695
Interaktion p-Wert									0,7988
Region									
Asien	14	9 (64,3)	1,4 [0,6; NE]	14	11 (78,6)	2,4 [0,7; 6,8]	1,19	[0,48; 2,87]	0,7057
Rest der Welt	32	14 (43,8)	2,1 [1,0;12,4]	35	18 (51,4)	0,8 [0,7; 1,5]	0,46	[0,22; 0,94]	0,0338*
Interaktion p-Wert									0,1075
Alter									
<65	25	12 (48,0)	2,1 [1,0; NE]	25	14 (56,0)	1,5 [0,7; 3,4]	0,86	[0,39; 1,86]	0,6948
>=65	21	11 (52,4)	1,6 [0,6;12,4]	24	15 (62,5)	0,8 [0,7; 2,2]	0,51	[0,23; 1,12]	0,0953
Interaktion p-Wert									0,3625
Abstammung									
Weiß	29	12 (41,4)	2,1 [1,0;12,4]	30	17 (56,7)	0,8 [0,7; 1,5]	0,49	[0,23; 1,03]	0,0604
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	0,6 [NE; NE]	NC	[NC]	NC
Asiatisch	14	9 (64,3)	1,4 [0,6; NE]	15	11 (73,3)	2,4 [0,7; 6,8]	1,18	[0,47; 2,86]	0,7128
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,1388
HRR Mutationsstatus									
HRRm	12	5 (41,7)	2,1 [0,7; NE]	15	8 (53,3)	0,8 [0,7; 2,2]	0,56	[0,17; 1,69]	0,3043
Nicht-HRRm	17	12 (70,6)	1,4 [0,6; 3,4]	21	14 (66,7)	0,8 [0,7; 2,2]	0,83	[0,37; 1,81]	0,6339
Unbekannt	17	6 (35,3)	NE [NE; NE]	13	7 (53,8)	2,9 [0,6; NE]	0,63	[0,20; 1,90]	0,4066
Interaktion p-Wert									0,8330
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 4.2.2.1.11 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Muskulärer Schmerz
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	18 (48,6)	2,1 [0,9; 4,1]	39	24 (61,5)	1,3 [0,8; 2,2]	0,69	[0,37; 1,27]	0,2355
Negativ	8	4 (50,0)	6,9 [0,6; NE]	8	5 (62,5)	0,8 [0,6; NE]	0,51	[0,13; 1,94]	0,3163
Unbekannt	1	1 (100)	1,0 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6846
Histologie									
Endometrioid	33	14 (42,4)	3,4 [1,0; NE]	41	26 (63,4)	0,8 [0,8; 2,2]	0,50	[0,25; 0,94]	0,0327*
Serös	2	2 (100)	1,8 [1,4; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	7 (63,6)	0,8 [0,6; 2,1]	6	3 (50,0)	1,3 [0,7; NE]	1,00	[0,27; 4,67]	0,9986
Interaktion p-Wert									0,3506
Histologischer Grad									
High grade (G3)	14	7 (50,0)	2,0 [0,6; NE]	12	5 (41,7)	2,7 [0,7; NE]	1,01	[0,32; 3,44]	0,9876
Low grade (G1+G2)	28	13 (46,4)	1,6 [0,8; NE]	33	21 (63,6)	0,8 [0,7; 1,5]	0,49	[0,24; 0,98]	0,0437*
Interaktion p-Wert									0,2932
ECOG Performance Status zu Baseline									
0	23	7 (30,4)	2,1 [0,6; NE]	29	20 (69,0)	0,8 [0,7; 2,2]	0,43	[0,17; 0,97]	0,0412*
1	23	16 (69,6)	1,4 [0,8; 4,1]	20	9 (45,0)	2,2 [0,8; 3,4]	1,09	[0,49; 2,58]	0,8372
Interaktion p-Wert									0,1118
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	2 (28,6)	NE [NE; NE]	3	1 (33,3)	NE [NE; NE]	0,87	[0,08; 18,71]	0,9084
IV	15	10 (66,7)	1,9 [0,6;12,4]	21	12 (57,1)	0,8 [0,7; 3,4]	0,71	[0,29; 1,68]	0,4317
Interaktion p-Wert									0,8747

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 4.2.2.1.12 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Haarausfall
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	15 (62,5)	0,8 [0,7; 1,0]	25	18 (72,0)	0,7 [0,7; 0,8]	1,14	[0,56; 2,29]	0,7096
Neu diagnostiziert	22	18 (81,8)	0,7 [0,6; 0,8]	24	16 (66,7)	0,7 [0,7; 0,8]	0,70	[0,35; 1,42]	0,3178
Interaktion p-Wert									0,3343
Region									
Asien	14	12 (85,7)	0,7 [0,6; 0,8]	14	13 (92,9)	0,7 [0,7; 0,7]	0,93	[0,42; 2,05]	0,8495
Rest der Welt	32	21 (65,6)	0,8 [0,7; 0,9]	35	21 (60,0)	0,8 [0,7; 0,8]	1,01	[0,55; 1,87]	0,9769
Interaktion p-Wert									0,8665
Alter									
<65	25	18 (72,0)	0,7 [0,7; 1,0]	25	19 (76,0)	0,7 [0,7; 0,8]	0,72	[0,37; 1,40]	0,3297
>=65	21	15 (71,4)	0,7 [0,6; 0,8]	24	15 (62,5)	0,8 [0,7; 0,8]	1,34	[0,65; 2,76]	0,4273
Interaktion p-Wert									0,2135
Abstammung									
Weiß	29	18 (62,1)	0,8 [0,7; 0,9]	30	21 (70,0)	0,7 [0,7; 0,8]	0,90	[0,47; 1,70]	0,7441
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	12 (85,7)	0,7 [0,6; 0,8]	15	13 (86,7)	0,7 [0,7; 0,7]	0,93	[0,42; 2,05]	0,8492
Andere	2	2 (100)	1,0 [0,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,9542
HRR Mutationsstatus									
HRRm	12	7 (58,3)	0,7 [0,7; 0,8]	15	9 (60,0)	0,7 [0,6; 0,8]	1,18	[0,42; 3,20]	0,7502
Nicht-HRRm	17	14 (82,4)	0,7 [0,6; 0,9]	21	17 (81,0)	0,7 [0,7; 0,8]	0,78	[0,37; 1,60]	0,4891
Unbekannt	17	12 (70,6)	0,8 [0,6; 1,4]	13	8 (61,5)	0,7 [0,6; 1,3]	1,34	[0,55; 3,45]	0,5205
Interaktion p-Wert									0,6116
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 4.2.2.1.12 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Haarausfall
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	26 (70,3)	0,7 [0,7; 0,8]	39	28 (71,8)	0,7 [0,7; 0,8]	1,31	[0,76; 2,25]	0,3343
Negativ	8	6 (75,0)	1,1 [0,6; NE]	8	5 (62,5)	0,7 [0,6; NE]	0,30	[0,09; 1,09]	0,0659
Unbekannt	1	1 (100)	1,0 [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0396*
Histologie									
Endometrioid	33	23 (69,7)	0,8 [0,7; 0,8]	41	31 (75,6)	0,7 [0,7; 0,8]	0,81	[0,47; 1,40]	0,4559
Serös	2	2 (100)	1,1 [0,7; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	8 (72,7)	0,7 [0,6; 0,9]	6	3 (50,0)	0,7 [0,7; NE]	1,31	[0,38; 5,97]	0,6884
Interaktion p-Wert									0,5083
Histologischer Grad									
High grade (G3)	14	10 (71,4)	0,8 [0,6; 0,9]	12	7 (58,3)	0,7 [0,6; NE]	0,86	[0,33; 2,38]	0,7631
Low grade (G1+G2)	28	20 (71,4)	0,7 [0,7; 1,0]	33	24 (72,7)	0,7 [0,7; 0,8]	0,85	[0,46; 1,56]	0,6075
Interaktion p-Wert									0,9898
ECOG Performance Status zu Baseline									
0	23	12 (52,2)	0,7 [0,6; 1,4]	29	22 (75,9)	0,7 [0,7; 0,8]	0,97	[0,46; 1,94]	0,9325
1	23	21 (91,3)	0,8 [0,7; 0,9]	20	12 (60,0)	0,8 [0,7; 0,8]	1,10	[0,55; 2,31]	0,7890
Interaktion p-Wert									0,8026
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	6 (85,7)	0,7 [0,6; NE]	3	2 (66,7)	0,7 [NE; NE]	0,51	[0,11; 3,66]	0,4548
IV	15	12 (80,0)	0,7 [0,6; 0,9]	21	14 (66,7)	0,7 [0,7; 0,8]	0,72	[0,31; 1,64]	0,4404
Interaktion p-Wert									0,7118

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 4.2.2.1.13 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Geschmacksveränderung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	10 (41,7)	2,1 [0,8; NE]	25	16 (64,0)	2,1 [0,8;10,5]	0,88	[0,39; 1,92]	0,7529
Neu diagnostiziert	22	14 (63,6)	1,7 [0,7; 2,9]	24	15 (62,5)	1,4 [0,8; 2,1]	0,72	[0,34; 1,52]	0,3897
Interaktion p-Wert									0,7219
Region									
Asien	14	8 (57,1)	2,4 [0,6; NE]	14	12 (85,7)	2,0 [1,3;10,5]	0,75	[0,29; 1,82]	0,5258
Rest der Welt	32	16 (50,0)	1,6 [0,8; 3,0]	35	19 (54,3)	1,5 [0,8; 2,8]	0,89	[0,45; 1,74]	0,7428
Interaktion p-Wert									0,7565
Alter									
<65	25	13 (52,0)	1,9 [0,7; 2,8]	25	18 (72,0)	2,0 [0,8; 3,5]	0,87	[0,42; 1,76]	0,6933
>=65	21	11 (52,4)	2,1 [0,7; 7,9]	24	13 (54,2)	1,5 [0,8; 2,8]	0,82	[0,36; 1,84]	0,6321
Interaktion p-Wert									0,9229
Abstammung									
Weiß	29	13 (44,8)	1,9 [0,8; 7,9]	30	19 (63,3)	1,4 [0,8; 2,8]	0,72	[0,35; 1,46]	0,3688
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	8 (57,1)	2,4 [0,6; NE]	15	12 (80,0)	2,0 [1,3;10,5]	0,75	[0,29; 1,82]	0,5273
Andere	2	2 (100)	1,0 [0,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,9516
HRR Mutationsstatus									
HRRm	12	5 (41,7)	2,1 [0,7; NE]	15	8 (53,3)	1,5 [0,7; 2,8]	0,62	[0,19; 1,87]	0,3986
Nicht-HRRm	17	11 (64,7)	1,4 [0,6; 7,9]	21	15 (71,4)	1,4 [0,8; 2,8]	0,99	[0,44; 2,14]	0,9759
Unbekannt	17	8 (47,1)	2,4 [0,7; NE]	13	8 (61,5)	2,8 [0,7; NE]	0,89	[0,33; 2,43]	0,8200
Interaktion p-Wert									0,7952
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 4.2.2.1.13 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Geschmacksveränderung
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	20 (54,1)	1,8 [0,8; 2,8]	39	25 (64,1)	2,0 [1,3; 2,8]	1,05	[0,57; 1,89]	0,8761
Negativ	8	3 (37,5)	2,9 [0,7; NE]	8	5 (62,5)	0,8 [0,6; NE]	0,27	[0,05; 1,10]	0,0673
Unbekannt	1	1 (100)	1,7 [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,0807
Histologie									
Endometrioid	33	17 (51,5)	2,0 [1,4; 2,9]	41	28 (68,3)	2,0 [0,8; 2,8]	0,84	[0,45; 1,52]	0,5709
Serös	2	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	7 (63,6)	0,7 [0,6; 3,0]	6	3 (50,0)	1,4 [1,3; NE]	0,81	[0,22; 3,84]	0,7684
Interaktion p-Wert									0,9617
Histologischer Grad									
High grade (G3)	14	8 (57,1)	1,7 [0,6; 3,0]	12	8 (66,7)	1,4 [0,8; 2,0]	0,68	[0,25; 1,88]	0,4543
Low grade (G1+G2)	28	15 (53,6)	1,7 [0,8; 2,9]	33	20 (60,6)	1,5 [0,8; 3,5]	0,98	[0,49; 1,90]	0,9453
Interaktion p-Wert									0,5615
ECOG Performance Status zu Baseline									
0	23	9 (39,1)	1,4 [0,6; NE]	29	19 (65,5)	2,0 [1,3; 2,8]	1,06	[0,45; 2,28]	0,8942
1	23	15 (65,2)	2,1 [0,9; 7,9]	20	12 (60,0)	1,7 [0,8; 3,5]	0,72	[0,34; 1,57]	0,3981
Interaktion p-Wert									0,4974
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	5 (71,4)	1,1 [0,6; NE]	3	1 (33,3)	NE [NE; NE]	3,70	[0,59; 71,02]	0,1757
IV	15	9 (60,0)	2,7 [0,6; NE]	21	14 (66,7)	1,4 [0,7; 2,1]	0,51	[0,21; 1,19]	0,1200
Interaktion p-Wert									0,0584

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 4.2.3.1.1 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EQ-5D-5L Visuelle Analogskala
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	10 (41,7)	1,8 [0,7;11,4]	25	9 (36,0)	7,0 [1,4; NE]	1,93	[0,78; 4,88]	0,1540
Neu diagnostiziert	22	10 (45,5)	3,5 [1,3; NE]	24	9 (37,5)	3,5 [1,4; NE]	0,89	[0,35; 2,25]	0,7946
Interaktion p-Wert									0,2336
Region									
Asien	14	6 (42,9)	NE [NE; NE]	14	9 (64,3)	5,2 [0,7; NE]	0,74	[0,25; 2,04]	0,5572
Rest der Welt	32	14 (43,8)	2,8 [1,0;11,4]	35	9 (25,7)	6,0 [1,4; NE]	1,89	[0,83; 4,56]	0,1320
Interaktion p-Wert									0,1593
Alter									
<65	25	10 (40,0)	3,5 [1,3; NE]	25	8 (32,0)	7,8 [1,4; NE]	1,39	[0,55; 3,65]	0,4884
>=65	21	10 (47,6)	1,8 [0,7; NE]	24	10 (41,7)	3,5 [1,3; 7,0]	1,24	[0,51; 3,05]	0,6287
Interaktion p-Wert									0,8665
Abstammung									
Weiß	29	11 (37,9)	3,5 [1,3;14,5]	30	8 (26,7)	6,0 [1,4; NE]	1,72	[0,69; 4,46]	0,2442
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	1,3 [NE; NE]	NC	[NC]	NC
Asiatisch	14	6 (42,9)	NE [NE; NE]	15	9 (60,0)	5,2 [0,7; NE]	0,73	[0,24; 2,02]	0,5448
Andere	2	2 (100)	1,0 [0,7; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,2187
HRR Mutationsstatus									
HRRm	12	7 (58,3)	1,4 [0,7; 2,8]	15	9 (60,0)	2,0 [0,6; 6,0]	1,47	[0,52; 3,97]	0,4566
Nicht-HRRm	17	9 (52,9)	1,4 [0,7;14,5]	21	5 (23,8)	NE [NE; NE]	2,50	[0,86; 8,19]	0,0938
Unbekannt	17	4 (23,5)	NE [NE; NE]	13	4 (30,8)	7,8 [0,6; NE]	0,71	[0,17; 3,02]	0,6337
Interaktion p-Wert									0,3780
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 4.2.3.1.1 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - EQ-5D-5L Visuelle Analogskala
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	37	16 (43,2)	3,4 [1,3;14,5]	39	15 (38,5)	6,0 [1,4; NE]	1,25	[0,61; 2,57]	0,5436
Negativ	8	4 (50,0)	2,5 [0,6; NE]	8	3 (37,5)	7,8 [1,3; NE]	1,88	[0,41; 9,58]	0,4095
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,6317
Histologie									
Endometrioid	33	15 (45,5)	3,4 [1,0;11,4]	41	16 (39,0)	6,0 [1,4; NE]	1,56	[0,76; 3,17]	0,2212
Serös	2	1 (50,0)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	4 (36,4)	NE [NE; NE]	6	2 (33,3)	2,0 [0,7; NE]	0,54	[0,10; 3,98]	0,5041
Interaktion p-Wert									0,2917
Histologischer Grad									
High grade (G3)	14	6 (42,9)	2,4 [0,6; NE]	12	3 (25,0)	NE [NE; NE]	1,43	[0,37; 6,80]	0,6094
Low grade (G1+G2)	28	12 (42,9)	3,5 [1,0;14,5]	33	14 (42,4)	6,0 [1,4; NE]	1,16	[0,52; 2,53]	0,7122
Interaktion p-Wert									0,7954
ECOG Performance Status zu Baseline									
0	23	8 (34,8)	3,1 [0,7; NE]	29	15 (51,7)	3,5 [1,4; 7,8]	1,02	[0,41; 2,37]	0,9649
1	23	12 (52,2)	4,1 [1,0;14,5]	20	3 (15,0)	NE [NE; NE]	2,83	[0,90; 12,43]	0,0780
Interaktion p-Wert									0,1727
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	4 (57,1)	2,4 [0,6; NE]	3	0	NE [NE; NE]	NC	[NC]	NC
IV	15	6 (40,0)	14,5 [1,4; NE]	21	9 (42,9)	3,4 [0,7; NE]	0,49	[0,15; 1,44]	0,1955
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 4.2.4.1.1 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - PGIS
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	8 (33,3)	1,7 [0,7; NE]	25	11 (44,0)	4,2 [1,4; NE]	1,40	[0,54; 3,47]	0,4717
Neu diagnostiziert	22	12 (54,5)	1,4 [0,7;15,2]	24	13 (54,2)	1,4 [0,7; 2,2]	0,78	[0,34; 1,73]	0,5326
Interaktion p-Wert									0,3427
Region									
Asien	14	9 (64,3)	1,4 [0,6; NE]	14	9 (64,3)	3,9 [1,3; NE]	1,45	[0,56; 3,71]	0,4376
Rest der Welt	32	11 (34,4)	1,0 [0,7; NE]	35	15 (42,9)	1,4 [0,8; 4,2]	0,85	[0,38; 1,84]	0,6755
Interaktion p-Wert									0,3868
Alter									
<65	25	8 (32,0)	2,1 [0,8; NE]	25	11 (44,0)	2,2 [1,4; NE]	0,79	[0,30; 1,95]	0,6078
>=65	21	12 (57,1)	0,8 [0,6; 2,1]	24	13 (54,2)	1,5 [0,7; 6,0]	1,49	[0,67; 3,31]	0,3235
Interaktion p-Wert									0,2979
Abstammung									
Weiß	29	9 (31,0)	2,1 [0,7; NE]	30	14 (46,7)	1,4 [0,8; 4,2]	0,71	[0,29; 1,63]	0,4209
Schwarz/Afroamerikanisch	0	0	NE	2	1 (50,0)	6,0 [NE; NE]	NC	[NC]	NC
Asiatisch	14	9 (64,3)	1,4 [0,6; NE]	15	9 (60,0)	3,9 [1,3; NE]	1,45	[0,56; 3,72]	0,4368
Andere	2	1 (50,0)	0,7 [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,2643
HRR Mutationsstatus									
HRRm	12	5 (41,7)	1,0 [0,7; NE]	15	9 (60,0)	1,4 [0,7; 2,7]	0,77	[0,24; 2,23]	0,6340
Nicht-HRRm	17	9 (52,9)	1,1 [0,6; NE]	21	10 (47,6)	2,2 [0,8;10,6]	1,27	[0,50; 3,15]	0,6107
Unbekannt	17	6 (35,3)	1,8 [0,6; NE]	13	5 (38,5)	9,7 [0,8; NE]	1,29	[0,39; 4,50]	0,6747
Interaktion p-Wert									0,7472
PD-L1 Expression									
Positiv	37	16 (43,2)	1,4 [0,8; 2,1]	39	20 (51,3)	2,2 [1,4; 6,0]	1,10	[0,56; 2,12]	0,7833

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 4.2.4.1.1 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - PGIS
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	8	4 (50,0)	0,8 [0,6; NE]	8	4 (50,0)	1,4 [0,7; NE]	1,14	[0,27; 4,84]	0,8535
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9615
Histologie									
Endometrioid	33	16 (48,5)	1,2 [0,7; 2,1]	41	22 (53,7)	1,4 [1,3; 5,1]	1,39	[0,72; 2,63]	0,3226
Serös	2	1 (50,0)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	3 (27,3)	NE [NE; NE]	6	2 (33,3)	2,7 [0,7; NE]	0,53	[0,09; 4,05]	0,4984
Interaktion p-Wert									0,3389
Histologischer Grad									
High grade (G3)	14	9 (64,3)	1,4 [0,6; 2,1]	12	3 (25,0)	NE [NE; NE]	2,89	[0,85; 13,14]	0,0906
Low grade (G1+G2)	28	11 (39,3)	1,0 [0,7; NE]	33	19 (57,6)	1,4 [0,8; 4,2]	0,85	[0,39; 1,75]	0,6598
Interaktion p-Wert									0,0949
ECOG Performance Status zu Baseline									
0	23	9 (39,1)	1,4 [0,6; NE]	29	18 (62,1)	1,4 [0,8; 2,7]	0,98	[0,41; 2,15]	0,9524
1	23	11 (47,8)	1,5 [0,8; NE]	20	6 (30,0)	13,3 [0,8; NE]	1,59	[0,60; 4,62]	0,3522
Interaktion p-Wert									0,4522
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	6 (85,7)	0,7 [0,6; NE]	3	1 (33,3)	10,6 [NE; NE]	9,81	[1,54;192,19]	0,0130*
IV	15	6 (40,0)	15,2 [0,8; NE]	21	12 (57,1)	1,4 [0,7; 1,4]	0,31	[0,10; 0,86]	0,0237*
Interaktion p-Wert									0,0012*

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 4.2.5.1.1 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - PGIC
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	24	4 (16,7)	NE [NE; NE]	25	6 (24,0)	NE [NE; NE]	0,84	[0,21; 2,93]	0,7811
Neu diagnostiziert	22	3 (13,6)	NE [NE; NE]	24	5 (20,8)	NE [NE; NE]	0,40	[0,08; 1,63]	0,1998
Interaktion p-Wert									0,4468
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	1,11	[0,04; 28,08]	0,9406
Rest der Welt	32	6 (18,8)	NE [NE; NE]	35	10 (28,6)	11,5 [4,2; NE]	0,44	[0,15; 1,20]	0,1083
Interaktion p-Wert									0,5403
Alter									
<65	25	3 (12,0)	NE [NE; NE]	25	4 (16,0)	NE [NE; NE]	0,61	[0,12; 2,79]	0,5203
>=65	21	4 (19,0)	NE [NE; NE]	24	7 (29,2)	11,5 [2,8; NE]	0,56	[0,15; 1,88]	0,3534
Interaktion p-Wert									0,9314
Abstammung									
Weiß	29	5 (17,2)	NE [NE; NE]	30	10 (33,3)	11,5 [2,8; NE]	0,35	[0,11; 1,02]	0,0546
Schwarz/Afroamerikanisch	0	0	NE	2	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	1,17	[0,05; 29,55]	0,9120
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,4404
HRR Mutationsstatus									
HRRm	12	2 (16,7)	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	3 (17,6)	NE [NE; NE]	21	6 (28,6)	11,5 [2,7; NE]	NC	[NC]	NC
Unbekannt	17	2 (11,8)	NE [NE; NE]	13	1 (7,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
PD-L1 Expression									
Positiv	37	6 (16,2)	NE [NE; NE]	39	8 (20,5)	NE [NE; NE]	0,63	[0,21; 1,83]	0,3966

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 4.2.5.1.1 DUO-E (dMMR Durva): Summary of subgroup analysis of Zeit bis zur ersten Verschlechterung - PGIC
Full Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=46)			CTx (N=49)					
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	8	1 (12,5)	NE [NE; NE]	8	2 (25,0)	NE [NE; NE]	0,62	[0,03; 6,47]	0,6887
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9870
Histologie									
Endometrioid	33	5 (15,2)	NE [NE; NE]	41	10 (24,4)	NE [NE; NE]	0,57	[0,18; 1,61]	0,2949
Serös	2	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Andere	11	2 (18,2)	NE [NE; NE]	6	1 (16,7)	NE [NE; NE]	0,78	[0,07; 16,80]	0,8418
Interaktion p-Wert									0,8135
Histologischer Grad									
High grade (G3)	14	3 (21,4)	NE [NE; NE]	12	2 (16,7)	NE [NE; NE]	1,01	[0,17; 7,77]	0,9872
Low grade (G1+G2)	28	4 (14,3)	NE [NE; NE]	33	9 (27,3)	NE [NE; NE]	0,42	[0,11; 1,31]	0,1375
Interaktion p-Wert									0,4187
ECOG Performance Status zu Baseline									
0	23	1 (4,3)	NE [NE; NE]	29	8 (27,6)	NE [NE; NE]	NC	[NC]	NC
1	23	6 (26,1)	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	3	1 (33,3)	11,5 [NE; NE]	NC	[NC]	NC
IV	15	2 (13,3)	NE [NE; NE]	21	4 (19,0)	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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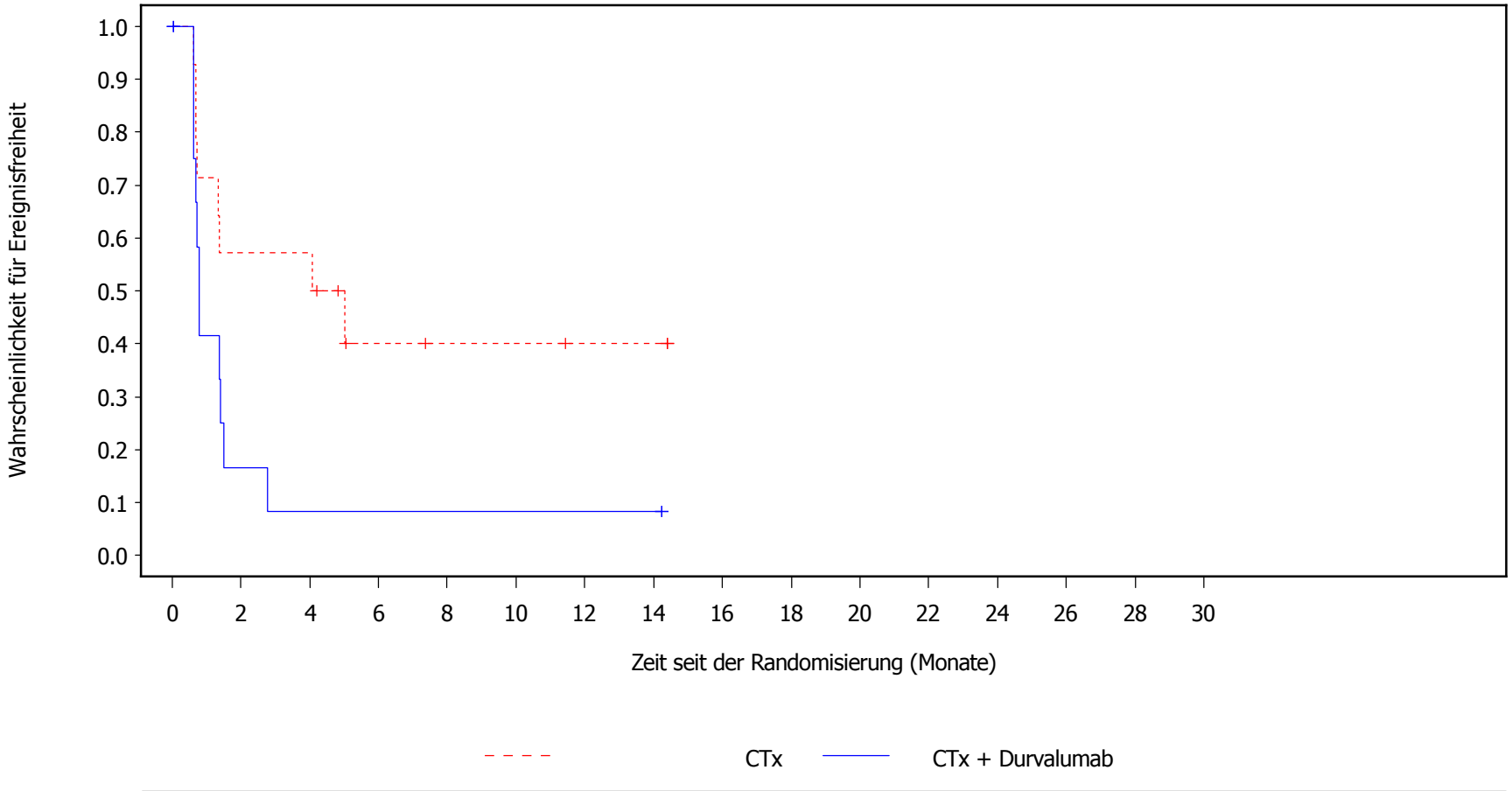
Figure 4.2.7.1.1 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Funktionsskala: Sozial for Region=Asien
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

14	2	1	1	1	1	1	1	0	0	0	0	0	0	0	0	CTx + Durvalumab
14	8	8	3	2	2	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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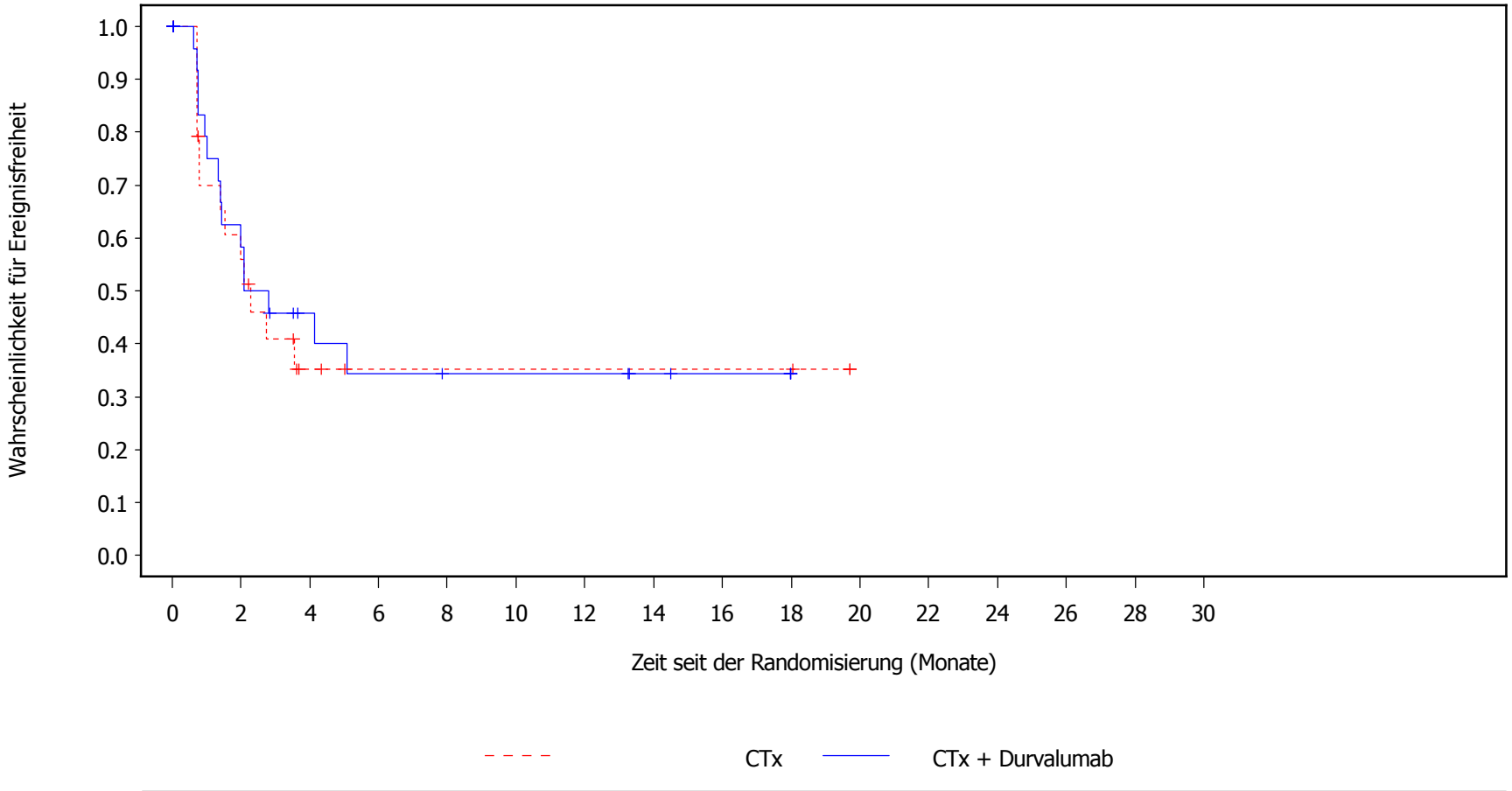
Figure 4.2.7.1.2 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Funktionsskala: Sozial for Region=Rest der Welt
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

32	15	8	6	5	5	5	3	2	0	0	0	0	0	0	0	CTx + Durvalumab
35	13	4	2	2	2	2	2	2	2	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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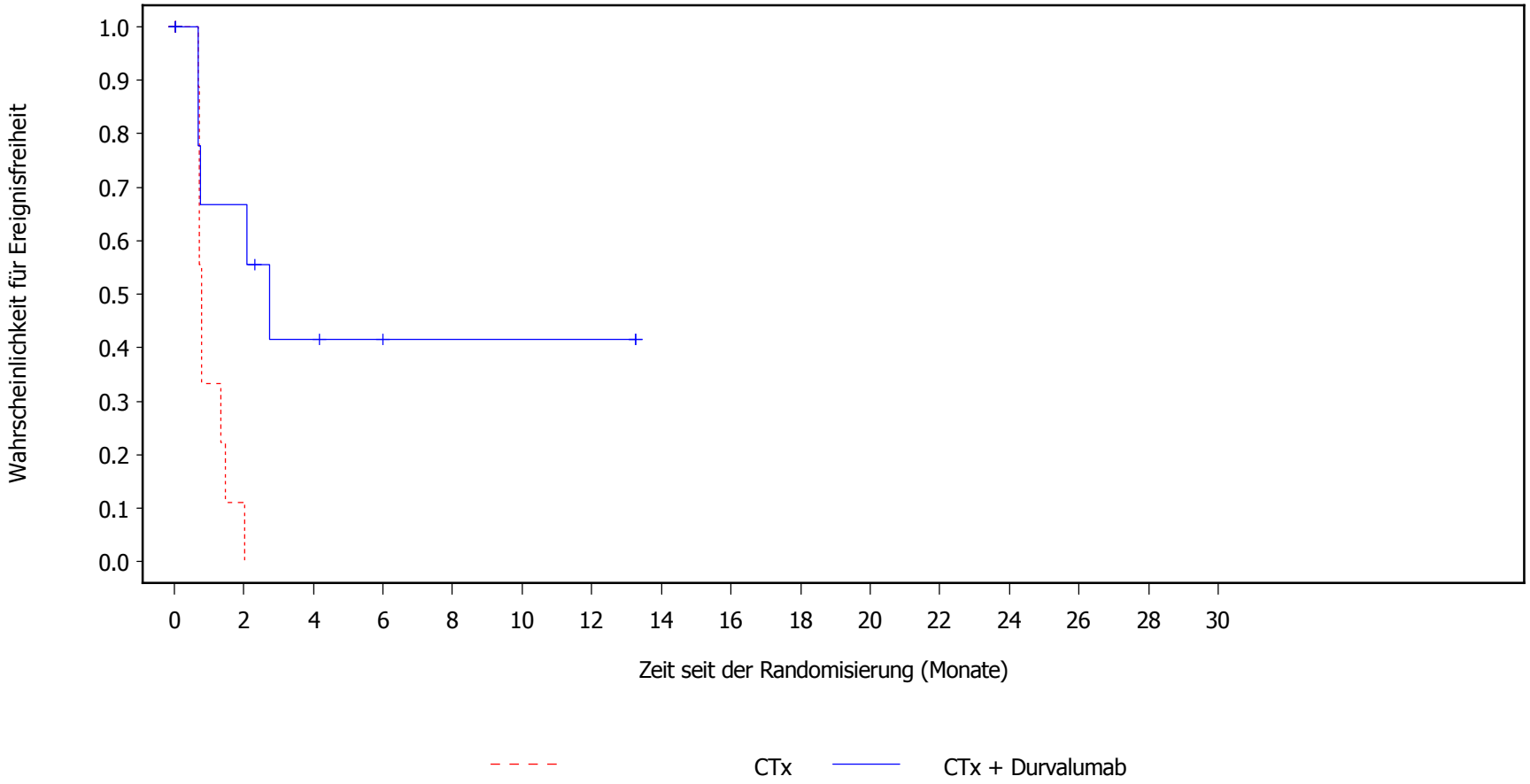
Figure 4.2.7.1.3 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Fatigue for HRR Mutationsstatus=HRRm
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

12	6	3	2	1	1	1	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
15	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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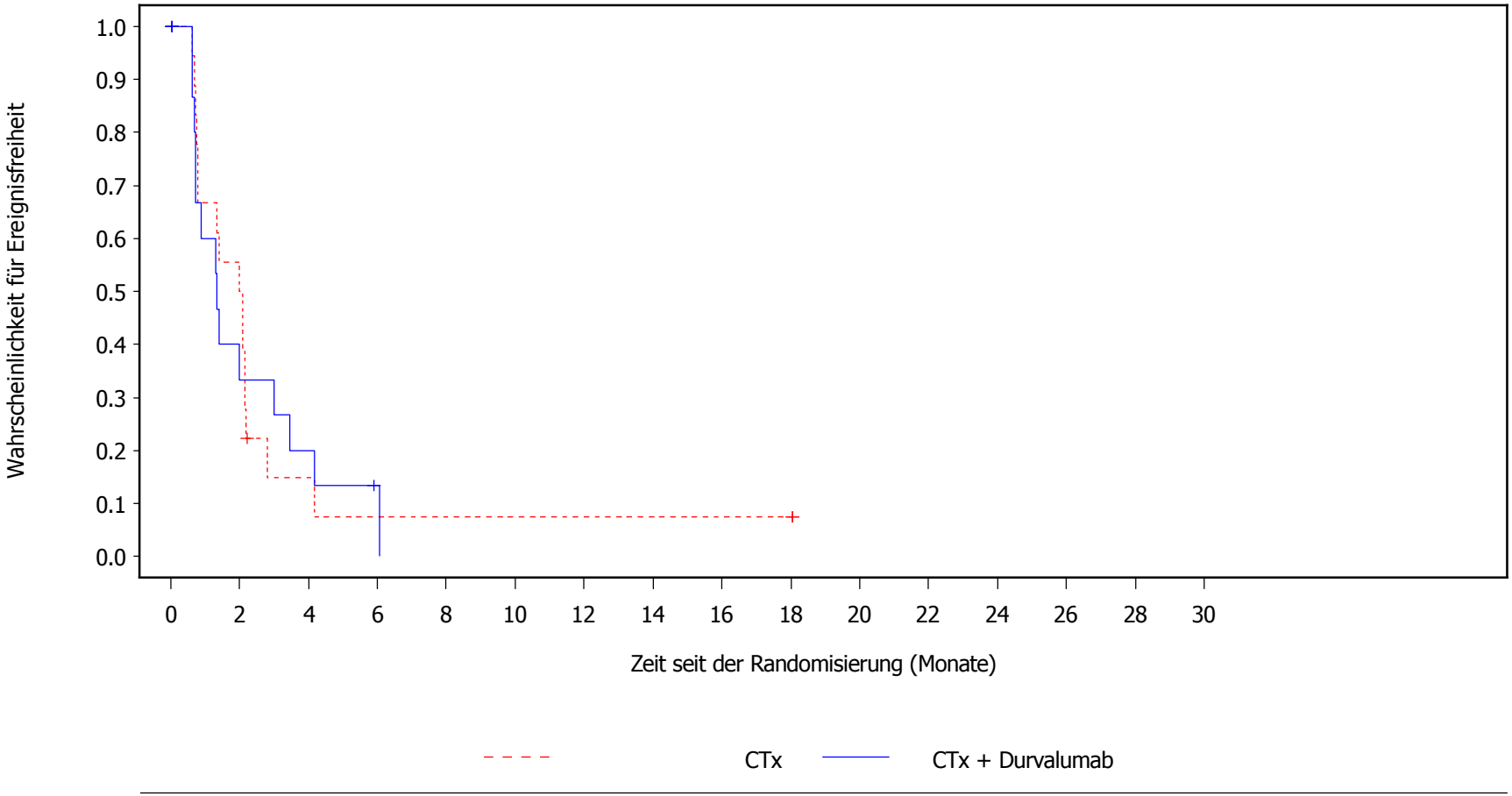
Figure 4.2.7.1.4 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Fatigue for HRR
Mutationsstatus=Nicht-HRRm
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

17	6	3	1	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
21	10	2	1	1	1	1	1	1	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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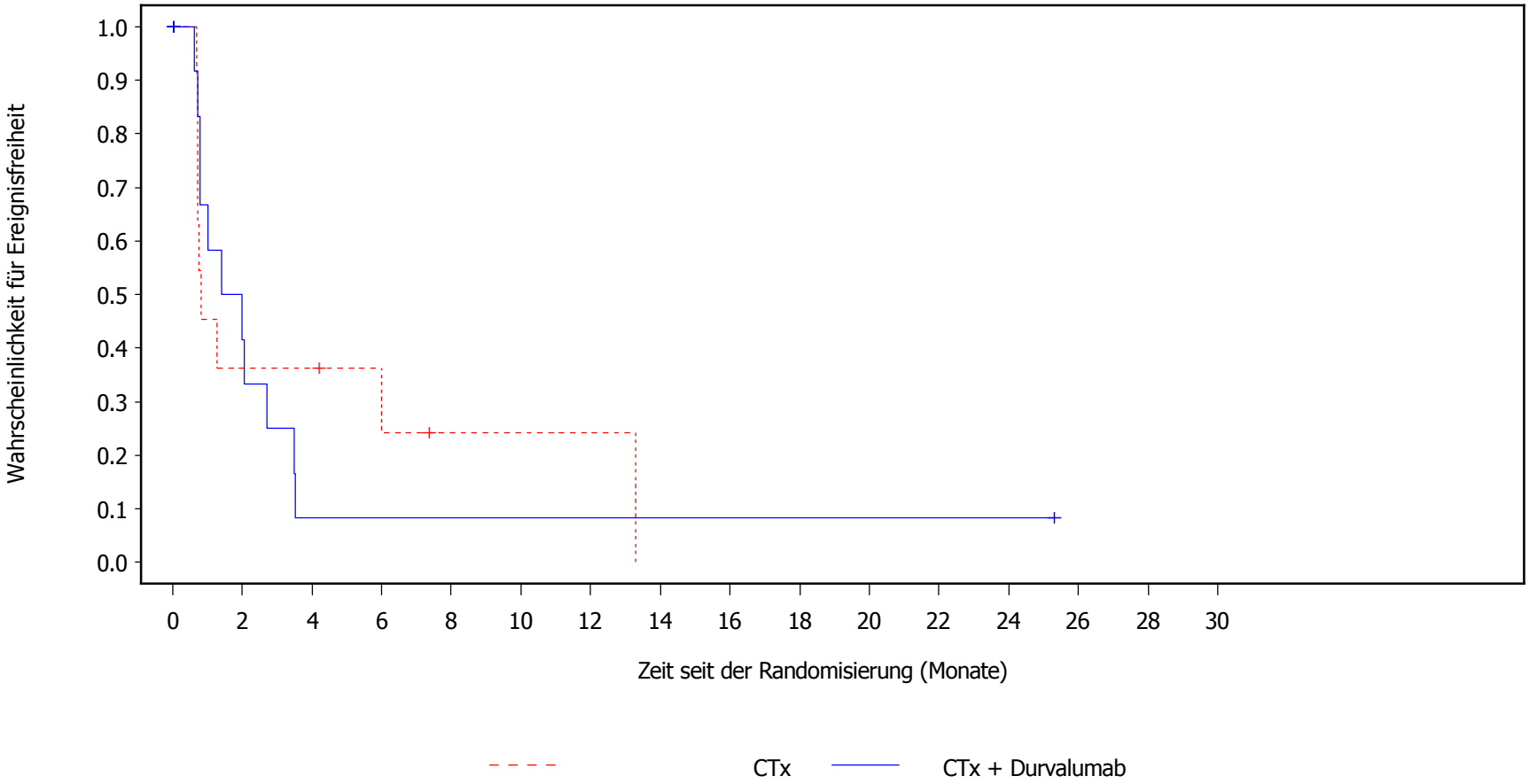
Figure 4.2.7.1.5 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Fatigue for HRR Mutationsstatus=Unbekannt
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

17	6	1	1	1	1	1	1	1	1	1	1	1	0	0	0	CTx + Durvalumab
13	4	4	3	1	1	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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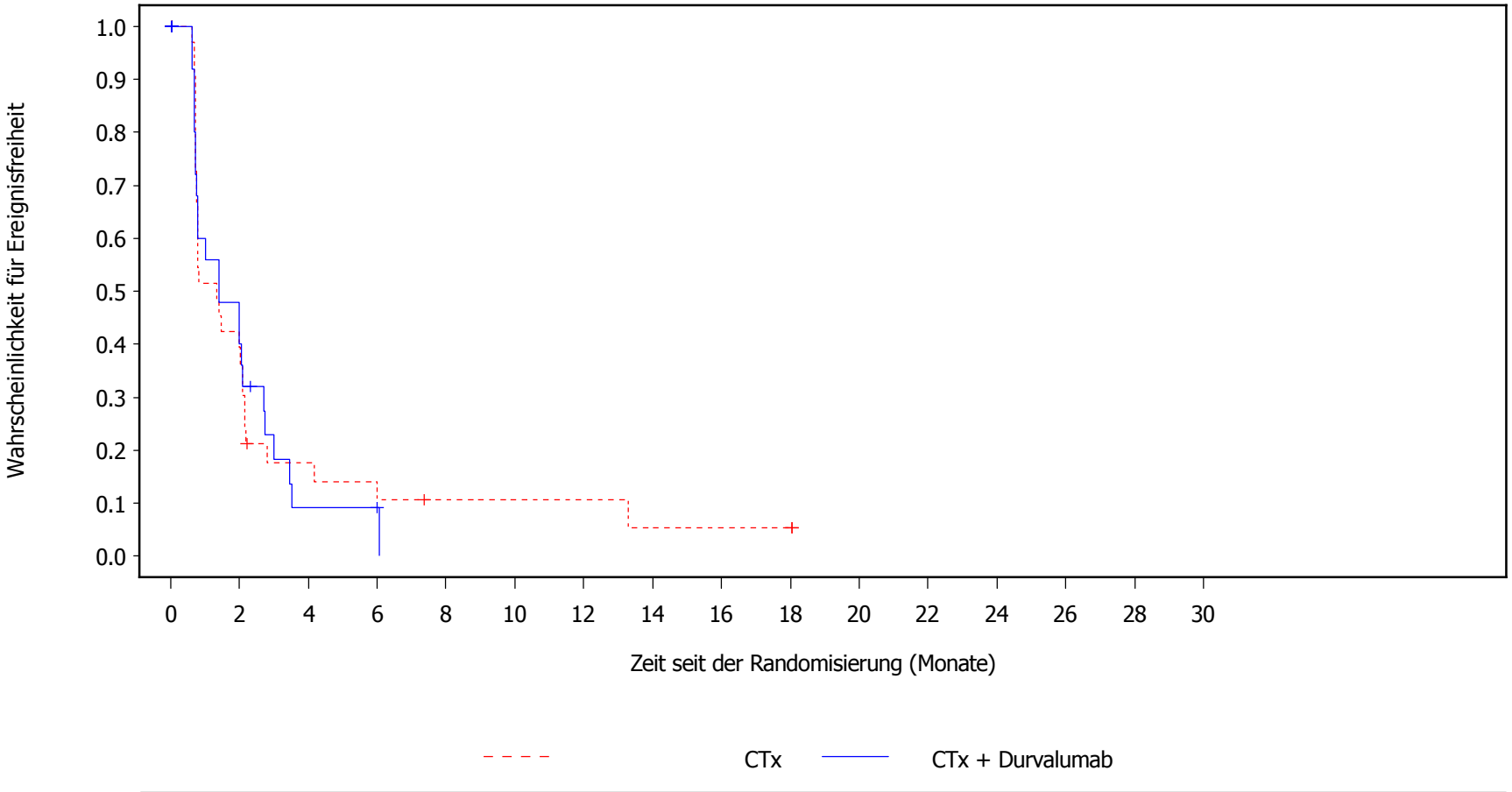
Figure 4.2.7.1.6 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Fatigue for Histologie=Endometrioid
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

33	12	2	2	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
41	14	5	4	2	2	2	1	1	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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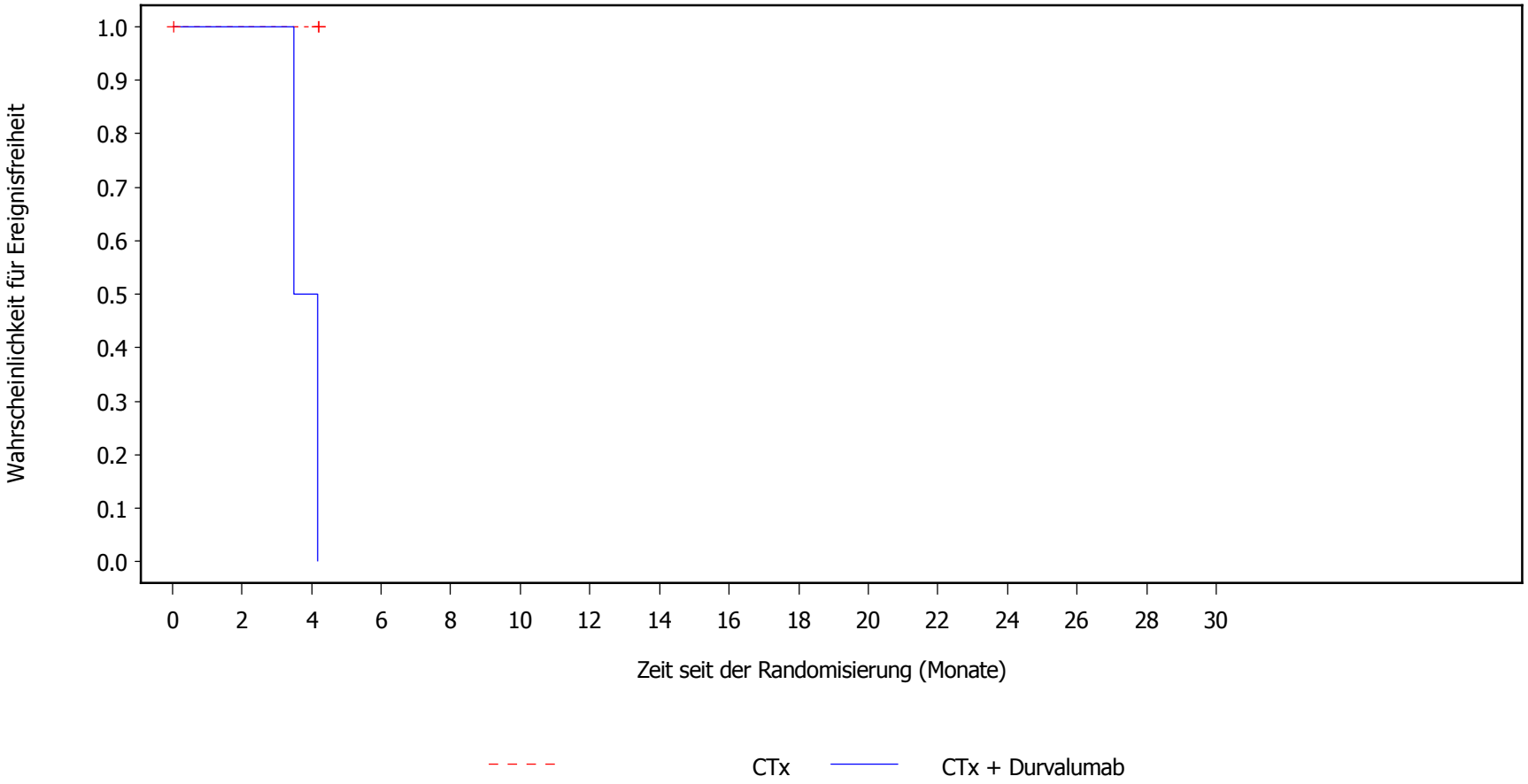
Figure 4.2.7.1.7 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Fatigue for Histologie=Serös
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
2	1	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 unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
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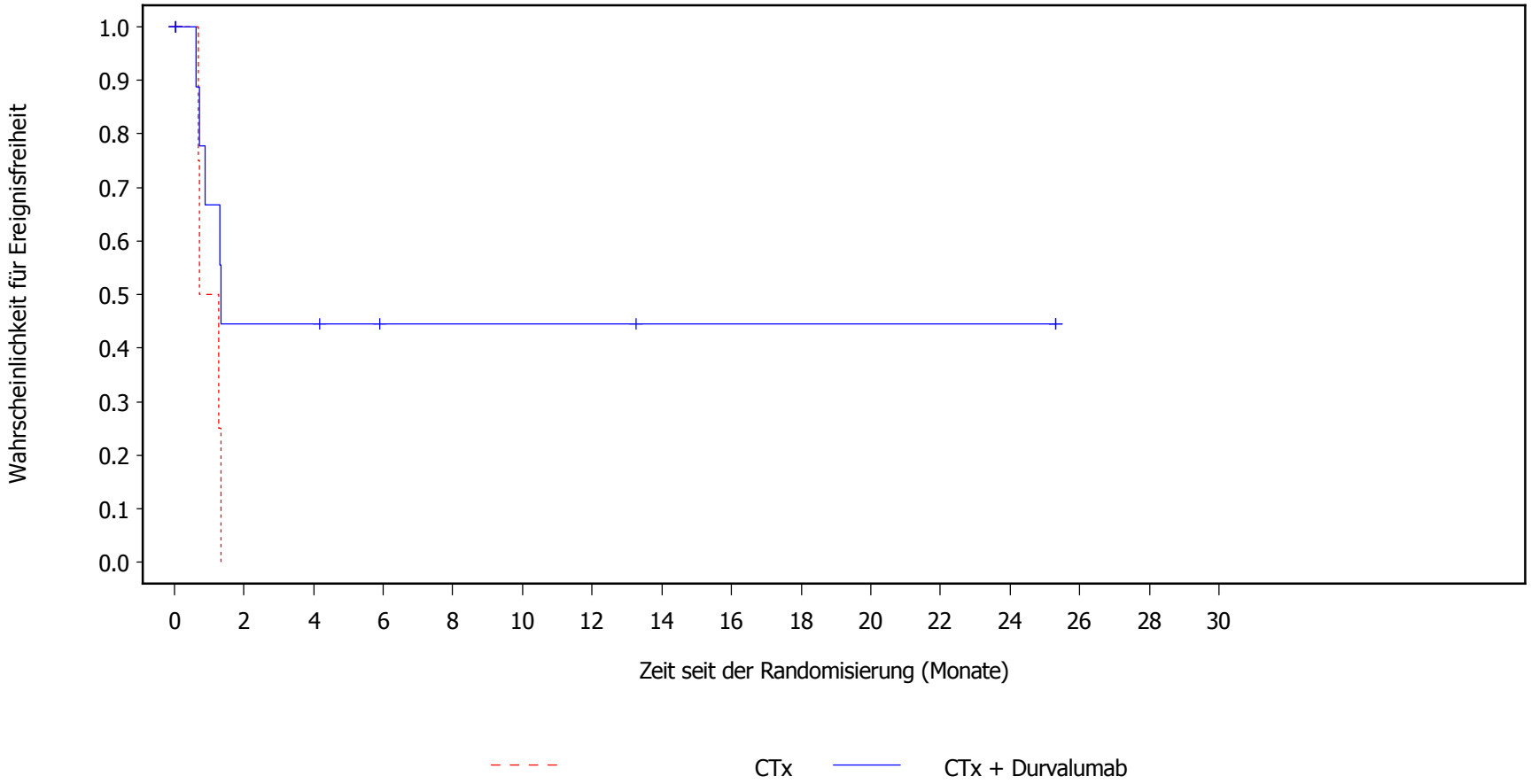
Figure 4.2.7.1.8 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Fatigue for Histologie=Andere
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

11	4	4	2	2	2	2	1	1	1	1	1	1	0	0	0	CTx + Durvalumab
6	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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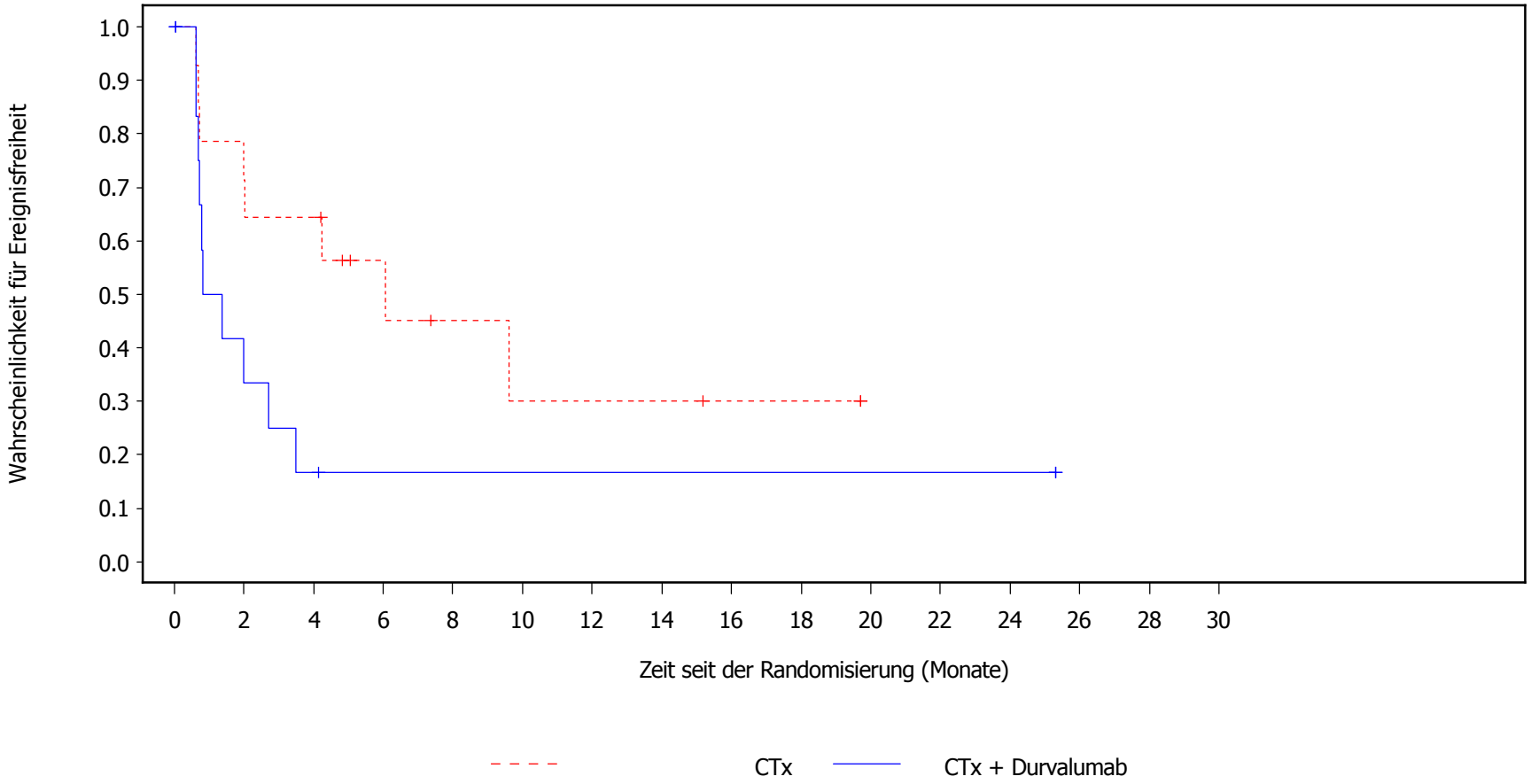
Figure 4.2.7.1.9 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen for Region=Asien
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

14	5	2	1	1	1	1	1	1	1	1	1	1	0	0	0	CTx + Durvalumab
14	11	9	5	3	2	2	2	1	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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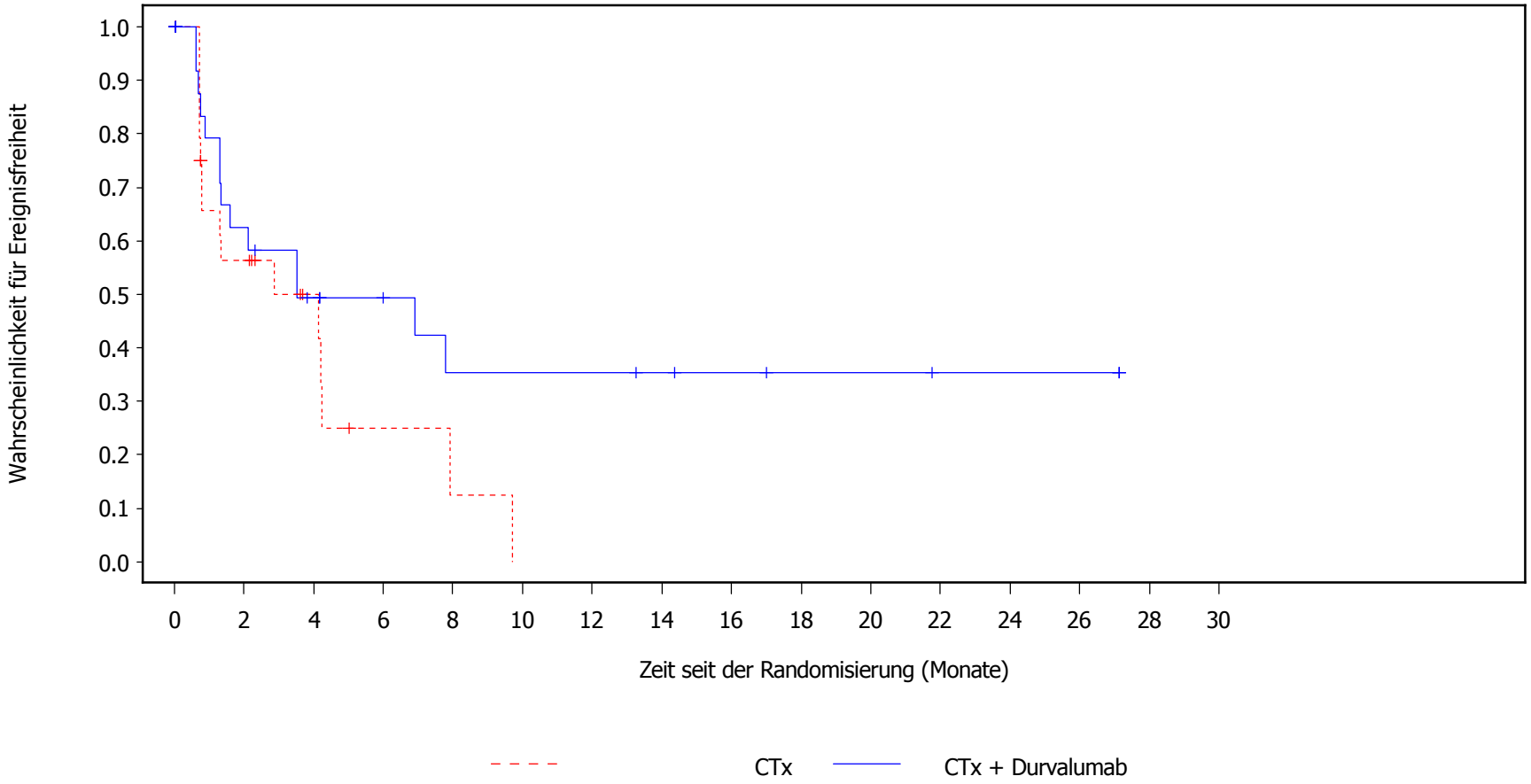
Figure 4.2.7.1.10 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen for Region=Rest der Welt
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

32	15	10	8	5	5	5	4	3	2	2	1	1	1	0	0	CTx + Durvalumab
35	12	6	2	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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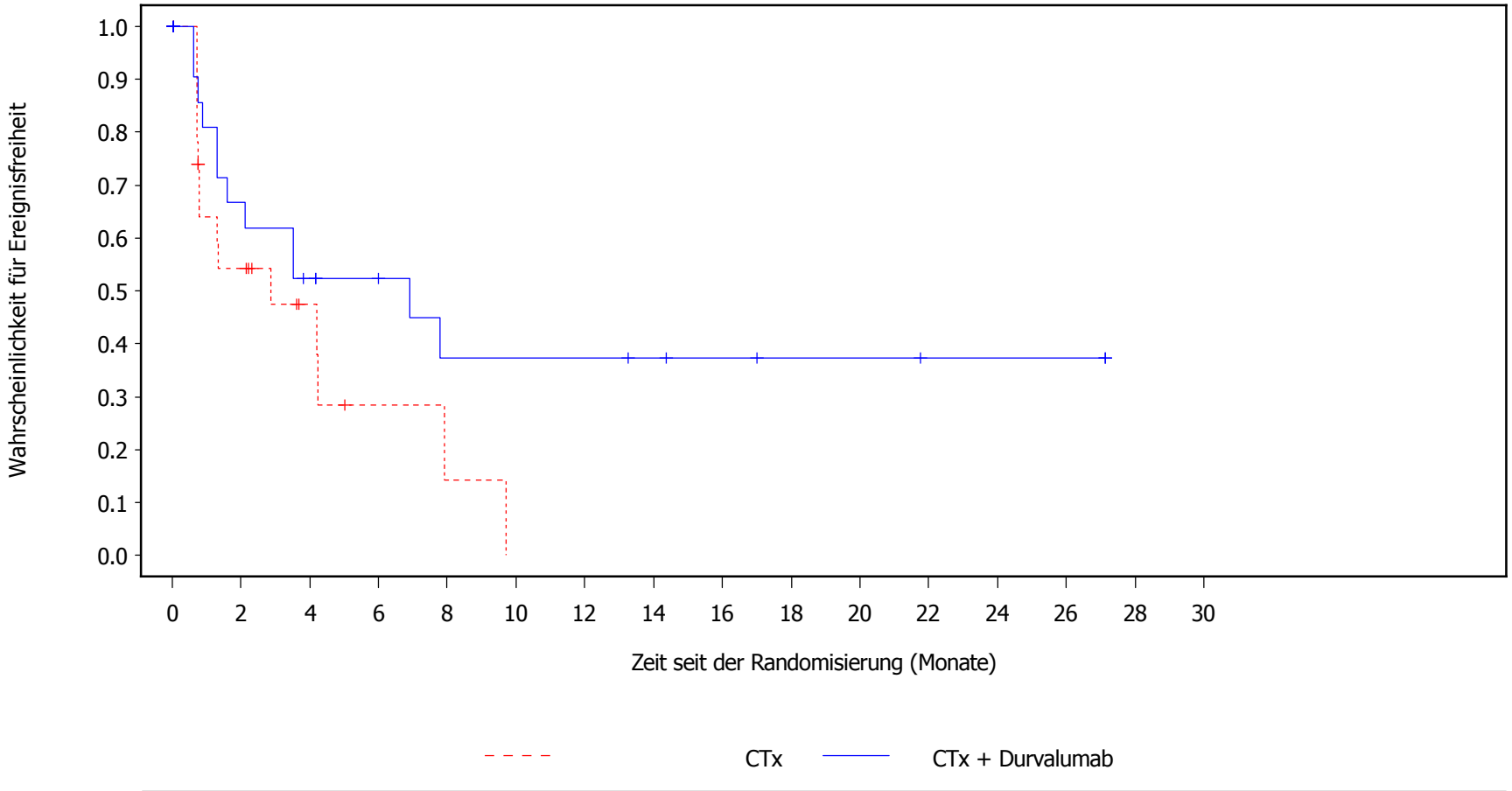
Figure 4.2.7.1.11 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen for Abstammung=Weiß
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

29	14	10	8	5	5	5	4	3	2	2	1	1	1	0	0	CTx + Durvalumab
30	11	5	2	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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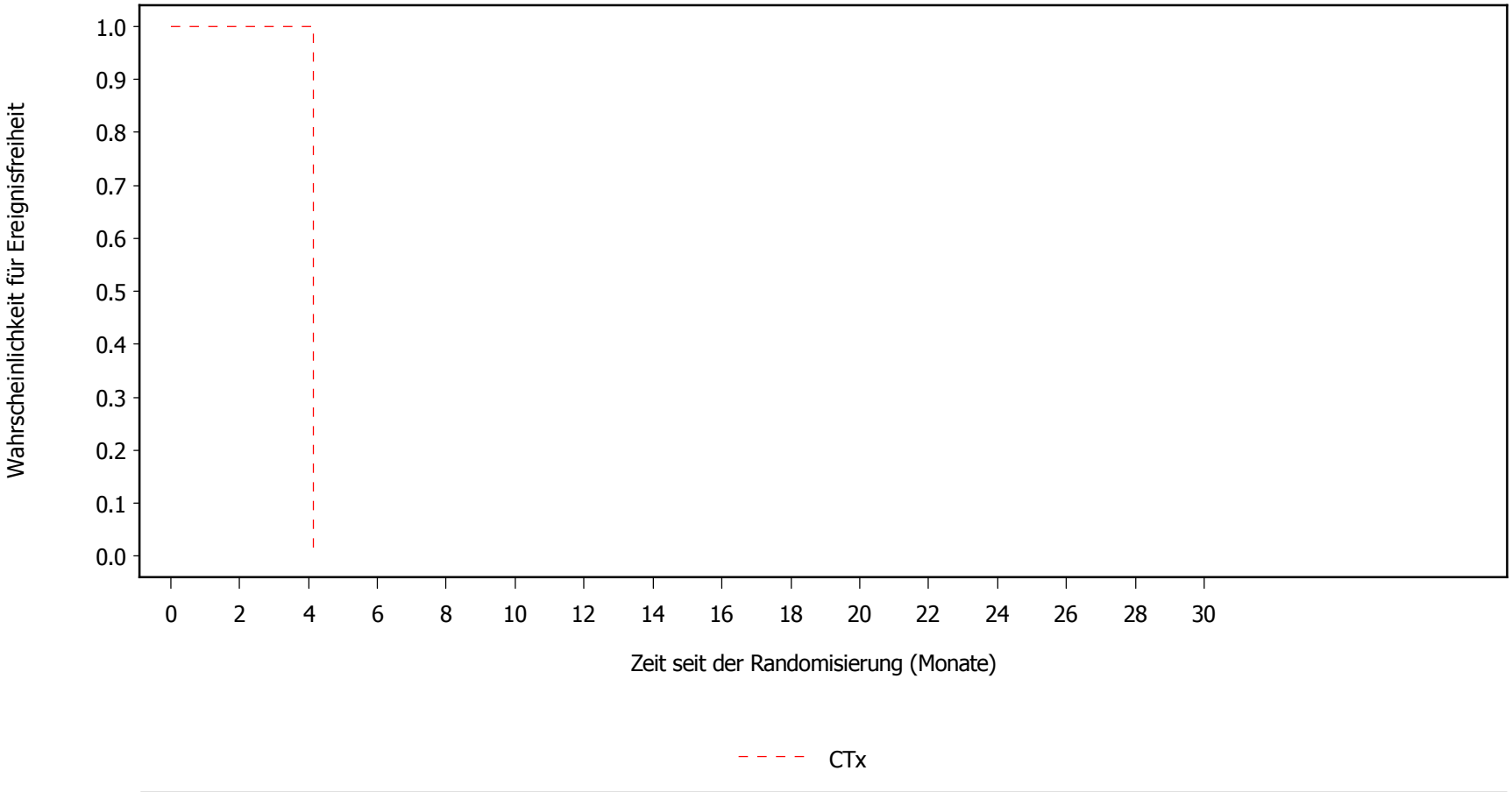
Figure 4.2.7.1.12 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen for Abstammung=Schwarz/Afroamerikanisch
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

2	1	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 unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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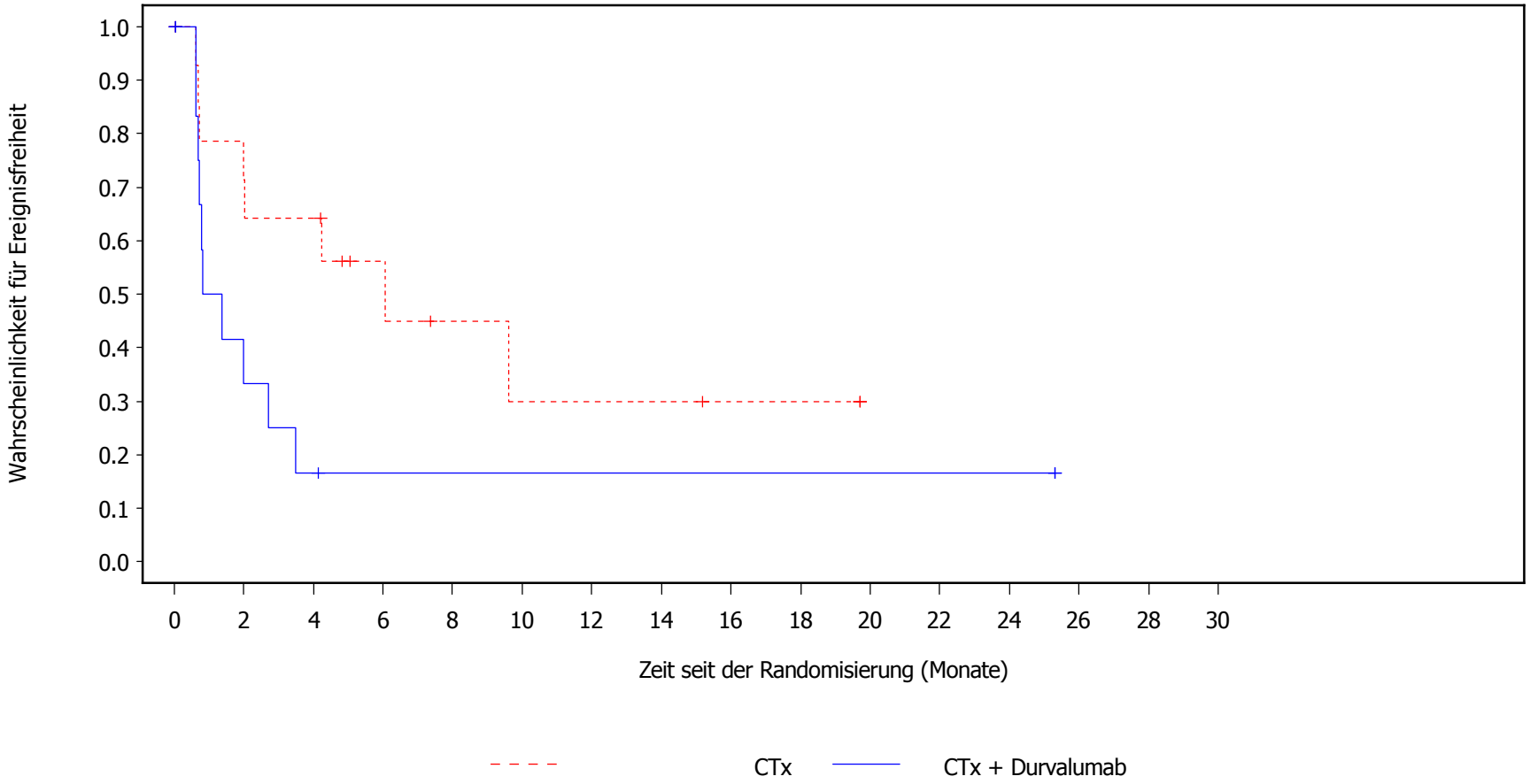
Figure 4.2.7.1.13 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen for Abstammung=Asiatisch
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

14	5	2	1	1	1	1	1	1	1	1	1	1	0	0	0	CTx + Durvalumab
15	11	9	5	3	2	2	2	1	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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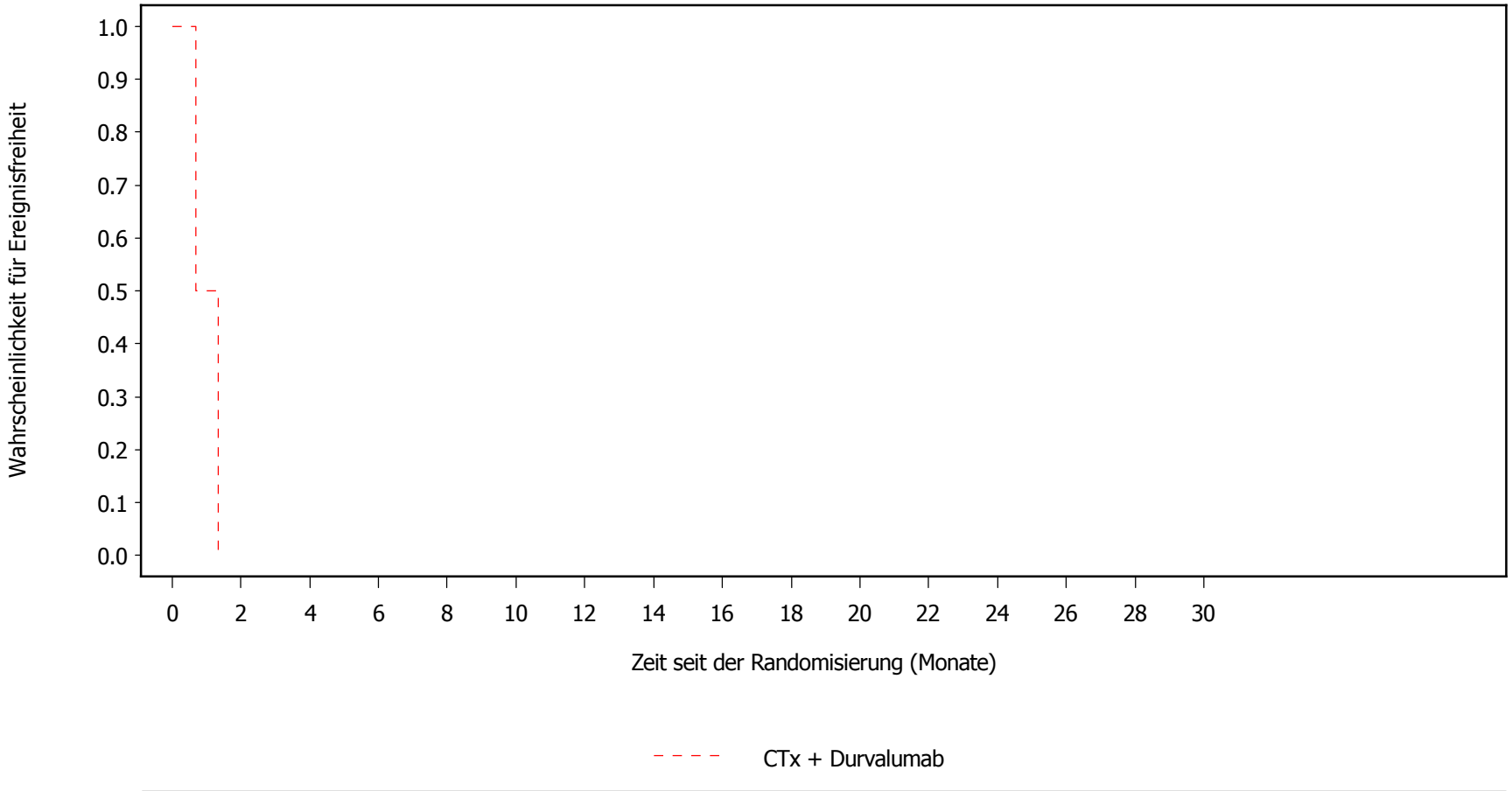
Figure 4.2.7.1.14 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen for Abstammung=Andere
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab

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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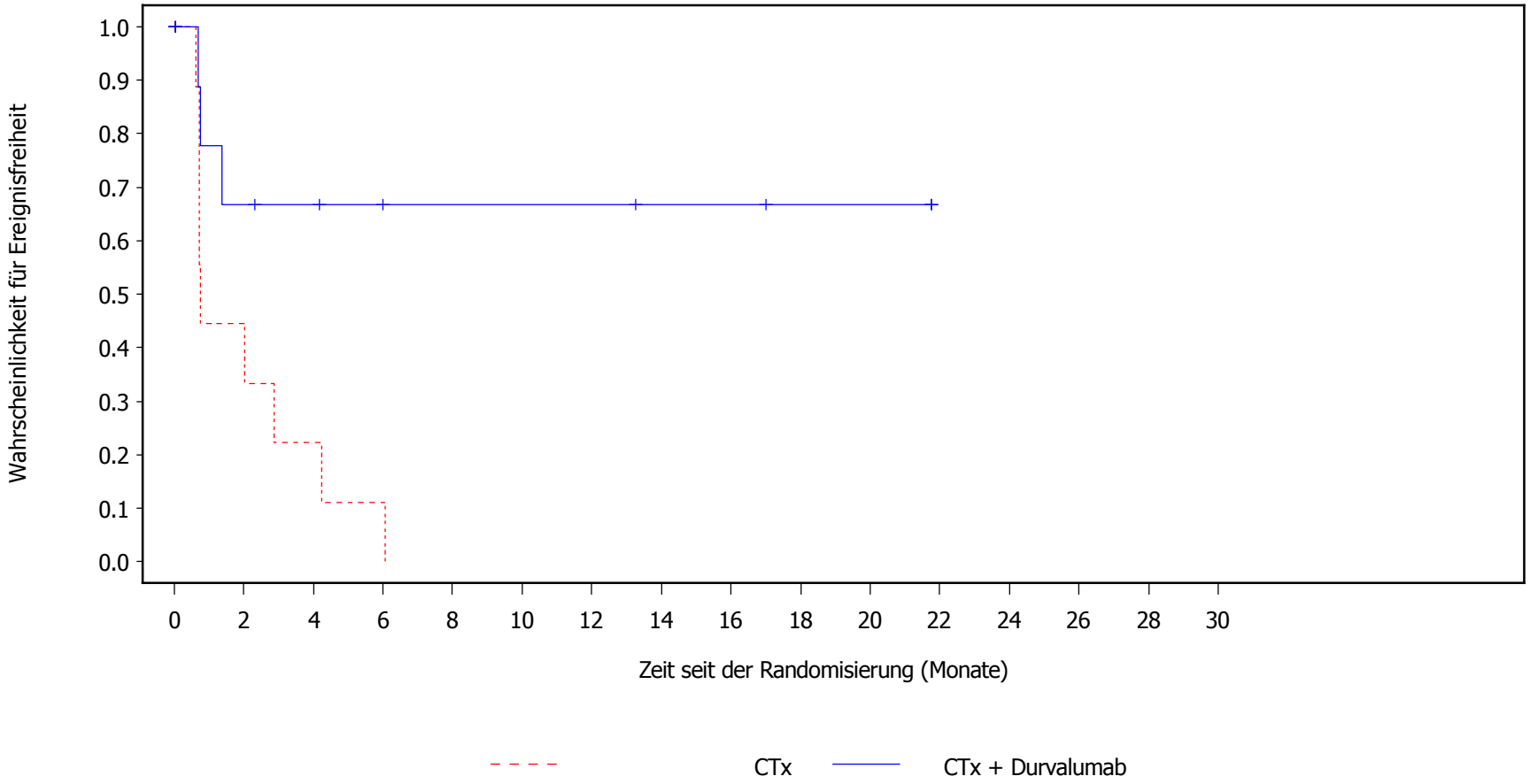
Figure 4.2.7.1.15 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen for HRR Mutationsstatus=HRRm
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

12	6	5	4	3	3	3	2	2	1	1	0	0	0	0	0	CTx + Durvalumab
15	4	2	1	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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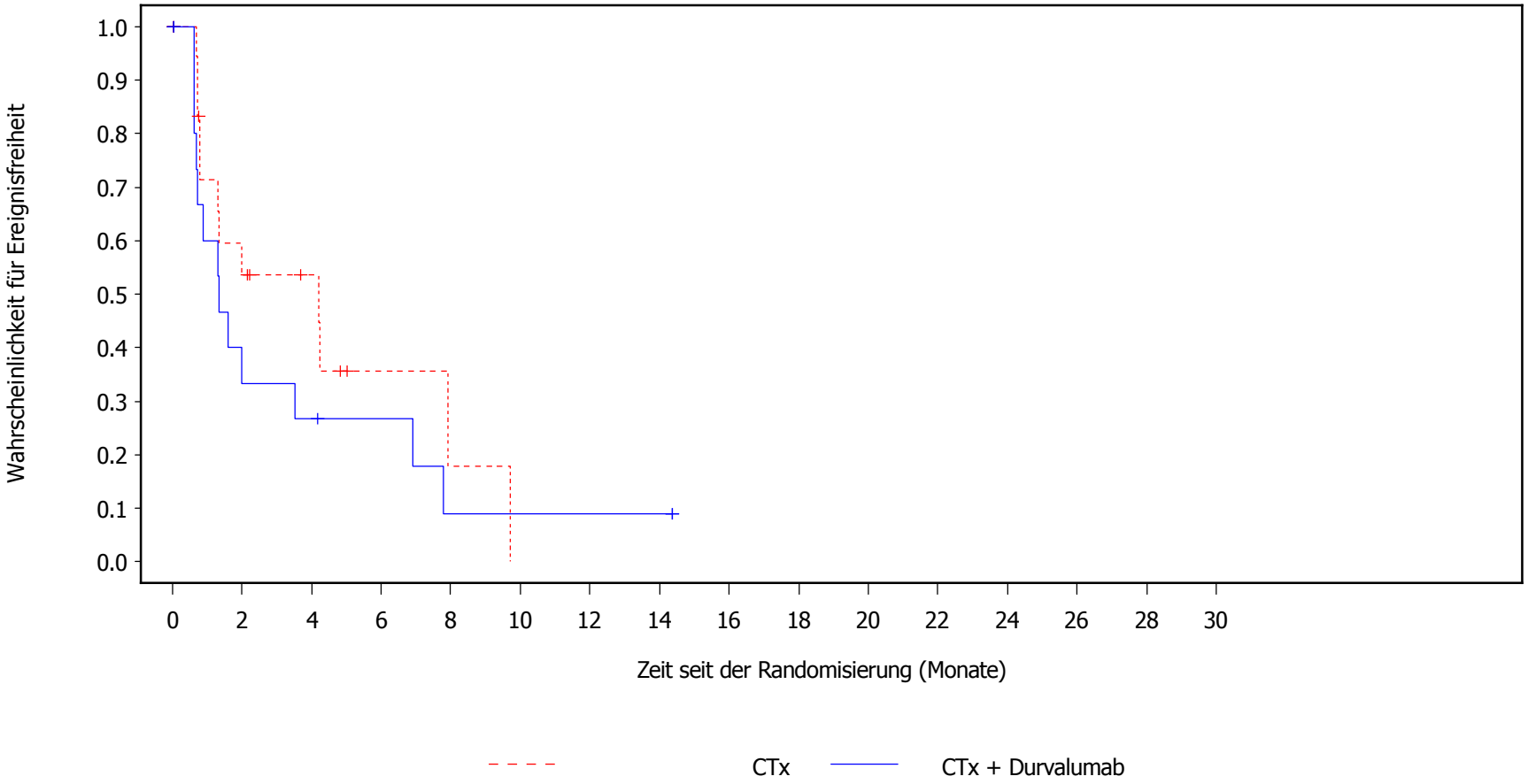
Figure 4.2.7.1.16 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen for HRR Mutationsstatus=Nicht-HRRm
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

17	6	4	3	1	1	1	1	0	0	0	0	0	0	0	0	CTx + Durvalumab
21	10	6	2	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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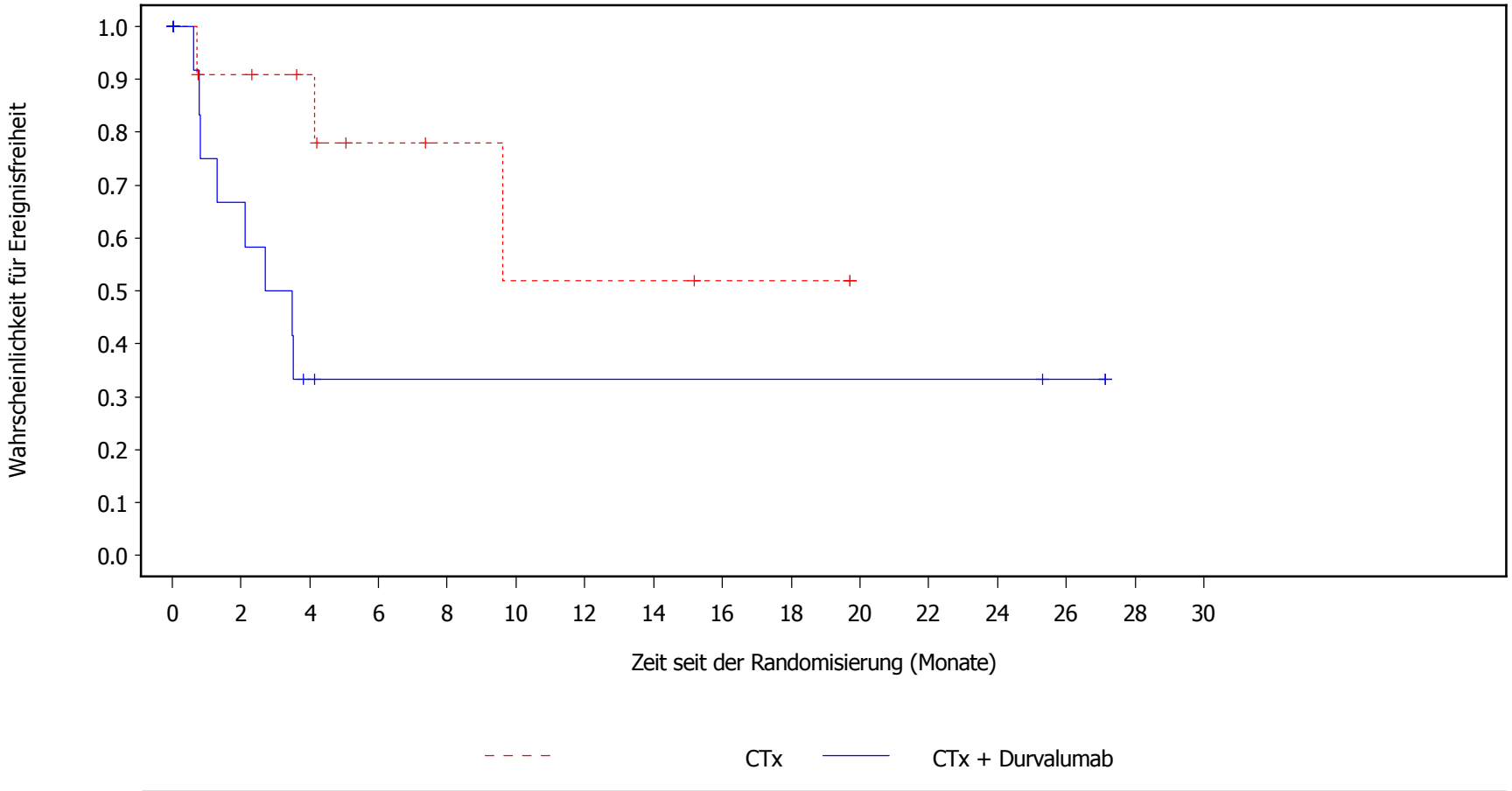
Figure 4.2.7.1.17 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Schmerzen for HRR Mutationsstatus=Unbekannt
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

17	8	3	2	2	2	2	2	2	2	2	2	2	1	0	0	CTx + Durvalumab
13	9	7	4	3	2	2	2	1	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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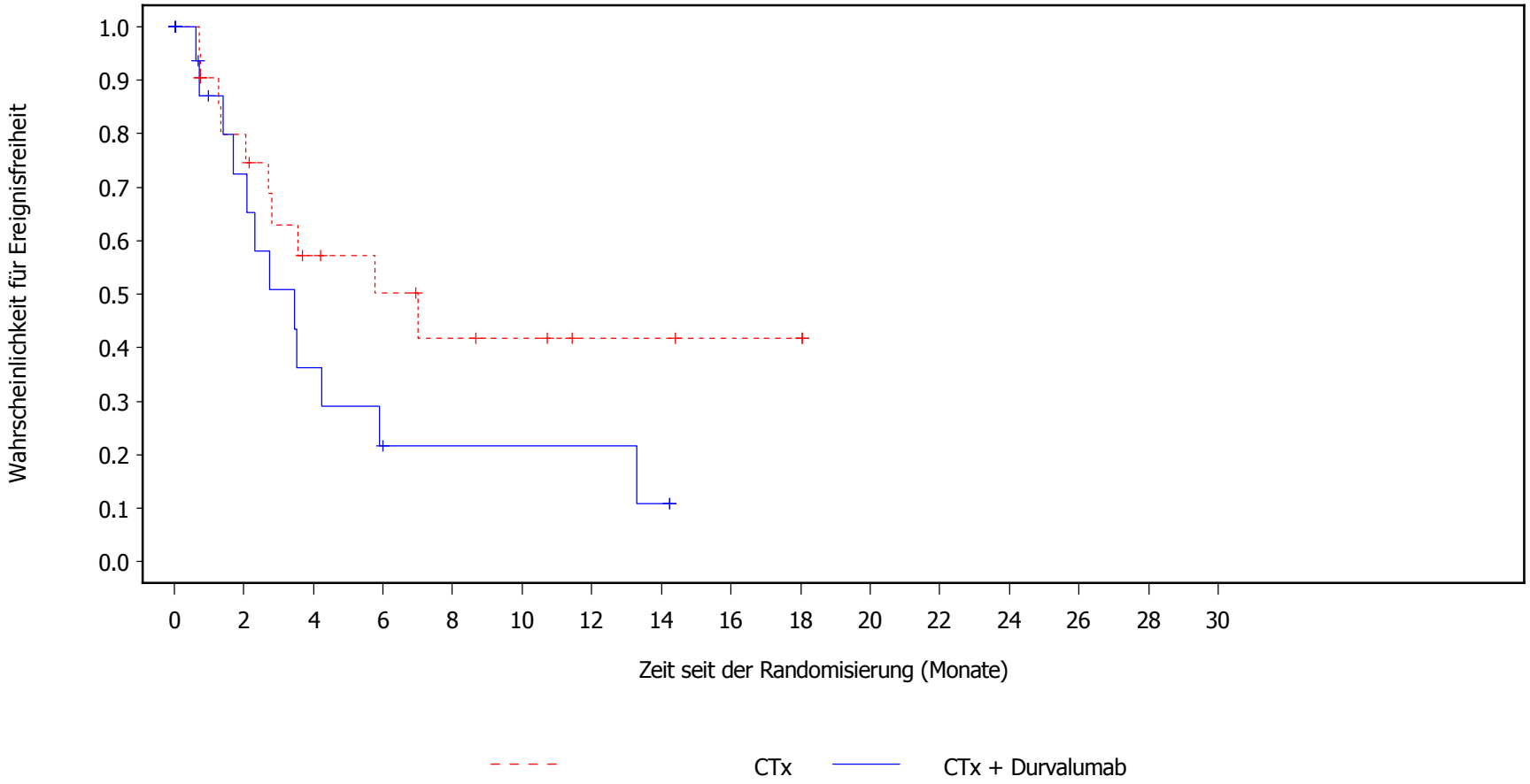
Figure 4.2.7.1.18 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Diarrhö for Krankheitsstatus=Rezidivierend
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

24	10	5	3	2	2	2	1	0	0	0	0	0	0	0	0	CTx + Durvalumab
25	15	9	7	5	4	2	2	1	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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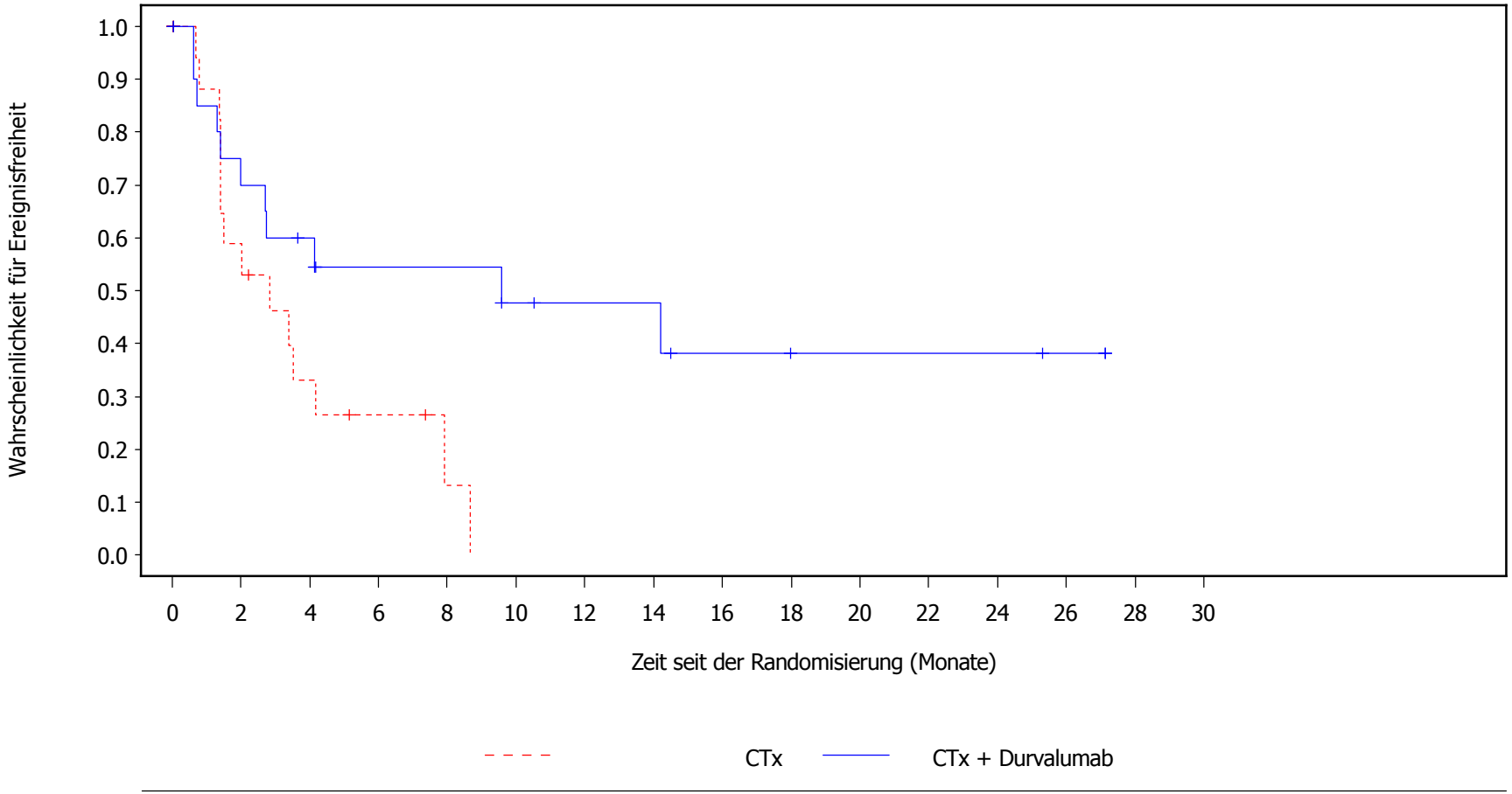
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.7.1.19 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Diarrhö for Krankheitsstatus=Neu diagnostiziert
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

22	15	11	8	8	6	5	5	3	2	2	2	2	1	0	0	CTx + Durvalumab
24	10	5	3	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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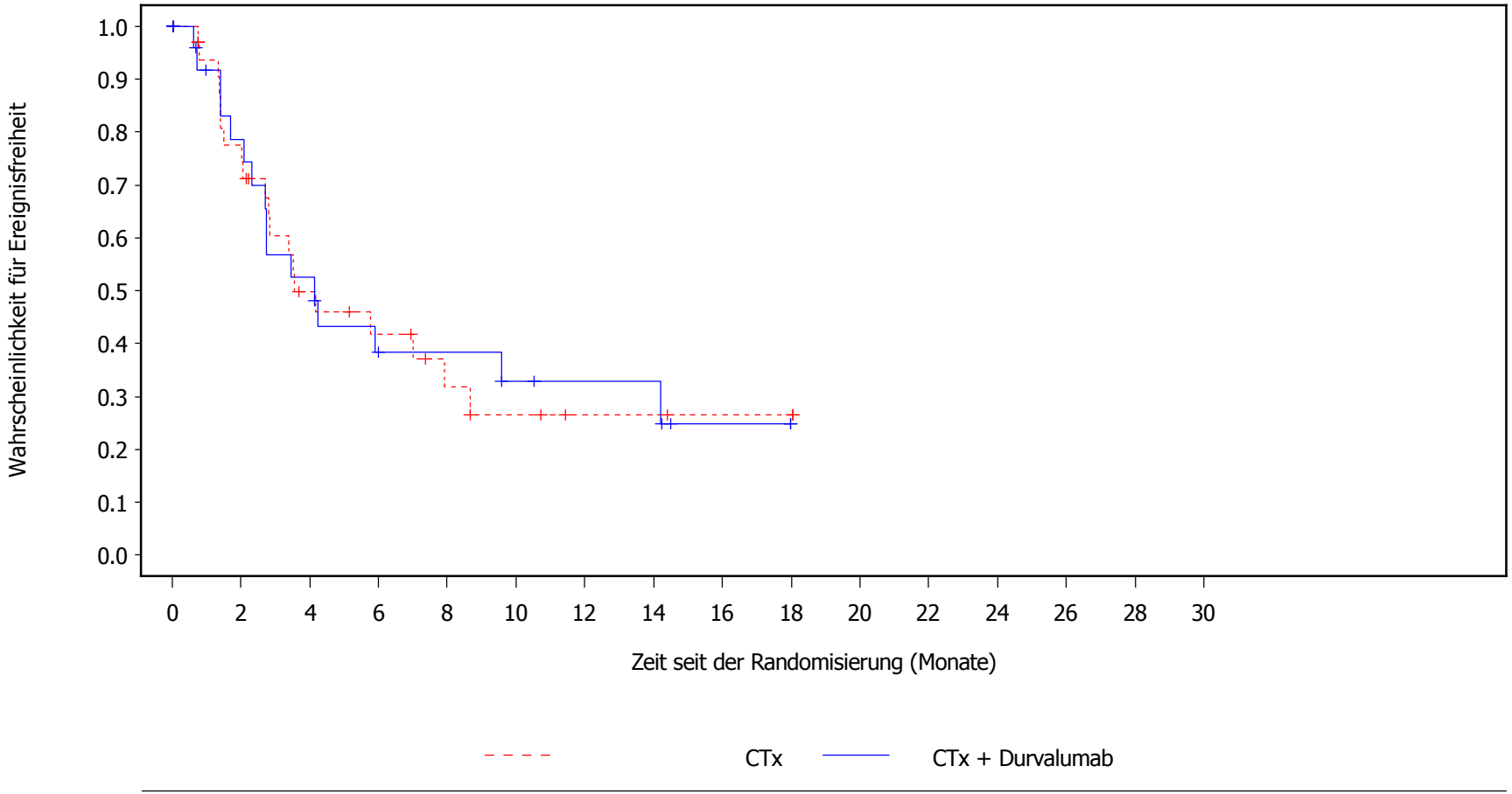
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.7.1.20 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Diarrhö for Histologie=Endometrioid
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

33	18	12	8	7	5	4	4	1	0	0	0	0	0	0	0	CTx + Durvalumab
41	24	13	10	6	4	2	2	1	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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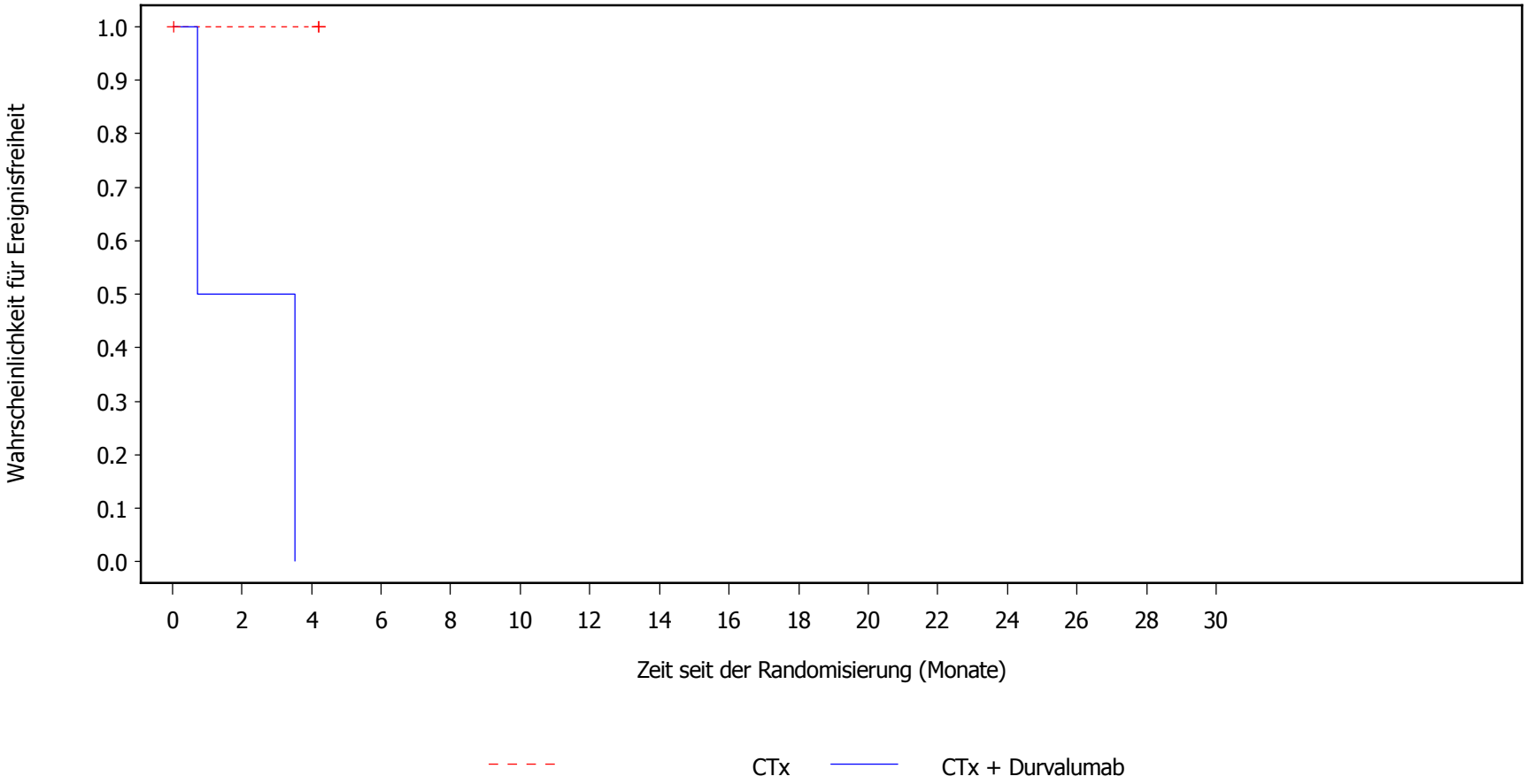
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.7.1.21 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Diarrhö for Histologie=Serös
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

2	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
2	1	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 unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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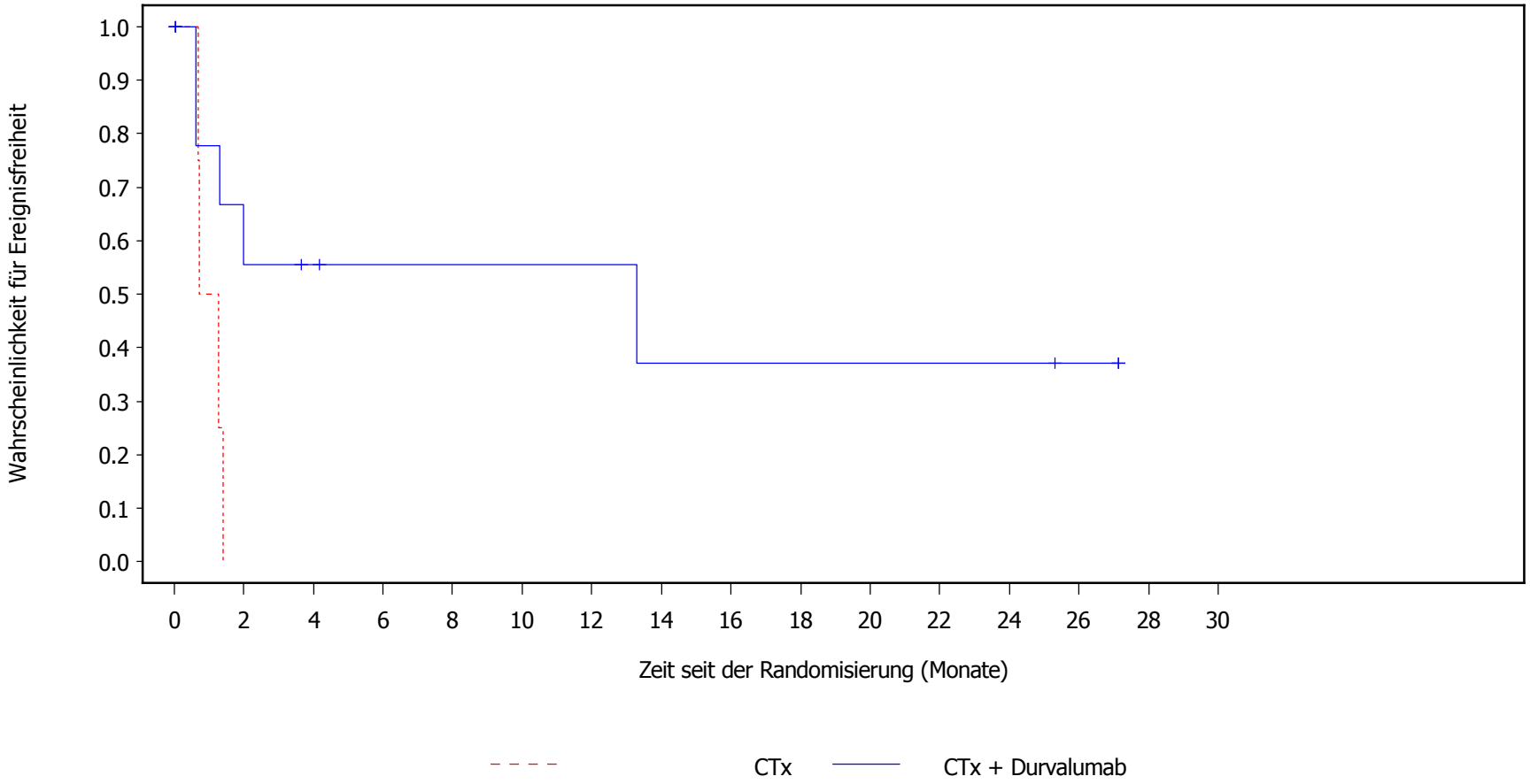
Figure 4.2.7.1.22 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-C30 Diarrhö for Histologie=Andere
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

11	6	4	3	3	3	3	2	2	2	2	2	2	1	0	0	CTx + Durvalumab
6	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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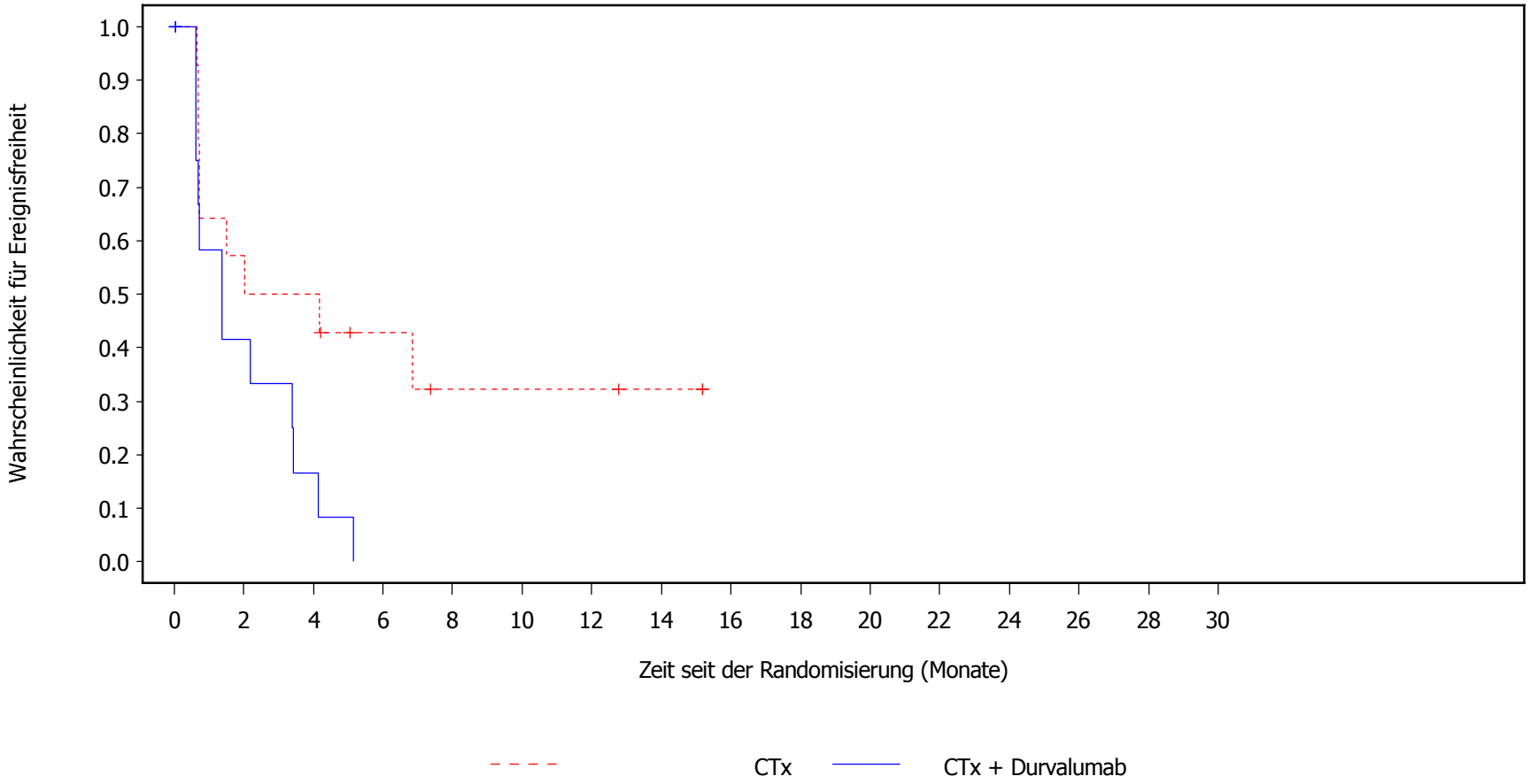
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.8.1.1 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Lymphödem for Region=Asien
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

14	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
14	8	7	4	2	2	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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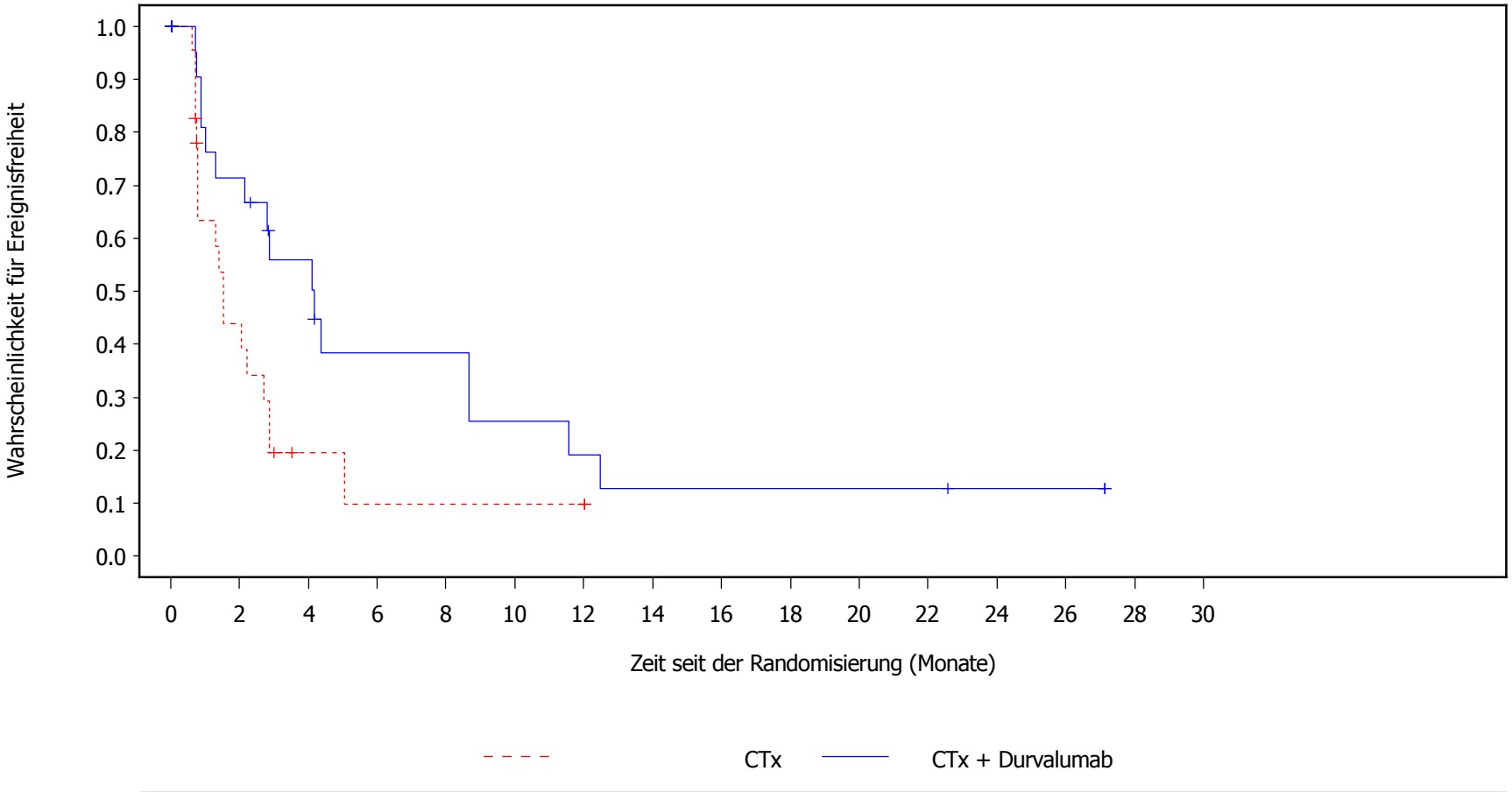
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.8.1.2 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Lymphödem for Region=Rest der Welt
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

32	15	10	6	6	4	3	2	2	2	2	2	1	1	0	0	CTx + Durvalumab
35	9	2	1	1	1	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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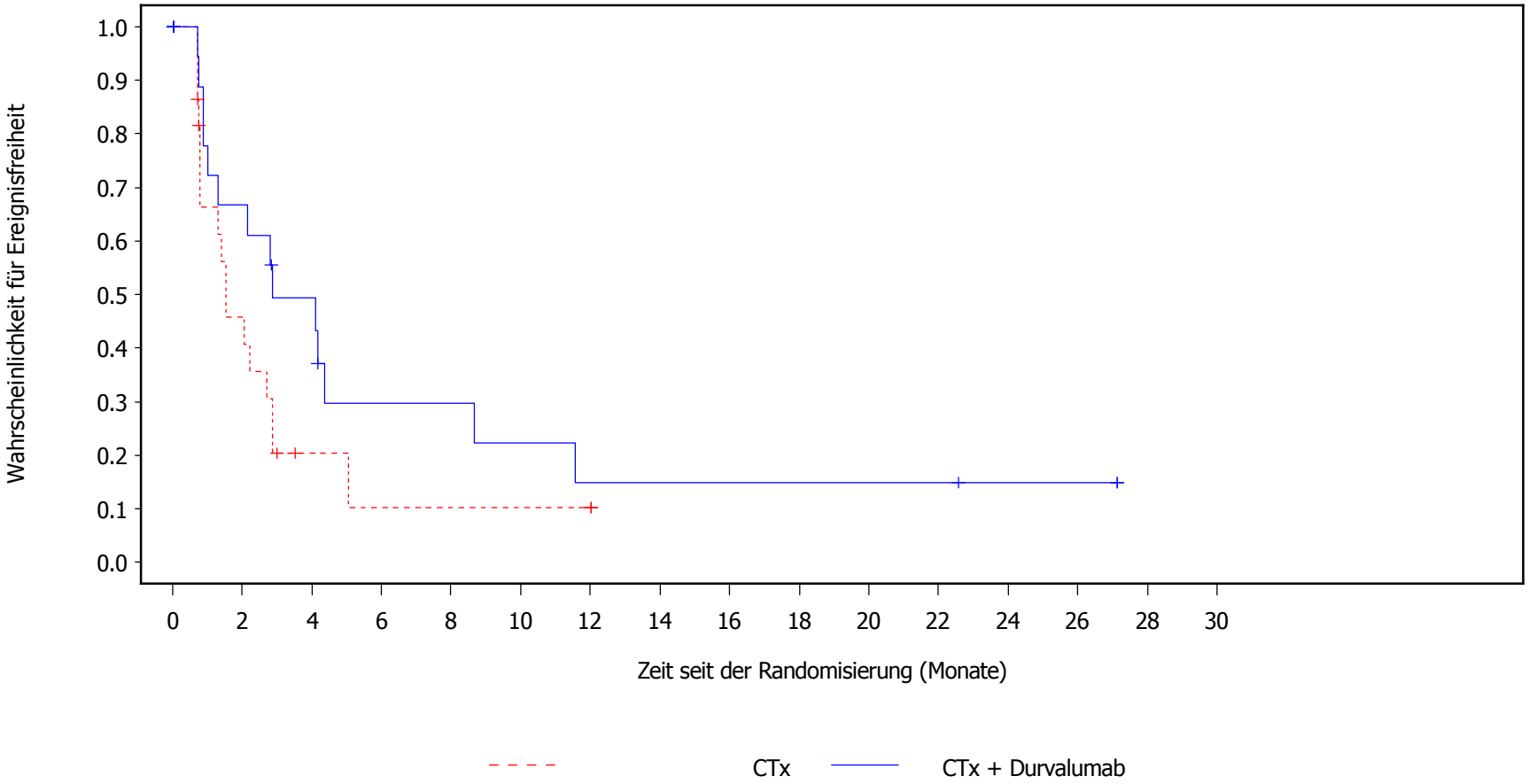
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.8.1.3 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Lymphödem for Abstammung=Weiß
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

29	12	8	4	4	3	2	2	2	2	2	2	1	1	0	0	CTx + Durvalumab
30	9	2	1	1	1	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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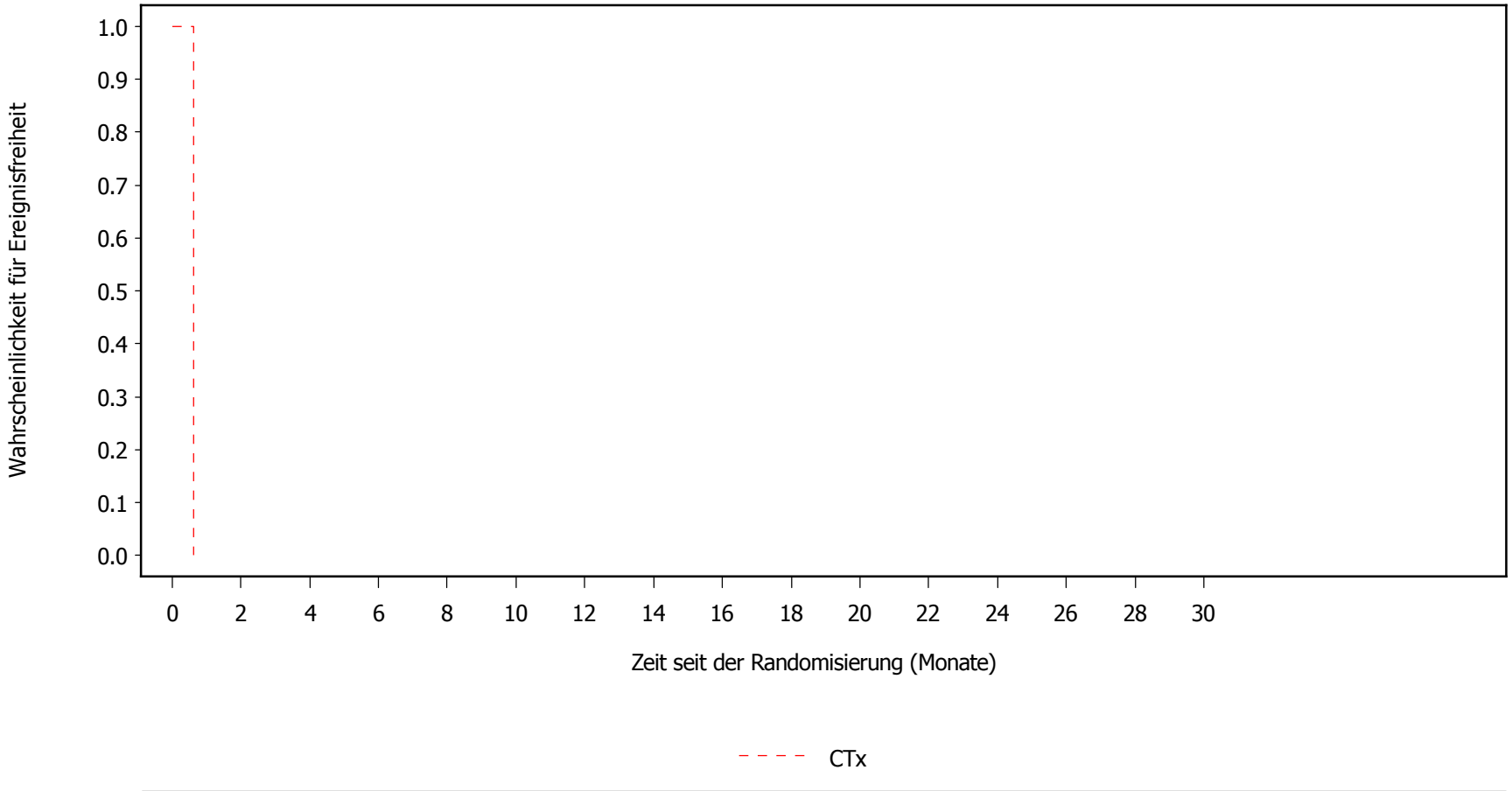
Figure 4.2.8.1.4 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Lymphödem for Abstammung=Schwarz/Afroamerikanisch
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

2	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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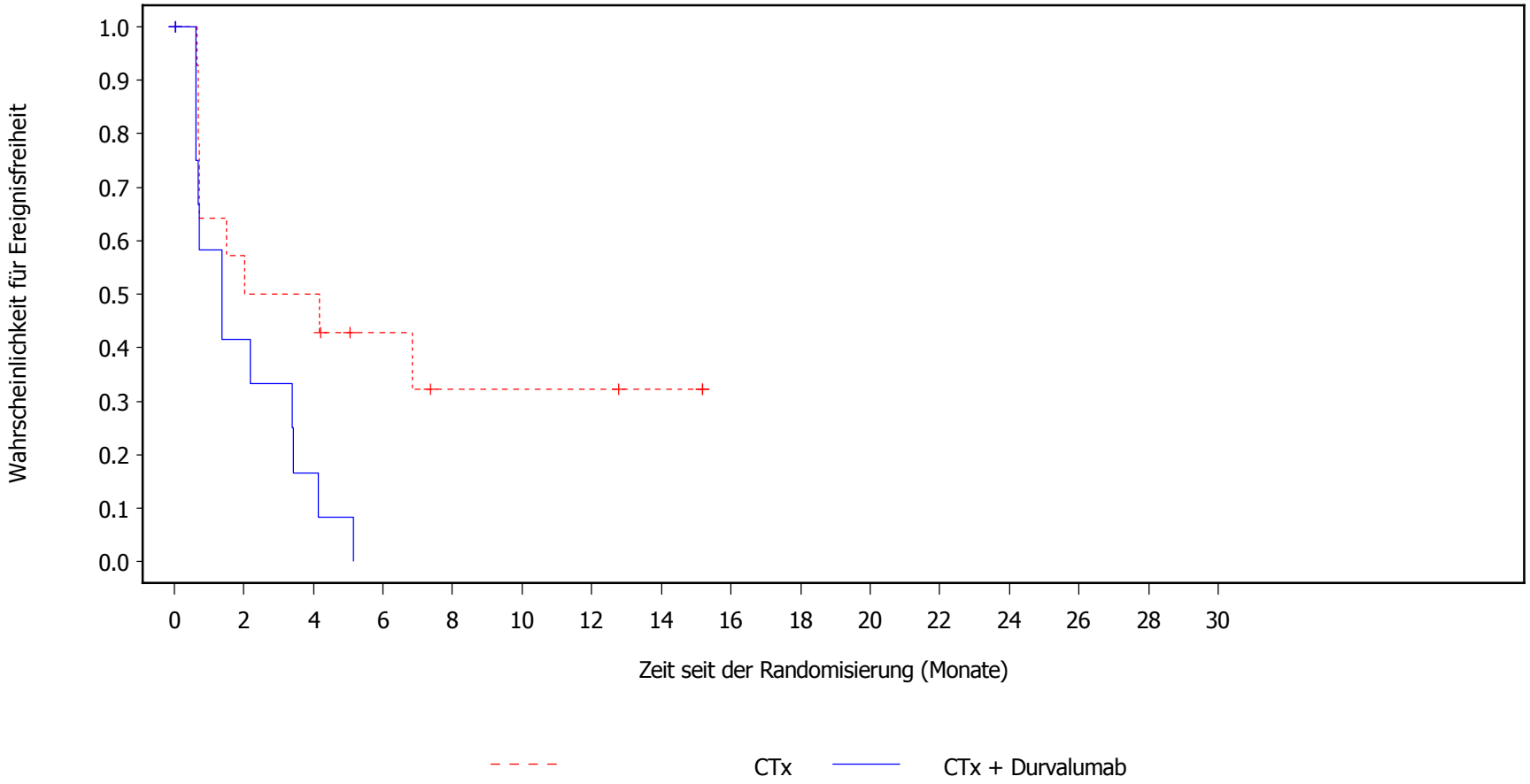
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.8.1.5 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Lymphödem for Abstammung=Asiatisch
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

14	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
15	8	7	4	2	2	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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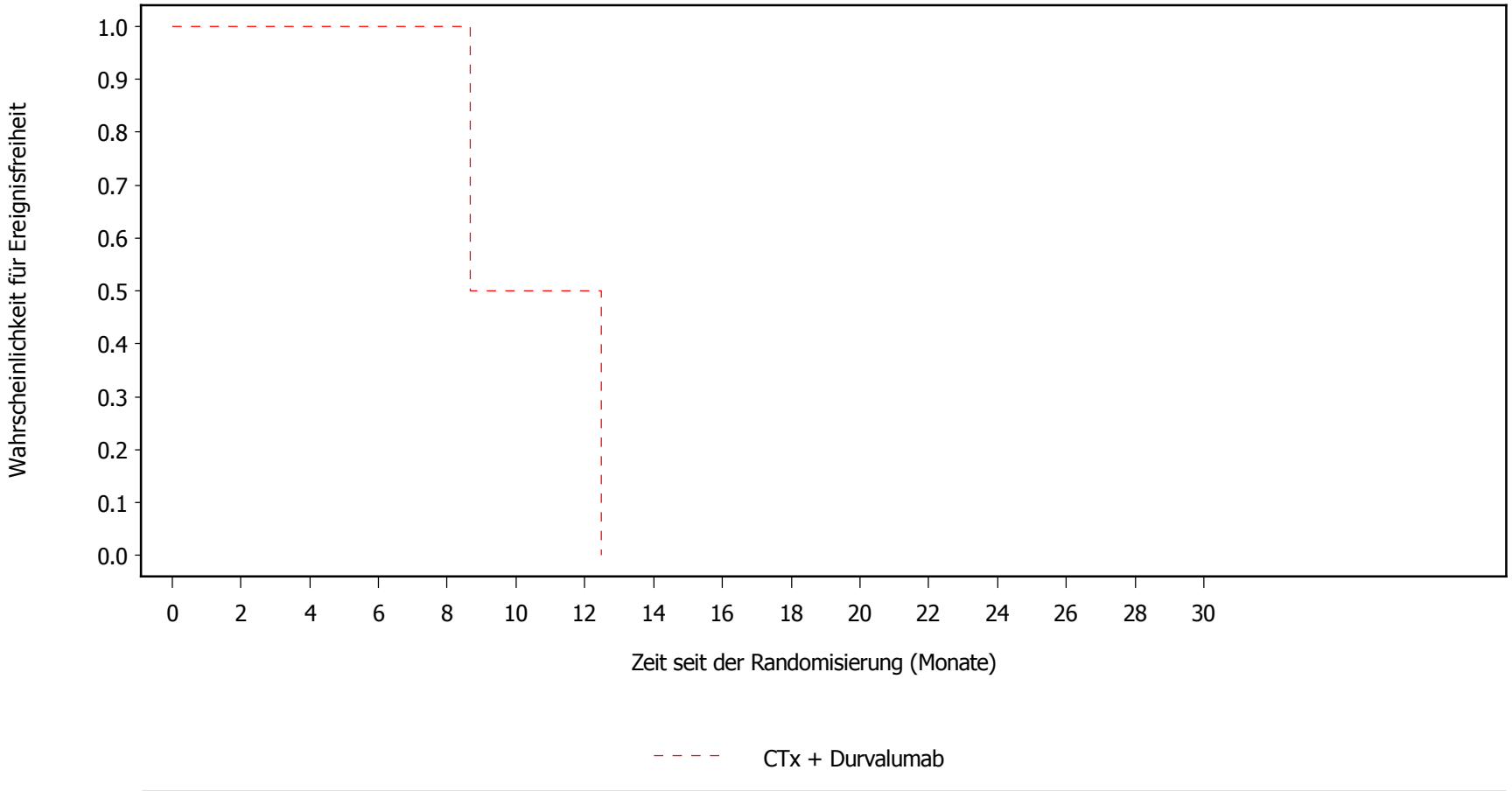
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.8.1.6 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Lymphödem for Abstammung=Andere
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

2	2	2	2	2	1	1	0	0	0	0	0	0	0	0	0	CTx + Durvalumab

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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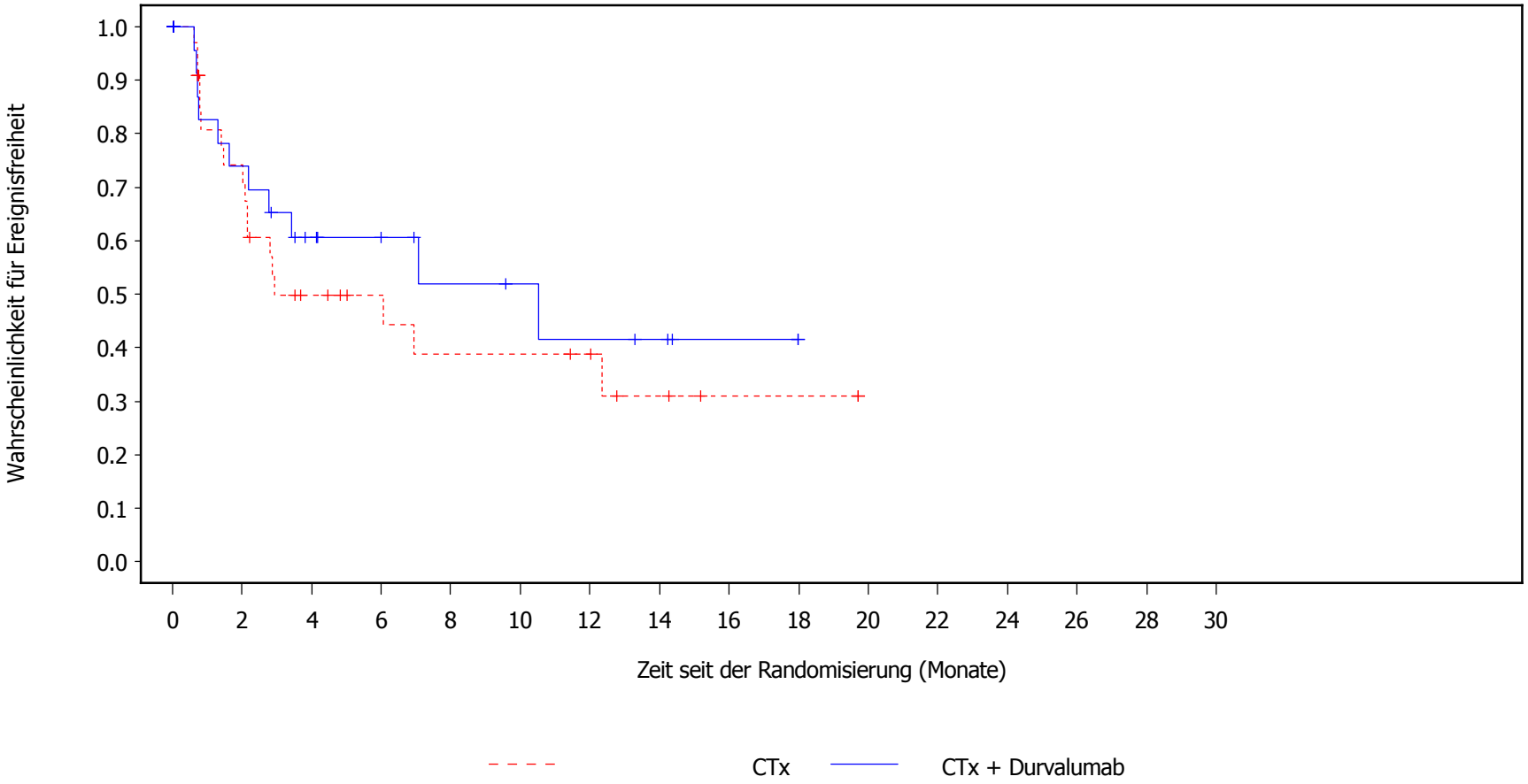
Figure 4.2.8.1.7 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Rücken- und Beckenschmerzen for Histologie=Endometrioid
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

33	17	11	9	6	5	4	3	1	0	0	0	0	0	0	0	CTx + Durvalumab
41	22	12	9	7	7	6	3	1	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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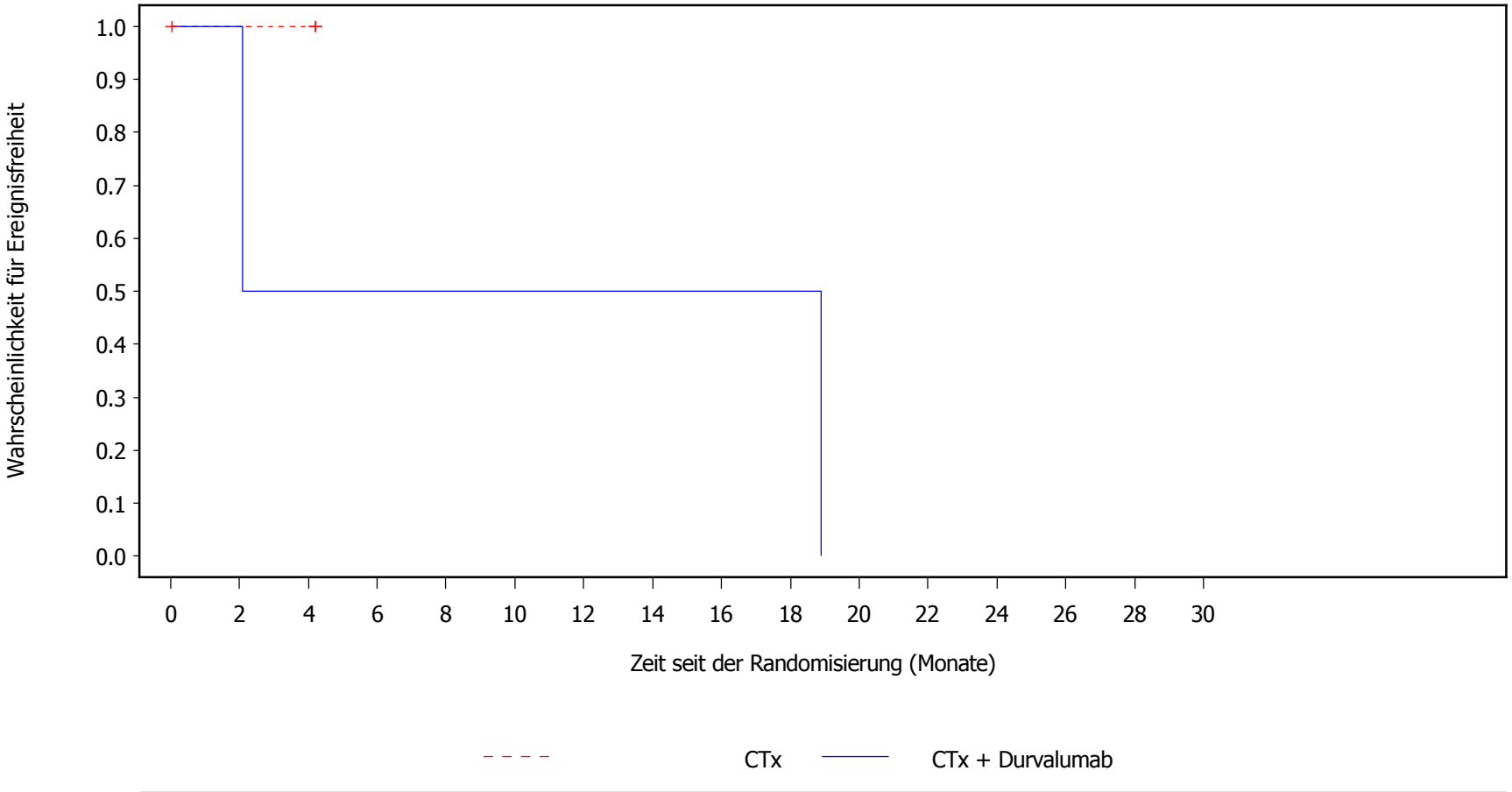
Figure 4.2.8.1.8 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Rücken- und Beckenschmerzen for Histologie=Serös
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

2	2	1	1	1	1	1	1	1	1	0	0	0	0	0	0	CTx + Durvalumab
2	1	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 unstratified Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.

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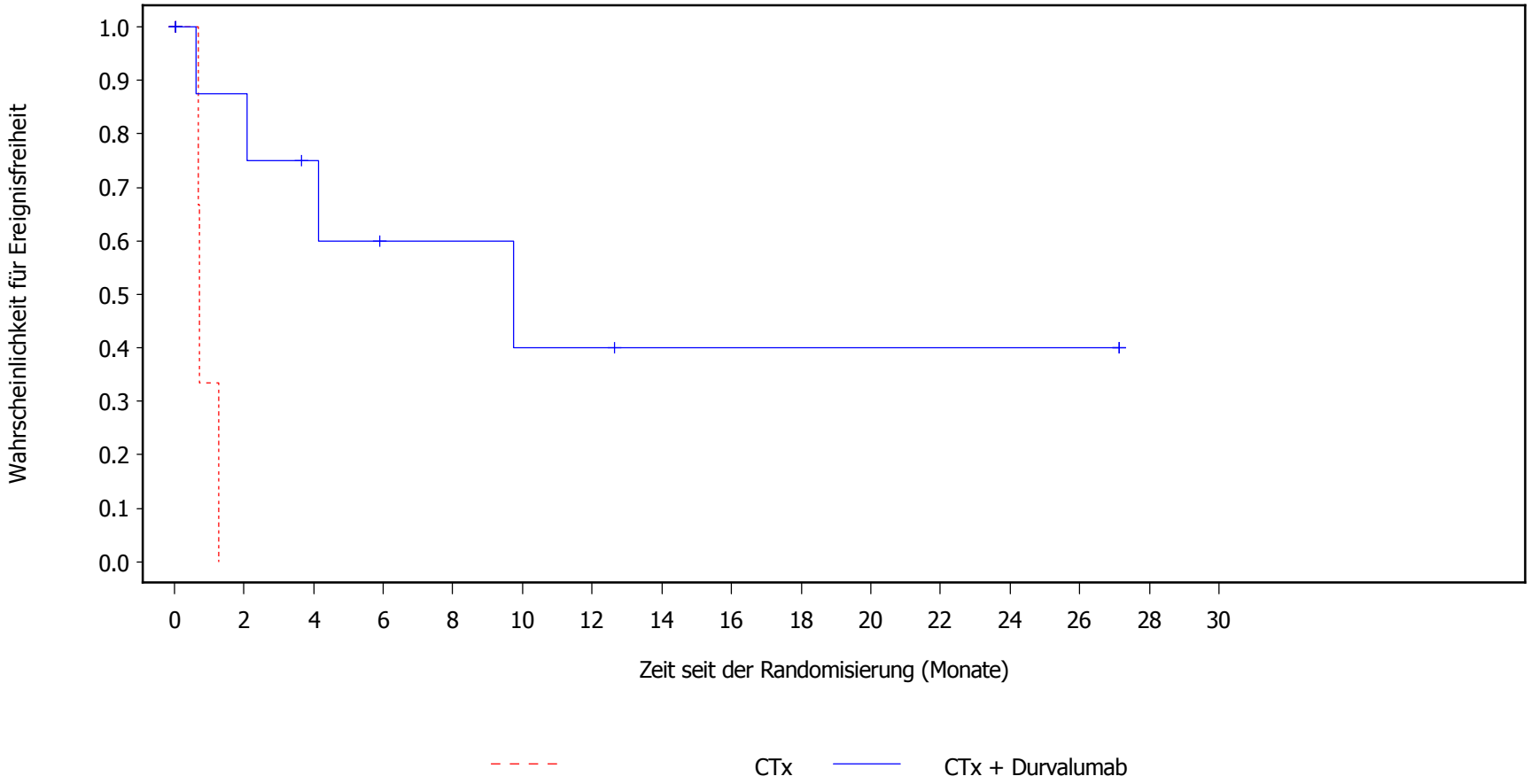
Figure 4.2.8.1.9 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Rücken- und Beckenschmerzen for Histologie=Andere
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

11	7	5	3	3	2	2	1	1	1	1	1	1	1	0	0	CTx + Durvalumab
6	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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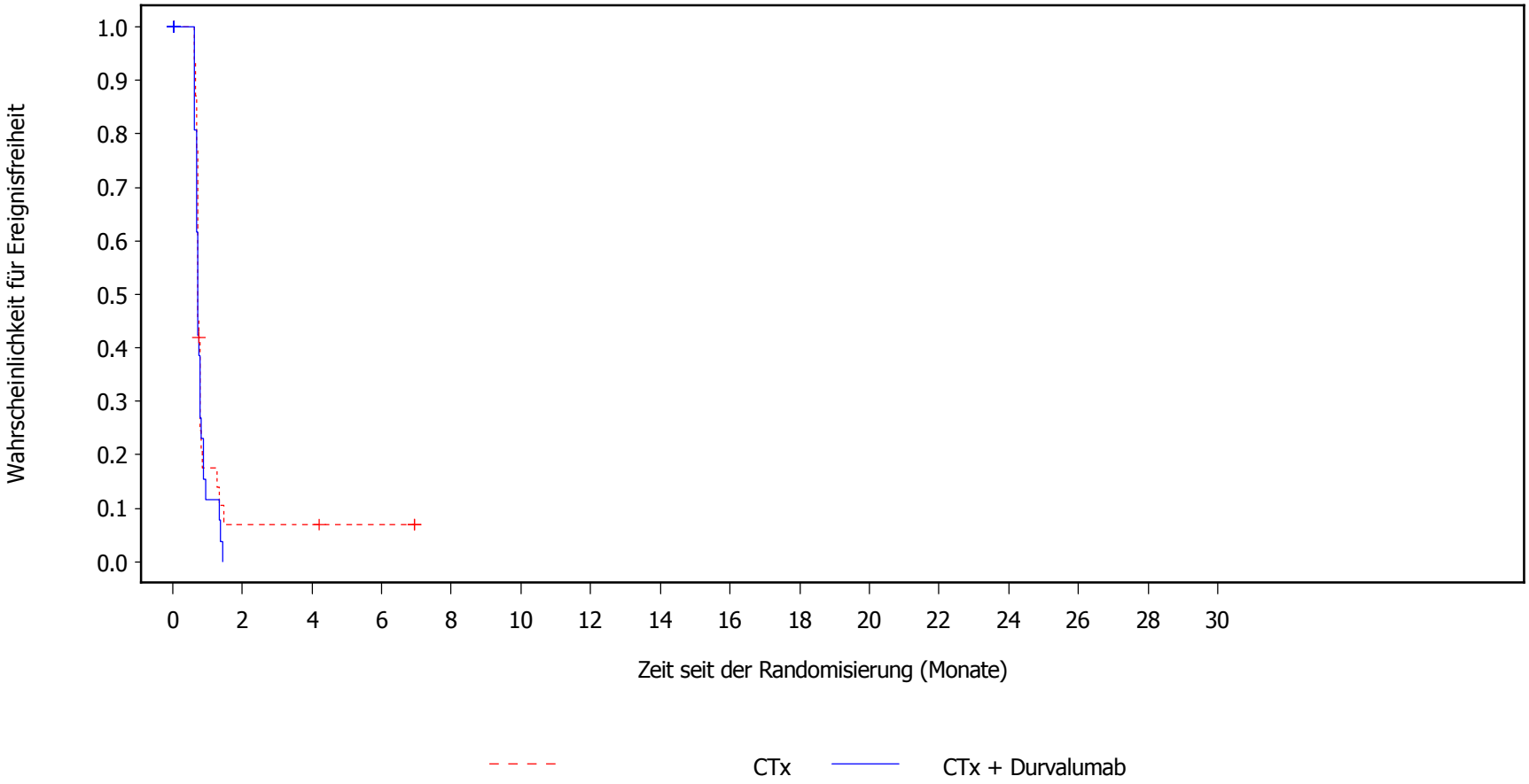
Figure 4.2.8.1.10 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Haarausfall for PD-L1 Expression=Positiv
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

37	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
39	2	2	1	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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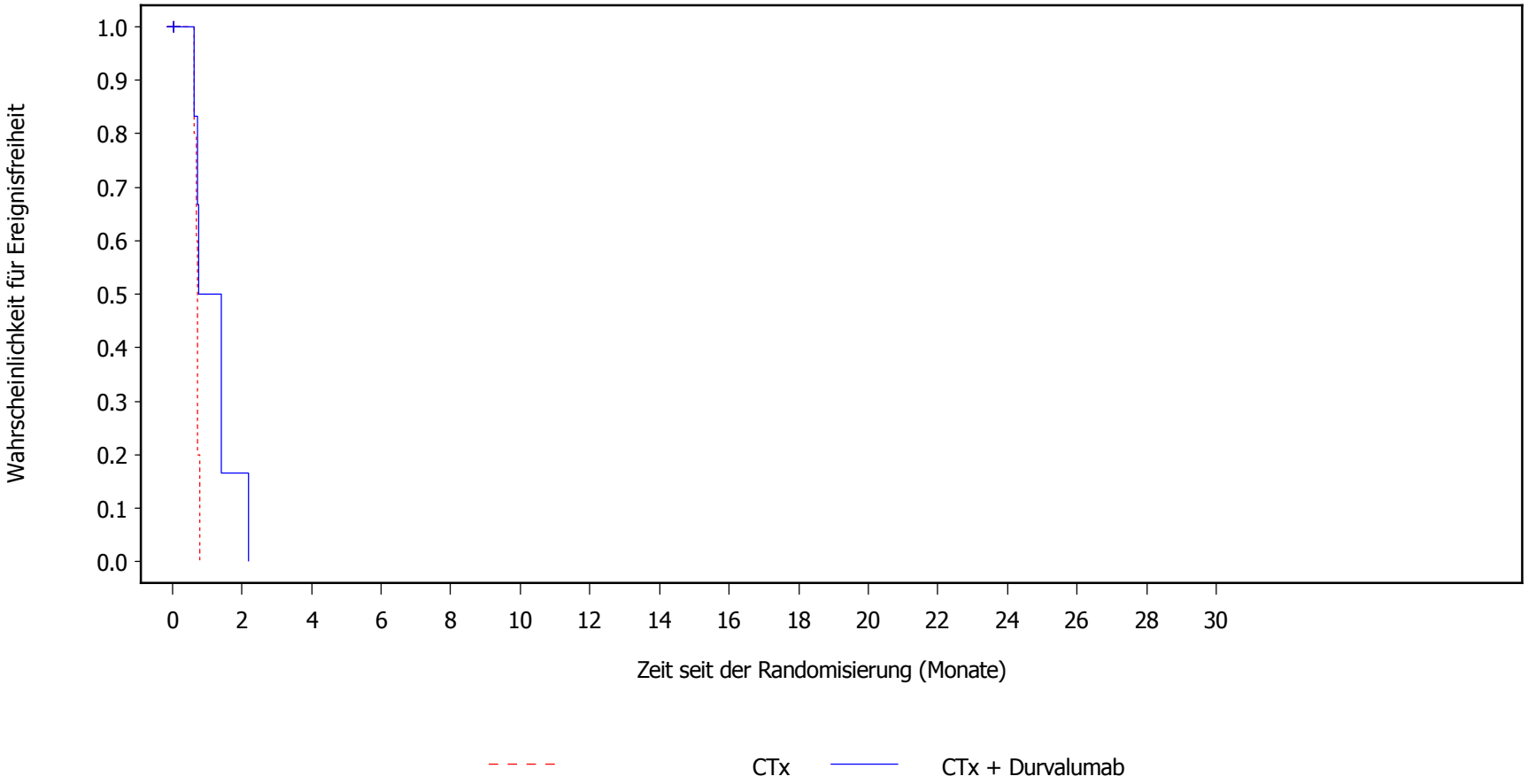
Figure 4.2.8.1.11 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Haarausfall for PD-L1 Expression=Negativ
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

8	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
8	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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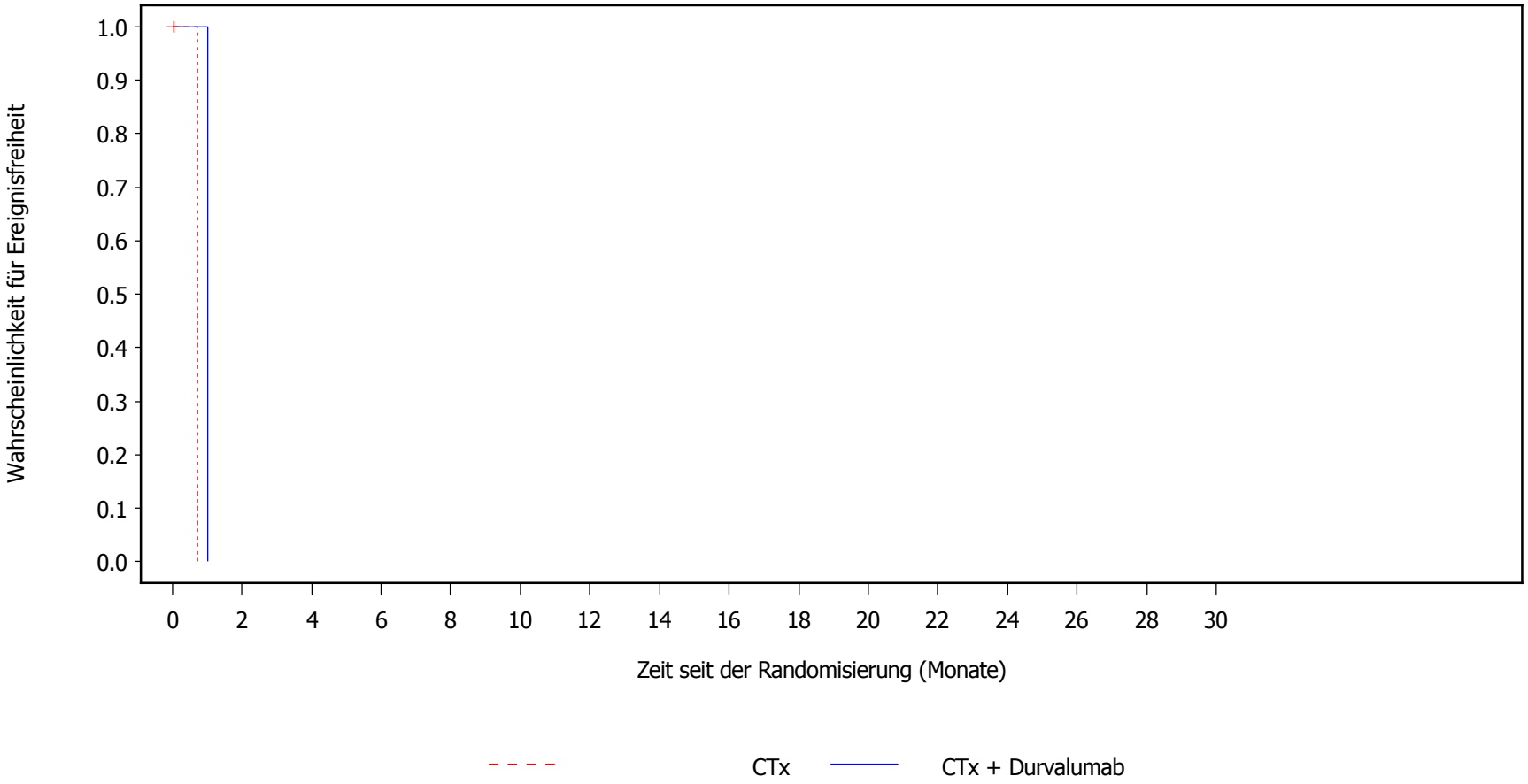
Figure 4.2.8.1.12 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - EORTC QLQ-EN24 Haarausfall for PD-L1 Expression=Unbekannt
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
2	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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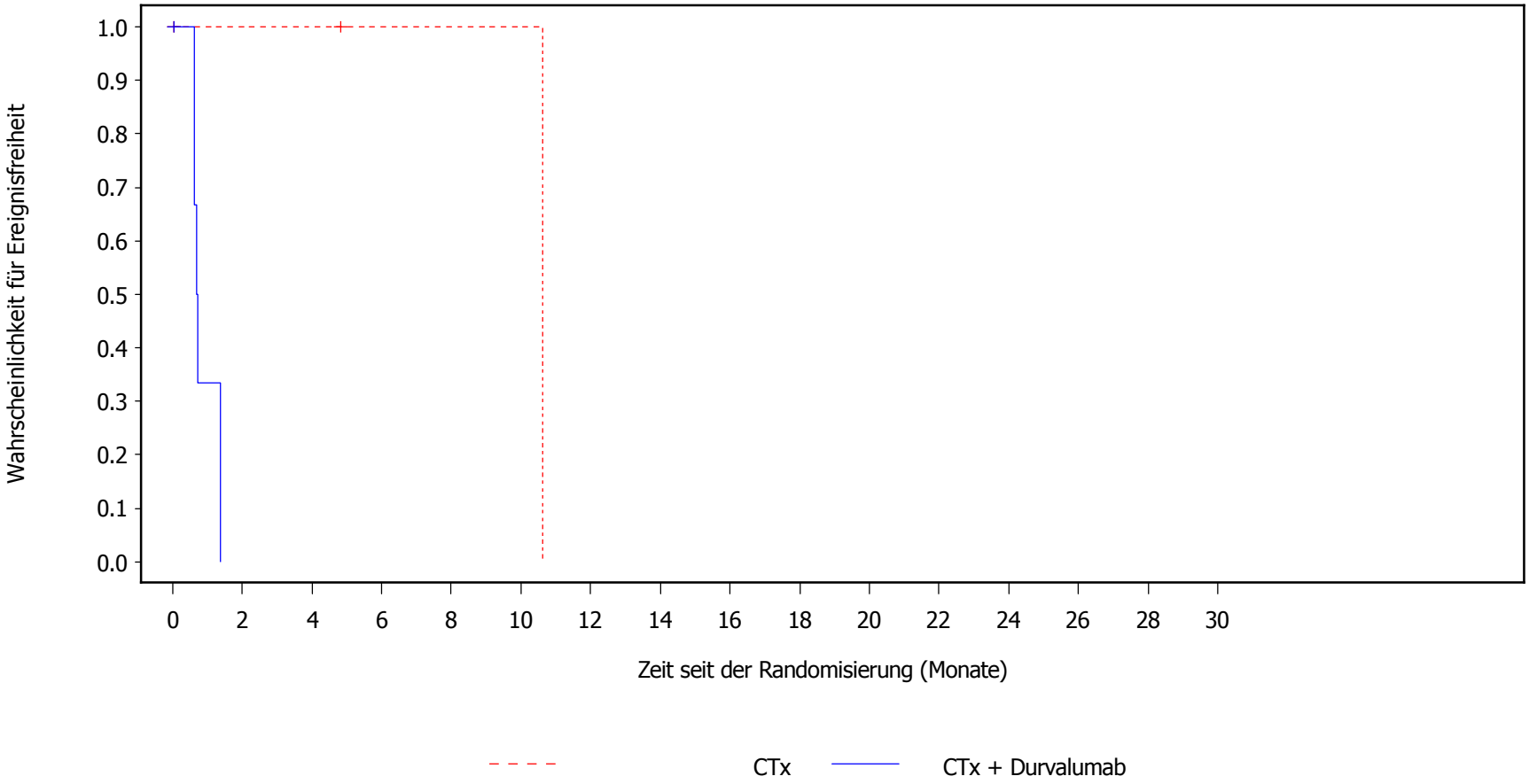
Figure 4.2.10.1.1 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - PGIS for FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen=III
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

73	2	2	1	1	1	0	0	0	0	0	0	0	0	0	0	CTx
70	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab

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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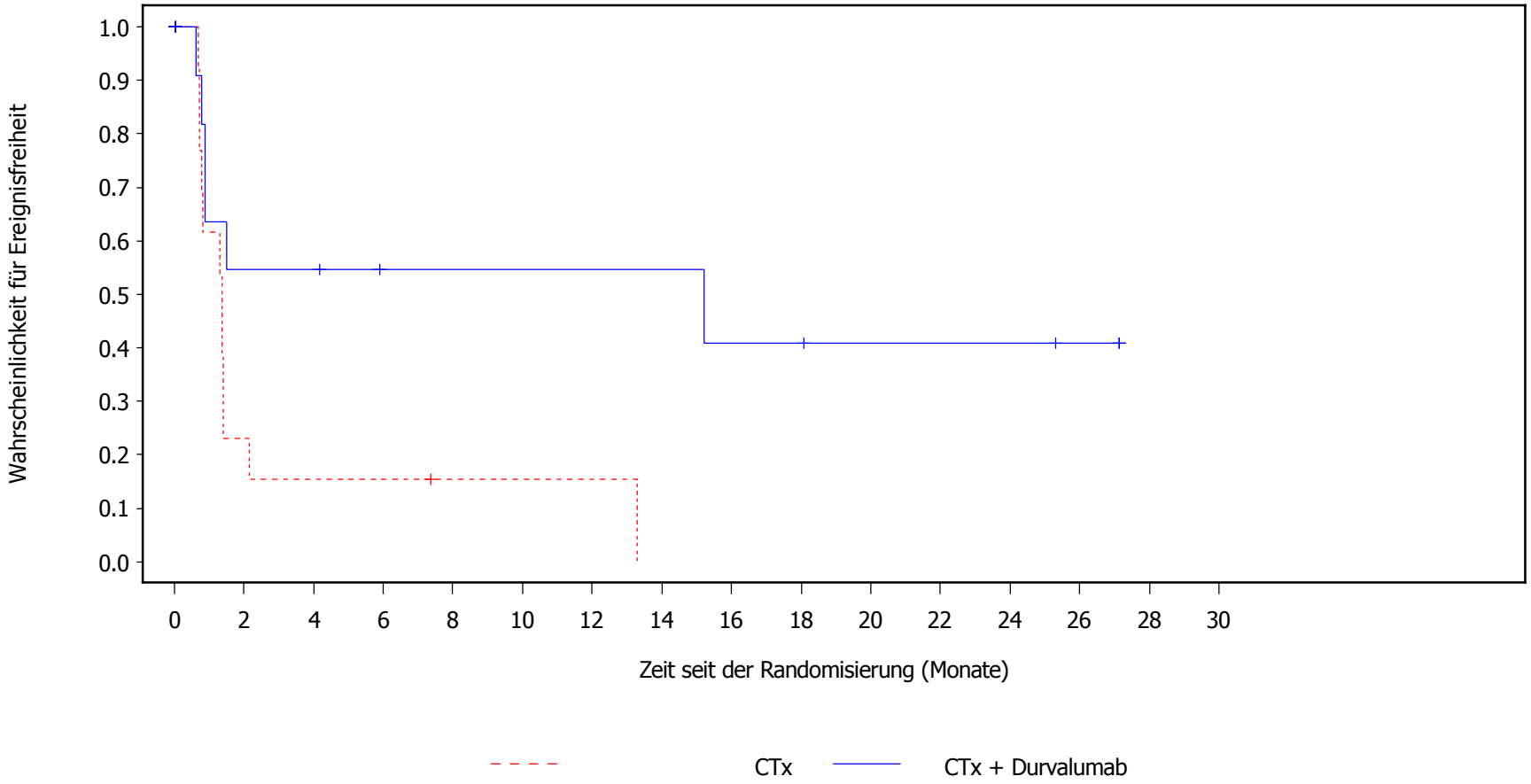
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.2.10.1.2 DUO-E (dMMR Durva): Kaplan-Meier plot of Zeit bis zur ersten Verschlechterung - PGIS for FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen=IV
Full Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

15	6	6	4	4	4	4	4	3	3	2	2	2	1	0	0	CTx + Durvalumab
21	3	2	2	1	1	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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Table 4.3.1.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	23 (100)	0,1 [0,1; 0,1]	24	24 (100)	0,1 [0,1; 0,6]	1,60	[0,89; 2,89]	0,1138
Neu diagnostiziert	21	21 (100)	0,1 [0,1; 0,3]	22	22 (100)	0,1 [0,0; 0,1]	0,76	[0,42; 1,40]	0,3826
Interaktion p-Wert									0,0836
Region									
Asien	14	14 (100)	0,1 [0,0; 0,1]	14	14 (100)	0,1 [0,0; 0,1]	1,06	[0,50; 2,26]	0,8714
Rest der Welt	30	30 (100)	0,1 [0,1; 0,2]	32	32 (100)	0,1 [0,1; 0,3]	1,17	[0,70; 1,94]	0,5448
Interaktion p-Wert									0,8361
Alter									
<65	24	24 (100)	0,1 [0,1; 0,2]	24	24 (100)	0,1 [0,0; 0,3]	1,06	[0,59; 1,89]	0,8509
>=65	20	20 (100)	0,1 [0,0; 0,1]	22	22 (100)	0,1 [0,0; 0,1]	1,29	[0,70; 2,38]	0,4151
Interaktion p-Wert									0,6405
Abstammung									
Weiß	27	27 (100)	0,1 [0,1; 0,1]	29	29 (100)	0,1 [0,1; 0,3]	1,21	[0,71; 2,06]	0,4876
Schwarz/Afroamerikanisch	0	0	NE	1	1 (100)	1,4 [NE; NE]	NC	[NC]	NC
Asiatisch	14	14 (100)	0,1 [0,0; 0,1]	15	15 (100)	0,1 [0,0; 0,1]	1,01	[0,48; 2,11]	0,9812
Andere	2	2 (100)	0,4 [0,1; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6966
HRR Mutationsstatus									
HRRm	11	11 (100)	0,1 [0,0; 0,3]	15	15 (100)	0,1 [0,0; 0,1]	0,77	[0,34; 1,67]	0,5079
Nicht-HRRm	17	17 (100)	0,1 [0,0; 0,5]	20	20 (100)	0,1 [0,0; 0,3]	1,18	[0,60; 2,28]	0,6266
Unbekannt	16	16 (100)	0,1 [0,1; 0,1]	11	11 (100)	0,1 [0,0; 0,8]	1,58	[0,73; 3,55]	0,2500
Interaktion p-Wert									0,4400
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 4.3.1.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	36 (100)	0,1 [0,1; 0,1]	37	37 (100)	0,1 [0,1; 0,3]	1,19	[0,75; 1,90]	0,4606
Negativ	7	7 (100)	0,1 [0,0; 0,5]	7	7 (100)	0,1 [0,0; 0,1]	0,82	[0,28; 2,41]	0,7089
Unbekannt	1	1 (100)	0,1 [NE; NE]	2	2 (100)	0,4 [0,0; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5226
Histologie									
Endometrioid	32	32 (100)	0,1 [0,1; 0,1]	40	40 (100)	0,1 [0,1; 0,1]	1,50	[0,92; 2,46]	0,1063
Serös	2	2 (100)	3,2 [0,1; NE]	1	1 (100)	0,6 [NE; NE]	NC	[NC]	NC
Andere	10	10 (100)	0,1 [0,0; 0,5]	5	5 (100)	0,1 [0,0; NE]	0,71	[0,25; 2,29]	0,5387
Interaktion p-Wert									0,2365
Histologischer Grad									
High grade (G3)	12	12 (100)	0,1 [0,0; 0,3]	11	11 (100)	0,1 [0,0; 1,1]	1,44	[0,62; 3,39]	0,3985
Low grade (G1+G2)	28	28 (100)	0,1 [0,1; 0,1]	31	31 (100)	0,1 [0,0; 0,1]	1,09	[0,65; 1,83]	0,7445
Interaktion p-Wert									0,5815
ECOG Performance Status zu Baseline									
0	21	21 (100)	0,1 [0,1; 0,3]	29	29 (100)	0,1 [0,0; 0,1]	0,72	[0,40; 1,26]	0,2446
1	23	23 (100)	0,1 [0,0; 0,1]	17	17 (100)	0,1 [0,0; 0,7]	2,26	[1,17; 4,46]	0,0148*
Interaktion p-Wert									0,0096*
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	7 (100)	0,3 [0,0; NE]	2	2 (100)	0,0 [NE; NE]	NC	[NC]	NC
IV	14	14 (100)	0,1 [0,1; 0,3]	20	20 (100)	0,1 [0,0; 0,1]	0,83	[0,40; 1,66]	0,6029
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 4.3.1.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Asthenie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	4 (17,4)	NE [NE; NE]	24	3 (12,5)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	3 (10,0)	NE [NE; NE]	32	6 (18,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	2 (8,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	2 (10,0)	NE [NE; NE]	22	6 (27,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	6 (20,7)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	3 (20,0)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	2 (11,8)	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.1.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Asthenie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	2 (5,6)	NE [NE; NE]	37	5 (13,5)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	2 (28,6)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	3 (9,4)	NE [NE; NE]	40	6 (15,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	13,0 [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	3 (10,7)	NE [NE; NE]	31	4 (12,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	NC	[NC]	NC
1	23	3 (13,0)	NE [NE; NE]	17	2 (11,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	3 (15,0)	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 4.3.1.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SOC: Endokrine Erkrankungen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	3 (14,3)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	4 (13,3)	NE [NE; NE]	32	4 (12,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	2 (13,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	1 (9,1)	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 4.3.1.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SOC: Endokrine Erkrankungen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	3 (8,3)	NE [NE; NE]	37	4 (10,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	2 (28,6)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	4 (12,5)	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	4 (14,3)	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
1	23	4 (17,4)	NE [NE; NE]	17	1 (5,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	2 (14,3)	NE [NE; NE]	20	3 (15,0)	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 4.3.1.1.1D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Hypothyreose
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	3 (14,3)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	4 (13,3)	NE [NE; NE]	32	2 (6,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	1 (9,1)	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 4.3.1.1.1D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Hypothyreose
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	3 (8,3)	NE [NE; NE]	37	2 (5,4)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	2 (28,6)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	4 (12,5)	NE [NE; NE]	40	2 (5,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	4 (14,3)	NE [NE; NE]	31	2 (6,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
1	23	4 (17,4)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	2 (14,3)	NE [NE; NE]	20	2 (10,0)	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 4.3.1.1.1D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	5 (21,7)	NE [NE; NE]	24	6 (25,0)	NE [NE; NE]	0,69	[0,20; 2,30]	0,5360
Neu diagnostiziert	21	2 (9,5)	NE [NE; NE]	22	7 (31,8)	19,2 [5,0; NE]	0,18	[0,03; 0,77]	0,0198*
Interaktion p-Wert									0,1697
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	5 (35,7)	19,2 [5,0; NE]	0,16	[0,01; 1,03]	0,0539
Rest der Welt	30	6 (20,0)	NE [NE; NE]	32	8 (25,0)	NE [NE; NE]	0,53	[0,17; 1,55]	0,2427
Interaktion p-Wert									0,3016
Alter									
<65	24	3 (12,5)	NE [NE; NE]	24	7 (29,2)	19,2 [12,5; NE]	0,29	[0,06; 1,08]	0,0663
>=65	20	4 (20,0)	NE [NE; NE]	22	6 (27,3)	NE [NE; NE]	0,52	[0,13; 1,86]	0,3131
Interaktion p-Wert									0,5449
Abstammung									
Weiß	27	5 (18,5)	NE [NE; NE]	29	8 (27,6)	NE [NE; NE]	0,37	[0,10; 1,20]	0,0978
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	5 (33,3)	19,2 [5,0; NE]	0,18	[0,01; 1,13]	0,0693
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,5283
HRR Mutationsstatus									
HRRm	11	2 (18,2)	NE [NE; NE]	15	6 (40,0)	19,2 [2,8; NE]	NC	[NC]	NC
Nicht-HRRm	17	3 (17,6)	NE [NE; NE]	20	6 (30,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	2 (12,5)	NE [NE; NE]	11	1 (9,1)	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 4.3.1.1.1D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	6 (16,7)	NE [NE; NE]	37	10 (27,0)	19,2 [12,5; NE]	0,42	[0,13; 1,17]	0,0965
Negativ	7	1 (14,3)	NE [NE; NE]	7	2 (28,6)	NE [NE; NE]	0,47	[0,02; 4,93]	0,5273
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	1,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9262
Histologie									
Endometrioid	32	5 (15,6)	NE [NE; NE]	40	11 (27,5)	NE [NE; NE]	0,45	[0,14; 1,26]	0,1314
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	2 (40,0)	NE [NE; NE]	0,12	[0,01; 1,30]	0,0787
Interaktion p-Wert									0,3071
Histologischer Grad									
High grade (G3)	12	2 (16,7)	NE [NE; NE]	11	3 (27,3)	NE [NE; NE]	0,32	[0,04; 2,04]	0,2211
Low grade (G1+G2)	28	5 (17,9)	NE [NE; NE]	31	10 (32,3)	19,2 [12,5; NE]	0,42	[0,13; 1,20]	0,1080
Interaktion p-Wert									0,7905
ECOG Performance Status zu Baseline									
0	21	3 (14,3)	NE [NE; NE]	29	9 (31,0)	19,2 [5,6; NE]	0,30	[0,07; 1,05]	0,0594
1	23	4 (17,4)	NE [NE; NE]	17	4 (23,5)	NE [NE; NE]	0,54	[0,12; 2,32]	0,3927
Interaktion p-Wert									0,5533
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	2 (14,3)	NE [NE; NE]	20	7 (35,0)	19,2 [4,6; 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 4.3.1.1.1D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Thrombozytopenie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	3 (12,5)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	3 (14,3)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	2 (14,3)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	3 (10,0)	NE [NE; NE]	32	3 (9,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	2 (14,3)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	2 (18,2)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	1 (9,1)	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 4.3.1.1.1D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Thrombozytopenie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	4 (11,1)	NE [NE; NE]	37	4 (10,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	1 (14,3)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	3 (9,4)	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	2 (16,7)	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	2 (9,5)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
1	23	3 (13,0)	NE [NE; NE]	17	1 (5,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	3 (21,4)	NE [NE; NE]	20	1 (5,0)	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 4.3.1.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	23 (100)	0,1 [0,1; 0,1]	24	24 (100)	0,1 [0,1; 0,6]	1,60	[0,89; 2,89]	0,1138
Neu diagnostiziert	21	21 (100)	0,1 [0,1; 0,3]	22	22 (100)	0,1 [0,0; 0,1]	0,76	[0,42; 1,40]	0,3826
Interaktion p-Wert									0,0836
Region									
Asien	14	14 (100)	0,1 [0,0; 0,1]	14	14 (100)	0,1 [0,0; 0,1]	1,06	[0,50; 2,26]	0,8714
Rest der Welt	30	30 (100)	0,1 [0,1; 0,2]	32	32 (100)	0,1 [0,1; 0,3]	1,17	[0,70; 1,94]	0,5448
Interaktion p-Wert									0,8361
Alter									
<65	24	24 (100)	0,1 [0,1; 0,2]	24	24 (100)	0,1 [0,0; 0,3]	1,06	[0,59; 1,89]	0,8509
>=65	20	20 (100)	0,1 [0,0; 0,1]	22	22 (100)	0,1 [0,0; 0,1]	1,29	[0,70; 2,38]	0,4151
Interaktion p-Wert									0,6405
Abstammung									
Weiß	27	27 (100)	0,1 [0,1; 0,1]	29	29 (100)	0,1 [0,1; 0,3]	1,21	[0,71; 2,06]	0,4876
Schwarz/Afroamerikanisch	0	0	NE	1	1 (100)	1,4 [NE; NE]	NC	[NC]	NC
Asiatisch	14	14 (100)	0,1 [0,0; 0,1]	15	15 (100)	0,1 [0,0; 0,1]	1,01	[0,48; 2,11]	0,9812
Andere	2	2 (100)	0,4 [0,1; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6966
HRR Mutationsstatus									
HRRm	11	11 (100)	0,1 [0,0; 0,3]	15	15 (100)	0,1 [0,0; 0,1]	0,77	[0,34; 1,67]	0,5079
Nicht-HRRm	17	17 (100)	0,1 [0,0; 0,5]	20	20 (100)	0,1 [0,0; 0,3]	1,18	[0,60; 2,28]	0,6266
Unbekannt	16	16 (100)	0,1 [0,1; 0,1]	11	11 (100)	0,1 [0,0; 0,8]	1,58	[0,73; 3,55]	0,2500
Interaktion p-Wert									0,4400
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 4.3.1.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	36 (100)	0,1 [0,1; 0,1]	37	37 (100)	0,1 [0,1; 0,3]	1,19	[0,75; 1,90]	0,4606
Negativ	7	7 (100)	0,1 [0,0; 0,5]	7	7 (100)	0,1 [0,0; 0,1]	0,82	[0,28; 2,41]	0,7089
Unbekannt	1	1 (100)	0,1 [NE; NE]	2	2 (100)	0,4 [0,0; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5226
Histologie									
Endometrioid	32	32 (100)	0,1 [0,1; 0,1]	40	40 (100)	0,1 [0,1; 0,1]	1,50	[0,92; 2,46]	0,1063
Serös	2	2 (100)	3,2 [0,1; NE]	1	1 (100)	0,6 [NE; NE]	NC	[NC]	NC
Andere	10	10 (100)	0,1 [0,0; 0,5]	5	5 (100)	0,1 [0,0; NE]	0,71	[0,25; 2,29]	0,5387
Interaktion p-Wert									0,2365
Histologischer Grad									
High grade (G3)	12	12 (100)	0,1 [0,0; 0,3]	11	11 (100)	0,1 [0,0; 1,1]	1,44	[0,62; 3,39]	0,3985
Low grade (G1+G2)	28	28 (100)	0,1 [0,1; 0,1]	31	31 (100)	0,1 [0,0; 0,1]	1,09	[0,65; 1,83]	0,7445
Interaktion p-Wert									0,5815
ECOG Performance Status zu Baseline									
0	21	21 (100)	0,1 [0,1; 0,3]	29	29 (100)	0,1 [0,0; 0,1]	0,72	[0,40; 1,26]	0,2446
1	23	23 (100)	0,1 [0,0; 0,1]	17	17 (100)	0,1 [0,0; 0,7]	2,26	[1,17; 4,46]	0,0148*
Interaktion p-Wert									0,0096*
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	7 (100)	0,3 [0,0; NE]	2	2 (100)	0,0 [NE; NE]	NC	[NC]	NC
IV	14	14 (100)	0,1 [0,1; 0,3]	20	20 (100)	0,1 [0,0; 0,1]	0,83	[0,40; 1,66]	0,6029
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 4.3.1.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Asthenie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	4 (17,4)	NE [NE; NE]	24	3 (12,5)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	3 (10,0)	NE [NE; NE]	32	6 (18,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	2 (8,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	2 (10,0)	NE [NE; NE]	22	6 (27,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	6 (20,7)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	3 (20,0)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	2 (11,8)	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.1.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Asthenie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	2 (5,6)	NE [NE; NE]	37	5 (13,5)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	2 (28,6)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	3 (9,4)	NE [NE; NE]	40	6 (15,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	13,0 [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	3 (10,7)	NE [NE; NE]	31	4 (12,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	NC	[NC]	NC
1	23	3 (13,0)	NE [NE; NE]	17	2 (11,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	3 (15,0)	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 4.3.1.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SOC: Endokrine Erkrankungen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	3 (14,3)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	4 (13,3)	NE [NE; NE]	32	4 (12,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	2 (13,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	1 (9,1)	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 4.3.1.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SOC: Endokrine Erkrankungen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	3 (8,3)	NE [NE; NE]	37	4 (10,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	2 (28,6)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	4 (12,5)	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	4 (14,3)	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
1	23	4 (17,4)	NE [NE; NE]	17	1 (5,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	2 (14,3)	NE [NE; NE]	20	3 (15,0)	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 4.3.1.1.2D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Hypothyreose
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	3 (14,3)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	4 (13,3)	NE [NE; NE]	32	2 (6,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	1 (9,1)	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 4.3.1.1.2D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Hypothyreose
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	3 (8,3)	NE [NE; NE]	37	2 (5,4)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	2 (28,6)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	4 (12,5)	NE [NE; NE]	40	2 (5,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	4 (14,3)	NE [NE; NE]	31	2 (6,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
1	23	4 (17,4)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	2 (14,3)	NE [NE; NE]	20	2 (10,0)	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 4.3.1.1.2D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Thrombozytopenie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	3 (12,5)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	3 (14,3)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	2 (14,3)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	3 (10,0)	NE [NE; NE]	32	3 (9,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	2 (14,3)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	2 (18,2)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	1 (9,1)	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 4.3.1.1.2D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Thrombozytopenie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	4 (11,1)	NE [NE; NE]	37	4 (10,8)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	1 (14,3)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	3 (9,4)	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	2 (16,7)	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	2 (9,5)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
1	23	3 (13,0)	NE [NE; NE]	17	1 (5,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	3 (21,4)	NE [NE; NE]	20	1 (5,0)	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 4.3.1.1.2D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Hypokaliaemie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	4 (17,4)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	4 (19,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	3 (21,4)	NE [NE; NE]	14	2 (14,3)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	5 (16,7)	NE [NE; NE]	32	3 (9,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	3 (12,5)	NE [NE; NE]	NC	[NC]	NC
>=65	20	4 (20,0)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	5 (18,5)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	3 (21,4)	NE [NE; NE]	15	2 (13,3)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	6 (35,3)	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	1 (9,1)	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 4.3.1.1.2D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first PT: Hypokaliaemie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	6 (16,7)	NE [NE; NE]	37	5 (13,5)	NE [NE; NE]	1,18	[0,35; 4,10]	0,7902
Negativ	7	2 (28,6)	23,2 [0,8; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	6 (18,8)	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	1,80	[0,51; 7,05]	0,3604
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	2 (20,0)	NE [NE; NE]	5	1 (20,0)	NE [NE; NE]	0,85	[0,08; 18,36]	0,8968
Interaktion p-Wert									0,6014
Histologischer Grad									
High grade (G3)	12	2 (16,7)	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	1,67	[0,16; 36,04]	0,6690
Low grade (G1+G2)	28	6 (21,4)	NE [NE; NE]	31	4 (12,9)	NE [NE; NE]	1,52	[0,43; 5,98]	0,5128
Interaktion p-Wert									0,9466
ECOG Performance Status zu Baseline									
0	21	2 (9,5)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
1	23	6 (26,1)	NE [NE; NE]	17	2 (11,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	3 (21,4)	NE [NE; NE]	20	1 (5,0)	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 4.3.2.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	7 (30,4)	NE [NE; NE]	24	10 (41,7)	NE [NE; NE]	0,61	[0,22; 1,60]	0,3149
Neu diagnostiziert	21	6 (28,6)	NE [NE; NE]	22	5 (22,7)	NE [NE; NE]	1,19	[0,36; 4,12]	0,7772
Interaktion p-Wert									0,3926
Region									
Asien	14	7 (50,0)	9,7 [0,3; NE]	14	3 (21,4)	NE [NE; NE]	2,95	[0,82; 13,72]	0,0993
Rest der Welt	30	6 (20,0)	NE [NE; NE]	32	12 (37,5)	NE [NE; NE]	0,41	[0,14; 1,06]	0,0673
Interaktion p-Wert									0,0157*
Alter									
<65	24	8 (33,3)	NE [NE; NE]	24	7 (29,2)	NE [NE; NE]	1,10	[0,39; 3,14]	0,8546
>=65	20	5 (25,0)	18,9 [18,9; NE]	22	8 (36,4)	NE [NE; NE]	0,57	[0,17; 1,71]	0,3140
Interaktion p-Wert									0,3866
Abstammung									
Weiß	27	6 (22,2)	NE [NE; NE]	29	11 (37,9)	NE [NE; NE]	0,44	[0,15; 1,16]	0,0988
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	7 (50,0)	9,7 [0,3; NE]	15	4 (26,7)	NE [NE; NE]	2,28	[0,69; 8,72]	0,1784
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,0372*
HRR Mutationsstatus									
HRRm	11	5 (45,5)	7,2 [0,5; NE]	15	7 (46,7)	NE [NE; NE]	1,07	[0,32; 3,36]	0,9070
Nicht-HRRm	17	3 (17,6)	NE [NE; NE]	20	6 (30,0)	NE [NE; NE]	0,50	[0,11; 1,90]	0,3142
Unbekannt	16	5 (31,3)	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	1,49	[0,32; 10,40]	0,6272
Interaktion p-Wert									0,5496
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 4.3.2.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	11 (30,6)	NE [NE; NE]	37	13 (35,1)	NE [NE; NE]	0,80	[0,35; 1,79]	0,5824
Negativ	7	2 (28,6)	18,9 [6,6; NE]	7	1 (14,3)	NE [NE; NE]	1,89	[0,18; 40,72]	0,5921
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	1,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,4911
Histologie									
Endometrioid	32	8 (25,0)	NE [NE; NE]	40	12 (30,0)	NE [NE; NE]	0,79	[0,31; 1,91]	0,6004
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	4 (40,0)	NE [NE; NE]	5	3 (60,0)	2,0 [1,4; NE]	0,49	[0,11; 2,52]	0,3684
Interaktion p-Wert									0,6004
Histologischer Grad									
High grade (G3)	12	4 (33,3)	18,9 [0,3; NE]	11	5 (45,5)	6,3 [2,0; NE]	0,75	[0,18; 2,84]	0,6645
Low grade (G1+G2)	28	5 (17,9)	NE [NE; NE]	31	10 (32,3)	NE [NE; NE]	0,51	[0,16; 1,43]	0,2017
Interaktion p-Wert									0,6542
ECOG Performance Status zu Baseline									
0	21	6 (28,6)	NE [NE; NE]	29	10 (34,5)	NE [NE; NE]	0,75	[0,26; 2,04]	0,5825
1	23	7 (30,4)	18,9 [6,6; NE]	17	5 (29,4)	NE [NE; NE]	0,92	[0,29; 3,10]	0,8803
Interaktion p-Wert									0,8041
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	2 (28,6)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	4 (28,6)	NE [NE; NE]	20	5 (25,0)	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 4.3.2.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	3 (9,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.2.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	0	NE [NE; NE]	37	3 (8,1)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	1,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	3 (17,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	2 (10,0)	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 4.3.2.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	4 (12,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	2 (13,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	2 (10,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	1 (9,1)	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 4.3.2.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	5 (13,5)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	1 (20,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	4 (12,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	2 (11,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	1 (5,0)	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 4.3.2.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	9 (39,1)	NE [NE; NE]	24	10 (41,7)	NE [NE; NE]	0,73	[0,29; 1,82]	0,4931
Neu diagnostiziert	21	7 (33,3)	NE [NE; NE]	22	5 (22,7)	NE [NE; NE]	1,32	[0,42; 4,48]	0,6317
Interaktion p-Wert									0,4204
Region									
Asien	14	7 (50,0)	9,7 [0,3; NE]	14	3 (21,4)	NE [NE; NE]	3,07	[0,85; 14,26]	0,0882
Rest der Welt	30	9 (30,0)	NE [NE; NE]	32	12 (37,5)	NE [NE; NE]	0,56	[0,23; 1,34]	0,1925
Interaktion p-Wert									0,0325*
Alter									
<65	24	8 (33,3)	NE [NE; NE]	24	7 (29,2)	NE [NE; NE]	1,05	[0,38; 3,00]	0,9256
>=65	20	8 (40,0)	20,2 [18,8; NE]	22	8 (36,4)	NE [NE; NE]	0,84	[0,31; 2,30]	0,7271
Interaktion p-Wert									0,7552
Abstammung									
Weiß	27	9 (33,3)	NE [NE; NE]	29	11 (37,9)	NE [NE; NE]	0,59	[0,24; 1,46]	0,2541
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	7 (50,0)	9,7 [0,3; NE]	15	4 (26,7)	NE [NE; NE]	2,36	[0,71; 9,05]	0,1609
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,0717
HRR Mutationsstatus									
HRRm	11	5 (45,5)	7,2 [0,5; NE]	15	7 (46,7)	NE [NE; NE]	1,01	[0,30; 3,18]	0,9843
Nicht-HRRm	17	5 (29,4)	21,8 [18,9; NE]	20	6 (30,0)	NE [NE; NE]	0,80	[0,23; 2,68]	0,7188
Unbekannt	16	6 (37,5)	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	1,65	[0,38; 11,26]	0,5275
Interaktion p-Wert									0,7702
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 4.3.2.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	14 (38,9)	NE [NE; NE]	37	13 (35,1)	NE [NE; NE]	0,96	[0,44; 2,08]	0,9107
Negativ	7	2 (28,6)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	1,86	[0,18; 39,91]	0,6040
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	1,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,5976
Histologie									
Endometrioid	32	11 (34,4)	NE [NE; NE]	40	12 (30,0)	NE [NE; NE]	1,01	[0,44; 2,31]	0,9864
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	4 (40,0)	NE [NE; NE]	5	3 (60,0)	2,0 [1,4; NE]	0,49	[0,11; 2,49]	0,3623
Interaktion p-Wert									0,4134
Histologischer Grad									
High grade (G3)	12	4 (33,3)	NE [NE; NE]	11	5 (45,5)	6,3 [2,0; NE]	0,67	[0,17; 2,57]	0,5583
Low grade (G1+G2)	28	8 (28,6)	NE [NE; NE]	31	10 (32,3)	NE [NE; NE]	0,73	[0,28; 1,87]	0,5170
Interaktion p-Wert									0,9163
ECOG Performance Status zu Baseline									
0	21	9 (42,9)	21,8 [7,2; NE]	29	10 (34,5)	NE [NE; NE]	1,06	[0,42; 2,65]	0,8969
1	23	7 (30,4)	NE [NE; NE]	17	5 (29,4)	NE [NE; NE]	0,87	[0,28; 2,95]	0,8123
Interaktion p-Wert									0,7886
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	3 (42,9)	20,2 [0,1; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	4 (28,6)	NE [NE; NE]	20	5 (25,0)	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 4.3.2.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	3 (9,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.2.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	0	NE [NE; NE]	37	3 (8,1)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	1,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	3 (17,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	2 (10,0)	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 4.3.2.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	4 (12,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	2 (13,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	2 (10,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	1 (9,1)	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 4.3.2.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUE SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	5 (13,5)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	1 (20,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	4 (12,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	2 (11,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	1 (5,0)	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 4.3.3.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first Therapieabbruch aufgrund von UE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	4 (17,4)	NE [NE; NE]	24	5 (20,8)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	5 (23,8)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	3 (21,4)	NE [NE; NE]	14	2 (14,3)	NE [NE; NE]	1,54	[0,26; 11,71]	0,6324
Rest der Welt	30	6 (20,0)	NE [NE; NE]	32	5 (15,6)	NE [NE; NE]	1,19	[0,36; 4,13]	0,7778
Interaktion p-Wert									0,8108
Alter									
<65	24	6 (25,0)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	1,45	[0,41; 5,70]	0,5599
>=65	20	3 (15,0)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	1,05	[0,19; 5,66]	0,9561
Interaktion p-Wert									0,7522
Abstammung									
Weiß	27	5 (18,5)	NE [NE; NE]	29	5 (17,2)	NE [NE; NE]	0,94	[0,26; 3,39]	0,9201
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	3 (21,4)	NE [NE; NE]	15	2 (13,3)	NE [NE; NE]	1,65	[0,27; 12,56]	0,5782
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6085
HRR Mutationsstatus									
HRRm	11	4 (36,4)	18,8 [0,8; NE]	15	2 (13,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	2 (11,8)	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	2 (18,2)	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 4.3.3.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first Therapieabbruch aufgrund von UE
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	9 (25,0)	NE [NE; NE]	37	5 (13,5)	NE [NE; NE]	1,87	[0,64; 6,09]	0,2553
Negativ	7	0	NE [NE; NE]	7	2 (28,6)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	6 (18,8)	NE [NE; NE]	40	5 (12,5)	NE [NE; NE]	1,59	[0,48; 5,52]	0,4429
Serös	2	1 (50,0)	NE [NE; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Andere	10	2 (20,0)	NE [NE; NE]	5	1 (20,0)	NE [NE; NE]	0,88	[0,08; 19,05]	0,9204
Interaktion p-Wert									0,6752
Histologischer Grad									
High grade (G3)	12	2 (16,7)	NE [NE; NE]	11	3 (27,3)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	5 (17,9)	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	6 (28,6)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	2,10	[0,60; 8,22]	0,2455
1	23	3 (13,0)	NE [NE; NE]	17	3 (17,6)	NE [NE; NE]	0,64	[0,12; 3,45]	0,5827
Interaktion p-Wert									0,2534
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	2 (28,6)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	3 (21,4)	NE [NE; NE]	20	2 (10,0)	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 4.3.3.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first Therapieabbruch aufgrund von UE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	4 (17,4)	NE [NE; NE]	24	5 (20,8)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	5 (23,8)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	3 (21,4)	NE [NE; NE]	14	2 (14,3)	NE [NE; NE]	1,49	[0,25; 11,36]	0,6584
Rest der Welt	30	6 (20,0)	NE [NE; NE]	32	4 (12,5)	NE [NE; NE]	1,49	[0,42; 5,85]	0,5331
Interaktion p-Wert									0,9994
Alter									
<65	24	6 (25,0)	NE [NE; NE]	24	3 (12,5)	NE [NE; NE]	NC	[NC]	NC
>=65	20	3 (15,0)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	5 (18,5)	NE [NE; NE]	29	4 (13,8)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	3 (21,4)	NE [NE; NE]	15	2 (13,3)	NE [NE; NE]	NC	[NC]	NC
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	4 (36,4)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	2 (11,8)	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	2 (18,2)	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 4.3.3.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first Therapieabbruch aufgrund von UE
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	9 (25,0)	NE [NE; NE]	37	5 (13,5)	NE [NE; NE]	1,85	[0,64; 6,06]	0,2610
Negativ	7	0	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	6 (18,8)	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	1,94	[0,55; 7,60]	0,3002
Serös	2	1 (50,0)	NE [NE; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Andere	10	2 (20,0)	NE [NE; NE]	5	1 (20,0)	NE [NE; NE]	0,91	[0,09; 19,55]	0,9370
Interaktion p-Wert									0,5949
Histologischer Grad									
High grade (G3)	12	2 (16,7)	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	5 (17,9)	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	6 (28,6)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
1	23	3 (13,0)	NE [NE; NE]	17	3 (17,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	2 (28,6)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	3 (21,4)	NE [NE; NE]	20	1 (5,0)	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 4.3.4.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UE mit CTCAE Grad >=3
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	13 (56,5)	6,6 [1,2; NE]	24	17 (70,8)	1,4 [0,5; 3,8]	0,67	[0,32; 1,38]	0,2777
Neu diagnostiziert	21	10 (47,6)	NE [NE; NE]	22	12 (54,5)	4,9 [0,7; NE]	0,71	[0,30; 1,65]	0,4247
Interaktion p-Wert									0,9185
Region									
Asien	14	8 (57,1)	4,3 [1,6; NE]	14	10 (71,4)	1,0 [0,4; NE]	0,58	[0,22; 1,48]	0,2540
Rest der Welt	30	15 (50,0)	13,0 [1,4; NE]	32	19 (59,4)	3,6 [0,7; NE]	0,73	[0,36; 1,43]	0,3598
Interaktion p-Wert									0,7017
Alter									
<65	24	11 (45,8)	NE [NE; NE]	24	13 (54,2)	4,9 [0,7; NE]	0,69	[0,30; 1,53]	0,3557
>=65	20	12 (60,0)	1,6 [1,3; NE]	22	16 (72,7)	1,7 [0,5; 3,8]	0,71	[0,33; 1,49]	0,3625
Interaktion p-Wert									0,9551
Abstammung									
Weiß	27	15 (55,6)	7,2 [1,3; NE]	29	18 (62,1)	3,4 [0,7; NE]	0,77	[0,38; 1,52]	0,4489
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	8 (57,1)	4,3 [1,6; NE]	15	11 (73,3)	1,2 [0,4; 3,4]	0,57	[0,22; 1,42]	0,2281
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6150
HRR Mutationsstatus									
HRRm	11	7 (63,6)	4,3 [0,0; NE]	15	10 (66,7)	1,6 [0,3; NE]	1,01	[0,37; 2,63]	0,9844
Nicht-HRRm	17	7 (41,2)	NE [NE; NE]	20	12 (60,0)	3,6 [0,7; NE]	0,52	[0,19; 1,29]	0,1590
Unbekannt	16	9 (56,3)	4,3 [0,8; NE]	11	7 (63,6)	1,4 [0,3; NE]	0,69	[0,25; 1,92]	0,4585
Interaktion p-Wert									0,6227
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 4.3.4.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UE mit CTCAE Grad >=3
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	19 (52,8)	7,2 [1,6; NE]	37	24 (64,9)	1,6 [0,7; NE]	0,67	[0,36; 1,22]	0,1879
Negativ	7	4 (57,1)	6,6 [0,7; NE]	7	3 (42,9)	NE [NE; NE]	1,42	[0,31; 7,23]	0,6424
Unbekannt	1	0	NE [NE; NE]	2	2 (100)	0,4 [0,2; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3558
Histologie									
Endometrioid	32	17 (53,1)	4,3 [1,3; NE]	40	23 (57,5)	3,6 [1,1; NE]	0,90	[0,47; 1,67]	0,7317
Serös	2	2 (100)	7,5 [2,0; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Andere	10	4 (40,0)	NE [NE; NE]	5	5 (100)	0,7 [0,3; NE]	0,16	[0,04; 0,61]	0,0088*
Interaktion p-Wert									0,0234*
Histologischer Grad									
High grade (G3)	12	6 (50,0)	4,3 [0,3; NE]	11	10 (90,9)	1,1 [0,3; 3,7]	0,35	[0,12; 0,96]	0,0412*
Low grade (G1+G2)	28	13 (46,4)	NE [NE; NE]	31	16 (51,6)	3,8 [0,7; NE]	0,85	[0,40; 1,76]	0,6543
Interaktion p-Wert									0,1692
ECOG Performance Status zu Baseline									
0	21	9 (42,9)	NE [NE; NE]	29	16 (55,2)	3,7 [0,7; NE]	0,62	[0,26; 1,38]	0,2433
1	23	14 (60,9)	2,0 [1,3; NE]	17	13 (76,5)	1,1 [0,4; 3,8]	0,62	[0,29; 1,35]	0,2259
Interaktion p-Wert									0,9899
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	2 (28,6)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	8 (57,1)	4,3 [1,6; NE]	20	12 (60,0)	2,8 [0,7; NE]	0,76	[0,30; 1,84]	0,5441
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 4.3.4.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	3 (9,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.4.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	0	NE [NE; NE]	37	3 (8,1)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	1,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	3 (17,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	2 (10,0)	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 4.3.4.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	3 (13,0)	NE [NE; NE]	24	8 (33,3)	NE [NE; NE]	0,36	[0,08; 1,24]	0,1091
Neu diagnostiziert	21	5 (23,8)	NE [NE; NE]	22	6 (27,3)	NE [NE; NE]	0,77	[0,22; 2,56]	0,6677
Interaktion p-Wert									0,3957
Region									
Asien	14	4 (28,6)	NE [NE; NE]	14	6 (42,9)	NE [NE; NE]	0,63	[0,16; 2,21]	0,4728
Rest der Welt	30	4 (13,3)	NE [NE; NE]	32	8 (25,0)	NE [NE; NE]	0,47	[0,13; 1,49]	0,2037
Interaktion p-Wert									0,7393
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	9 (37,5)	NE [NE; NE]	0,36	[0,10; 1,12]	0,0791
>=65	20	4 (20,0)	NE [NE; NE]	22	5 (22,7)	NE [NE; NE]	0,87	[0,22; 3,30]	0,8396
Interaktion p-Wert									0,3320
Abstammung									
Weiß	27	4 (14,8)	NE [NE; NE]	29	8 (27,6)	NE [NE; NE]	0,46	[0,12; 1,47]	0,1933
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	4 (28,6)	NE [NE; NE]	15	6 (40,0)	NE [NE; NE]	0,69	[0,18; 2,41]	0,5604
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6534
HRR Mutationsstatus									
HRRm	11	2 (18,2)	NE [NE; NE]	15	5 (33,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	2 (11,8)	NE [NE; NE]	20	5 (25,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	4 (25,0)	NE [NE; NE]	11	4 (36,4)	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 4.3.4.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	6 (16,7)	NE [NE; NE]	37	12 (32,4)	NE [NE; NE]	0,46	[0,16; 1,18]	0,1067
Negativ	7	2 (28,6)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	2,41	[0,23; 51,76]	0,4583
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1938
Histologie									
Endometrioid	32	5 (15,6)	NE [NE; NE]	40	11 (27,5)	NE [NE; NE]	0,53	[0,17; 1,47]	0,2306
Serös	2	1 (50,0)	NE [NE; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Andere	10	2 (20,0)	NE [NE; NE]	5	2 (40,0)	NE [NE; NE]	0,41	[0,05; 3,45]	0,3848
Interaktion p-Wert									0,8213
Histologischer Grad									
High grade (G3)	12	4 (33,3)	NE [NE; NE]	11	4 (36,4)	NE [NE; NE]	0,75	[0,18; 3,18]	0,6870
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	9 (29,0)	NE [NE; NE]	0,23	[0,03; 0,88]	0,0307*
Interaktion p-Wert									0,2423
ECOG Performance Status zu Baseline									
0	21	3 (14,3)	NE [NE; NE]	29	7 (24,1)	NE [NE; NE]	0,53	[0,11; 1,92]	0,3452
1	23	5 (21,7)	NE [NE; NE]	17	7 (41,2)	NE [NE; NE]	0,45	[0,13; 1,41]	0,1699
Interaktion p-Wert									0,8534
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	4 (28,6)	NE [NE; NE]	20	6 (30,0)	NE [NE; NE]	0,86	[0,22; 3,01]	0,8149
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 4.3.4.1.1D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 PT: Anaemie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	5 (20,8)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	5 (22,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	4 (28,6)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	3 (10,0)	NE [NE; NE]	32	6 (18,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	6 (25,0)	NE [NE; NE]	NC	[NC]	NC
>=65	20	2 (10,0)	NE [NE; NE]	22	4 (18,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	6 (20,7)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	3 (27,3)	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 4.3.4.1.1D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 PT: Anaemie
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	8 (21,6)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	2 (28,6)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	3 (9,4)	NE [NE; NE]	40	7 (17,5)	NE [NE; NE]	0,53	[0,11; 1,90]	0,3396
Serös	2	0	NE [NE; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	2 (40,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	3 (27,3)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	6 (19,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	5 (17,2)	NE [NE; NE]	NC	[NC]	NC
1	23	3 (13,0)	NE [NE; NE]	17	5 (29,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	5 (25,0)	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 4.3.4.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UE mit CTCAE Grad >=3
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	13 (56,5)	6,6 [1,2; NE]	24	17 (70,8)	1,4 [0,5; 3,8]	0,67	[0,32; 1,38]	0,2803
Neu diagnostiziert	21	11 (52,4)	22,9 [2,0; NE]	22	12 (54,5)	4,9 [0,7; NE]	0,77	[0,33; 1,75]	0,5230
Interaktion p-Wert									0,8160
Region									
Asien	14	8 (57,1)	4,3 [1,6; NE]	14	10 (71,4)	1,0 [0,4; NE]	0,58	[0,22; 1,47]	0,2487
Rest der Welt	30	16 (53,3)	13,0 [1,4; NE]	32	19 (59,4)	3,6 [0,7; NE]	0,77	[0,39; 1,50]	0,4385
Interaktion p-Wert									0,6268
Alter									
<65	24	11 (45,8)	NE [NE; NE]	24	13 (54,2)	4,9 [0,7; NE]	0,68	[0,30; 1,52]	0,3476
>=65	20	13 (65,0)	1,6 [1,3; NE]	22	16 (72,7)	1,7 [0,5; 3,8]	0,75	[0,35; 1,57]	0,4464
Interaktion p-Wert									0,8569
Abstammung									
Weiß	27	16 (59,3)	7,2 [1,3; NE]	29	18 (62,1)	3,4 [0,7; NE]	0,80	[0,40; 1,58]	0,5241
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	8 (57,1)	4,3 [1,6; NE]	15	11 (73,3)	1,2 [0,4; 3,4]	0,57	[0,22; 1,41]	0,2221
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,5504
HRR Mutationsstatus									
HRRm	11	7 (63,6)	4,3 [0,0; NE]	15	10 (66,7)	1,6 [0,3; NE]	1,04	[0,38; 2,70]	0,9443
Nicht-HRRm	17	8 (47,1)	22,9 [1,4; NE]	20	12 (60,0)	3,6 [0,7; NE]	0,59	[0,23; 1,42]	0,2354
Unbekannt	16	9 (56,3)	4,3 [0,8; NE]	11	7 (63,6)	1,4 [0,3; NE]	0,66	[0,24; 1,85]	0,4179
Interaktion p-Wert									0,6833
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 4.3.4.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UE mit CTCAE Grad >=3
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	20 (55,6)	7,2 [1,6; NE]	37	24 (64,9)	1,6 [0,7; NE]	0,69	[0,38; 1,25]	0,2231
Negativ	7	4 (57,1)	6,6 [0,7; NE]	7	3 (42,9)	NE [NE; NE]	1,45	[0,32; 7,36]	0,6257
Unbekannt	1	0	NE [NE; NE]	2	2 (100)	0,4 [0,2; NE]	NC	[NC]	NC
Interaktion p-Wert									0,3658
Histologie									
Endometrioid	32	18 (56,3)	4,3 [1,3; NE]	40	23 (57,5)	3,6 [1,1; NE]	0,94	[0,50; 1,74]	0,8462
Serös	2	2 (100)	7,5 [2,0; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Andere	10	4 (40,0)	NE [NE; NE]	5	5 (100)	0,7 [0,3; NE]	0,15	[0,04; 0,59]	0,0077*
Interaktion p-Wert									0,0173*
Histologischer Grad									
High grade (G3)	12	6 (50,0)	4,3 [0,3; NE]	11	10 (90,9)	1,1 [0,3; 3,7]	0,34	[0,11; 0,92]	0,0344*
Low grade (G1+G2)	28	14 (50,0)	22,9 [1,3; NE]	31	16 (51,6)	3,8 [0,7; NE]	0,91	[0,44; 1,86]	0,7859
Interaktion p-Wert									0,1197
ECOG Performance Status zu Baseline									
0	21	10 (47,6)	22,9 [4,3; NE]	29	16 (55,2)	3,7 [0,7; NE]	0,68	[0,30; 1,47]	0,3258
1	23	14 (60,9)	2,0 [1,3; NE]	17	13 (76,5)	1,1 [0,4; 3,8]	0,62	[0,29; 1,35]	0,2243
Interaktion p-Wert									0,8857
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	3 (42,9)	22,9 [0,3; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	8 (57,1)	4,3 [1,6; NE]	20	12 (60,0)	2,8 [0,7; NE]	0,76	[0,30; 1,84]	0,5441
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 4.3.4.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	3 (9,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.4.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen der Nieren und Harnwege
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	0	NE [NE; NE]	37	3 (8,1)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	1,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	4 (10,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	3 (17,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	2 (10,0)	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 4.3.4.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	3 (13,0)	NE [NE; NE]	24	8 (33,3)	NE [NE; NE]	0,36	[0,08; 1,24]	0,1091
Neu diagnostiziert	21	5 (23,8)	NE [NE; NE]	22	6 (27,3)	NE [NE; NE]	0,77	[0,22; 2,56]	0,6677
Interaktion p-Wert									0,3957
Region									
Asien	14	4 (28,6)	NE [NE; NE]	14	6 (42,9)	NE [NE; NE]	0,63	[0,16; 2,21]	0,4728
Rest der Welt	30	4 (13,3)	NE [NE; NE]	32	8 (25,0)	NE [NE; NE]	0,47	[0,13; 1,49]	0,2037
Interaktion p-Wert									0,7393
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	9 (37,5)	NE [NE; NE]	0,36	[0,10; 1,12]	0,0791
>=65	20	4 (20,0)	NE [NE; NE]	22	5 (22,7)	NE [NE; NE]	0,87	[0,22; 3,30]	0,8396
Interaktion p-Wert									0,3320
Abstammung									
Weiß	27	4 (14,8)	NE [NE; NE]	29	8 (27,6)	NE [NE; NE]	0,46	[0,12; 1,47]	0,1933
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	4 (28,6)	NE [NE; NE]	15	6 (40,0)	NE [NE; NE]	0,69	[0,18; 2,41]	0,5604
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6534
HRR Mutationsstatus									
HRRm	11	2 (18,2)	NE [NE; NE]	15	5 (33,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	2 (11,8)	NE [NE; NE]	20	5 (25,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	4 (25,0)	NE [NE; NE]	11	4 (36,4)	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 4.3.4.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	6 (16,7)	NE [NE; NE]	37	12 (32,4)	NE [NE; NE]	0,46	[0,16; 1,18]	0,1067
Negativ	7	2 (28,6)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	2,41	[0,23; 51,76]	0,4583
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1938
Histologie									
Endometrioid	32	5 (15,6)	NE [NE; NE]	40	11 (27,5)	NE [NE; NE]	0,53	[0,17; 1,47]	0,2306
Serös	2	1 (50,0)	NE [NE; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Andere	10	2 (20,0)	NE [NE; NE]	5	2 (40,0)	NE [NE; NE]	0,41	[0,05; 3,45]	0,3848
Interaktion p-Wert									0,8213
Histologischer Grad									
High grade (G3)	12	4 (33,3)	NE [NE; NE]	11	4 (36,4)	NE [NE; NE]	0,75	[0,18; 3,18]	0,6870
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	9 (29,0)	NE [NE; NE]	0,23	[0,03; 0,88]	0,0307*
Interaktion p-Wert									0,2423
ECOG Performance Status zu Baseline									
0	21	3 (14,3)	NE [NE; NE]	29	7 (24,1)	NE [NE; NE]	0,53	[0,11; 1,92]	0,3452
1	23	5 (21,7)	NE [NE; NE]	17	7 (41,2)	NE [NE; NE]	0,45	[0,13; 1,41]	0,1699
Interaktion p-Wert									0,8534
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	4 (28,6)	NE [NE; NE]	20	6 (30,0)	NE [NE; NE]	0,86	[0,22; 3,01]	0,8149
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 4.3.4.1.2D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 PT: Anaemie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	5 (20,8)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	5 (22,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	4 (28,6)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	3 (10,0)	NE [NE; NE]	32	6 (18,8)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	6 (25,0)	NE [NE; NE]	NC	[NC]	NC
>=65	20	2 (10,0)	NE [NE; NE]	22	4 (18,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	6 (20,7)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	3 (15,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	3 (27,3)	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 4.3.4.1.2D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first G>=3 PT: Anaemie
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	8 (21,6)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	2 (28,6)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	0,7 [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	3 (9,4)	NE [NE; NE]	40	7 (17,5)	NE [NE; NE]	0,53	[0,11; 1,90]	0,3396
Serös	2	0	NE [NE; NE]	1	1 (100)	0,7 [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	2 (40,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	3 (27,3)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	6 (19,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	5 (17,2)	NE [NE; NE]	NC	[NC]	NC
1	23	3 (13,0)	NE [NE; NE]	17	5 (29,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	5 (25,0)	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 4.3.5.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	14 (60,9)	1,3 [0,3; NE]	24	12 (50,0)	5,5 [2,2; NE]	1,65	[0,76; 3,63]	0,2052
Neu diagnostiziert	21	12 (57,1)	12,8 [0,8; NE]	22	10 (45,5)	NE [NE; NE]	1,38	[0,60; 3,28]	0,4476
Interaktion p-Wert									0,7643
Region									
Asien	14	9 (64,3)	1,2 [0,2; NE]	14	6 (42,9)	NE [NE; NE]	2,13	[0,77; 6,36]	0,1474
Rest der Welt	30	17 (56,7)	3,7 [0,9; NE]	32	16 (50,0)	6,3 [2,2; NE]	1,29	[0,65; 2,58]	0,4676
Interaktion p-Wert									0,4250
Alter									
<65	24	14 (58,3)	2,0 [0,4; NE]	24	11 (45,8)	NE [NE; NE]	1,60	[0,73; 3,62]	0,2413
>=65	20	12 (60,0)	2,8 [0,3; NE]	22	11 (50,0)	5,5 [1,2; NE]	1,41	[0,62; 3,25]	0,4151
Interaktion p-Wert									0,8224
Abstammung									
Weiß	27	16 (59,3)	3,7 [0,7; NE]	29	14 (48,3)	6,3 [2,2; NE]	1,45	[0,71; 3,02]	0,3105
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	9 (64,3)	1,2 [0,2; NE]	15	7 (46,7)	NE [NE; NE]	1,89	[0,70; 5,29]	0,2065
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6724
HRR Mutationsstatus									
HRRm	11	5 (45,5)	NE [NE; NE]	15	8 (53,3)	7,7 [0,7; NE]	1,00	[0,30; 2,99]	0,9952
Nicht-HRRm	17	13 (76,5)	1,8 [0,2;12,8]	20	9 (45,0)	NE [NE; NE]	2,32	[0,999; 5,64]	0,0501
Unbekannt	16	8 (50,0)	18,1 [0,3; NE]	11	5 (45,5)	6,3 [0,2; NE]	1,21	[0,40; 4,02]	0,7350
Interaktion p-Wert									0,4326
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 4.3.5.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	20 (55,6)	3,7 [0,9; NE]	37	17 (45,9)	NE [NE; NE]	1,45	[0,76; 2,80]	0,2612
Negativ	7	5 (71,4)	0,7 [0,0; NE]	7	4 (57,1)	3,5 [0,0; NE]	1,75	[0,46; 7,10]	0,4027
Unbekannt	1	1 (100)	0,1 [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7992
Histologie									
Endometrioid	32	19 (59,4)	1,8 [0,3; NE]	40	20 (50,0)	7,7 [3,3; NE]	1,52	[0,80; 2,86]	0,1985
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	6 (60,0)	10,1 [0,2; NE]	5	2 (40,0)	NE [NE; NE]	1,63	[0,38; 11,12]	0,5347
Interaktion p-Wert									0,9336
Histologischer Grad									
High grade (G3)	12	5 (41,7)	NE [NE; NE]	11	4 (36,4)	NE [NE; NE]	1,20	[0,32; 4,86]	0,7824
Low grade (G1+G2)	28	19 (67,9)	1,1 [0,3; 3,9]	31	16 (51,6)	7,7 [2,2; NE]	1,84	[0,94; 3,64]	0,0738
Interaktion p-Wert									0,5750
ECOG Performance Status zu Baseline									
0	21	10 (47,6)	NE [NE; NE]	29	14 (48,3)	7,7 [3,3; NE]	1,13	[0,49; 2,52]	0,7756
1	23	16 (69,6)	1,8 [0,4;18,1]	17	8 (47,1)	NE [NE; NE]	1,90	[0,83; 4,70]	0,1278
Interaktion p-Wert									0,3774
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	4 (57,1)	3,7 [0,2; NE]	2	2 (100)	1,1 [0,8; NE]	NC	[NC]	NC
IV	14	8 (57,1)	12,8 [0,4; NE]	20	8 (40,0)	NE [NE; NE]	1,47	[0,54; 4,00]	0,4452
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 4.3.5.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.5.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.5.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	6 (26,1)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	1,73	[0,49; 6,79]	0,3927
Neu diagnostiziert	21	10 (47,6)	18,1 [1,2; NE]	22	6 (27,3)	NE [NE; NE]	2,01	[0,74; 5,90]	0,1700
Interaktion p-Wert									0,8579
Region									
Asien	14	7 (50,0)	18,1 [0,2; NE]	14	4 (28,6)	NE [NE; NE]	2,58	[0,77; 9,86]	0,1230
Rest der Welt	30	9 (30,0)	NE [NE; NE]	32	6 (18,8)	NE [NE; NE]	1,62	[0,58; 4,85]	0,3567
Interaktion p-Wert									0,5718
Alter									
<65	24	10 (41,7)	NE [NE; NE]	24	7 (29,2)	NE [NE; NE]	1,65	[0,63; 4,58]	0,3059
>=65	20	6 (30,0)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	2,42	[0,64; 11,46]	0,1968
Interaktion p-Wert									0,6577
Abstammung									
Weiß	27	9 (33,3)	NE [NE; NE]	29	5 (17,2)	NE [NE; NE]	1,98	[0,68; 6,46]	0,2123
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	7 (50,0)	18,1 [0,2; NE]	15	4 (26,7)	NE [NE; NE]	2,78	[0,84; 10,63]	0,0954
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6865
HRR Mutationsstatus									
HRRm	11	3 (27,3)	NE [NE; NE]	15	3 (20,0)	NE [NE; NE]	1,92	[0,35; 10,39]	0,4309
Nicht-HRRm	17	6 (35,3)	NE [NE; NE]	20	5 (25,0)	NE [NE; NE]	1,47	[0,44; 5,11]	0,5243
Unbekannt	16	7 (43,8)	18,1 [0,3; NE]	11	2 (18,2)	NE [NE; NE]	2,53	[0,61; 17,03]	0,2144
Interaktion p-Wert									0,8584
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 4.3.5.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	12 (33,3)	NE [NE; NE]	37	7 (18,9)	NE [NE; NE]	2,02	[0,81; 5,43]	0,1342
Negativ	7	3 (42,9)	12,8 [0,2; NE]	7	2 (28,6)	NE [NE; NE]	1,50	[0,25; 11,42]	0,6544
Unbekannt	1	1 (100)	0,2 [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,7759
Histologie									
Endometrioid	32	12 (37,5)	NE [NE; NE]	40	9 (22,5)	NE [NE; NE]	1,96	[0,83; 4,81]	0,1256
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	3 (30,0)	NE [NE; NE]	5	1 (20,0)	NE [NE; NE]	1,55	[0,20; 31,35]	0,6949
Interaktion p-Wert									0,8518
Histologischer Grad									
High grade (G3)	12	4 (33,3)	NE [NE; NE]	11	2 (18,2)	NE [NE; NE]	1,96	[0,38; 14,17]	0,4277
Low grade (G1+G2)	28	10 (35,7)	NE [NE; NE]	31	6 (19,4)	NE [NE; NE]	2,28	[0,85; 6,72]	0,1035
Interaktion p-Wert									0,8788
ECOG Performance Status zu Baseline									
0	21	8 (38,1)	NE [NE; NE]	29	6 (20,7)	NE [NE; NE]	2,17	[0,75; 6,62]	0,1489
1	23	8 (34,8)	18,1 [12,8; NE]	17	4 (23,5)	NE [NE; NE]	1,53	[0,48; 5,76]	0,4828
Interaktion p-Wert									0,6674
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	4 (57,1)	3,7 [0,2; NE]	2	2 (100)	1,1 [0,8; NE]	NC	[NC]	NC
IV	14	6 (42,9)	18,1 [0,9; NE]	20	4 (20,0)	NE [NE; NE]	2,21	[0,63; 8,70]	0,2168
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 4.3.5.1.1D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	8 (34,8)	NE [NE; NE]	24	8 (33,3)	NE [NE; NE]	1,07	[0,39; 2,93]	0,8901
Neu diagnostiziert	21	5 (23,8)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	1,71	[0,42; 8,34]	0,4562
Interaktion p-Wert									0,5955
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	3 (21,4)	NE [NE; NE]	0,31	[0,02; 2,47]	0,2816
Rest der Welt	30	12 (40,0)	NE [NE; NE]	32	8 (25,0)	NE [NE; NE]	1,67	[0,69; 4,27]	0,2577
Interaktion p-Wert									0,1485
Alter									
<65	24	6 (25,0)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	1,55	[0,44; 6,09]	0,4929
>=65	20	7 (35,0)	16,3 [1,8; NE]	22	7 (31,8)	NE [NE; NE]	1,07	[0,37; 3,13]	0,9000
Interaktion p-Wert									0,6564
Abstammung									
Weiß	27	12 (44,4)	16,3 [1,3; NE]	29	7 (24,1)	NE [NE; NE]	1,97	[0,79; 5,31]	0,1477
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	0,24	[0,01; 1,64]	0,1558
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,0546
HRR Mutationsstatus									
HRRm	11	4 (36,4)	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	1,90	[0,45; 8,08]	0,3697
Nicht-HRRm	17	6 (35,3)	NE [NE; NE]	20	4 (20,0)	NE [NE; NE]	1,60	[0,45; 6,28]	0,4636
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	3 (27,3)	NE [NE; NE]	0,62	[0,11; 3,37]	0,5613
Interaktion p-Wert									0,5539
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 4.3.5.1.1D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	11 (30,6)	NE [NE; NE]	37	8 (21,6)	NE [NE; NE]	1,46	[0,59; 3,78]	0,4167
Negativ	7	1 (14,3)	NE [NE; NE]	7	3 (42,9)	NE [NE; NE]	0,29	[0,01; 2,26]	0,2441
Unbekannt	1	1 (100)	0,1 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1621
Histologie									
Endometrioid	32	11 (34,4)	NE [NE; NE]	40	10 (25,0)	NE [NE; NE]	1,54	[0,65; 3,69]	0,3275
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	2 (20,0)	NE [NE; NE]	5	1 (20,0)	NE [NE; NE]	0,76	[0,07; 16,36]	0,8249
Interaktion p-Wert									0,6016
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	13 (46,4)	16,3 [1,8; NE]	31	9 (29,0)	NE [NE; NE]	1,85	[0,80; 4,48]	0,1539
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	4 (19,0)	NE [NE; NE]	29	7 (24,1)	NE [NE; NE]	0,74	[0,19; 2,45]	0,6259
1	23	9 (39,1)	NE [NE; NE]	17	4 (23,5)	NE [NE; NE]	1,74	[0,56; 6,44]	0,3455
Interaktion p-Wert									0,3151
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	2 (28,6)	16,3 [0,8; NE]	2	1 (50,0)	8,3 [NE; NE]	NC	[NC]	NC
IV	14	3 (21,4)	NE [NE; NE]	20	2 (10,0)	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 4.3.5.1.1D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Hyperthyreose Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	2 (9,5)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	3 (9,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	2 (13,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	2 (12,5)	NE [NE; NE]	11	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 4.3.5.1.1D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Hyperthyreose Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	3 (8,1)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	1 (14,3)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	2 (6,3)	NE [NE; NE]	40	3 (7,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	2 (6,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
1	23	2 (8,7)	NE [NE; NE]	17	1 (5,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	2 (14,3)	NE [NE; NE]	20	2 (10,0)	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 4.3.5.1.1D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Hypothyreose Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	3 (14,3)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	4 (13,3)	NE [NE; NE]	32	2 (6,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	1 (9,1)	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 4.3.5.1.1D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Hypothyreose Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	3 (8,3)	NE [NE; NE]	37	2 (5,4)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	2 (28,6)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	4 (12,5)	NE [NE; NE]	40	2 (5,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	4 (14,3)	NE [NE; NE]	31	2 (6,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
1	23	4 (17,4)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	2 (14,3)	NE [NE; NE]	20	2 (10,0)	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 4.3.5.1.1D.7 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	2 (6,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
>=65	20	2 (10,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	1 (9,1)	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 4.3.5.1.1D.7 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	1 (2,7)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	1 (14,3)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	2 (6,3)	NE [NE; NE]	40	3 (7,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
1	23	2 (8,7)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	2 (10,0)	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 4.3.5.1.1D.8 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Myositis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.5.1.1D.8 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Myositis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.5.1.1D.9 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.5.1.1D.9 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.5.1.1D.10 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	2 (9,5)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	3 (21,4)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	3 (12,5)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	3 (21,4)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	2 (12,5)	NE [NE; NE]	11	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 4.3.5.1.1D.10 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	3 (8,3)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	2 (6,3)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	3 (14,3)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.5.1.1D.11 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Thyreoiditis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	2 (6,7)	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	2 (8,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.5.1.1D.11 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Thyreoiditis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	2 (5,6)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	2 (8,7)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.5.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	14 (60,9)	1,3 [0,3; NE]	24	12 (50,0)	5,5 [2,2; NE]	1,65	[0,76; 3,65]	0,2017
Neu diagnostiziert	21	13 (61,9)	12,8 [0,8; NE]	22	10 (45,5)	NE [NE; NE]	1,45	[0,64; 3,41]	0,3729
Interaktion p-Wert									0,8224
Region									
Asien	14	9 (64,3)	1,2 [0,2; NE]	14	6 (42,9)	NE [NE; NE]	2,16	[0,78; 6,46]	0,1404
Rest der Welt	30	18 (60,0)	3,7 [0,9; NE]	32	16 (50,0)	6,3 [2,2; NE]	1,33	[0,67; 2,64]	0,4110
Interaktion p-Wert									0,4386
Alter									
<65	24	15 (62,5)	2,0 [0,4; NE]	24	11 (45,8)	NE [NE; NE]	1,71	[0,79; 3,82]	0,1768
>=65	20	12 (60,0)	2,8 [0,3; NE]	22	11 (50,0)	5,5 [1,2; NE]	1,37	[0,60; 3,16]	0,4476
Interaktion p-Wert									0,7067
Abstammung									
Weiß	27	17 (63,0)	3,7 [0,7;30,8]	29	14 (48,3)	6,3 [2,2; NE]	1,49	[0,74; 3,09]	0,2659
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	9 (64,3)	1,2 [0,2; NE]	15	7 (46,7)	NE [NE; NE]	1,91	[0,71; 5,35]	0,1994
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,6946
HRR Mutationsstatus									
HRRm	11	5 (45,5)	NE [NE; NE]	15	8 (53,3)	7,7 [0,7; NE]	1,02	[0,31; 3,06]	0,9760
Nicht-HRRm	17	13 (76,5)	1,8 [0,2;12,8]	20	9 (45,0)	NE [NE; NE]	2,34	[1,01; 5,69]	0,0476*
Unbekannt	16	9 (56,3)	18,1 [0,3; NE]	11	5 (45,5)	6,3 [0,2; NE]	1,28	[0,44; 4,19]	0,6602
Interaktion p-Wert									0,4517
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 4.3.5.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	21 (58,3)	3,7 [0,9; NE]	37	17 (45,9)	NE [NE; NE]	1,50	[0,79; 2,89]	0,2117
Negativ	7	5 (71,4)	0,7 [0,0; NE]	7	4 (57,1)	3,5 [0,0; NE]	1,70	[0,45; 6,86]	0,4295
Unbekannt	1	1 (100)	0,1 [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,8704
Histologie									
Endometrioid	32	20 (62,5)	1,8 [0,3; NE]	40	20 (50,0)	7,7 [3,3; NE]	1,57	[0,84; 2,95]	0,1544
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	6 (60,0)	10,1 [0,2; NE]	5	2 (40,0)	NE [NE; NE]	1,55	[0,36; 10,61]	0,5784
Interaktion p-Wert									0,9870
Histologischer Grad									
High grade (G3)	12	6 (50,0)	30,8 [0,3; NE]	11	4 (36,4)	NE [NE; NE]	1,40	[0,40; 5,48]	0,6003
Low grade (G1+G2)	28	19 (67,9)	1,1 [0,3; 3,9]	31	16 (51,6)	7,7 [2,2; NE]	1,85	[0,95; 3,66]	0,0713
Interaktion p-Wert									0,7042
ECOG Performance Status zu Baseline									
0	21	11 (52,4)	30,8 [0,3; NE]	29	14 (48,3)	7,7 [3,3; NE]	1,20	[0,53; 2,64]	0,6557
1	23	16 (69,6)	1,8 [0,4;18,1]	17	8 (47,1)	NE [NE; NE]	1,90	[0,83; 4,69]	0,1281
Interaktion p-Wert									0,4320
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	4 (57,1)	3,7 [0,2; NE]	2	2 (100)	1,1 [0,8; NE]	NC	[NC]	NC
IV	14	9 (64,3)	12,8 [0,4; NE]	20	8 (40,0)	NE [NE; NE]	1,55	[0,59; 4,16]	0,3712
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 4.3.5.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.5.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.5.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	7 (30,4)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	1,94	[0,58; 7,45]	0,2831
Neu diagnostiziert	21	11 (52,4)	18,1 [1,2; NE]	22	6 (27,3)	NE [NE; NE]	1,98	[0,73; 5,83]	0,1777
Interaktion p-Wert									0,9796
Region									
Asien	14	7 (50,0)	18,1 [0,2; NE]	14	4 (28,6)	NE [NE; NE]	2,62	[0,79; 10,09]	0,1172
Rest der Welt	30	11 (36,7)	35,7 [12,8; NE]	32	6 (18,8)	NE [NE; NE]	1,72	[0,63; 5,10]	0,2895
Interaktion p-Wert									0,6076
Alter									
<65	24	12 (50,0)	23,3 [0,9; NE]	24	7 (29,2)	NE [NE; NE]	1,79	[0,70; 4,89]	0,2251
>=65	20	6 (30,0)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	2,34	[0,62; 11,10]	0,2147
Interaktion p-Wert									0,7533
Abstammung									
Weiß	27	11 (40,7)	35,7 [3,7; NE]	29	5 (17,2)	NE [NE; NE]	2,10	[0,74; 6,80]	0,1664
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	7 (50,0)	18,1 [0,2; NE]	15	4 (26,7)	NE [NE; NE]	2,81	[0,84; 10,79]	0,0931
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,7306
HRR Mutationsstatus									
HRRm	11	3 (27,3)	NE [NE; NE]	15	3 (20,0)	NE [NE; NE]	1,83	[0,34; 9,91]	0,4646
Nicht-HRRm	17	6 (35,3)	NE [NE; NE]	20	5 (25,0)	NE [NE; NE]	1,48	[0,45; 5,15]	0,5141
Unbekannt	16	9 (56,3)	23,3 [0,3; NE]	11	2 (18,2)	NE [NE; NE]	2,75	[0,68; 18,29]	0,1659
Interaktion p-Wert									0,8195
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 4.3.5.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	13 (36,1)	35,7 [3,7; NE]	37	7 (18,9)	NE [NE; NE]	1,96	[0,78; 5,29]	0,1508
Negativ	7	4 (57,1)	12,8 [0,2; NE]	7	2 (28,6)	NE [NE; NE]	1,93	[0,37; 14,01]	0,4352
Unbekannt	1	1 (100)	0,2 [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,9889
Histologie									
Endometrioid	32	14 (43,8)	23,3 [1,6; NE]	40	9 (22,5)	NE [NE; NE]	2,07	[0,89; 5,04]	0,0908
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	3 (30,0)	NE [NE; NE]	5	1 (20,0)	NE [NE; NE]	1,53	[0,20; 30,90]	0,7050
Interaktion p-Wert									0,8088
Histologischer Grad									
High grade (G3)	12	5 (41,7)	35,7 [0,3; NE]	11	2 (18,2)	NE [NE; NE]	1,96	[0,38; 14,17]	0,4272
Low grade (G1+G2)	28	11 (39,3)	NE [NE; NE]	31	6 (19,4)	NE [NE; NE]	2,40	[0,91; 6,99]	0,0787
Interaktion p-Wert									0,8412
ECOG Performance Status zu Baseline									
0	21	9 (42,9)	35,7 [0,9; NE]	29	6 (20,7)	NE [NE; NE]	2,05	[0,71; 6,26]	0,1851
1	23	9 (39,1)	18,1 [12,8; NE]	17	4 (23,5)	NE [NE; NE]	1,71	[0,55; 6,35]	0,3591
Interaktion p-Wert									0,8260
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	4 (57,1)	3,7 [0,2; NE]	2	2 (100)	1,1 [0,8; NE]	NC	[NC]	NC
IV	14	7 (50,0)	18,1 [0,9; NE]	20	4 (20,0)	NE [NE; NE]	2,21	[0,63; 8,70]	0,2168
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 4.3.5.1.2D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	8 (34,8)	NE [NE; NE]	24	8 (33,3)	NE [NE; NE]	1,06	[0,39; 2,89]	0,9098
Neu diagnostiziert	21	6 (28,6)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	1,92	[0,50; 9,14]	0,3463
Interaktion p-Wert									0,4886
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	3 (21,4)	NE [NE; NE]	0,31	[0,02; 2,45]	0,2785
Rest der Welt	30	13 (43,3)	30,8 [1,8; NE]	32	8 (25,0)	NE [NE; NE]	1,72	[0,72; 4,37]	0,2249
Interaktion p-Wert									0,1387
Alter									
<65	24	7 (29,2)	NE [NE; NE]	24	4 (16,7)	NE [NE; NE]	1,74	[0,52; 6,67]	0,3707
>=65	20	7 (35,0)	NE [NE; NE]	22	7 (31,8)	NE [NE; NE]	1,02	[0,35; 3,00]	0,9708
Interaktion p-Wert									0,5146
Abstammung									
Weiß	27	13 (48,1)	30,8 [1,3; NE]	29	7 (24,1)	NE [NE; NE]	2,03	[0,83; 5,45]	0,1239
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	0,24	[0,01; 1,63]	0,1531
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									0,0491*
HRR Mutationsstatus									
HRRm	11	4 (36,4)	NE [NE; NE]	15	4 (26,7)	NE [NE; NE]	1,94	[0,46; 8,25]	0,3564
Nicht-HRRm	17	6 (35,3)	NE [NE; NE]	20	4 (20,0)	NE [NE; NE]	1,62	[0,46; 6,34]	0,4535
Unbekannt	16	4 (25,0)	NE [NE; NE]	11	3 (27,3)	NE [NE; NE]	0,71	[0,15; 3,69]	0,6620
Interaktion p-Wert									0,6124
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 4.3.5.1.2D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	12 (33,3)	NE [NE; NE]	37	8 (21,6)	NE [NE; NE]	1,52	[0,62; 3,90]	0,3590
Negativ	7	1 (14,3)	NE [NE; NE]	7	3 (42,9)	NE [NE; NE]	0,28	[0,01; 2,22]	0,2370
Unbekannt	1	1 (100)	0,1 [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									0,1454
Histologie									
Endometrioid	32	12 (37,5)	30,8 [5,7; NE]	40	10 (25,0)	NE [NE; NE]	1,64	[0,70; 3,89]	0,2502
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	2 (20,0)	NE [NE; NE]	5	1 (20,0)	NE [NE; NE]	0,66	[0,06; 14,41]	0,7457
Interaktion p-Wert									0,5092
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	0,67	[0,03; 17,03]	0,7777
Low grade (G1+G2)	28	13 (46,4)	16,3 [1,8; NE]	31	9 (29,0)	NE [NE; NE]	1,82	[0,78; 4,41]	0,1655
Interaktion p-Wert									0,5074
ECOG Performance Status zu Baseline									
0	21	5 (23,8)	NE [NE; NE]	29	7 (24,1)	NE [NE; NE]	0,89	[0,26; 2,81]	0,8462
1	23	9 (39,1)	NE [NE; NE]	17	4 (23,5)	NE [NE; NE]	1,65	[0,53; 6,13]	0,3952
Interaktion p-Wert									0,4582
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	2 (28,6)	NE [NE; NE]	2	1 (50,0)	8,3 [NE; NE]	NC	[NC]	NC
IV	14	4 (28,6)	NE [NE; NE]	20	2 (10,0)	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 4.3.5.1.2D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Hepatische Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.5.1.2D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Hepatische Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.5.1.2D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Hyperthyreose Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	2 (9,5)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	3 (9,4)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	3 (13,6)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	2 (13,3)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	2 (12,5)	NE [NE; NE]	11	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 4.3.5.1.2D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Hyperthyreose Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	3 (8,1)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	1 (14,3)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	2 (6,3)	NE [NE; NE]	40	3 (7,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	1 (9,1)	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	2 (6,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
1	23	2 (8,7)	NE [NE; NE]	17	1 (5,9)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	2 (14,3)	NE [NE; NE]	20	2 (10,0)	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 4.3.5.1.2D.7 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Hypothyreose Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	3 (14,3)	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	4 (13,3)	NE [NE; NE]	32	2 (6,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	4 (16,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	3 (18,8)	NE [NE; NE]	11	1 (9,1)	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 4.3.5.1.2D.7 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Hypothyreose Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	3 (8,3)	NE [NE; NE]	37	2 (5,4)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	2 (28,6)	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	4 (12,5)	NE [NE; NE]	40	2 (5,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	4 (14,3)	NE [NE; NE]	31	2 (6,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
1	23	4 (17,4)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	2 (14,3)	NE [NE; NE]	20	2 (10,0)	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 4.3.5.1.2D.8 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	2 (9,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	1 (7,1)	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	2 (6,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
>=65	20	2 (10,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	1 (9,1)	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 4.3.5.1.2D.8 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Infusions- und Überempfindlichkeitsreaktionen
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	1 (2,7)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	1 (14,3)	NE [NE; NE]	7	1 (14,3)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	2 (6,3)	NE [NE; NE]	40	3 (7,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	3 (9,7)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	3 (10,3)	NE [NE; NE]	NC	[NC]	NC
1	23	2 (8,7)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	2 (10,0)	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 4.3.5.1.2D.9 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Myositis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.5.1.2D.9 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Myositis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.5.1.2D.10 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.5.1.2D.10 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Neue primäre Malignität
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.5.1.2D.11 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	2 (9,5)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	3 (21,4)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	3 (12,5)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	3 (21,4)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	2 (12,5)	NE [NE; NE]	11	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 4.3.5.1.2D.11 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	3 (8,3)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	2 (6,3)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	3 (14,3)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.5.1.2D.12 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Thyreoiditis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	2 (6,7)	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	2 (8,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	1 (50,0)	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.5.1.2D.12 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI GT: Thyreoiditis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	2 (5,6)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	2 (8,7)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.6.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	3 (13,0)	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	2 (9,5)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	2 (14,3)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	3 (10,0)	NE [NE; NE]	32	2 (6,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	2 (8,3)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	3 (15,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	3 (11,1)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	2 (14,3)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	2 (18,2)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	2 (12,5)	NE [NE; NE]	11	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 4.3.6.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	5 (13,9)	NE [NE; NE]	37	1 (2,7)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	3 (9,4)	NE [NE; NE]	40	2 (5,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	3 (10,7)	NE [NE; NE]	31	2 (6,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	4 (19,0)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.6.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.6.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.6.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.6.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.6.1.1D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	2 (6,7)	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	2 (10,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	2 (7,4)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.6.1.1D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	2 (5,6)	NE [NE; NE]	37	1 (2,7)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	2 (9,5)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.6.1.1D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Neue primäre Malignität
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.6.1.1D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Neue primäre Malignität
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	0	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.6.1.1D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.6.1.1D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.6.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	4 (17,4)	NE [NE; NE]	24	2 (8,3)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	2 (9,5)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	2 (14,3)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	4 (13,3)	NE [NE; NE]	32	2 (6,3)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	2 (8,3)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	4 (20,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	4 (14,8)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	2 (14,3)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	3 (27,3)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	2 (12,5)	NE [NE; NE]	11	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 4.3.6.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	6 (16,7)	NE [NE; NE]	37	1 (2,7)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	4 (12,5)	NE [NE; NE]	40	2 (5,0)	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	4 (14,3)	NE [NE; NE]	31	2 (6,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	4 (19,0)	NE [NE; NE]	29	2 (6,9)	NE [NE; NE]	NC	[NC]	NC
1	23	2 (8,7)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.6.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.6.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.6.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.6.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.6.1.2D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	2 (8,7)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	2 (6,7)	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	2 (10,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	2 (7,4)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.6.1.2D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	2 (5,6)	NE [NE; NE]	37	1 (2,7)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	2 (7,1)	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	2 (9,5)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.6.1.2D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Hepatische Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.6.1.2D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Hepatische Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.6.1.2D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Neue primäre Malignität
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	1 (5,0)	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.6.1.2D.6 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Neue primäre Malignität
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	0	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	1 (50,0)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.6.1.2D.7 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.6.1.2D.7 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first UESI G>=3 GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.7.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	3 (13,0)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	2 (9,5)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	3 (21,4)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	2 (6,7)	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	3 (12,5)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	2 (10,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	2 (7,4)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	3 (21,4)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	2 (18,2)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	2 (12,5)	NE [NE; NE]	11	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 4.3.7.1.1D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	5 (13,9)	NE [NE; NE]	37	1 (2,7)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	3 (9,4)	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	3 (10,7)	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	4 (19,0)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.7.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.7.1.1D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.7.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	2 (14,3)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	2 (8,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	2 (14,3)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.7.1.1D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	2 (5,6)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	2 (6,3)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	2 (9,5)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.7.1.1D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.7.1.1D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	1 (2,7)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.7.1.1D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.7.1.1D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Pneumonitis
Safety Analysis Set, DCO 12APR2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.7.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	3 (13,0)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	2 (9,5)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	3 (21,4)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	2 (6,7)	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	3 (12,5)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	2 (10,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	2 (7,4)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	3 (21,4)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	2 (18,2)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	2 (12,5)	NE [NE; NE]	11	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 4.3.7.1.2D.1 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	5 (13,9)	NE [NE; NE]	37	1 (2,7)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	3 (9,4)	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	3 (10,7)	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	4 (19,0)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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 4.3.7.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.7.1.2D.2 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Andere seltene/sonstige Ereignisse
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	1 (3,1)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	1 (4,3)	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.7.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	2 (14,3)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	2 (8,3)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	2 (14,3)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	1 (5,9)	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.7.1.2D.3 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Dermatitis/Hautausschlag
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	2 (5,6)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	2 (6,3)	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	1 (8,3)	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	2 (9,5)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	1 (14,3)	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.7.1.2D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	1 (4,3)	NE [NE; NE]	24	1 (4,2)	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	0	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	1 (3,3)	NE [NE; NE]	32	1 (3,1)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	1 (5,0)	NE [NE; NE]	22	1 (4,5)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	1 (3,7)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	1 (9,1)	NE [NE; NE]	15	1 (6,7)	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	0	NE [NE; NE]	11	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 4.3.7.1.2D.4 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Diarrhö/Kolitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	1 (2,7)	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	1 (2,5)	NE [NE; NE]	NC	[NC]	NC
Serös	2	0	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	1 (10,0)	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	1 (3,6)	NE [NE; NE]	31	1 (3,2)	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	1 (3,4)	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	0	NE [NE; NE]	20	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 4.3.7.1.2D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	23	0	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
Neu diagnostiziert	21	1 (4,8)	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Region									
Asien	14	1 (7,1)	NE [NE; NE]	14	0	NE [NE; NE]	NC	[NC]	NC
Rest der Welt	30	0	NE [NE; NE]	32	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Alter									
<65	24	1 (4,2)	NE [NE; NE]	24	0	NE [NE; NE]	NC	[NC]	NC
>=65	20	0	NE [NE; NE]	22	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Abstammung									
Weiß	27	0	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
Schwarz/Afroamerikanisch	0	0	NE	1	0	NE [NE; NE]	NC	[NC]	NC
Asiatisch	14	1 (7,1)	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Andere	2	0	NE [NE; NE]	0	0	NE	NC	[NC]	NC
Interaktion p-Wert									NC
HRR Mutationsstatus									
HRRm	11	0	NE [NE; NE]	15	0	NE [NE; NE]	NC	[NC]	NC
Nicht-HRRm	17	0	NE [NE; NE]	20	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	16	1 (6,3)	NE [NE; NE]	11	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 4.3.7.1.2D.5 DUO-E (dMMR Durva): Summary of subgroup analysis of time to first SUESI GT: Pneumonitis
Safety Analysis Set, DCO 18OCT2023

	CTx + Durvalumab (N=44)			CTx (N=46)					
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	36	1 (2,8)	NE [NE; NE]	37	0	NE [NE; NE]	NC	[NC]	NC
Negativ	7	0	NE [NE; NE]	7	0	NE [NE; NE]	NC	[NC]	NC
Unbekannt	1	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologie									
Endometrioid	32	0	NE [NE; NE]	40	0	NE [NE; NE]	NC	[NC]	NC
Serös	2	1 (50,0)	NE [NE; NE]	1	0	NE [NE; NE]	NC	[NC]	NC
Andere	10	0	NE [NE; NE]	5	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
Histologischer Grad									
High grade (G3)	12	0	NE [NE; NE]	11	0	NE [NE; NE]	NC	[NC]	NC
Low grade (G1+G2)	28	0	NE [NE; NE]	31	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
ECOG Performance Status zu Baseline									
0	21	1 (4,8)	NE [NE; NE]	29	0	NE [NE; NE]	NC	[NC]	NC
1	23	0	NE [NE; NE]	17	0	NE [NE; NE]	NC	[NC]	NC
Interaktion p-Wert									NC
FIGO Stadium bei initialer Diagnose für neu diagnostizierte Patientinnen									
III	7	0	NE [NE; NE]	2	0	NE [NE; NE]	NC	[NC]	NC
IV	14	1 (7,1)	NE [NE; NE]	20	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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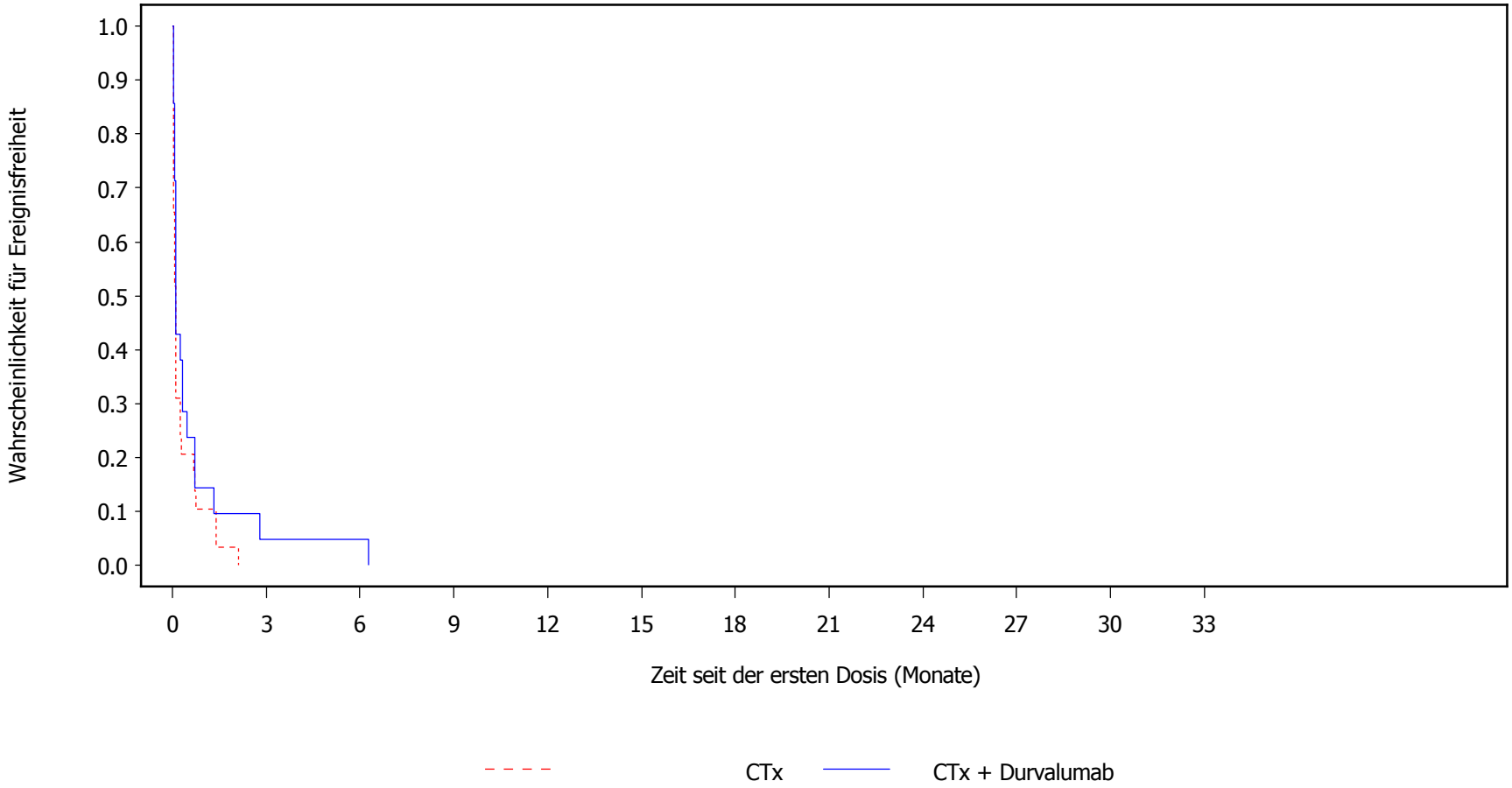
Figure 4.4.1.1.1D.1 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UE for ECOG Performance Status zu Baseline=0
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

21	1	1	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
29	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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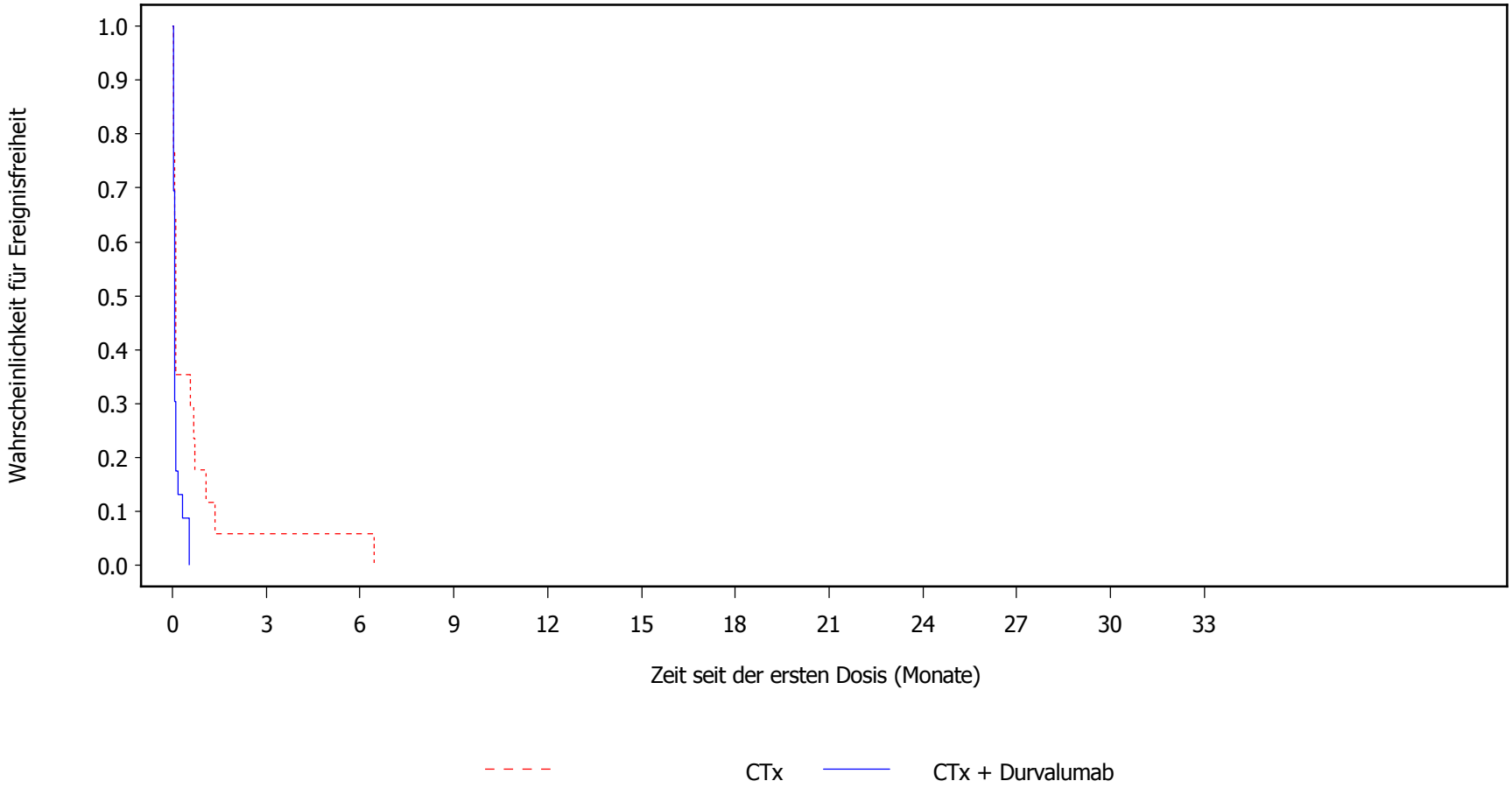
Figure 4.4.1.1.1D.2 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UE for ECOG Performance Status zu Baseline=1
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

23	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
17	1	1	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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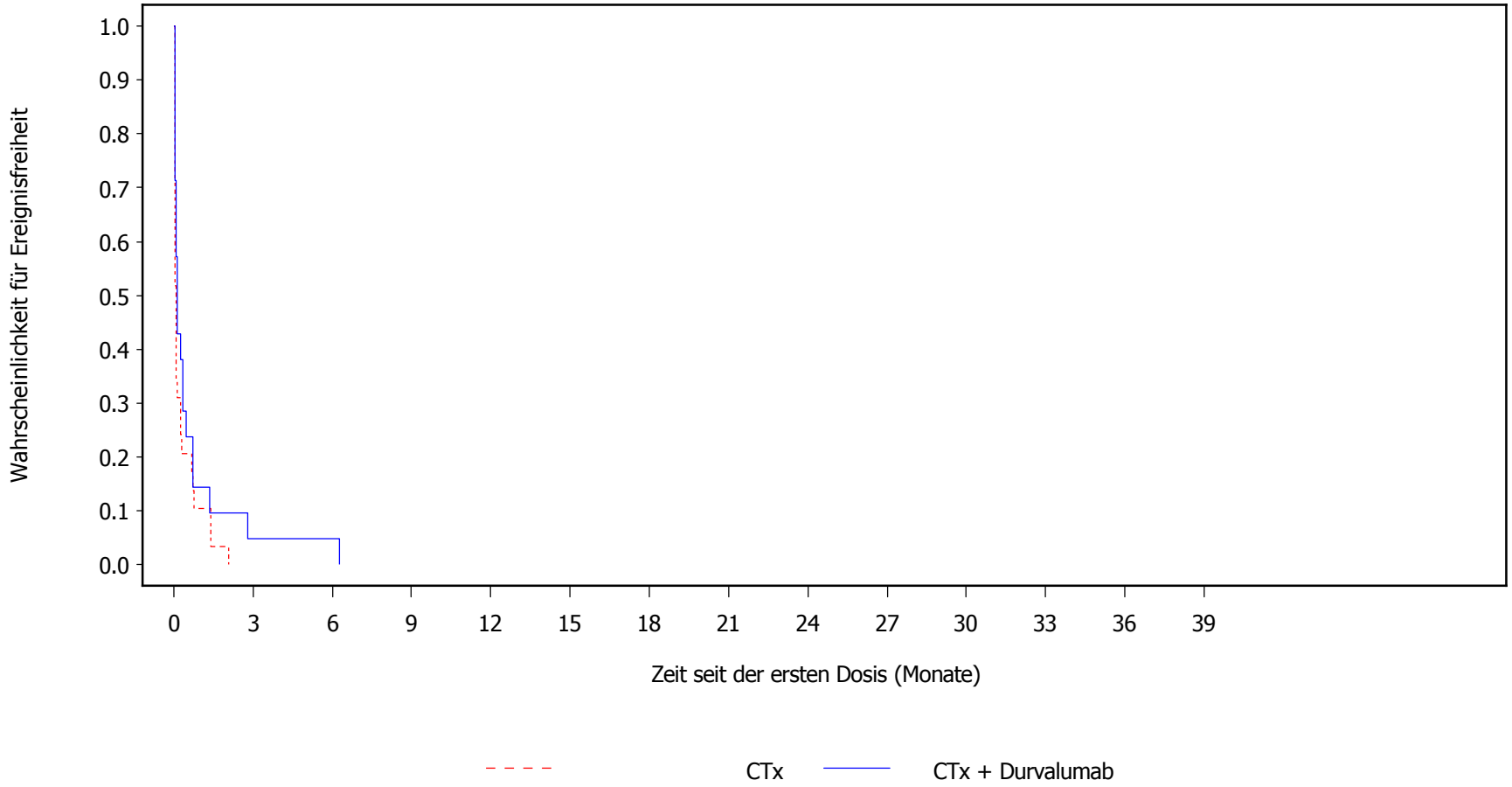
Figure 4.4.1.1.2D.1 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UE for ECOG Performance Status zu Baseline=0
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

21	1	1	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
29	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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc2.sas gttesubaedc2haa 29MAY2024:15:58

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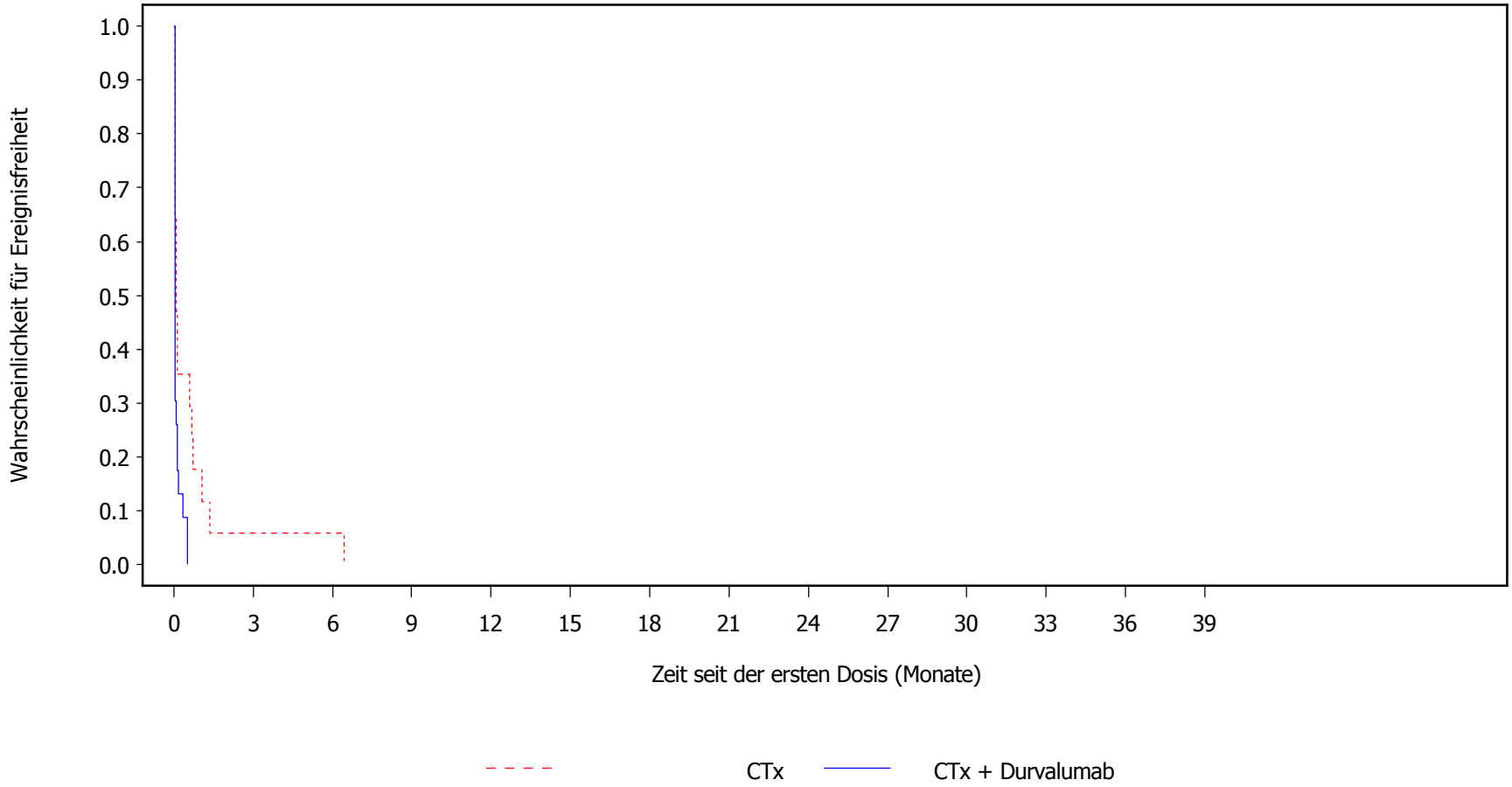
Figure 4.4.1.1.2D.2 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UE for ECOG Performance Status zu Baseline=1
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

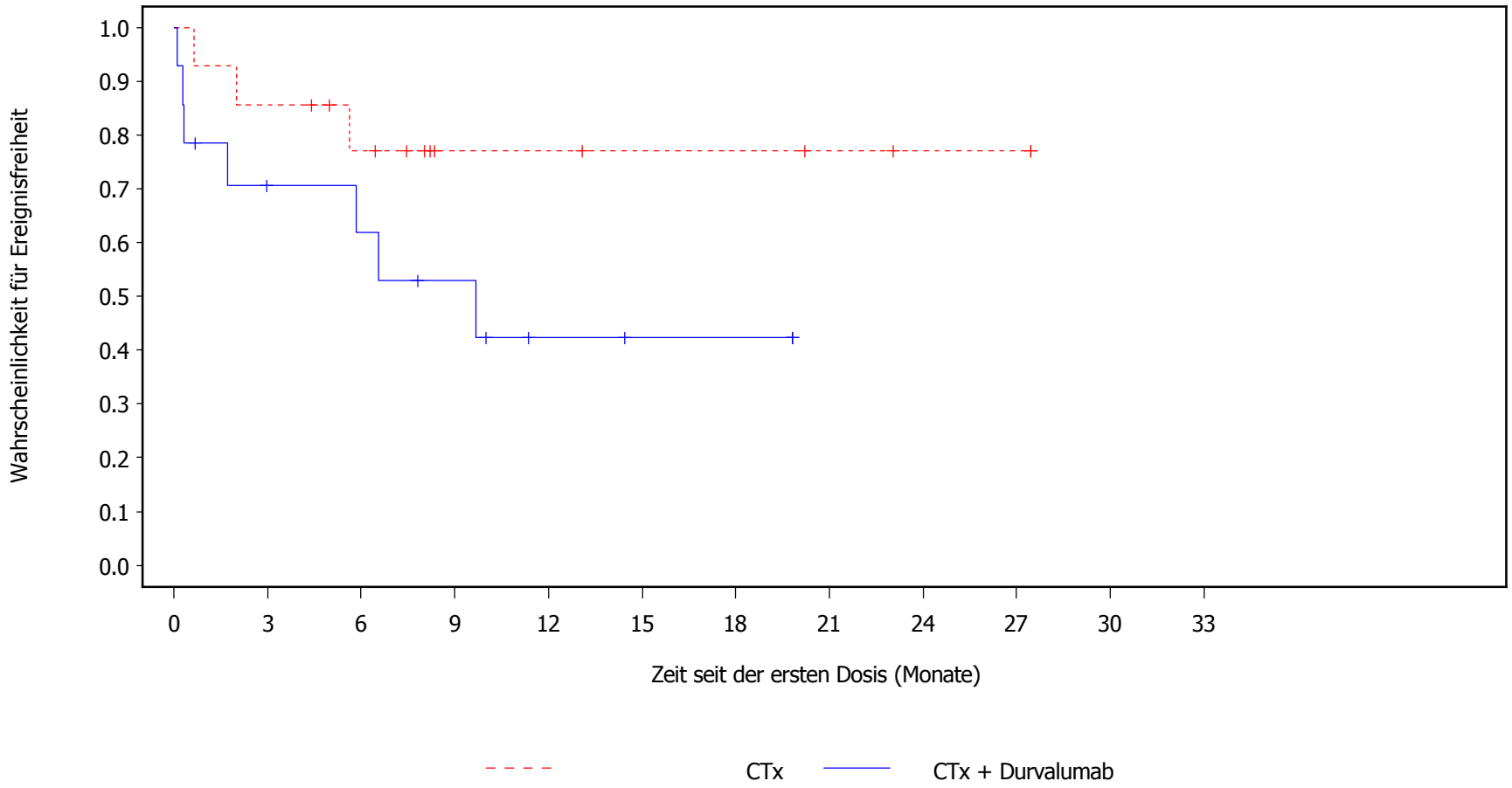
23	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
17	1	1	0	0	0	0	0	0	0	0	0	0	0	CTx

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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc2.sas gttesubaedc2hab 29MAY2024:15:58

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.2.1.1D.1 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of SUE for Region=Asien
Safety Analysis Set, DCO 12APR2023



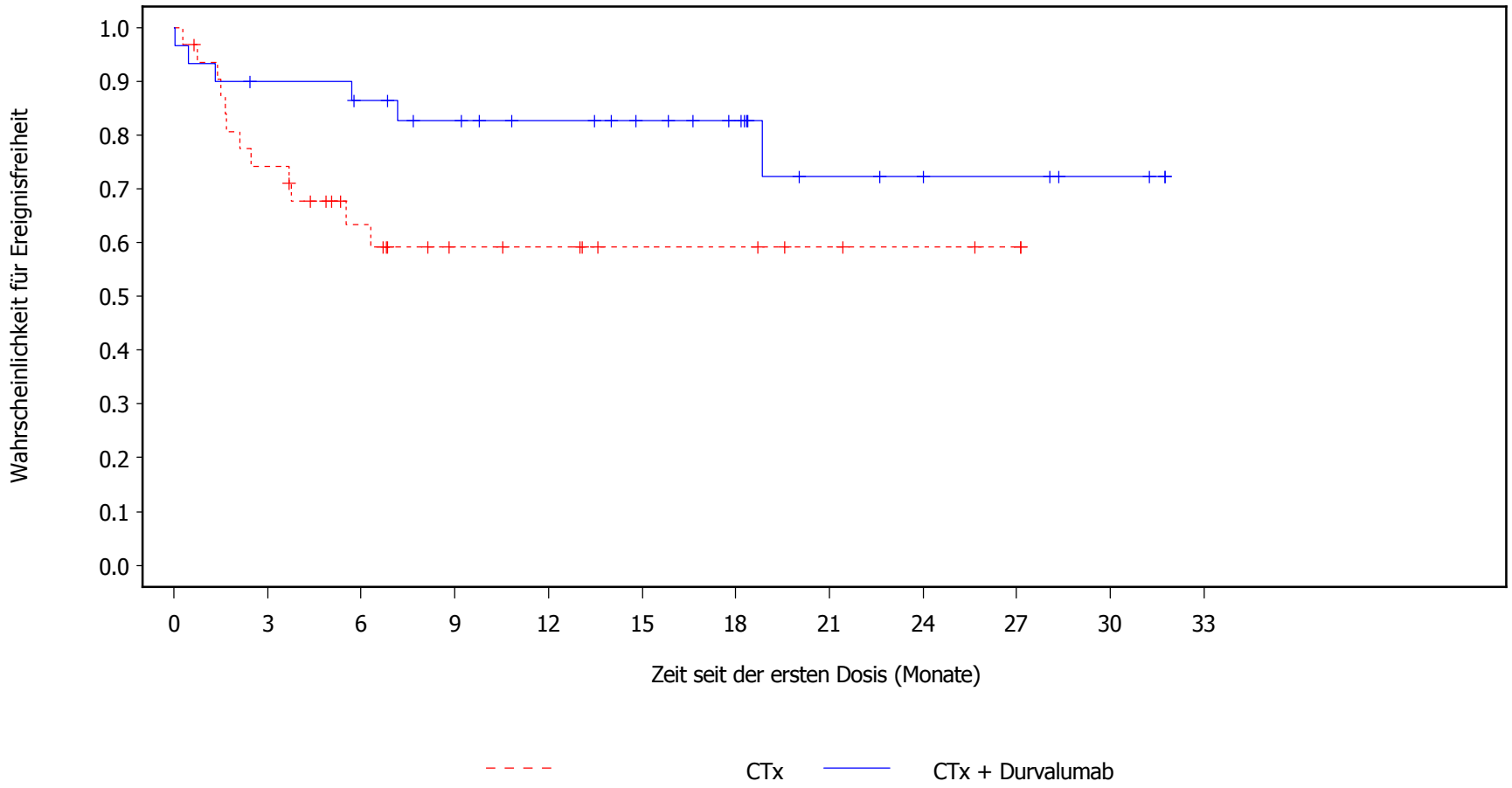
Anzahl an Patienten unter Risiko:

14	8	7	5	2	1	1	0	0	0	0	0	CTx + Durvalumab
14	12	9	4	4	3	3	2	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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc1.sas gttesubaedc1iaa 29MAY2024:15:55

Figure 4.4.2.1.1D.2 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of SUE for Region=Rest der Welt
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

30	26	24	21	18	15	12	6	5	4	2	0	CTx + Durvalumab
32	23	15	9	8	5	5	3	2	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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc1.sas gttesubaedc1iab 29MAY2024:15:55

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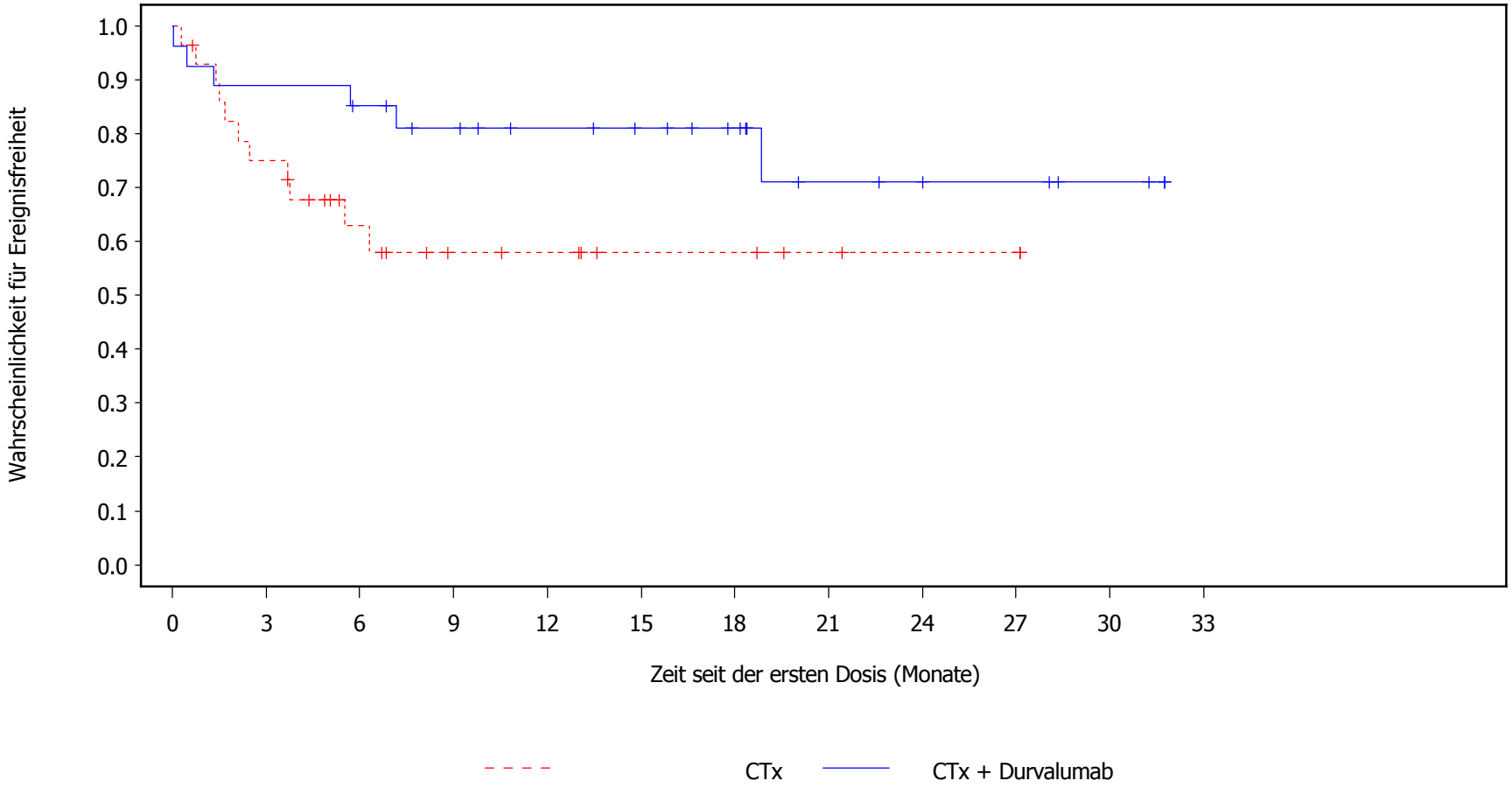
Figure 4.4.2.1.1D.3 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of SUE for Abstammung=Weiß
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

27	24	22	19	16	14	11	6	5	4	2	0	CTx + Durvalumab
29	21	13	8	7	4	4	2	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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc1.sas gttesubaedc1iac 29MAY2024:15:55

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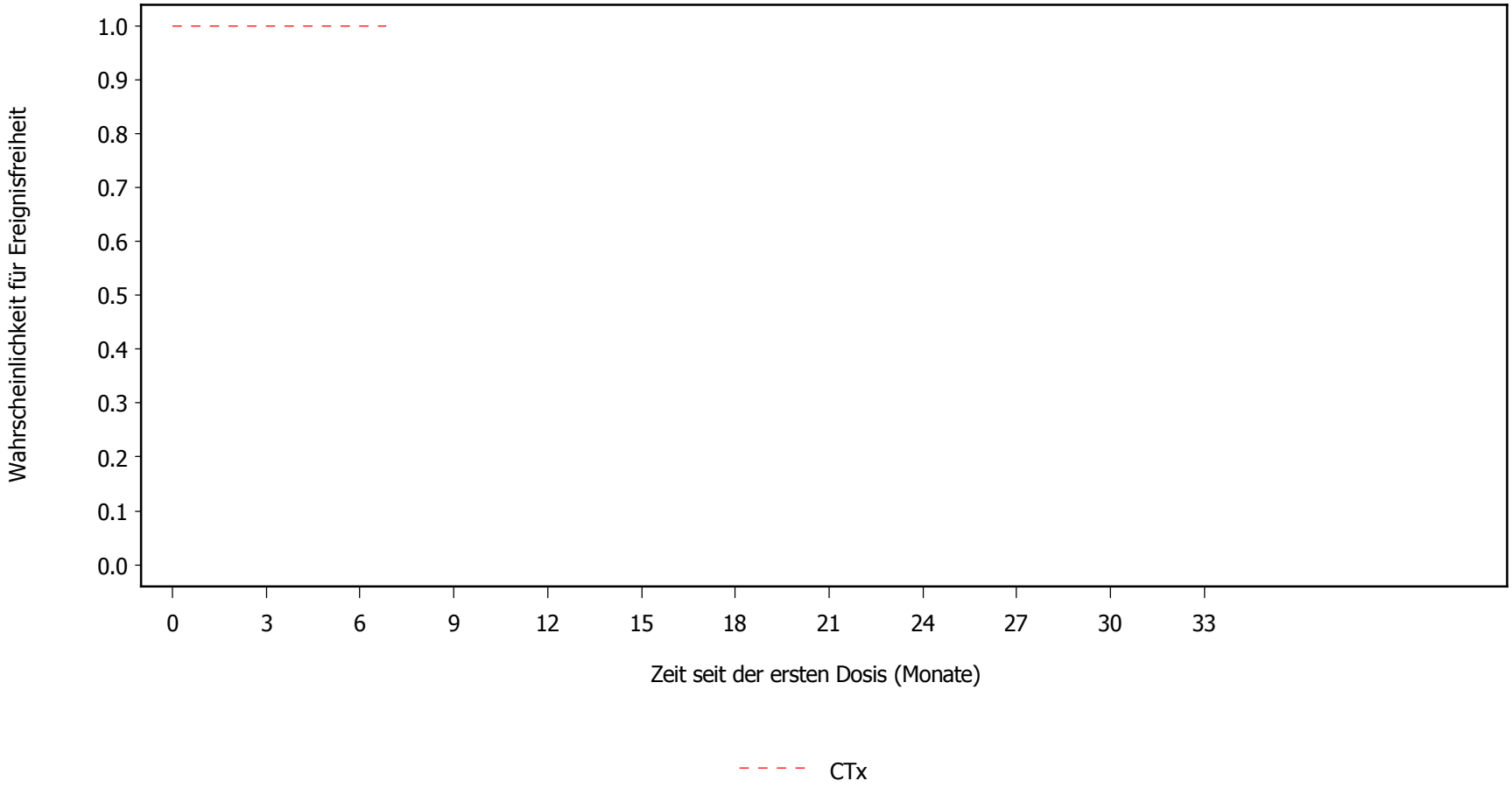
Figure 4.4.2.1.1D.4 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of SUE for Abstammung=Schwarz/Afroamerikanisch
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

1	1	1	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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc1.sas gttesubaedc1iad 29MAY2024:15:55

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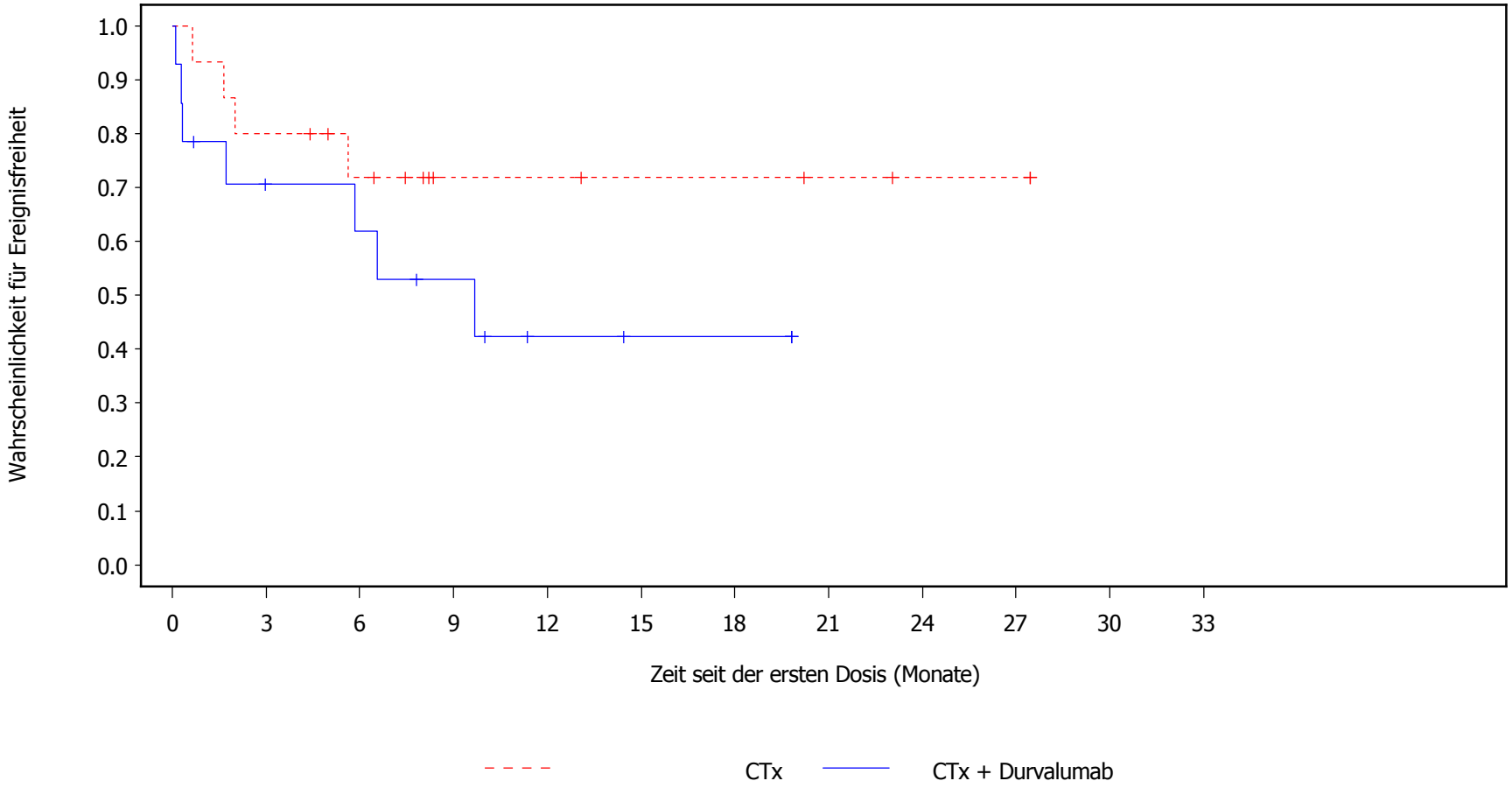
Figure 4.4.2.1.1D.5 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of SUE for Abstammung=Asiatisch
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

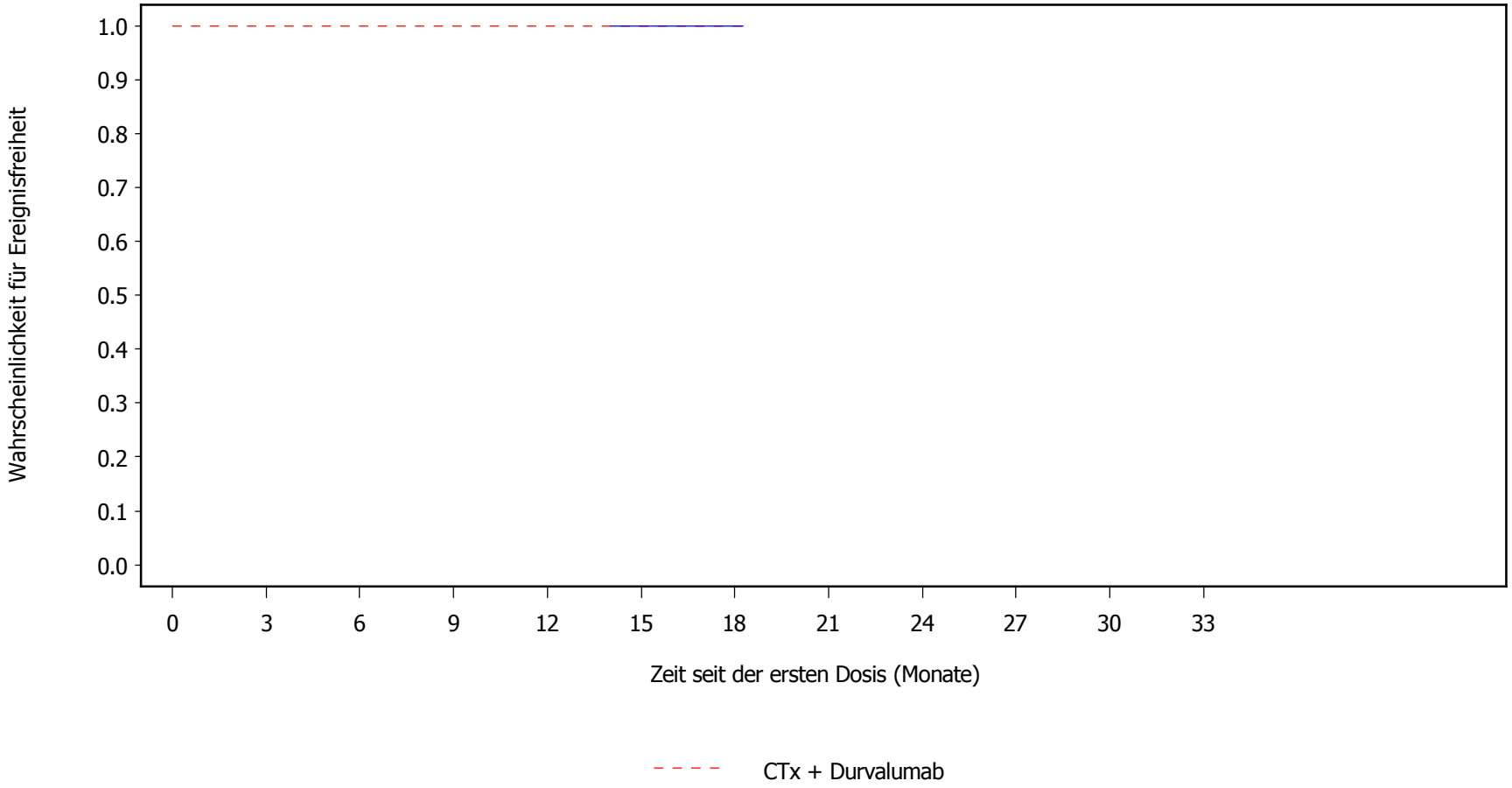
14	8	7	5	2	1	1	0	0	0	0	0	CTx + Durvalumab
15	12	9	4	4	3	3	2	1	1	0	0	CTx

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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc1.sas gttesubaedc1iae 29MAY2024:15:55

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.2.1.1D.6 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of SUE for Abstammung=Andere
Safety Analysis Set, DCO 12APR2023



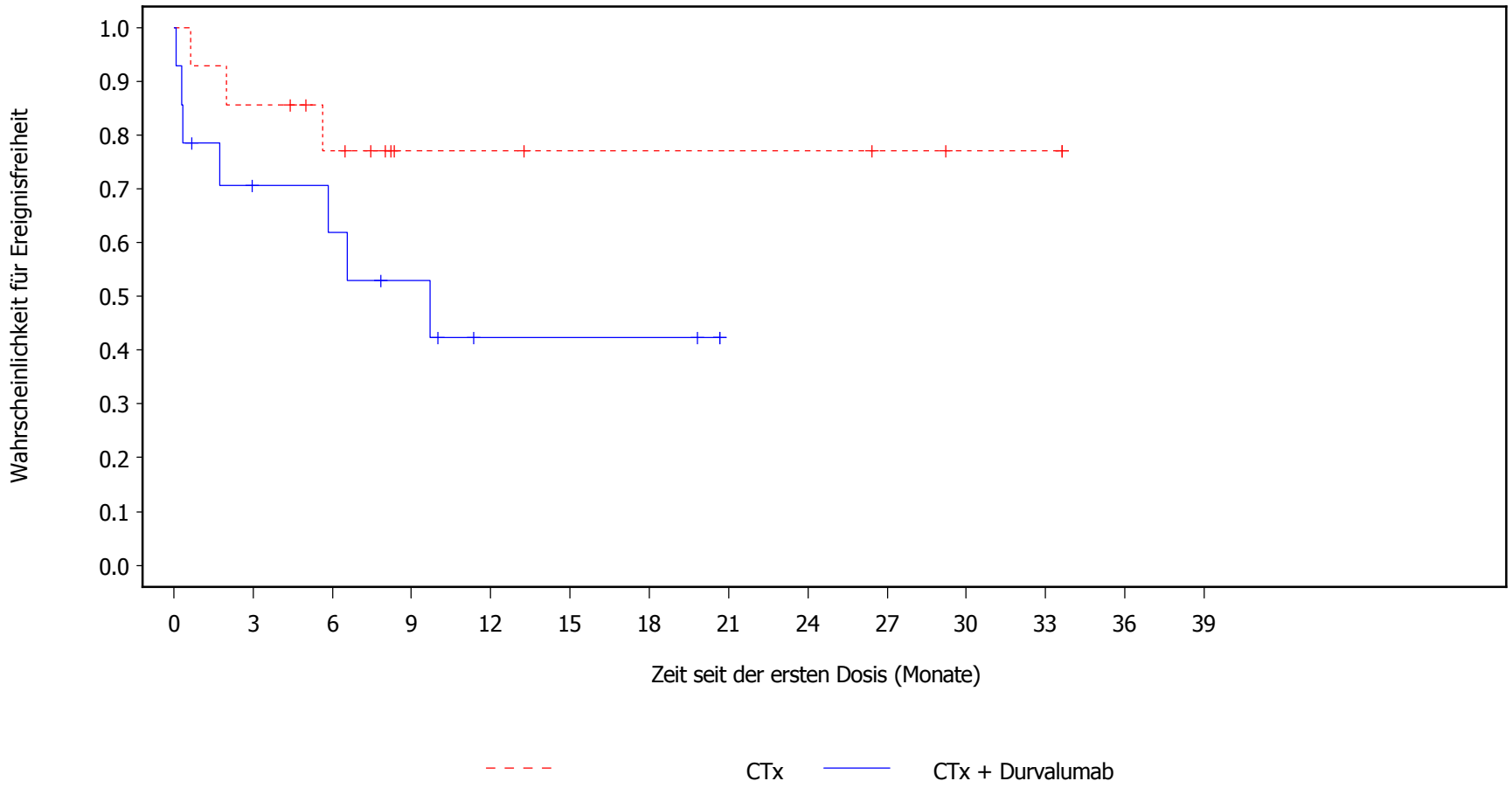
Anzahl an Patienten unter Risiko:

2	2	2	2	2	1	1	0	0	0	0	0	CTx + Durvalumab

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/ttesubaedc1.sas gttesubaedc1iaf 29MAY2024:15:55

Figure 4.4.2.1.2D.1 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of SUE for Region=Asien
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

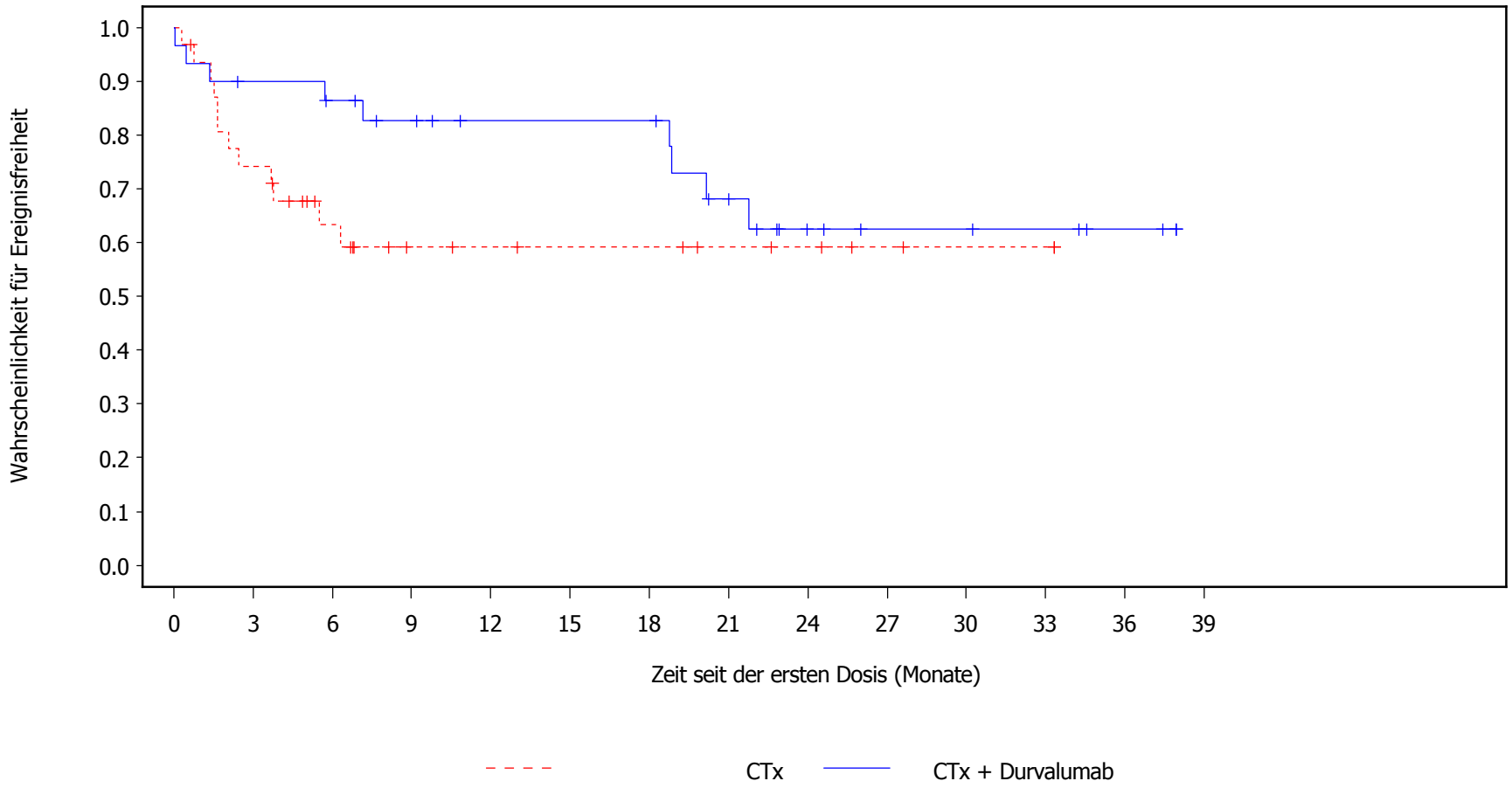
14	8	7	5	2	2	2	0	0	0	0	0	0	0	CTx + Durvalumab
14	12	9	4	4	3	3	3	3	2	1	1	0	0	CTx

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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc2.sas gttesubaedc2iaa 29MAY2024:15:58

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.2.1.2D.2 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of SUE for Region=Rest der Welt
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

30	26	24	21	18	18	18	12	7	5	5	4	2	0 CTx + Durvalumab
32	23	15	9	8	7	7	5	4	2	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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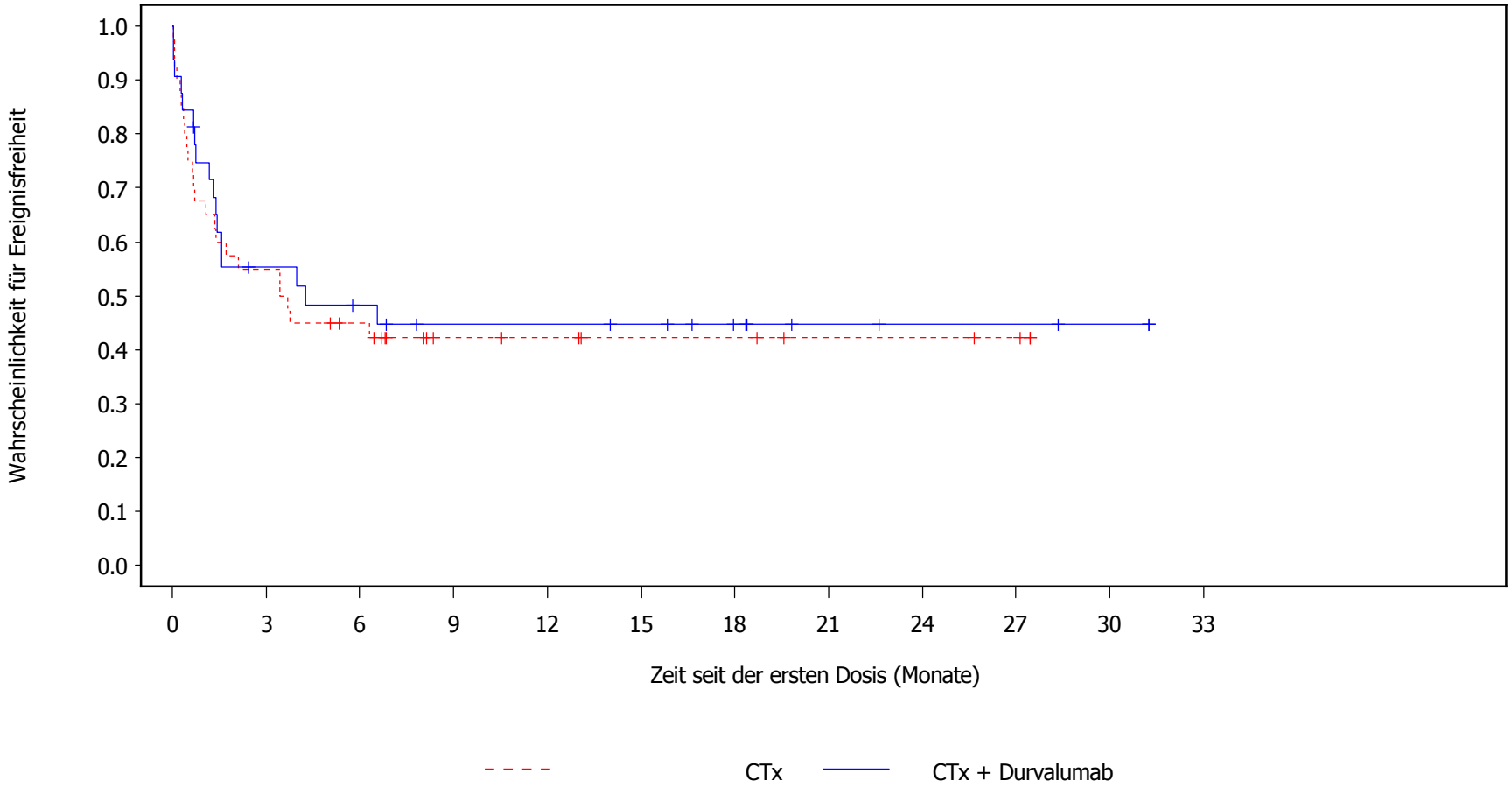
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.1.1D.1 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Histologie=Endometrioid
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

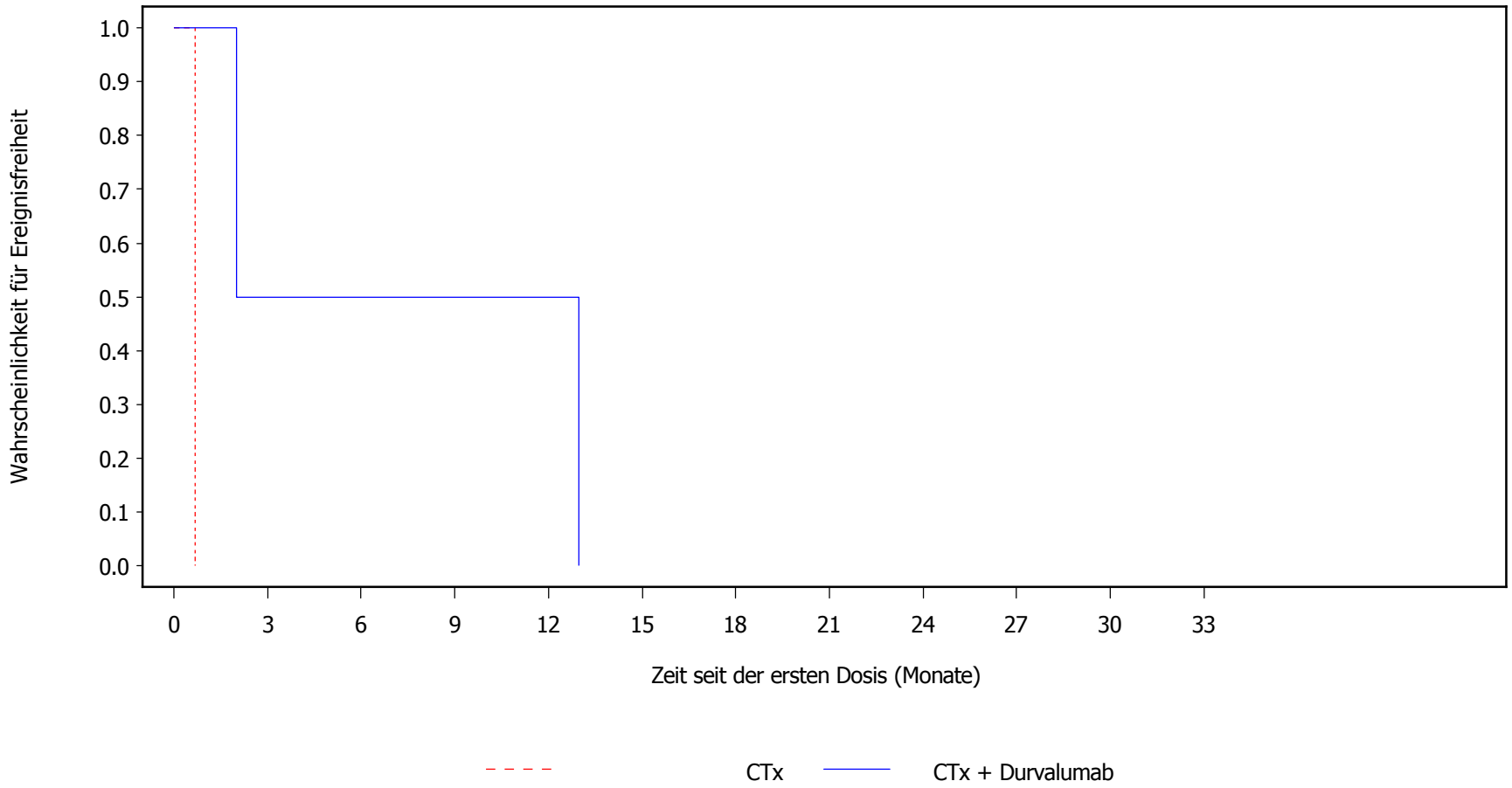
32	16	13	10	10	9	6	3	2	2	1	0	CTx + Durvalumab
40	22	16	8	7	5	5	3	3	2	0	0	CTx

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/ttesubaedc1.sas gttesubaedc1kaa 29MAY2024:15:55

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.1.1D.2 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Histologie=Serös
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

2	1	1	1	1	0	0	0	0	0	0	0	CTx + Durvalumab
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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc1.sas gttesubaedc1kab 29MAY2024:15:55

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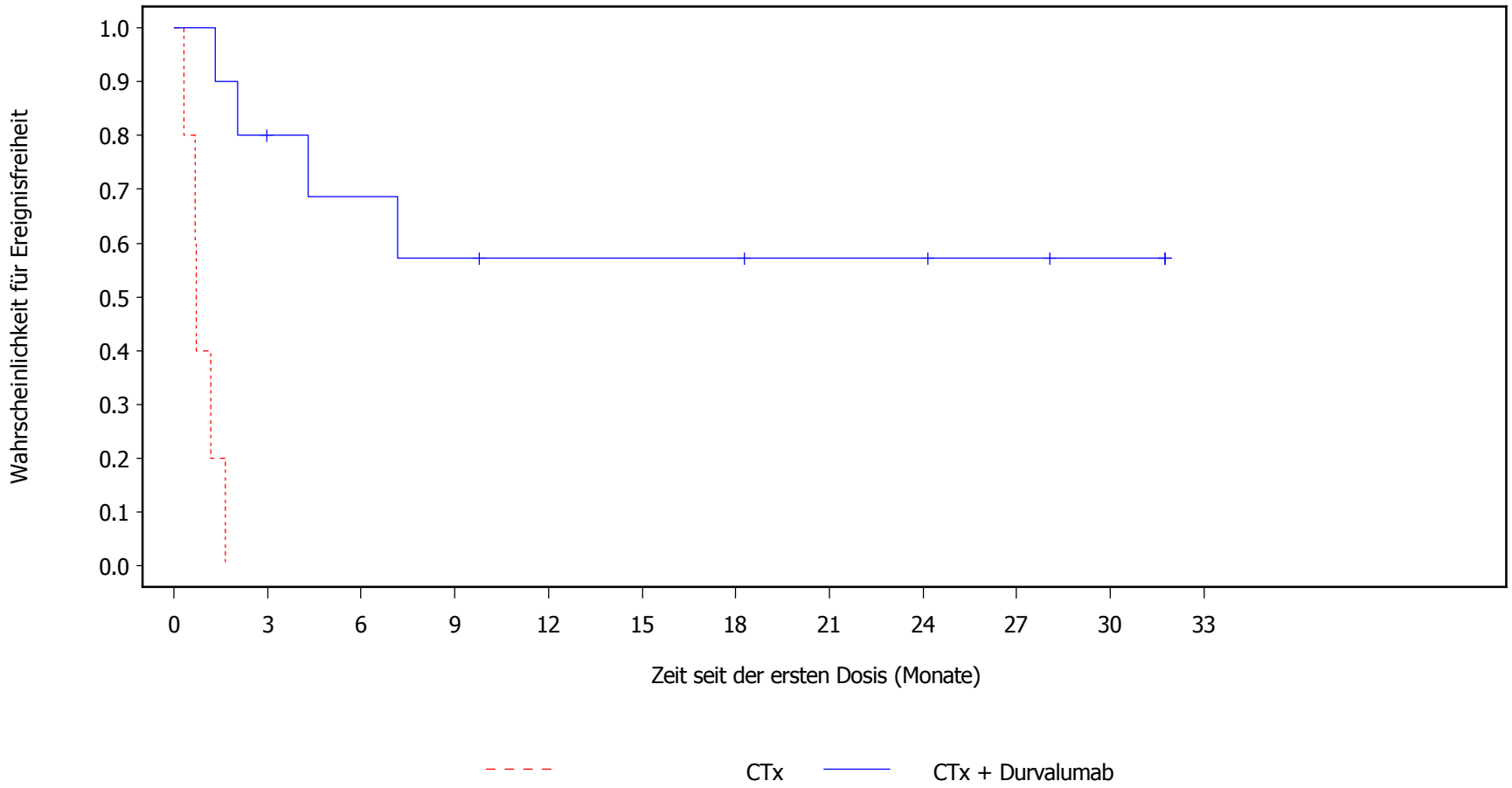
Figure 4.4.4.1.1D.3 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Histologie=Andere
Safety Analysis Set, DCO 12APR2023



Anzahl an Patienten unter Risiko:

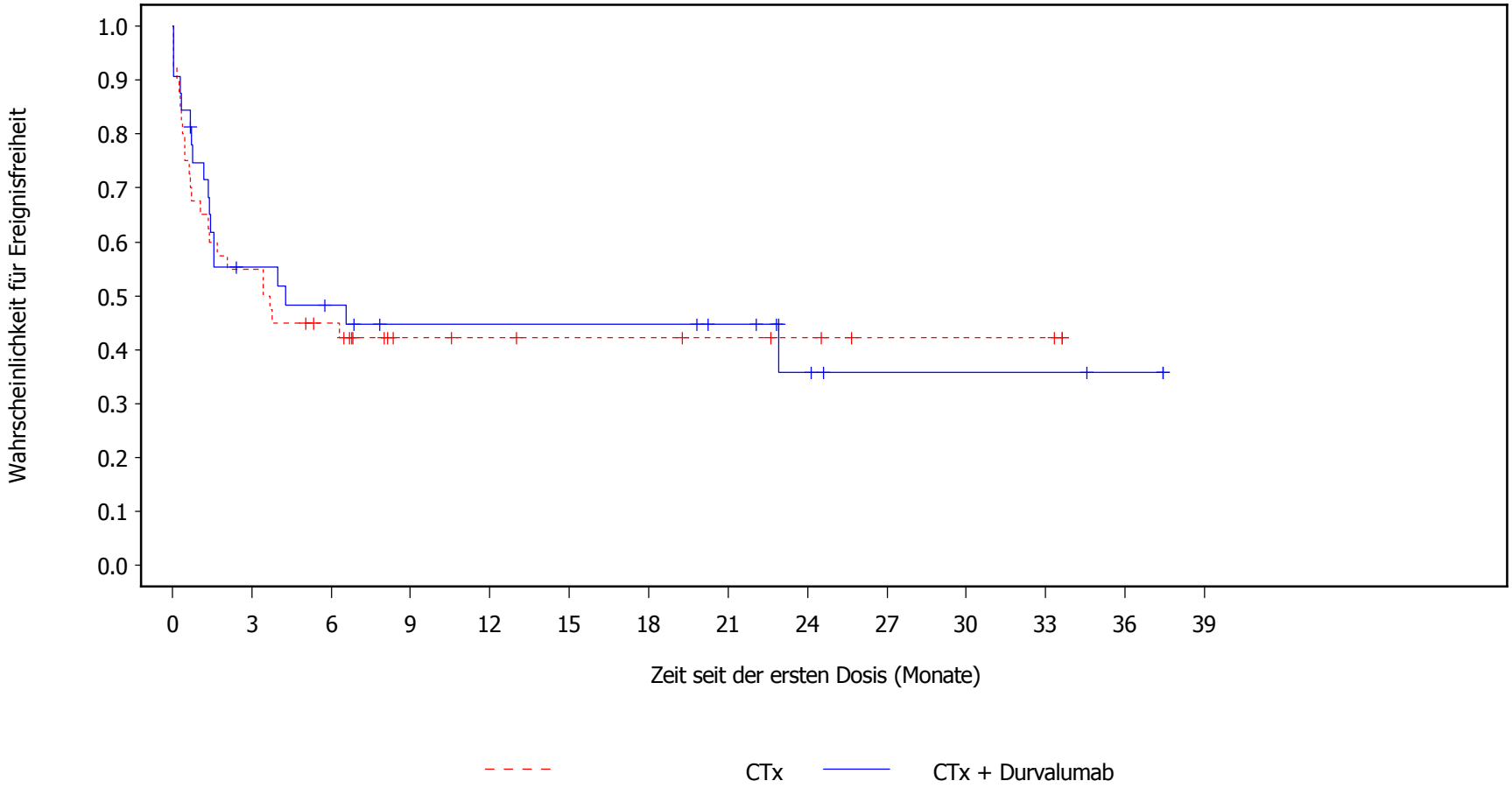
10	7	6	5	4	4	4	3	3	2	1	0	CTx + Durvalumab
5	0	0	0	0	0	0	0	0	0	0	0	CTx

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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc1.sas gttesubaedc1kac 29MAY2024:15:55

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.1.2D.1 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Histologie=Endometrioid
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

32	16	13	10	10	10	10	8	4	2	2	2	1	0	CTx + Durvalumab
40	22	16	8	7	6	6	5	4	2	2	2	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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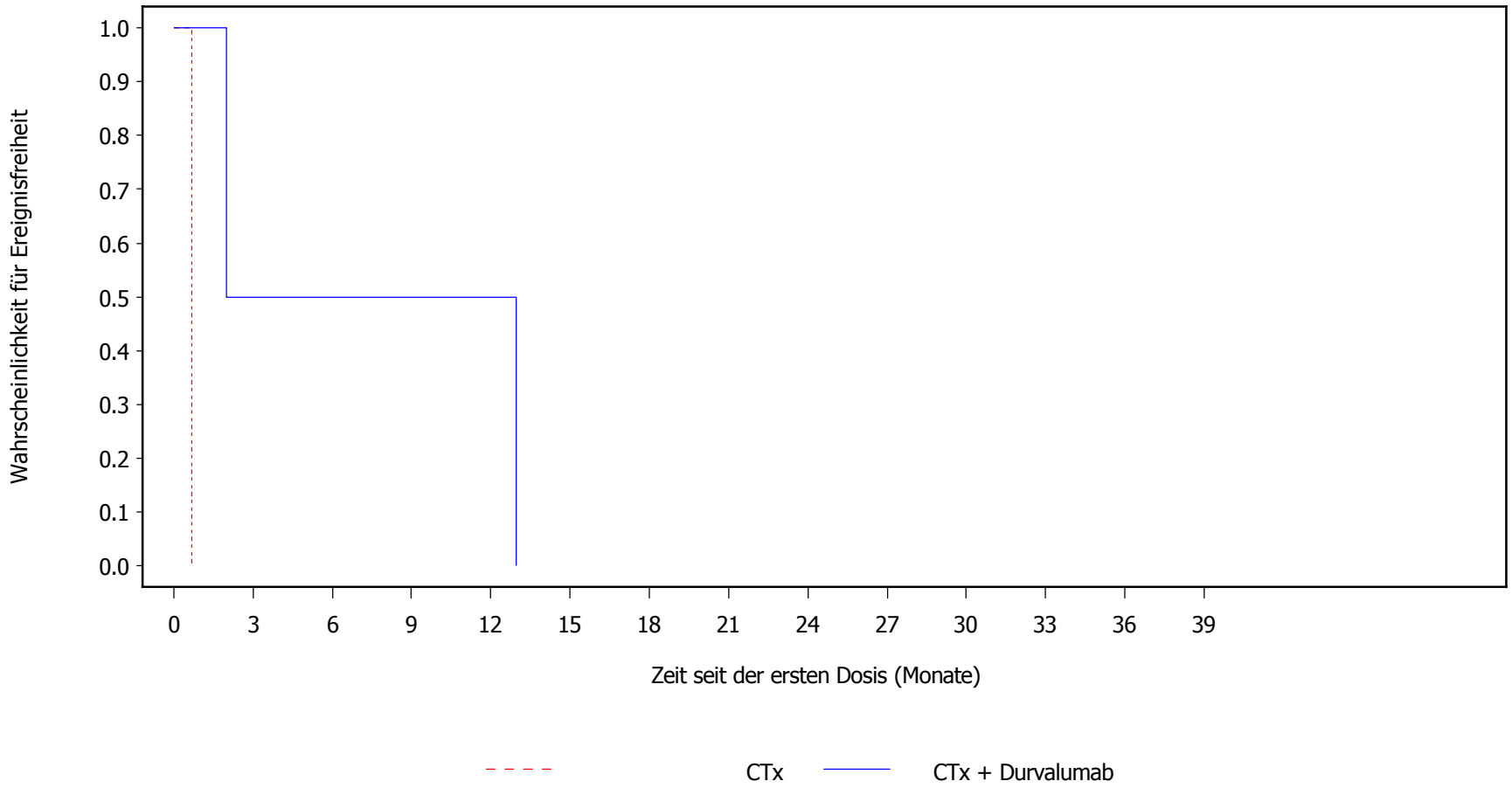
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.1.2D.2 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Histologie=Serös
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

2	1	1	1	1	0	0	0	0	0	0	0	0	0	CTx + Durvalumab
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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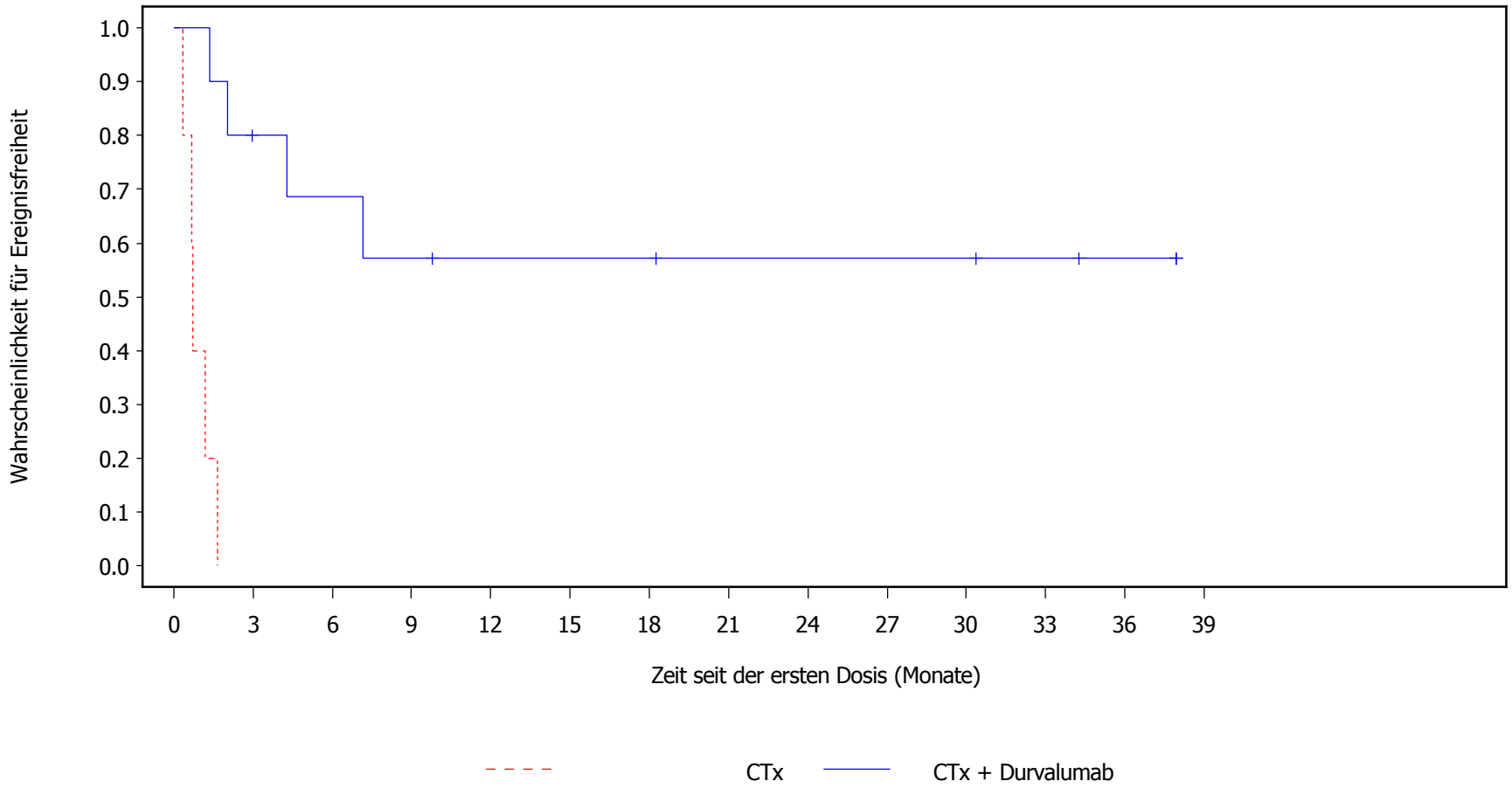
Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.4.1.2D.3 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UE mit CTCAE Grad >=3 for Histologie=Andere
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

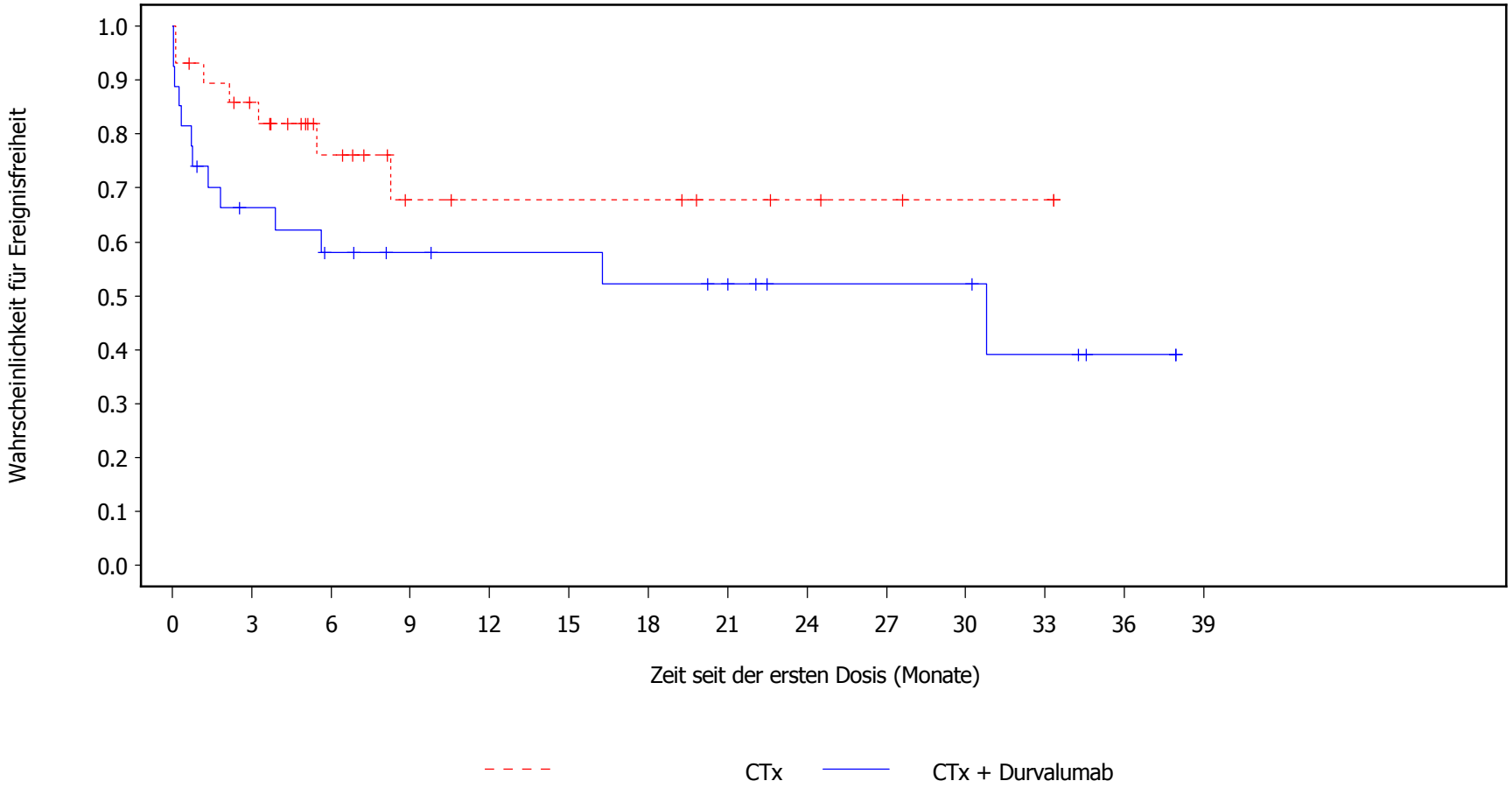
10	7	6	5	4	4	4	3	3	3	3	2	1	0	CTx + Durvalumab
5	0	0	0	0	0	0	0	0	0	0	0	0	0	CTx

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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc2.sas gttesubaedc2kac 29MAY2024:15:58

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.5.1.2D.1 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UESI GT: Diarrhö/Kolitis for Abstammung=Weiß
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

27	16	13	11	10	10	9	7	5	5	5	3	1	0	CTx + Durvalumab
29	22	13	7	6	6	6	4	3	2	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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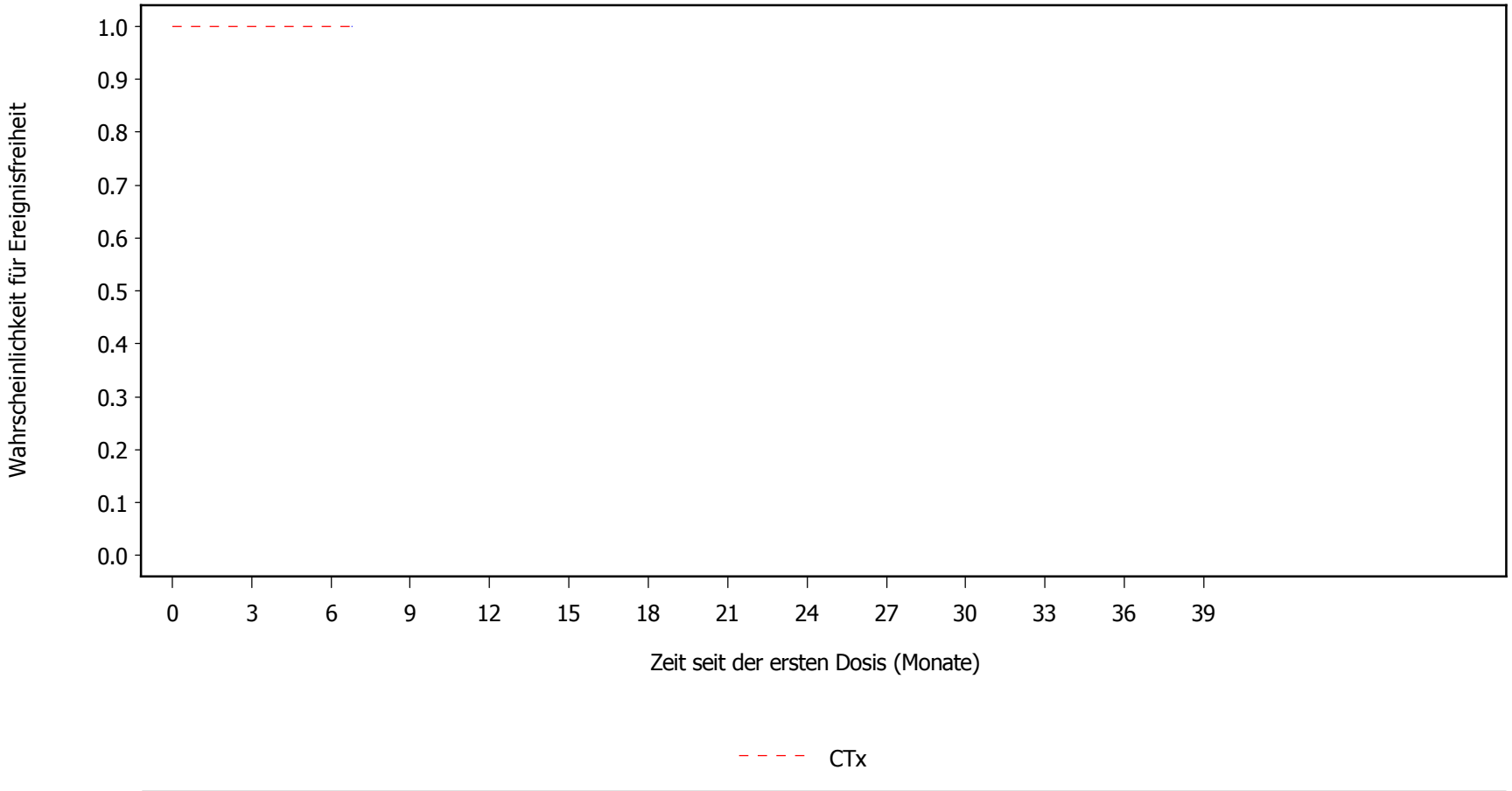
Figure 4.4.5.1.2D.2 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UESI GT: Diarrhö/Kolitis for Abstammung=Schwarz/Afroamerikanisch
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc2.sas gttesubaedc2lab 29MAY2024:15:58

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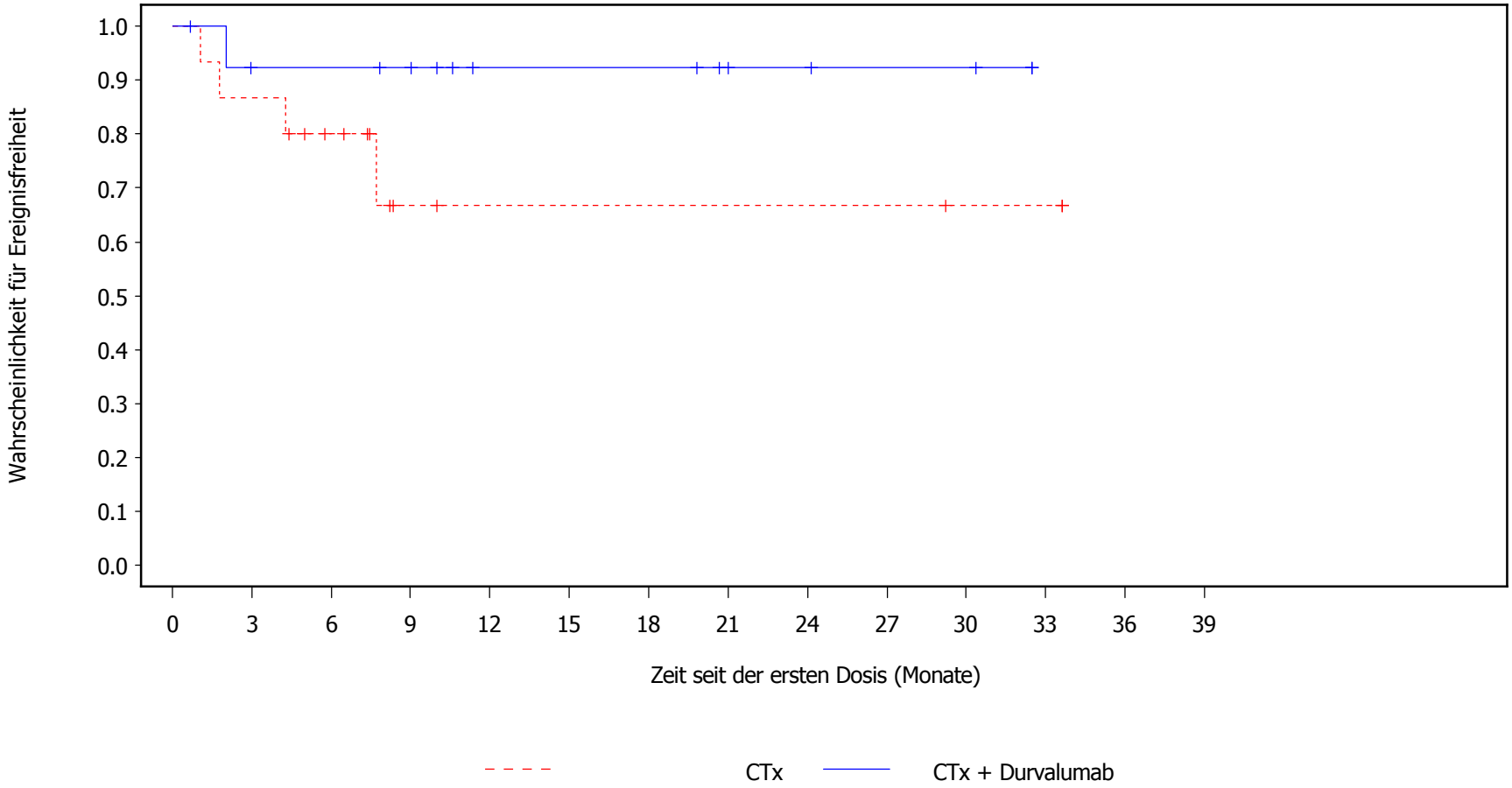
Figure 4.4.5.1.2D.3 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UESI GT: Diarrhö/Kolitis for Abstammung=Asiatisch
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

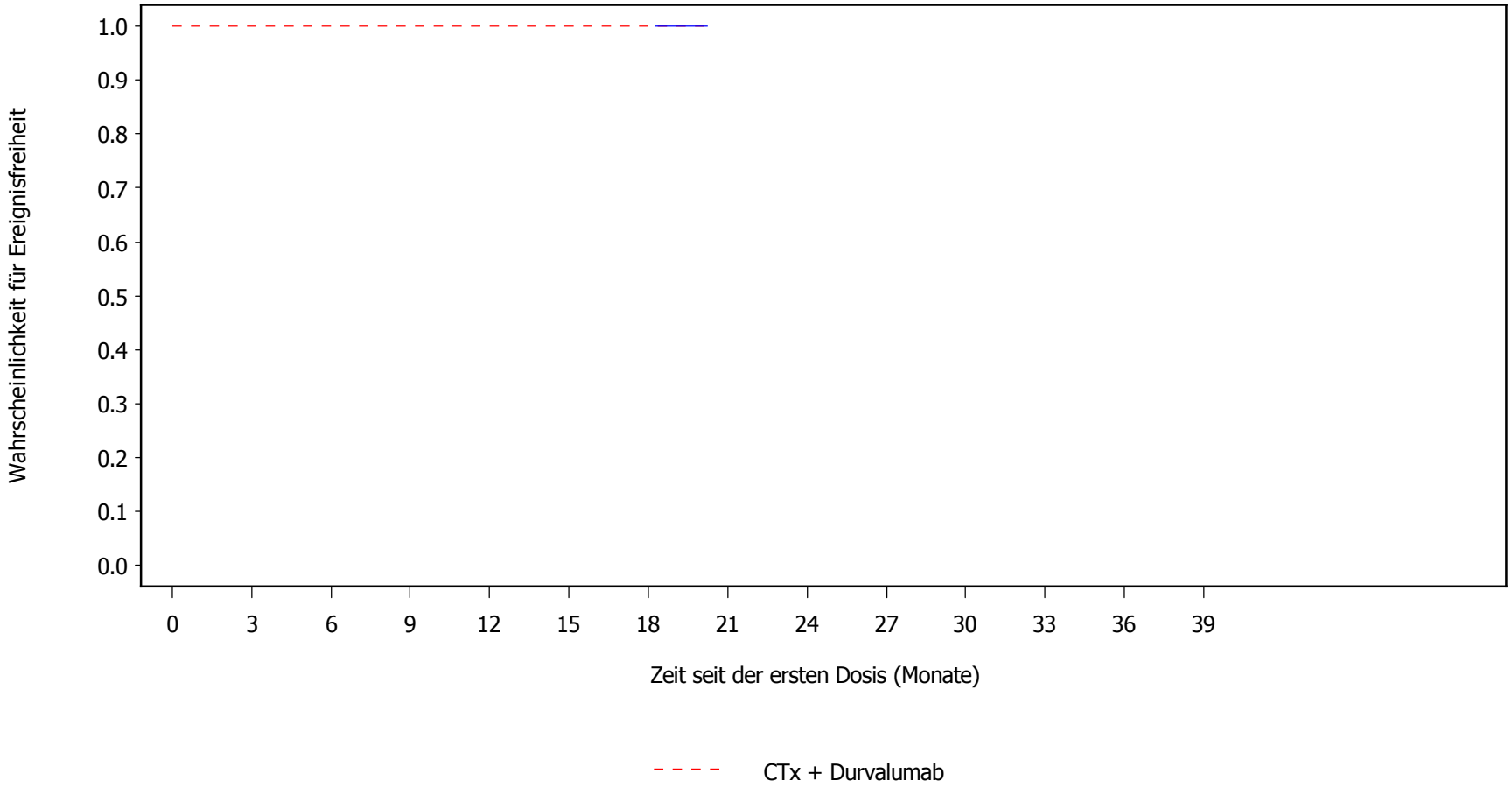
14	11	11	10	6	6	6	3	3	2	2	0	0	0	CTx + Durvalumab
15	13	9	3	2	2	2	2	2	2	1	1	0	0	CTx

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.

root/cdar/d081/d9311c00001/ar/german_payer/tlf/prod/program/ttesubaedc2.sas gttesubaedc2lac 29MAY2024:15:58

Nutzenbewertung nach AMNOG Seite 1 von 1

Figure 4.4.5.1.2D.4 DUO-E (dMMR Durva) Subgroup Analysis: Kaplan-Meier plot of UESI GT: Diarrhö/Kolitis for Abstammung=Andere
Safety Analysis Set, DCO 18OCT2023



Anzahl an Patienten unter Risiko:

2	2	2	2	2	2	2	0	0	0	0	0	0	0	CTx + Durvalumab

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 gttesubaedc2lad 29MAY2024:15:58