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Durvalumab (IMFINZI®)

AstraZeneca GmbH

Modul 4 A – Anhang 4-G

Durvalumab in Kombination mit FLOT-Chemotherapie als neoadjuvante und adjuvante Behandlung gefolgt von einer adjuvanten Durvalumab-Monotherapie zur Behandlung von Erwachsenen mit resezierbarem Adenokarzinom des Magens oder des gastroösophagealen Übergangs

Analysen und Kaplan-Meier-Kurven
zur Studie MATTERHORN

Stand: 24.07.2026

Anhang 4-G: Daten zur Studie MATTERHORN

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Table 1.1 Summary of observation period (months) for efficacy endpoints
Full Analysis Set, DCO 01SEP2025

		Durva + FLOT (N=474)	Placebo + FLOT (N=474)
Gesamtüberleben	n	474	474
	Mediane	39,56	38,64
	Min	0,3	0,0
	Max	57,0	56,5
Ereignisfreies Überleben	n	474	474
	Mediane	33,86	28,09
	Min	0,0	0,0
	Max	54,8	54,0
krankheitsfreies Überleben	n	339	323
	Mediane	33,15	33,08
	Min	0,0	0,0
	Max	49,7	49,9

Observation period for an efficacy endpoint is defined as the time from randomisation to the date of that event, if occurred or otherwise, to the date of the last evaluable assessment of that efficacy endpoint.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 1.2.1 Summary of observation period (months) for PRO endpoints (Morbidity, hrQoL)
Full Analysis Set, DCO 01SEP2025

		Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EORTC QLQ-C30	n	474	474
	Mediane	20,47	18,09
	Min	0,0	0,0
	Max	55,1	54,3
EORTC QLQ-IL38	n	474	474
	Mediane	20,25	18,04
	Min	0,0	0,0
	Max	55,1	54,3
EORTC QLQ-STO22	n	474	474
	Mediane	20,25	18,04
	Min	0,0	0,0
	Max	55,1	54,3
EQ-5D-5L Visuelle Analogskala	n	474	474
	Mediane	20,25	18,04
	Min	0,0	0,0
	Max	55,1	54,3
Patient Global Impressions of Severity (PGIS)	n	474	474
	Mediane	20,25	18,04
	Min	0,0	0,0
	Max	55,1	54,3
Patient Global Impression of Change (PGIC)	n	474	474
	Mediane	20,25	18,04
	Min	0,0	0,0
	Max	55,1	54,3

Observation period for PROs is defined as the time from randomisation to the earliest date of the last assessment of questionnaire or date of data cut-off (DCO). Patients without any baseline or post baseline measurements are summarised with duration of 1 day.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel. PRO = Patient Reported Outcomes.
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Table 1.2.2 Summary of observation period (months) for PRO endpoints (Safety)
Safety Analysis Set, DCO 01SEP2025

		Durva + FLOT (N=475)	Placebo + FLOT (N=469)
Patient Global Impression of Treatment Tolerability (PGITT)	n	475	469
	Mediane	14,13	13,83
	Min	0,0	0,0
	Max	18,2	21,7

Observation period for PROs is defined as the time from randomisation to the earliest date of the last assessment of questionnaire or date of data cut-off (DCO). Patients without any baseline or post baseline measurements are summarised with duration of 1 day.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel. PRO = Patient Reported Outcomes.
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Table 1.3 Summary of observation period (months) for all safety outcomes
Safety Analysis Set, DCO 01SEP2025

		Durva + FLOT (N=475)	Placebo + FLOT (N=469)
UE	n	475	469
	Mediane	17,28	17,12
	Min	0,3	0,4
	Max	23,7	24,6

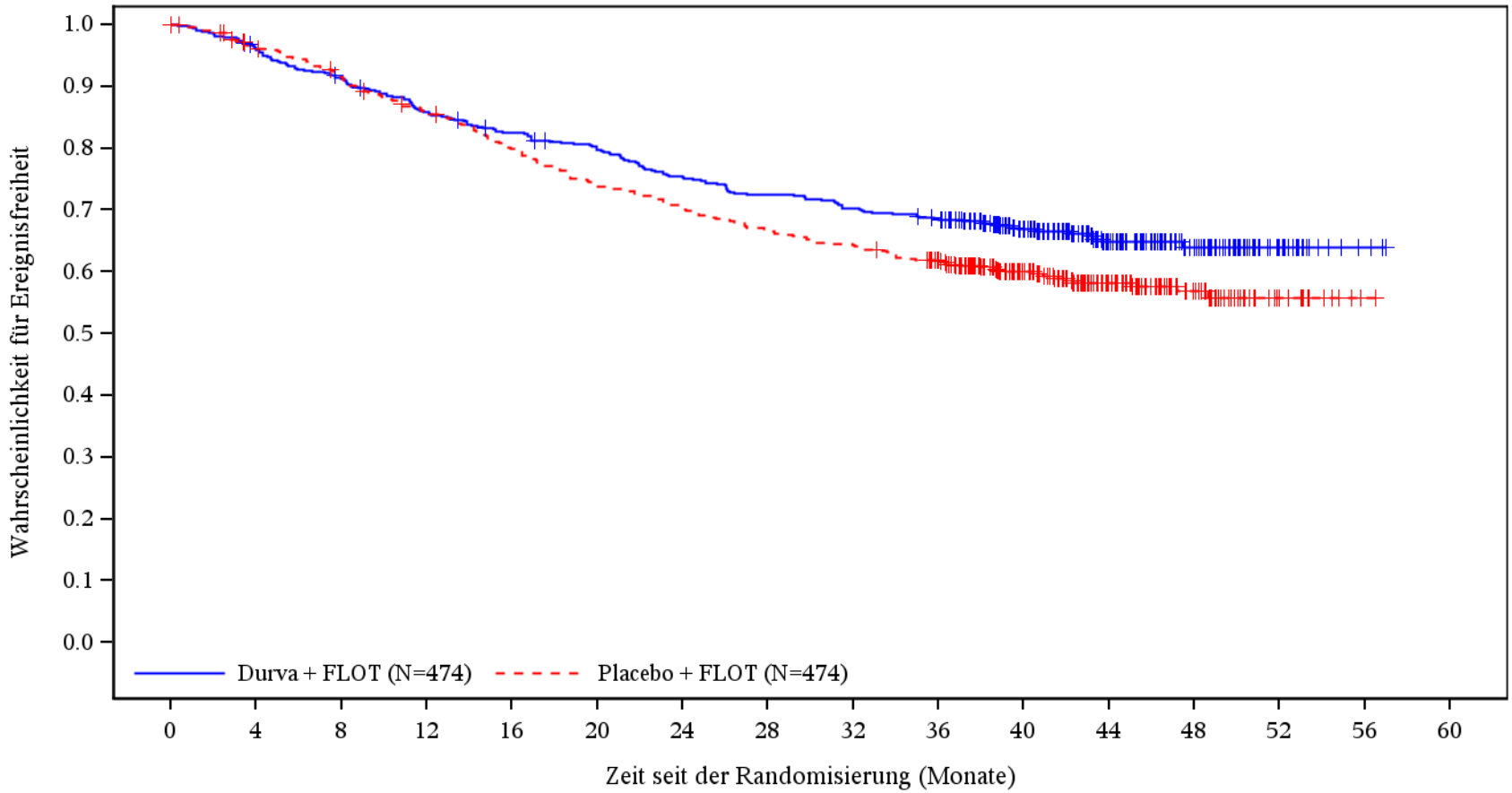
Observation period for all safety outcomes is defined as the duration from the date of first dose of study treatment to the earliest of the date of data cut-off, 90 days following last dose of study treatment, date of starting subsequent cancer therapy or date of death.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 2.1.1.1 Summary of analysis of Overall Survival (Mortality)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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	474	160 [33,8]	NE [NE; NE]	474	192 [40,5]	NE [NE; NE]	0,78	[0,63; 0,96]	0,0213*

[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic location, clinical lymph node status and PD-L1 status. Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 2.1.1.2 Kaplan-Meier plot of Overall Survival (Mortality)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

474	453	430	403	386	371	351	337	327	316	227	138	71	21	3	0
(0)	(2)	(3)	(4)	(6)	(8)	(8)	(8)	(8)	(11)	(93)	(177)	(243)	(293)	(311)	(314)
474	449	425	395	368	341	324	307	296	278	204	121	61	15	2	0
(0)	(8)	(10)	(12)	(13)	(13)	(13)	(13)	(13)	(20)	(86)	(164)	(222)	(267)	(280)	(282)

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

Table 2.1.2.1 Summary of subgroup analysis of Overall Survival (Mortality)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	23 [25,6]	NE [NE; NE]	90	31 [34,4]	NE [NE; NE]	0,74	[0,43; 1,26]	0,2680
Nicht-Asien	384	137 [35,7]	NE [NE; NE]	384	161 [41,9]	NE [NE; NE]	0,80	[0,63; 1,0003]	0,0503
Interaktion p-Wert									0,7988
Klinischer Lymphknotenstatus									
Positiv	329	110 [33,4]	NE [NE; NE]	330	146 [44,2]	NE [NE; NE]	0,69	[0,54; 0,88]	0,0032*
Negativ	145	50 [34,5]	NE [NE; NE]	144	46 [31,9]	NE [NE; NE]	1,11	[0,75; 1,66]	0,6018
Interaktion p-Wert									0,0469*
PD-L1-Status									
TAP >= 1%	426	143 [33,6]	NE [NE; NE]	427	172 [40,3]	NE [NE; NE]	0,79	[0,63; 0,99]	0,0395*
TAP < 1%	48	17 [35,4]	NE [NE; NE]	47	20 [42,6]	NE [NE; NE]	0,77	[0,40; 1,47]	0,4218
Interaktion p-Wert									0,9268
Alter bei Randomisierung (Jahre)									
<65	291	95 [32,6]	NE [NE; NE]	265	105 [39,6]	NE [NE; NE]	0,79	[0,59; 1,04]	0,0879
>=65	183	65 [35,5]	NE [NE; NE]	209	87 [41,6]	NE [NE; NE]	0,81	[0,58; 1,11]	0,1892
Interaktion p-Wert									0,9005
Geschlecht									
Männlich	326	105 [32,2]	NE [NE; NE]	356	145 [40,7]	NE [NE; NE]	0,74	[0,58; 0,95]	0,0191*
Weiblich	148	55 [37,2]	NE [NE; NE]	118	47 [39,8]	NE [NE; NE]	0,91	[0,61; 1,34]	0,6160
Interaktion p-Wert									0,3997
Tumorlokalisation									
GC	324	111 [34,3]	NE [NE; NE]	316	124 [39,2]	NE [NE; NE]	0,85	[0,66; 1,10]	0,2102

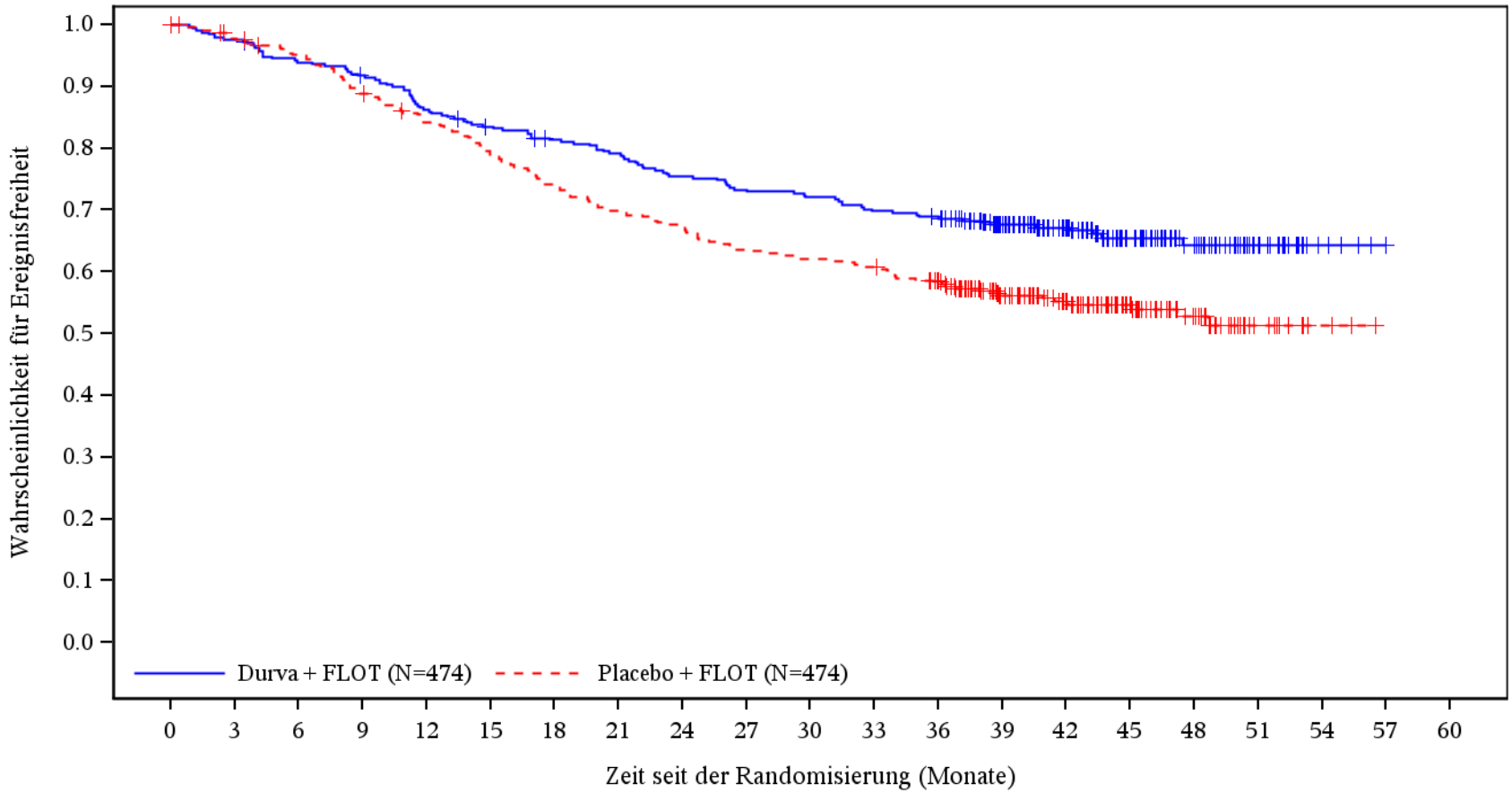
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 2.1.2.1 Summary of subgroup analysis of Overall Survival (Mortality)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
GEJC	150	49 [32,7]	NE [NE; NE]	158	68 [43,0]	NE [NE; NE]	0,68	[0,47; 0,98]	0,0408*
Interaktion p-Wert									0,3410

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 2.1.2.2 Subgroup Analysis: Kaplan-Meier plot of Overall Survival for Clinical lymph node status: Positive (Mortality)
Full Analysis Set, DCO 01SEP2025



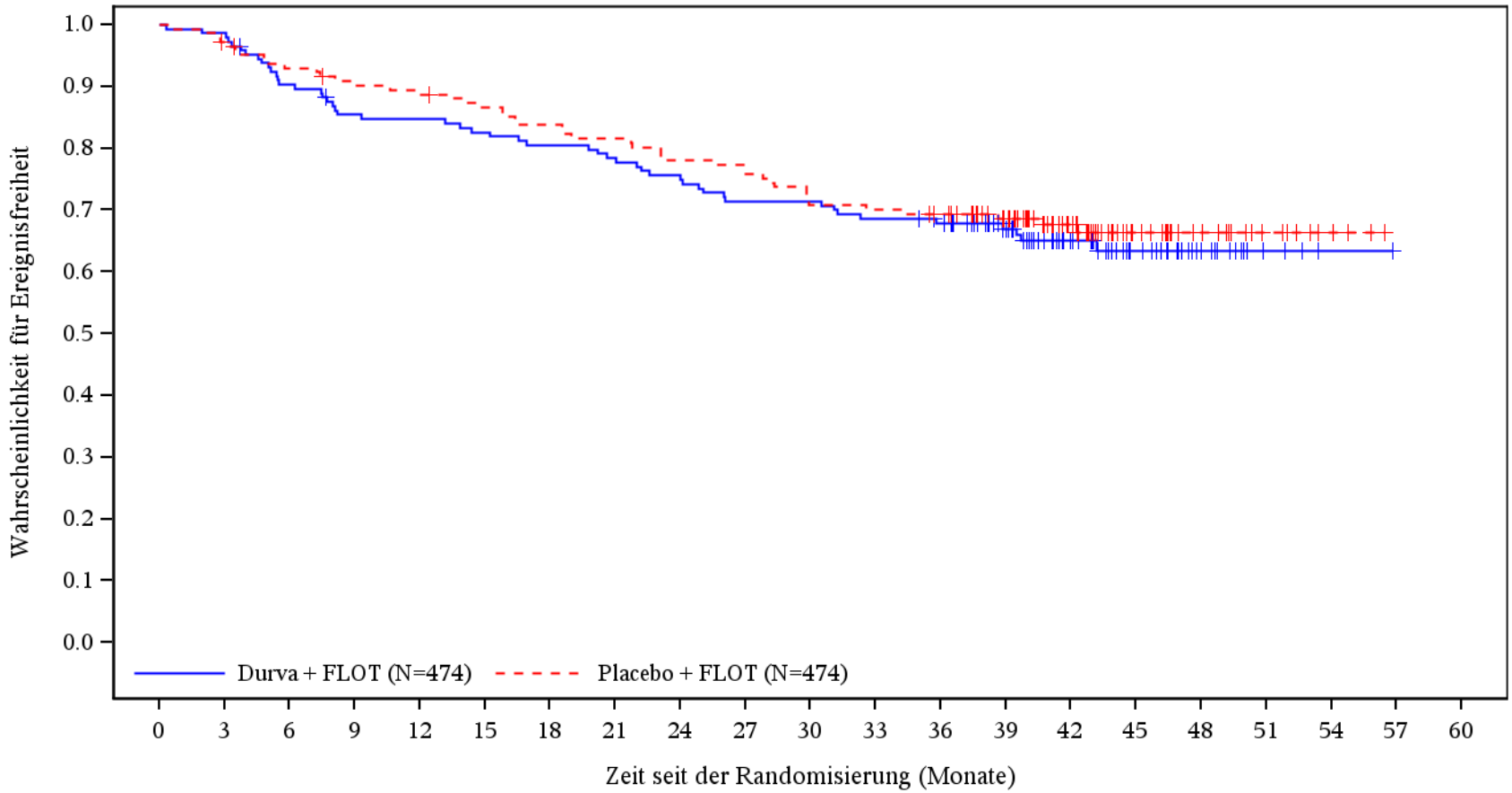
Anzahl im Risiko (Anzahl der zensierten Fälle)

329	321	308	300	282	271	262	255	243	236	232	225	221	182	136	83	56	25	5	1	0
(0)	(0)	(1)	(2)	(2)	(4)	(6)	(6)	(6)	(6)	(6)	(6)	(7)	(42)	(87)	(137)	(163)	(194)	(214)	(218)	(219)
330	318	307	287	270	253	238	224	215	203	199	195	183	141	112	67	44	14	3	0	0
(0)	(5)	(7)	(7)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(9)	(14)	(49)	(76)	(120)	(141)	(170)	(181)	(184)	(184)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 2.1.2.3 Subgroup Analysis: Kaplan-Meier plot of Overall Survival for Clinical lymph node status: Negative (Mortality)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

145	143	130	122	121	118	115	112	108	102	102	98	95	73	46	29	15	4	1	0	0
(0)	(0)	(1)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(4)	(25)	(50)	(66)	(80)	(91)	(94)	(95)	(95)
144	139	132	127	125	121	117	114	109	107	99	98	95	80	55	32	17	9	4	0	0
(0)	(1)	(2)	(3)	(3)	(4)	(4)	(4)	(4)	(4)	(4)	(4)	(6)	(20)	(44)	(66)	(81)	(89)	(94)	(98)	(98)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

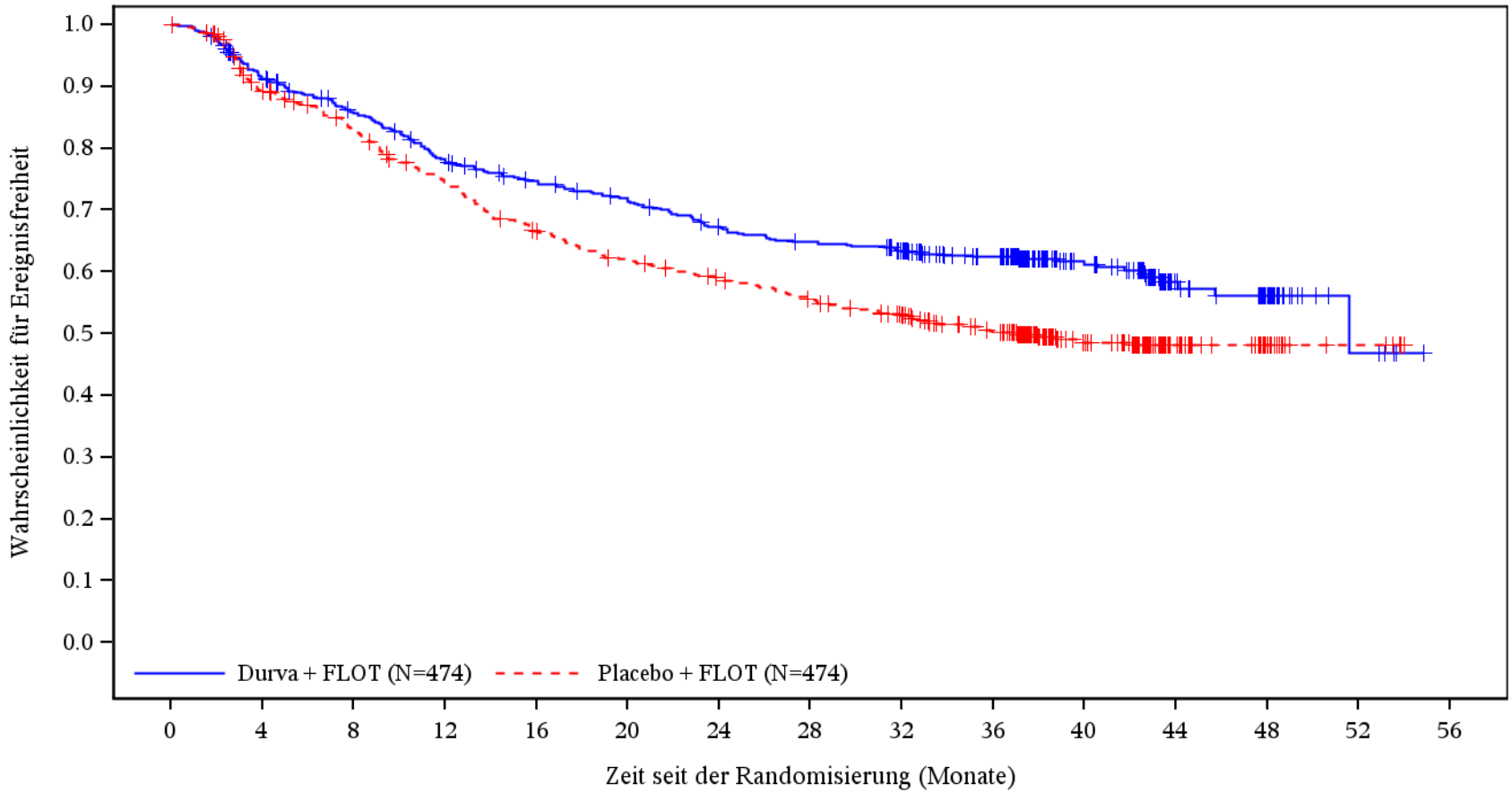
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Table 2.2.1.1 Summary of analysis of Event-Free Survival (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
Ereignisfreies Überleben	474	180 [38,0]	51,6 [51,6; NE]	474	226 [47,7]	37,1 [28,8; NE]	0,72	[0,59; 0,88]	0,0010*

[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic location, clinical lymph node status and PD-L1 status. Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 2.2.1.2 Kaplan-Meier plot of Event-Free Survival (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

474	422	389	353	330	313	292	280	267	230	133	56	34	5	0
(0)	(11)	(19)	(21)	(28)	(31)	(34)	(35)	(42)	(75)	(169)	(241)	(261)	(289)	(294)
474	408	374	330	294	272	255	237	220	187	107	49	23	5	0
(0)	(16)	(23)	(27)	(29)	(31)	(35)	(37)	(44)	(67)	(142)	(199)	(225)	(243)	(248)

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 2.2.2.1 Summary of subgroup analysis of Event-Free Survival (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	28 [31,1]	NE [NE; NE]	90	35 [38,9]	NE [NE; NE]	0,81	[0,49; 1,33]	0,4088
Nicht-Asien	384	152 [39,6]	NE [NE; NE]	384	191 [49,7]	32,8 [26,4; NE]	0,71	[0,58; 0,88]	0,0018*
Interaktion p-Wert									0,6389
Klinischer Lymphknotenstatus									
Positiv	329	127 [38,6]	51,6 [45,7; NE]	330	172 [52,1]	31,0 [22,1;39,8]	0,66	[0,52; 0,83]	0,0003*
Negativ	145	53 [36,6]	NE [NE; NE]	144	54 [37,5]	NE [NE; NE]	0,96	[0,66; 1,40]	0,8345
Interaktion p-Wert									0,0967
PD-L1-Status									
TAP >= 1%	426	160 [37,6]	51,6 [51,6; NE]	427	203 [47,5]	37,1 [28,3; NE]	0,72	[0,59; 0,89]	0,0022*
TAP < 1%	48	20 [41,7]	45,7 [18,4; NE]	47	23 [48,9]	32,6 [14,0; NE]	0,80	[0,44; 1,46]	0,4708
Interaktion p-Wert									0,7505
Alter bei Randomisierung (Jahre)									
<65	291	111 [38,1]	51,6 [44,1; NE]	265	124 [46,8]	42,1 [24,7; NE]	0,74	[0,57; 0,96]	0,0230*
>=65	183	69 [37,7]	NE [NE; NE]	209	102 [48,8]	37,1 [27,9; NE]	0,72	[0,53; 0,97]	0,0325*
Interaktion p-Wert									0,8683
Geschlecht									
Männlich	326	120 [36,8]	51,6 [51,6; NE]	356	175 [49,2]	35,7 [28,3; NE]	0,68	[0,54; 0,86]	0,0010*
Weiblich	148	60 [40,5]	NE [NE; NE]	118	51 [43,2]	NE [NE; NE]	0,87	[0,60; 1,27]	0,4792
Interaktion p-Wert									0,2610
Tumorlokalisation									
GC	324	124 [38,3]	51,6 [44,1; NE]	316	145 [45,9]	38,8 [30,6; NE]	0,79	[0,62; 1,001]	0,0513
GEJC	150	56 [37,3]	NE [NE; NE]	158	81 [51,3]	29,4 [17,3; NE]	0,63	[0,45; 0,88]	0,0075*
Interaktion p-Wert									0,2940

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 2.2.3 Summary of Event-free survival subcomponents frequencies
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EFS Ereignisse gesamt, n (%)	180 [38,0]	226 [47,7]
RECIST 1.1 (beurteilt durch BICR)	53 [11,2]	84 [17,7]
Krankheitsprogression in der neoadjuvanten Phase, die eine Operation ausschloss	5 [1,1]	2 [0,4]
Krankheitsprogression in der neoadjuvanten Phase, nachdem die Operation aus anderen als Gründen, als einer Progression nicht durchgeführt wurde	2 [0,4]	1 [0,2]
Wiederauftreten der Erkrankung in der adjuvanten Phase nach R0-Resektion	44 [9,3]	71 [15,0]
Krankheitsprogression in der adjuvanten Phase nach R1/R2-Resektion	2 [0,4]	10 [2,1]
Nicht-RECIST	55 [11,6]	61 [12,9]
Krankheitsprogression in der neoadjuvanten Phase, die eine Operation ausschloss	3 [0,6]	8 [1,7]
Krankheitsprogression entdeckt beim Versuch der Operation	18 [3,8]	28 [5,9]
Krankheitsprogression in der neoadjuvanten Phase, nachdem die Operation aus anderen als Gründen, als einer Progression nicht durchgeführt wurde	2 [0,4]	1 [0,2]
Krankheitsprogression/-rezidiv in der Operationsphase, bestätigt durch lokale pathologische Untersuchung	1 [0,2]	2 [0,4]
Krankheitsprogression/-rezidiv in der adjuvanten Phase, bestätigt durch lokale pathologische Untersuchung	31 [6,5]	22 [4,6]
Tod ohne Wiederauftreten der Erkrankung oder Progression	72 [15,2]	81 [17,1]
Tod ohne Progression bei unbehandelten Patienten	0	2 [0,4]
Tod ohne Progression während der neoadjuvanten Phase	22 [4,6]	19 [4,0]
Tod ohne Wiederauftreten der Erkrankung oder Progression während der Operationsphase	23 [4,9]	21 [4,4]
Tod ohne Wiederauftreten der Erkrankung oder Progression während der adjuvanten Phase	27 [5,7]	39 [8,2]
Zensierte Patienten, n (%)	294 [62,0]	248 [52,3]
Ereignisfrei zum Zeitpunkt der Analyse	281 [59,3]	229 [48,3]
Keine auswertbaren Krankheitsbeurteilungen bei neoadjuvantem Baseline oder post-neoadjuvantem Baseline	3 [0,6]	7 [1,5]
Keine adjuvante Baseline-Beurteilung nach der Operation	3 [0,6]	6 [1,3]
Zurückgezogene Einwilligung	7 [1,5]	6 [1,3]

[a] Events are defined as the earliest of RECIST 1.1 events, non-RECIST 1.1 events or deaths of any cause as defined in the SAP. Events are according to RECIST 1.1 per BICR assessment and/or local pathology testing.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

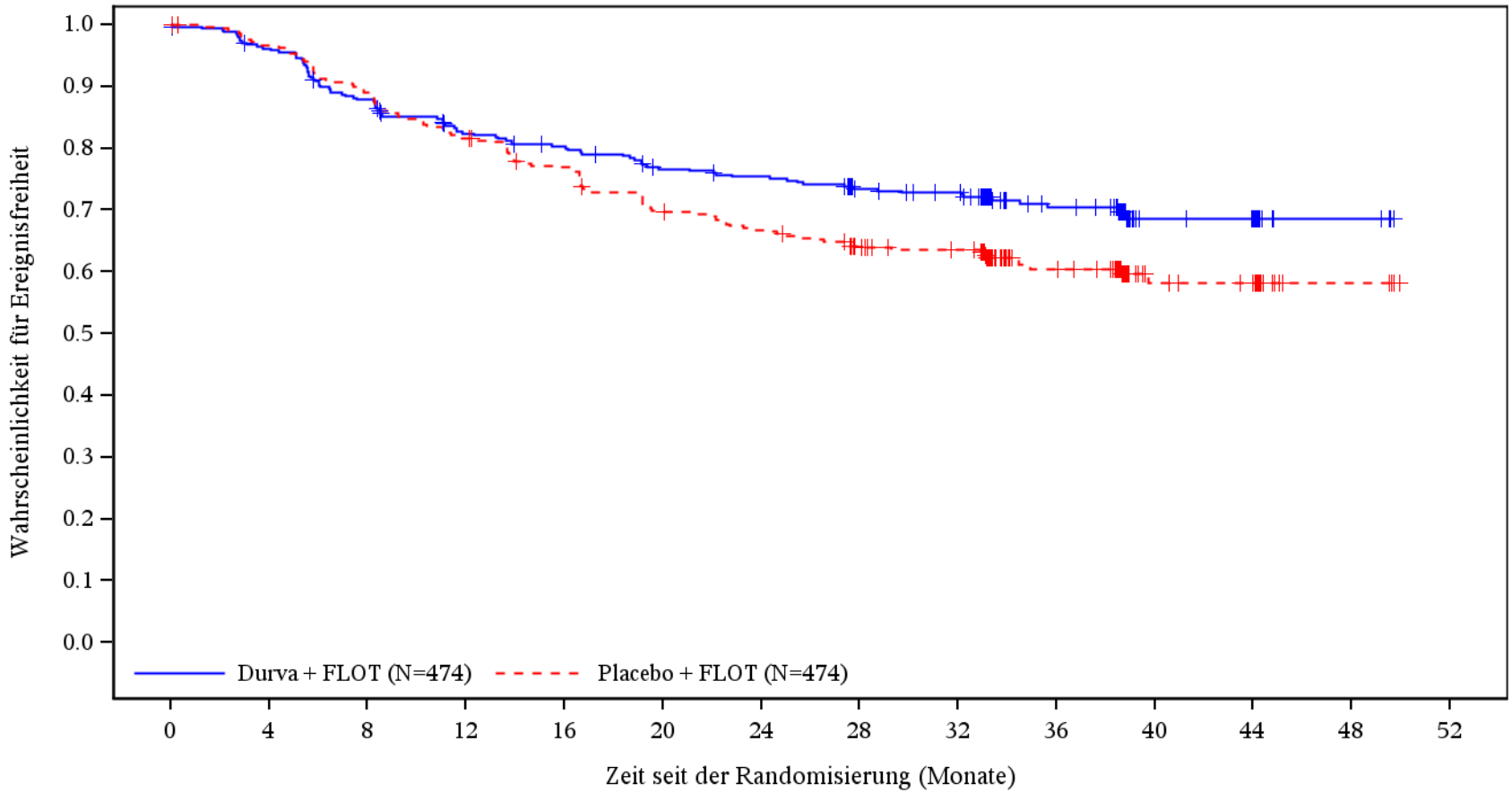
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Table 2.3.1.1 Summary of analysis of Disease-Free Survival (Morbidity)
Patients with R0 Resection

	Durva + FLOT (N=339)			Placebo + FLOT (N=323)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
krankheitsfreies Überleben	339	97 [28,6]	NE [NE; NE]	323	124 [38,4]	NE [NE; NE]	0,71	[0,54; 0,92]	0,0105*

[a] Median time to event based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic location, clinical lymph node status and PD-L1 status. Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 2.3.1.2 Kaplan-Meier plot of Disease-Free Survival (Morbidity)
Patients with R0 Resection



Anzahl im Risiko (Anzahl der zensierten Fälle)

339	324	295	272	263	248	243	213	207	119	45	35	5	0
(0)	(2)	(3)	(8)	(10)	(13)	(14)	(38)	(42)	(125)	(197)	(207)	(237)	(242)
323	310	286	262	244	221	210	183	176	100	38	33	5	0
(0)	(2)	(2)	(2)	(5)	(6)	(7)	(25)	(31)	(101)	(161)	(166)	(194)	(199)

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

Table 2.3.2.1 Summary of subgroup analysis of Disease-Free Survival (Morbidity)
Patients with R0 Resection

	Durva + FLOT (N=339)			Placebo + FLOT (N=323)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	68	11 [16,2]	NE [NE; NE]	74	28 [37,8]	NE [NE; NE]	0,39	[0,19; 0,77]	0,0059*
Nicht-Asien	271	86 [31,7]	NE [NE; NE]	249	96 [38,6]	NE [NE; NE]	0,81	[0,61; 1,09]	0,1628
Interaktion p-Wert									0,0529
Klinischer Lymphknotenstatus									
Positiv	241	72 [29,9]	NE [NE; NE]	222	94 [42,3]	NE [NE; NE]	0,67	[0,49; 0,91]	0,0098*
Negativ	98	25 [25,5]	NE [NE; NE]	101	30 [29,7]	NE [NE; NE]	0,89	[0,52; 1,51]	0,6553
Interaktion p-Wert									0,3697
PD-L1-Status									
TAP >= 1%	305	86 [28,2]	NE [NE; NE]	291	112 [38,5]	NE [NE; NE]	0,71	[0,53; 0,94]	0,0161*
TAP < 1%	34	11 [32,4]	NE [NE; NE]	32	12 [37,5]	NE [NE; NE]	0,89	[0,38; 2,02]	0,7718
Interaktion p-Wert									0,6153
Alter bei Randomisierung (Jahre)									
<65	215	67 [31,2]	NE [NE; NE]	186	72 [38,7]	NE [NE; NE]	0,78	[0,56; 1,09]	0,1501
>=65	124	30 [24,2]	NE [NE; NE]	137	52 [38,0]	NE [NE; NE]	0,62	[0,39; 0,96]	0,0324*
Interaktion p-Wert									0,4021
Geschlecht									
Männlich	237	66 [27,8]	NE [NE; NE]	249	99 [39,8]	NE [NE; NE]	0,67	[0,49; 0,91]	0,0110*
Weiblich	102	31 [30,4]	NE [NE; NE]	74	25 [33,8]	NE [NE; NE]	0,92	[0,54; 1,56]	0,7445
Interaktion p-Wert									0,3159
Tumorlokalisation									
GC	229	67 [29,3]	NE [NE; NE]	219	82 [37,4]	NE [NE; NE]	0,78	[0,56; 1,07]	0,1273
GEJC	110	30 [27,3]	NE [NE; NE]	104	42 [40,4]	NE [NE; NE]	0,63	[0,39; 0,998]	0,0492*
Interaktion p-Wert									0,4562

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 2.3.3 Summary of analysis (odds ratio, relative risk and risk differences) of Disease-Free Survival (Morbidity)
R0 Resected Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=339)		Placebo + FLOT (N=323)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
krankheitsfreies Überleben [a][d][h]	339	97[28,6]	323	124[38,4]	0,63[0,45; 0,87]	0,0049 *	0,74[0,59; 0,92]	0,0055 *	-0,10[-0,18; -0,03]	0,0040 *

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test.
All models include treatment, geographic location, clinical lymph node status and PD-L1 status.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 2.3.4 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of Disease-Free Survival (Morbidity)
R0 Resected Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=339)		Placebo + FLOT (N=323)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	68	11[16,2]	74	28[37,8]	0,32[0,14; 0,69]	0,0034 *	0,43[0,22; 0,76]	0,0034 *	-0,22[-0,36; -0,07]	0,0034 *
Nicht-Asien [a][d][g]	271	86[31,7]	249	96[38,6]	0,74[0,52; 1,06]	0,1034	0,82[0,65; 1,04]	0,1034	-0,07[-0,15; 0,01]	0,1034
Int. p-Wert [a][d][g]						0,0525		0,0402 *		0,0774
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	241	72[29,9]	222	94[42,3]	0,58[0,39; 0,85]	0,0052 *	0,71[0,55; 0,90]	0,0052 *	-0,12[-0,21; -0,04]	0,0052 *
Negativ [a][d][g]	98	25[25,5]	101	30[29,7]	0,81[0,43; 1,51]	0,5082	0,86[0,54; 1,35]	0,5082	-0,04[-0,17; 0,08]	0,5082
Int. p-Wert [a][d][g]						0,3711		0,4562		0,2842
PD-L1-Status										
TAP >= 1% [a][d][g]	305	86[28,2]	291	112[38,5]	0,63[0,44; 0,88]	0,0076 *	0,73[0,58; 0,92]	0,0076 *	-0,10[-0,18; -0,03]	0,0076 *
TAP < 1% [a][d][g]	34	11[32,4]	32	12[37,5]	0,80[0,29; 2,20]	0,6610	0,86[0,43; 1,69]	0,6610	-0,05[-0,28; 0,18]	0,6610
Int. p-Wert [a][d][g]						0,6620		0,6481		0,6766

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 2.3.4 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of Disease-Free Survival (Morbidity)
R0 Resected Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=339)		Placebo + FLOT (N=323)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	215	67[31,2]	186	72[38,7]	0,72[0,47; 1,08]	0,1135	0,81[0,61; 1,05]	0,1135	-0,08[-0,17; 0,02]	0,1135
>=65 [a][d][g]	124	30[24,2]	137	52[38,0]	0,52[0,30; 0,89]	0,0162 *	0,64[0,43; 0,92]	0,0162 *	-0,14[-0,25; -0,03]	0,0162 *
Int. p-Wert [a][d][g]						0,3565		0,3201		0,4016
Geschlecht										
Männlich [a][d][g]	237	66[27,8]	249	99[39,8]	0,58[0,40; 0,85]	0,0055 *	0,70[0,54; 0,90]	0,0055 *	-0,12[-0,20; -0,04]	0,0055 *
Weiblich [a][d][g]	102	31[30,4]	74	25[33,8]	0,86[0,45; 1,63]	0,6339	0,90[0,58; 1,40]	0,6339	-0,03[-0,17; 0,10]	0,6339
Int. p-Wert [a][d][g]						0,3161		0,3279		0,3068
Tumorlokalisation										
GC [a][d][g]	229	67[29,3]	219	82[37,4]	0,69[0,46; 1,02]	0,0659	0,78[0,60; 1,02]	0,0659	-0,08[-0,17; 0,01]	0,0659
GEJC [a][d][g]	110	30[27,3]	104	42[40,4]	0,55[0,31; 0,98]	0,0422 *	0,68[0,45; 0,99]	0,0422 *	-0,13[-0,26; -0,00]	0,0422 *
Int. p-Wert [a][d][g]						0,5323		0,5386		0,5283

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.1 Summary of compliance by visit for EORTC QLQ-C30 (Morbidity, hrQoL)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Baseline	Durva + FLOT	474	425	425	89,7	100
	Placebo + FLOT	470	433	433	92,1	100
Zyklus 2, Tag 29	Durva + FLOT	474	429	429	90,5	100
	Placebo + FLOT	470	410	410	87,2	100
Zyklus 3, Tag 1	Durva + FLOT	363	293	293	80,7	100
	Placebo + FLOT	352	277	277	78,7	100
Zyklus 4, Tag 29	Durva + FLOT	349	290	290	83,1	100
	Placebo + FLOT	340	278	278	81,8	100
Zyklus 5	Durva + FLOT	342	262	262	76,6	100
	Placebo + FLOT	332	260	260	78,3	100
Zyklus 6	Durva + FLOT	337	288	288	85,5	100
	Placebo + FLOT	322	276	276	85,7	100
Zyklus 7	Durva + FLOT	323	283	283	87,6	100
	Placebo + FLOT	312	266	266	85,3	100
Zyklus 8	Durva + FLOT	316	285	285	90,2	100
	Placebo + FLOT	308	268	268	87,0	100
Zyklus 9	Durva + FLOT	300	268	268	89,3	100
	Placebo + FLOT	297	260	260	87,5	100
Zyklus 10	Durva + FLOT	286	258	258	90,2	100
	Placebo + FLOT	286	257	257	89,9	100
Zyklus 11	Durva + FLOT	280	258	258	92,1	100
	Placebo + FLOT	279	240	240	86,0	100
Zyklus 12	Durva + FLOT	274	250	250	91,2	100
	Placebo + FLOT	270	233	233	86,3	100
Zyklus 13	Durva + FLOT	267	236	236	88,4	100
	Placebo + FLOT	261	222	222	85,1	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.1 Summary of compliance by visit for EORTC QLQ-C30 (Morbidity, hrQoL)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Zyklus 14	Durva + FLOT	263	251	251	95,4	100
	Placebo + FLOT	254	232	232	91,3	100
Tag 30 Follow-up	Durva + FLOT	454	248	248	54,6	100
	Placebo + FLOT	448	231	231	51,6	100
Monat 2 Follow-up	Durva + FLOT	434	238	238	54,8	100
	Placebo + FLOT	433	239	239	55,2	100
Monat 3 Follow-up	Durva + FLOT	410	252	252	61,5	100
	Placebo + FLOT	408	257	257	63,0	100
Monat 6 Follow-up	Durva + FLOT	388	208	208	53,6	100
	Placebo + FLOT	369	186	186	50,4	100
Monat 9 Follow-up	Durva + FLOT	371	198	198	53,4	100
	Placebo + FLOT	347	164	164	47,3	100
Monat 12 Follow-up	Durva + FLOT	354	163	163	46,0	100
	Placebo + FLOT	328	120	120	36,6	100
Monat 15 Follow-up	Durva + FLOT	342	85	85	24,9	100
	Placebo + FLOT	312	54	54	17,3	100
Monat 18 Follow-up	Durva + FLOT	333	116	116	34,8	100
	Placebo + FLOT	295	99	99	33,6	100
Monat 21 Follow-up	Durva + FLOT	304	77	77	25,3	100
	Placebo + FLOT	265	50	50	18,9	100
Monat 24 Follow-up	Durva + FLOT	233	76	76	32,6	100
	Placebo + FLOT	201	65	65	32,3	100
Monat 30 Follow-up	Durva + FLOT	161	86	86	53,4	100
	Placebo + FLOT	120	57	57	47,5	100
Monat 36 Follow-up	Durva + FLOT	62	37	37	59,7	100
	Placebo + FLOT	52	21	21	40,4	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.1 Summary of compliance by visit for EORTC QLQ-C30 (Morbidity, hrQoL)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Monat 42 Follow-up	Durva + FLOT	12	6	6	50,0	100
	Placebo + FLOT	15	8	8	53,3	100
Monat 48 Follow-up	Durva + FLOT	8	1	1	12,5	100
	Placebo + FLOT	8				
Gesamt	Durva + FLOT	474	459	459	96,8	100
	Placebo + FLOT	470	455	455	96,8	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.2 Summary of compliance by visit for EORTC QLQ-STO22 + IL38 (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Baseline	Durva + FLOT	474	423	423	89,2	100
	Placebo + FLOT	470	430	430	91,5	100
Zyklus 2, Tag 29	Durva + FLOT	474	419	419	88,4	100
	Placebo + FLOT	470	406	406	86,4	100
Zyklus 3, Tag 1	Durva + FLOT	363	285	285	78,5	100
	Placebo + FLOT	352	272	272	77,3	100
Zyklus 4, Tag 29	Durva + FLOT	349	285	285	81,7	100
	Placebo + FLOT	340	276	276	81,2	100
Zyklus 5	Durva + FLOT	342	257	257	75,1	100
	Placebo + FLOT	332	259	259	78,0	100
Zyklus 6	Durva + FLOT	336	283	283	84,2	100
	Placebo + FLOT	322	273	273	84,8	100
Zyklus 7	Durva + FLOT	323	279	279	86,4	100
	Placebo + FLOT	312	266	266	85,3	100
Zyklus 8	Durva + FLOT	316	283	283	89,6	100
	Placebo + FLOT	308	268	268	87,0	100
Zyklus 9	Durva + FLOT	299	267	267	89,3	100
	Placebo + FLOT	297	259	259	87,2	100
Zyklus 10	Durva + FLOT	286	258	258	90,2	100
	Placebo + FLOT	286	257	257	89,9	100
Zyklus 11	Durva + FLOT	280	256	256	91,4	100
	Placebo + FLOT	279	240	240	86,0	100
Zyklus 12	Durva + FLOT	274	250	250	91,2	100
	Placebo + FLOT	270	232	232	85,9	100
Zyklus 13	Durva + FLOT	266	232	232	87,2	100
	Placebo + FLOT	261	220	220	84,3	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.2 Summary of compliance by visit for EORTC QLQ-STO22 + IL38 (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Zyklus 14	Durva + FLOT	263	251	251	95,4	100
	Placebo + FLOT	254	232	232	91,3	100
Tag 30 Follow-up	Durva + FLOT	454	245	245	54,0	100
	Placebo + FLOT	448	231	231	51,6	100
Monat 2 Follow-up	Durva + FLOT	434	237	237	54,6	100
	Placebo + FLOT	433	237	237	54,7	100
Monat 3 Follow-up	Durva + FLOT	410	252	252	61,5	100
	Placebo + FLOT	408	254	254	62,3	100
Monat 6 Follow-up	Durva + FLOT	388	206	206	53,1	100
	Placebo + FLOT	369	185	185	50,1	100
Monat 9 Follow-up	Durva + FLOT	371	198	198	53,4	100
	Placebo + FLOT	347	162	162	46,7	100
Monat 12 Follow-up	Durva + FLOT	354	161	161	45,5	100
	Placebo + FLOT	328	117	117	35,7	100
Monat 15 Follow-up	Durva + FLOT	342	83	83	24,3	100
	Placebo + FLOT	312	54	54	17,3	100
Monat 18 Follow-up	Durva + FLOT	333	116	116	34,8	100
	Placebo + FLOT	295	98	98	33,2	100
Monat 21 Follow-up	Durva + FLOT	304	76	76	25,0	100
	Placebo + FLOT	265	50	50	18,9	100
Monat 24 Follow-up	Durva + FLOT	233	76	76	32,6	100
	Placebo + FLOT	201	65	65	32,3	100
Monat 30 Follow-up	Durva + FLOT	161	86	86	53,4	100
	Placebo + FLOT	119	55	55	46,2	100
Monat 36 Follow-up	Durva + FLOT	60	34	34	56,7	100
	Placebo + FLOT	52	21	21	40,4	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.2 Summary of compliance by visit for EORTC QLQ-STO22 + IL38 (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Monat 42 Follow-up	Durva + FLOT	12	6	6	50,0	100
	Placebo + FLOT	14	7	7	50,0	100
Monat 48 Follow-up	Durva + FLOT	8	1	1	12,5	100
	Placebo + FLOT	8				
Gesamt	Durva + FLOT	474	459	459	96,8	100
	Placebo + FLOT	470	455	455	96,8	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.3 Summary of compliance by visit for EQ-5D-5L Visual Analogue Scale (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Baseline	Durva + FLOT	474	423	423	89,2	100
	Placebo + FLOT	470	429	429	91,3	100
Zyklus 2, Tag 29	Durva + FLOT	474	416	416	87,8	100
	Placebo + FLOT	470	405	405	86,2	100
Zyklus 3, Tag 1	Durva + FLOT	363	282	282	77,7	100
	Placebo + FLOT	352	270	270	76,7	100
Zyklus 4, Tag 29	Durva + FLOT	349	285	285	81,7	100
	Placebo + FLOT	340	275	275	80,9	100
Zyklus 5	Durva + FLOT	342	255	255	74,6	100
	Placebo + FLOT	332	259	259	78,0	100
Zyklus 6	Durva + FLOT	336	282	282	83,9	100
	Placebo + FLOT	322	271	271	84,2	100
Zyklus 7	Durva + FLOT	323	278	278	86,1	100
	Placebo + FLOT	312	266	266	85,3	100
Zyklus 8	Durva + FLOT	316	283	283	89,6	100
	Placebo + FLOT	308	267	267	86,7	100
Zyklus 9	Durva + FLOT	299	266	266	89,0	100
	Placebo + FLOT	297	258	258	86,9	100
Zyklus 10	Durva + FLOT	286	257	257	89,9	100
	Placebo + FLOT	286	256	256	89,5	100
Zyklus 11	Durva + FLOT	280	256	256	91,4	100
	Placebo + FLOT	279	240	240	86,0	100
Zyklus 12	Durva + FLOT	274	250	250	91,2	100
	Placebo + FLOT	270	232	232	85,9	100
Zyklus 13	Durva + FLOT	266	232	232	87,2	100
	Placebo + FLOT	261	219	219	83,9	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.3 Summary of compliance by visit for EQ-5D-5L Visual Analogue Scale (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Zyklus 14	Durva + FLOT	263	249	249	94,7	100
	Placebo + FLOT	254	232	232	91,3	100
Tag 30 Follow-up	Durva + FLOT	454	245	245	54,0	100
	Placebo + FLOT	448	230	230	51,3	100
Monat 2 Follow-up	Durva + FLOT	434	237	237	54,6	100
	Placebo + FLOT	433	237	237	54,7	100
Monat 3 Follow-up	Durva + FLOT	410	252	252	61,5	100
	Placebo + FLOT	408	253	253	62,0	100
Monat 6 Follow-up	Durva + FLOT	388	206	206	53,1	100
	Placebo + FLOT	369	185	185	50,1	100
Monat 9 Follow-up	Durva + FLOT	371	195	195	52,6	100
	Placebo + FLOT	347	161	161	46,4	100
Monat 12 Follow-up	Durva + FLOT	354	161	161	45,5	100
	Placebo + FLOT	328	117	117	35,7	100
Monat 15 Follow-up	Durva + FLOT	342	82	82	24,0	100
	Placebo + FLOT	312	54	54	17,3	100
Monat 18 Follow-up	Durva + FLOT	333	116	116	34,8	100
	Placebo + FLOT	295	97	97	32,9	100
Monat 21 Follow-up	Durva + FLOT	304	76	76	25,0	100
	Placebo + FLOT	265	50	50	18,9	100
Monat 24 Follow-up	Durva + FLOT	233	76	76	32,6	100
	Placebo + FLOT	201	65	65	32,3	100
Monat 30 Follow-up	Durva + FLOT	161	86	86	53,4	100
	Placebo + FLOT	119	55	55	46,2	100
Monat 36 Follow-up	Durva + FLOT	60	34	34	56,7	100
	Placebo + FLOT	52	21	21	40,4	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.3 Summary of compliance by visit for EQ-5D-5L Visual Analogue Scale (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Monat 42 Follow-up	Durva + FLOT	12	6	6	50,0	100
	Placebo + FLOT	14	7	7	50,0	100
Monat 48 Follow-up	Durva + FLOT	8	1	1	12,5	100
	Placebo + FLOT	8				
Gesamt	Durva + FLOT	474	458	458	96,6	100
	Placebo + FLOT	470	455	455	96,8	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.4 Summary of compliance by visit for Patient Global Impressions of Severity (PGIS) (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Baseline	Durva + FLOT	474	421	421	88,8	100
	Placebo + FLOT	470	427	427	90,9	100
Zyklus 2, Tag 29	Durva + FLOT	474	412	412	86,9	100
	Placebo + FLOT	470	404	404	86,0	100
Zyklus 3, Tag 1	Durva + FLOT	363	281	281	77,4	100
	Placebo + FLOT	352	268	268	76,1	100
Zyklus 4, Tag 29	Durva + FLOT	349	282	282	80,8	100
	Placebo + FLOT	340	273	273	80,3	100
Zyklus 5	Durva + FLOT	342	250	250	73,1	100
	Placebo + FLOT	332	258	258	77,7	100
Zyklus 6	Durva + FLOT	336	279	279	83,0	100
	Placebo + FLOT	322	269	269	83,5	100
Zyklus 7	Durva + FLOT	323	275	275	85,1	100
	Placebo + FLOT	312	266	266	85,3	100
Zyklus 8	Durva + FLOT	315	280	280	88,9	100
	Placebo + FLOT	308	263	263	85,4	100
Zyklus 9	Durva + FLOT	299	264	264	88,3	100
	Placebo + FLOT	297	258	258	86,9	100
Zyklus 10	Durva + FLOT	286	257	257	89,9	100
	Placebo + FLOT	286	255	255	89,2	100
Zyklus 11	Durva + FLOT	280	256	256	91,4	100
	Placebo + FLOT	279	240	240	86,0	100
Zyklus 12	Durva + FLOT	274	248	248	90,5	100
	Placebo + FLOT	270	231	231	85,6	100
Zyklus 13	Durva + FLOT	266	231	231	86,8	100
	Placebo + FLOT	261	219	219	83,9	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.4 Summary of compliance by visit for Patient Global Impressions of Severity (PGIS) (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Zyklus 14	Durva + FLOT	263	249	249	94,7	100
	Placebo + FLOT	254	232	232	91,3	100
Tag 30 Follow-up	Durva + FLOT	454	243	243	53,5	100
	Placebo + FLOT	448	230	230	51,3	100
Monat 2 Follow-up	Durva + FLOT	434	237	237	54,6	100
	Placebo + FLOT	433	233	233	53,8	100
Monat 3 Follow-up	Durva + FLOT	410	250	250	61,0	100
	Placebo + FLOT	408	252	252	61,8	100
Monat 6 Follow-up	Durva + FLOT	388	205	205	52,8	100
	Placebo + FLOT	369	182	182	49,3	100
Monat 9 Follow-up	Durva + FLOT	371	193	193	52,0	100
	Placebo + FLOT	347	160	160	46,1	100
Monat 12 Follow-up	Durva + FLOT	354	161	161	45,5	100
	Placebo + FLOT	328	117	117	35,7	100
Monat 15 Follow-up	Durva + FLOT	342	81	81	23,7	100
	Placebo + FLOT	312	54	54	17,3	100
Monat 18 Follow-up	Durva + FLOT	333	116	116	34,8	100
	Placebo + FLOT	295	97	97	32,9	100
Monat 21 Follow-up	Durva + FLOT	304	76	76	25,0	100
	Placebo + FLOT	265	50	50	18,9	100
Monat 24 Follow-up	Durva + FLOT	232	75	75	32,3	100
	Placebo + FLOT	201	65	65	32,3	100
Monat 30 Follow-up	Durva + FLOT	161	86	86	53,4	100
	Placebo + FLOT	119	55	55	46,2	100
Monat 36 Follow-up	Durva + FLOT	60	34	34	56,7	100
	Placebo + FLOT	52	21	21	40,4	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.4 Summary of compliance by visit for Patient Global Impressions of Severity (PGIS) (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Monat 42 Follow-up	Durva + FLOT	12	6	6	50,0	100
	Placebo + FLOT	14	7	7	50,0	100
Monat 48 Follow-up	Durva + FLOT	8	1	1	12,5	100
	Placebo + FLOT	8				
Gesamt	Durva + FLOT	474	458	458	96,6	100
	Placebo + FLOT	470	455	455	96,8	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/comppr.sas gcomppraad 28JAN2026:09:27 khsk849

Table 3.1.5 Summary of compliance by visit for Patient Global Impression of Change (PGIC) (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Baseline	Durva + FLOT		1	1		100
Zyklus 2, Tag 29	Durva + FLOT	474	408	408	86,1	100
	Placebo + FLOT	470	400	400	85,1	100
Zyklus 3, Tag 1	Durva + FLOT	363	280	280	77,1	100
	Placebo + FLOT	352	269	269	76,4	100
Zyklus 4, Tag 29	Durva + FLOT	349	281	281	80,5	100
	Placebo + FLOT	340	273	273	80,3	100
Zyklus 5	Durva + FLOT	342	252	252	73,7	100
	Placebo + FLOT	332	259	259	78,0	100
Zyklus 6	Durva + FLOT	336	279	279	83,0	100
	Placebo + FLOT	322	269	269	83,5	100
Zyklus 7	Durva + FLOT	323	276	276	85,4	100
	Placebo + FLOT	312	266	266	85,3	100
Zyklus 8	Durva + FLOT	315	282	282	89,5	100
	Placebo + FLOT	308	263	263	85,4	100
Zyklus 9	Durva + FLOT	299	265	265	88,6	100
	Placebo + FLOT	297	258	258	86,9	100
Zyklus 10	Durva + FLOT	286	257	257	89,9	100
	Placebo + FLOT	286	255	255	89,2	100
Zyklus 11	Durva + FLOT	280	256	256	91,4	100
	Placebo + FLOT	279	240	240	86,0	100
Zyklus 12	Durva + FLOT	274	248	248	90,5	100
	Placebo + FLOT	270	232	232	85,9	100
Zyklus 13	Durva + FLOT	266	232	232	87,2	100
	Placebo + FLOT	261	219	219	83,9	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.5 Summary of compliance by visit for Patient Global Impression of Change (PGIC) (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Zyklus 14	Durva + FLOT	263	249	249	94,7	100
	Placebo + FLOT	254	232	232	91,3	100
Tag 30 Follow-up	Durva + FLOT	454	243	243	53,5	100
	Placebo + FLOT	448	230	230	51,3	100
Monat 2 Follow-up	Durva + FLOT	434	237	237	54,6	100
	Placebo + FLOT	433	234	234	54,0	100
Monat 3 Follow-up	Durva + FLOT	410	252	252	61,5	100
	Placebo + FLOT	408	252	252	61,8	100
Monat 6 Follow-up	Durva + FLOT	388	205	205	52,8	100
	Placebo + FLOT	369	185	185	50,1	100
Monat 9 Follow-up	Durva + FLOT	371	195	195	52,6	100
	Placebo + FLOT	347	160	160	46,1	100
Monat 12 Follow-up	Durva + FLOT	354	161	161	45,5	100
	Placebo + FLOT	328	117	117	35,7	100
Monat 15 Follow-up	Durva + FLOT	342	82	82	24,0	100
	Placebo + FLOT	312	54	54	17,3	100
Monat 18 Follow-up	Durva + FLOT	333	116	116	34,8	100
	Placebo + FLOT	295	97	97	32,9	100
Monat 21 Follow-up	Durva + FLOT	304	76	76	25,0	100
	Placebo + FLOT	265	50	50	18,9	100
Monat 24 Follow-up	Durva + FLOT	232	75	75	32,3	100
	Placebo + FLOT	201	65	65	32,3	100
Monat 30 Follow-up	Durva + FLOT	161	86	86	53,4	100
	Placebo + FLOT	119	55	55	46,2	100
Monat 36 Follow-up	Durva + FLOT	60	34	34	56,7	100
	Placebo + FLOT	52	21	21	40,4	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.5 Summary of compliance by visit for Patient Global Impression of Change (PGIC) (Morbidity)
Full Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Monat 42 Follow-up	Durva + FLOT	12	6	6	50,0	100
	Placebo + FLOT	14	7	7	50,0	100
Monat 48 Follow-up	Durva + FLOT	8	1	1	12,5	100
	Placebo + FLOT	8				
Gesamt	Durva + FLOT	474	439	439	92,6	100
	Placebo + FLOT	470	430	430	91,5	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.6 Summary of compliance by visit for Patient Global Impression of Treatment Tolerability (PGITT) (Safety)
Safety Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Baseline	Durva + FLOT	475	422	422	88,8	100
	Placebo + FLOT	469	426	426	90,8	100
Zyklus 2, Tag 29	Durva + FLOT	475	413	413	86,9	100
	Placebo + FLOT	469	403	403	85,9	100
Zyklus 3, Tag 1	Durva + FLOT	364	280	280	76,9	100
	Placebo + FLOT	351	267	267	76,1	100
Zyklus 4, Tag 29	Durva + FLOT	350	283	283	80,9	100
	Placebo + FLOT	339	269	269	79,4	100
Zyklus 5	Durva + FLOT	343	251	251	73,2	100
	Placebo + FLOT	331	256	256	77,3	100
Zyklus 6	Durva + FLOT	337	280	280	83,1	100
	Placebo + FLOT	321	268	268	83,5	100
Zyklus 7	Durva + FLOT	324	276	276	85,2	100
	Placebo + FLOT	311	265	265	85,2	100
Zyklus 8	Durva + FLOT	316	280	280	88,6	100
	Placebo + FLOT	307	262	262	85,3	100
Zyklus 9	Durva + FLOT	300	265	265	88,3	100
	Placebo + FLOT	296	257	257	86,8	100
Zyklus 10	Durva + FLOT	287	257	257	89,5	100
	Placebo + FLOT	285	254	254	89,1	100
Zyklus 11	Durva + FLOT	281	255	255	90,7	100
	Placebo + FLOT	278	237	237	85,3	100
Zyklus 12	Durva + FLOT	275	248	248	90,2	100
	Placebo + FLOT	269	229	229	85,1	100
Zyklus 13	Durva + FLOT	267	231	231	86,5	100
	Placebo + FLOT	260	218	218	83,8	100

[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.1.6 Summary of compliance by visit for Patient Global Impression of Treatment Tolerability (PGITT) (Safety)
Safety Analysis Set, DCO 01SEP2025

Zeitpunkt	Behandlung	Erwartet [a]	Erhalten [b]	Auswertbar [c]	Compliance-Rate (%) [d]	Auswertbarkeitsrate (%) [e]
Zyklus 14	Durva + FLOT	264	250	250	94,7	100
	Placebo + FLOT	253	231	231	91,3	100
Gesamt	Durva + FLOT	475	459	459	96,6	100
	Placebo + FLOT	469	454	454	96,8	100

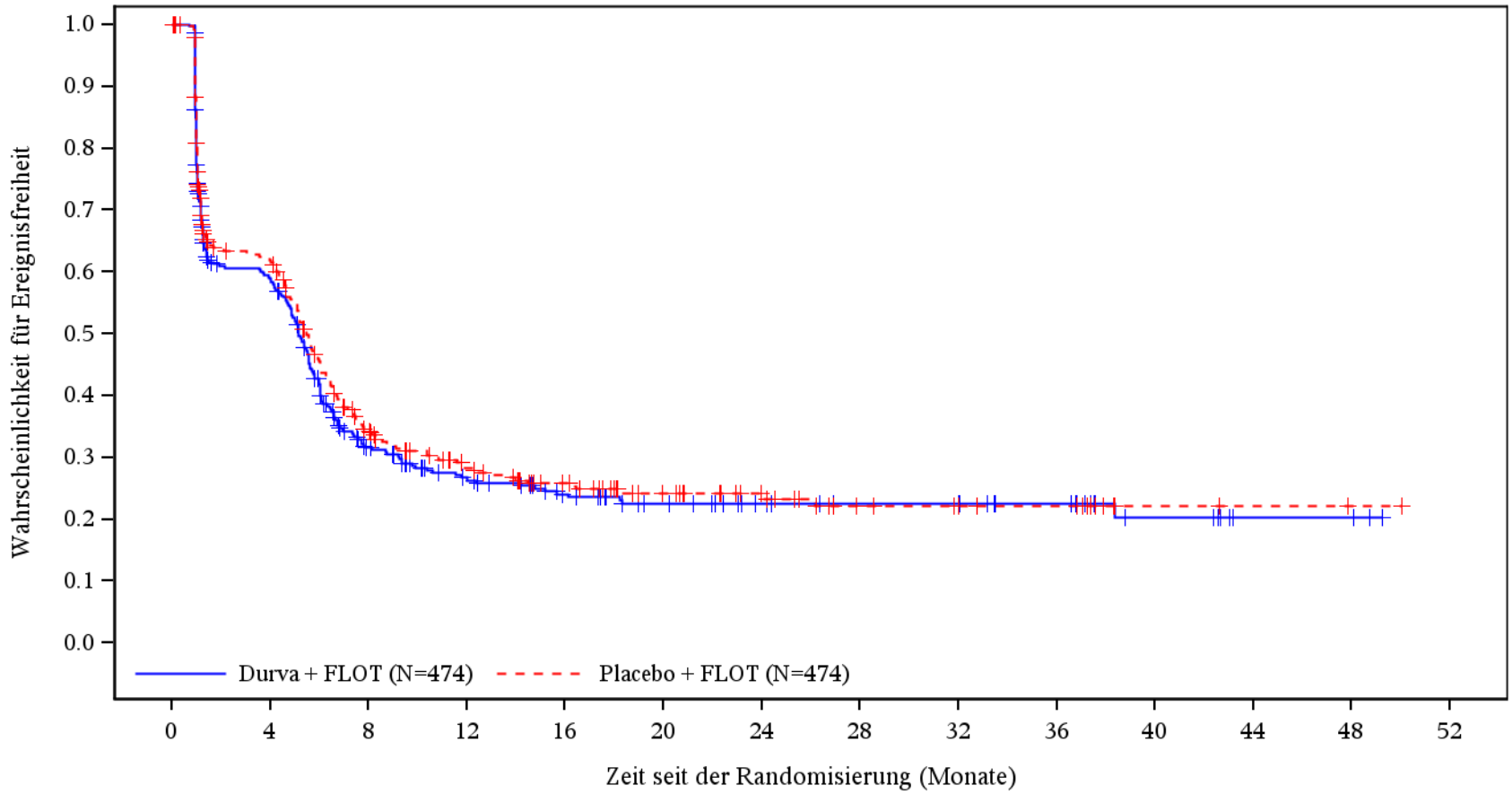
[a] Expected forms = number of subjects still under QoL follow-up (still on treatment) at given timepoint.
[b] Received forms = number of subjects who completed the form at a given timepoint.
[c] Evaluable forms = forms where at least one subscale can be determined.
[d] Compliance Rate = Evaluable/Expected * 100.
[e] Evaluability Rate = Evaluable/Received * 100.
NC = Not Calculable. Timepoints are reported by visit for each treatment arm.
In the overall row, patients are counted as Received/Evaluable if they have a Received/Evaluable baseline and at least one Received/Evaluable post-baseline form.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.1 Summary of analysis of time to deterioration in EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
EORTC QLQ-C30 Appetitverlust	474	269 [56,8]	5,2 [4,7; 5,6]	474	256 [54,0]	5,5 [4,9; 6,0]	1,08	[0,91; 1,28]	0,4067
EORTC QLQ-C30 Verstopfung	474	164 [34,6]	24,4 [14,6;37,2]	474	169 [35,7]	16,8 [11,0;28,0]	0,89	[0,71; 1,10]	0,2801
EORTC QLQ-C30 Diarrhö	474	314 [66,2]	1,6 [1,3; 4,5]	474	293 [61,8]	4,6 [4,1; 5,1]	1,20	[1,03; 1,41]	0,0277*
EORTC QLQ-C30 Dyspnoe	474	206 [43,5]	8,7 [7,3;14,5]	474	210 [44,3]	7,7 [6,9; 9,3]	0,90	[0,74; 1,10]	0,3072
EORTC QLQ-C30 Fatigue	474	335 [70,7]	1,4 [1,2; 4,0]	474	322 [67,9]	1,4 [1,2; 4,2]	1,10	[0,94; 1,29]	0,2483
EORTC QLQ-C30 Finanzielle Schwierigkeiten	474	175 [36,9]	14,8 [9,6;23,2]	474	188 [39,7]	9,5 [8,0;18,7]	0,94	[0,77; 1,16]	0,5732
EORTC QLQ-C30 Übelkeit und Erbrechen	474	285 [60,1]	4,9 [4,2; 5,3]	474	282 [59,5]	4,7 [4,1; 5,2]	1,00	[0,84; 1,18]	0,9572
EORTC QLQ-C30 Schmerzen	474	247 [52,1]	6,2 [5,6; 8,0]	474	255 [53,8]	5,8 [5,3; 7,1]	0,90	[0,75; 1,07]	0,2294
EORTC QLQ-C30 Schlaflosigkeit	474	228 [48,1]	7,1 [6,4; 8,9]	474	204 [43,0]	8,8 [7,4;11,8]	1,13	[0,93; 1,36]	0,2130

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 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 based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic region, clinical lymph node status and PD-L1 status
Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.2.2 Kaplan-Meier plot of EORTC QLQ-C30 Appetite Loss (Morbidity)
Full Analysis Set, DCO 01SEP2025



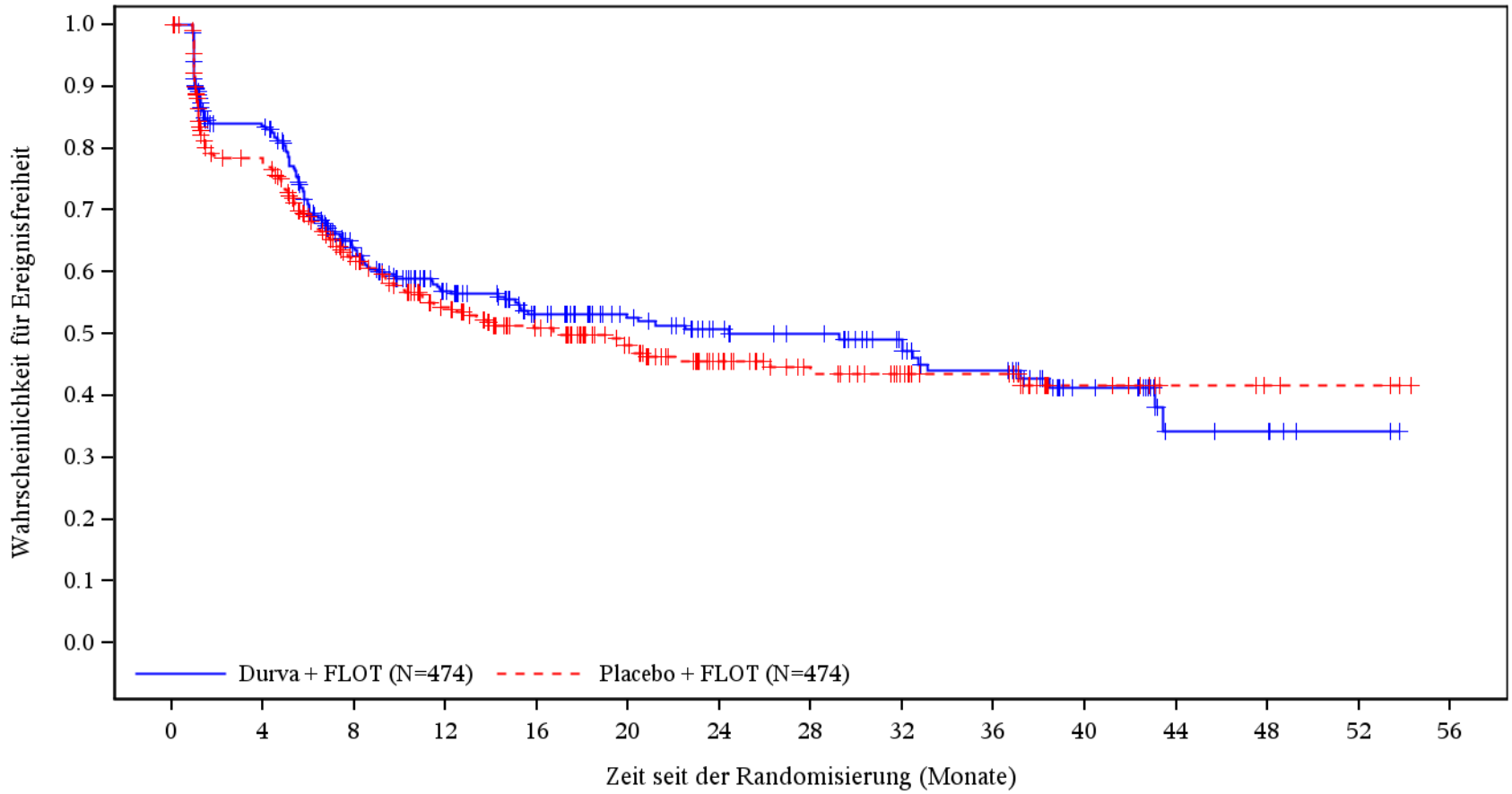
Anzahl im Risiko (Anzahl der zensierten Fälle)

474	199	92	66	48	37	27	22	22	17	8	3	3	0
(0)	(118)	(136)	(149)	(161)	(169)	(179)	(184)	(184)	(189)	(197)	(202)	(202)	(205)
474	200	99	70	53	36	26	16	14	12	3	2	1	0
(0)	(130)	(146)	(159)	(170)	(184)	(194)	(202)	(204)	(206)	(215)	(216)	(217)	(218)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.2.3 Kaplan-Meier plot of EORTC QLQ-C30 Constipation (Morbidity)
Full Analysis Set, DCO 01SEP2025



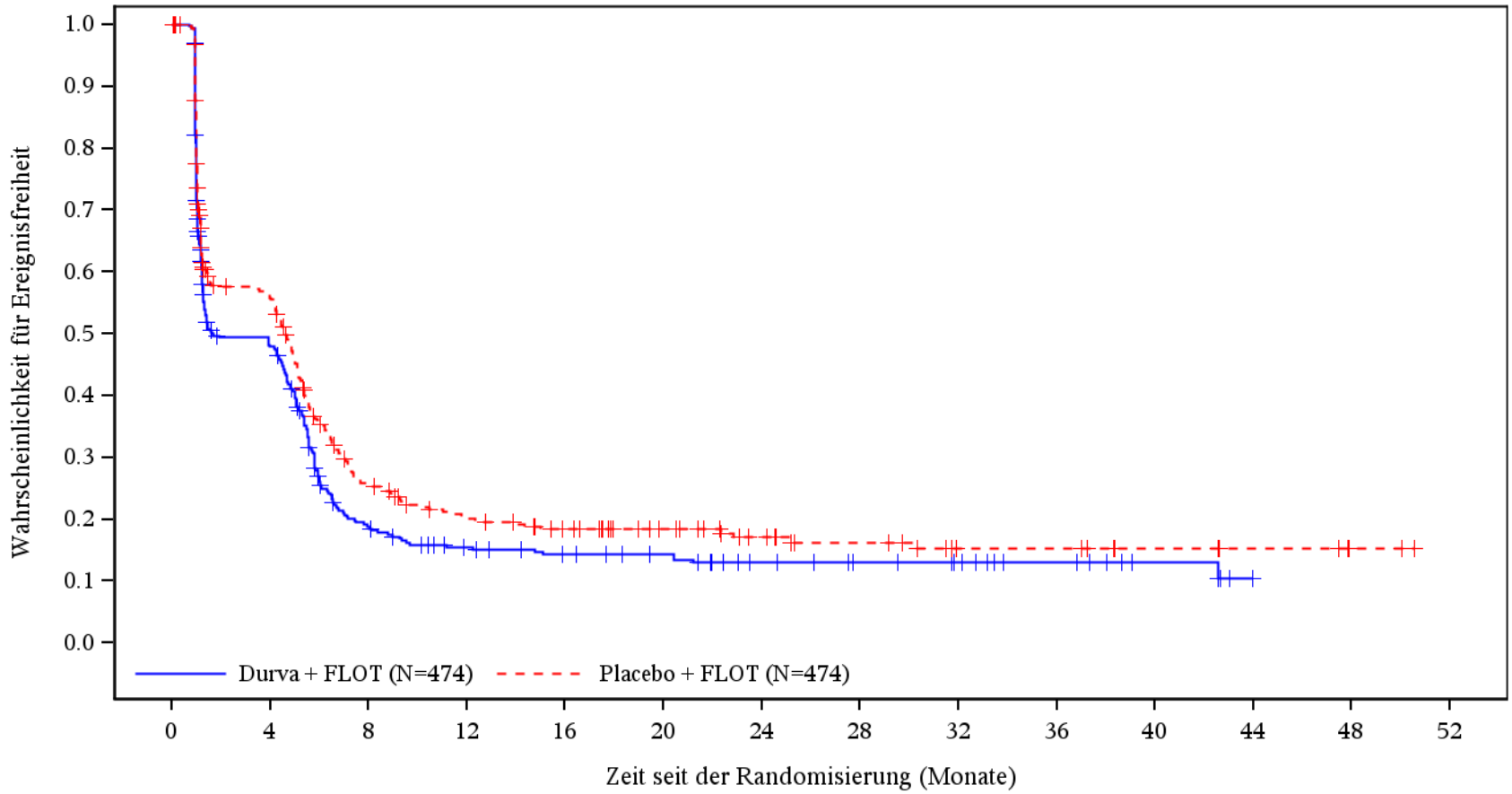
Anzahl im Risiko (Anzahl der zensierten Fälle)

474	272	178	137	106	88	70	61	50	41	21	8	7	2	0
(0)	(141)	(174)	(196)	(219)	(236)	(251)	(259)	(267)	(273)	(291)	(302)	(303)	(308)	(310)
474	249	175	136	108	81	55	41	31	26	13	6	4	3	0
(0)	(144)	(170)	(189)	(209)	(231)	(253)	(265)	(275)	(280)	(292)	(299)	(301)	(302)	(305)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.2.4 Kaplan-Meier plot of EORTC QLQ-C30 Diarrhea (Morbidity)
Full Analysis Set, DCO 01SEP2025

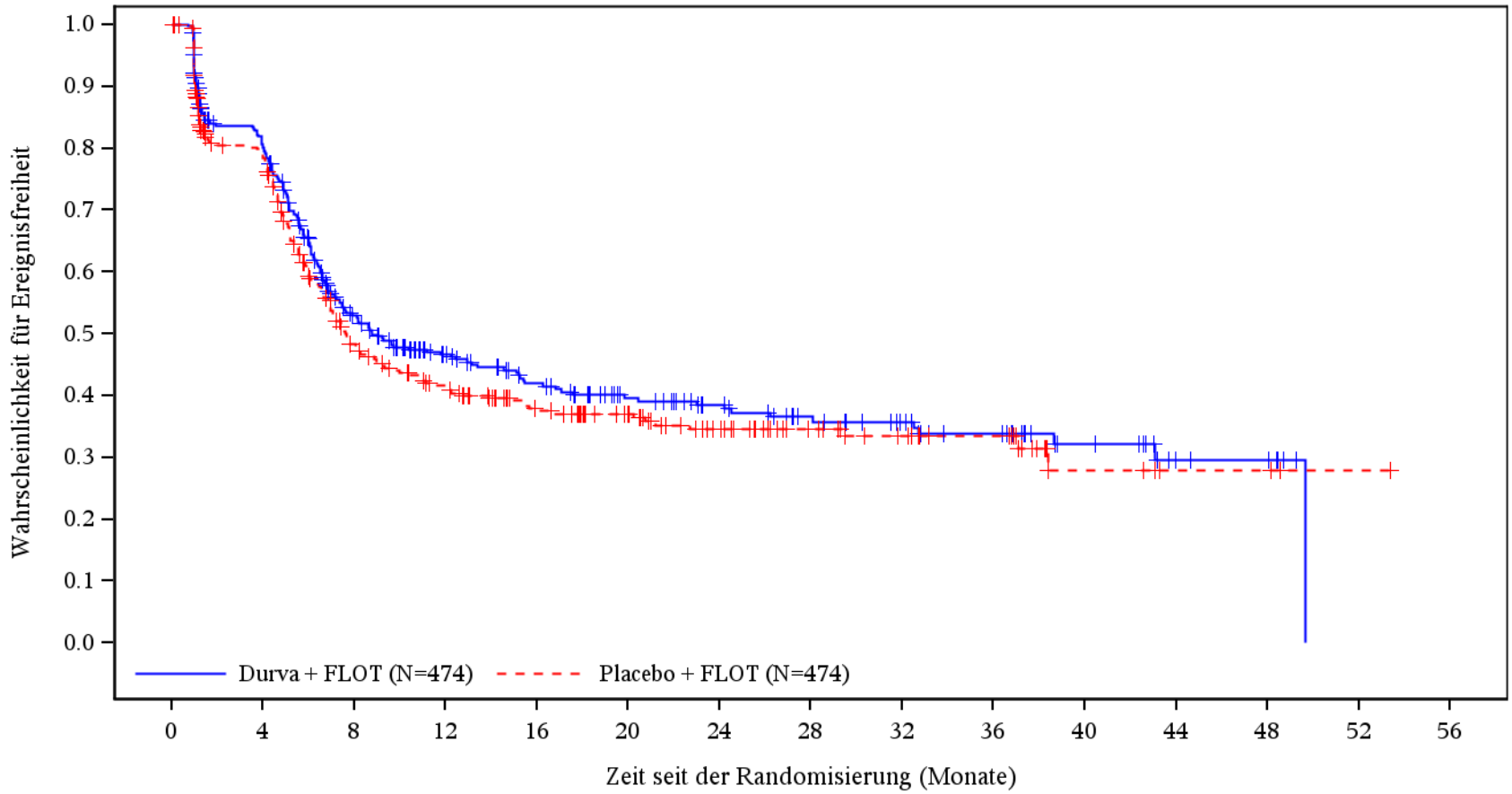


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	167	59	42	35	31	22	18	15	10	5	0	0	0
(0)	(107)	(118)	(125)	(129)	(133)	(139)	(143)	(146)	(151)	(156)	(160)	(160)	(160)
474	190	80	58	46	34	24	18	11	11	7	5	2	0
(0)	(115)	(126)	(132)	(139)	(151)	(159)	(164)	(170)	(170)	(174)	(176)	(179)	(181)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.2.5 Kaplan-Meier plot of EORTC QLQ-C30 Dyspnoea (Morbidity)
Full Analysis Set, DCO 01SEP2025



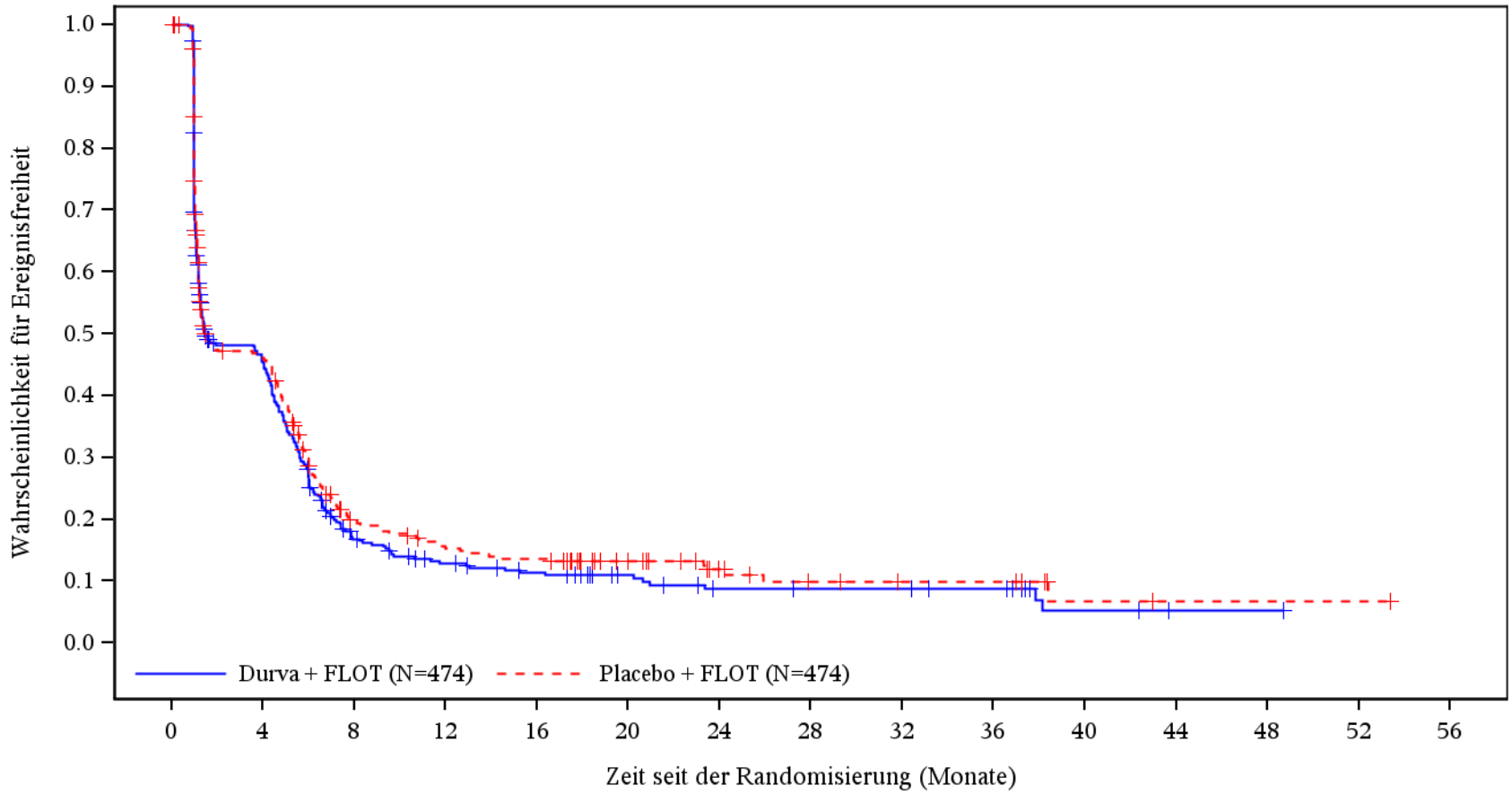
Anzahl im Risiko (Anzahl der zensierten Fälle)

474	270	157	116	94	75	62	48	40	31	17	8	7	0	0
(0)	(131)	(156)	(179)	(190)	(204)	(215)	(226)	(233)	(240)	(253)	(261)	(262)	(268)	(268)
474	257	140	111	85	66	48	34	26	21	7	3	3	1	0
(0)	(138)	(161)	(171)	(187)	(205)	(219)	(233)	(240)	(245)	(257)	(261)	(261)	(263)	(264)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.2.6 Kaplan-Meier plot of EORTC QLQ-C30 Fatigue (Morbidity)
Full Analysis Set, DCO 01SEP2025

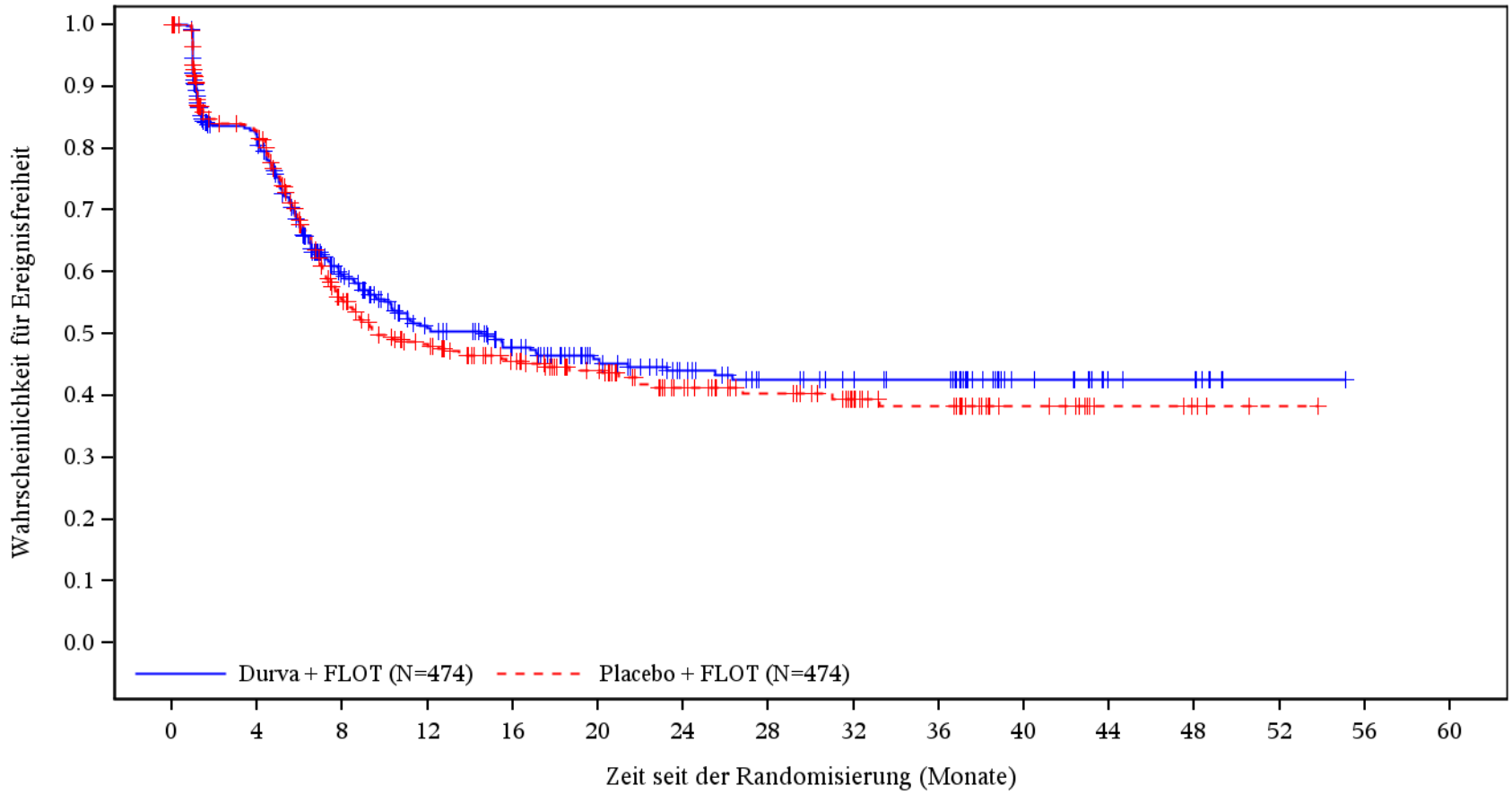


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	160	54	37	29	20	13	12	12	10	3	1	1	0	0
(0)	(101)	(108)	(113)	(117)	(125)	(128)	(129)	(129)	(131)	(136)	(138)	(138)	(139)	(139)
474	162	61	45	40	24	14	9	7	7	2	1	1	1	0
(0)	(103)	(116)	(118)	(118)	(133)	(141)	(144)	(146)	(146)	(150)	(151)	(151)	(151)	(152)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.2.7 Kaplan-Meier plot of EORTC QLQ-C30 Financial Difficulties (Morbidity)
Full Analysis Set, DCO 01SEP2025



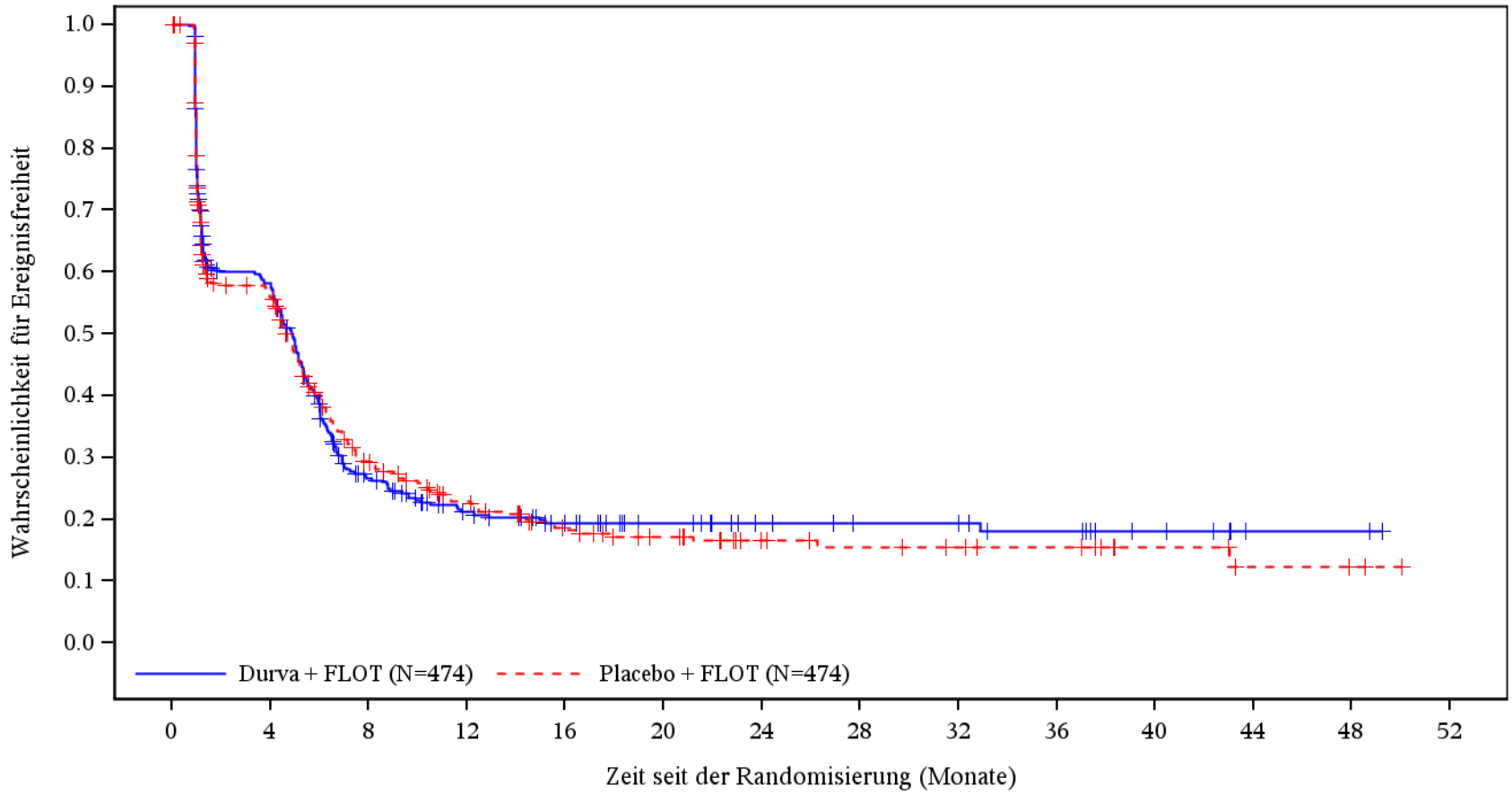
Anzahl im Risiko (Anzahl der zensierten Fälle)

474	264	167	125	105	80	62	50	45	42	20	9	8	1	0	0
(0)	(141)	(171)	(190)	(203)	(224)	(239)	(249)	(254)	(257)	(279)	(290)	(291)	(298)	(299)	(299)
474	273	165	131	107	84	62	50	38	31	16	6	4	1	0	0
(0)	(136)	(160)	(173)	(190)	(210)	(227)	(238)	(249)	(255)	(270)	(280)	(282)	(285)	(286)	(286)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.2.8 Kaplan-Meier plot of EORTC QLQ-C30 Nausea and Vomiting (Morbidity)
Full Analysis Set, DCO 01SEP2025



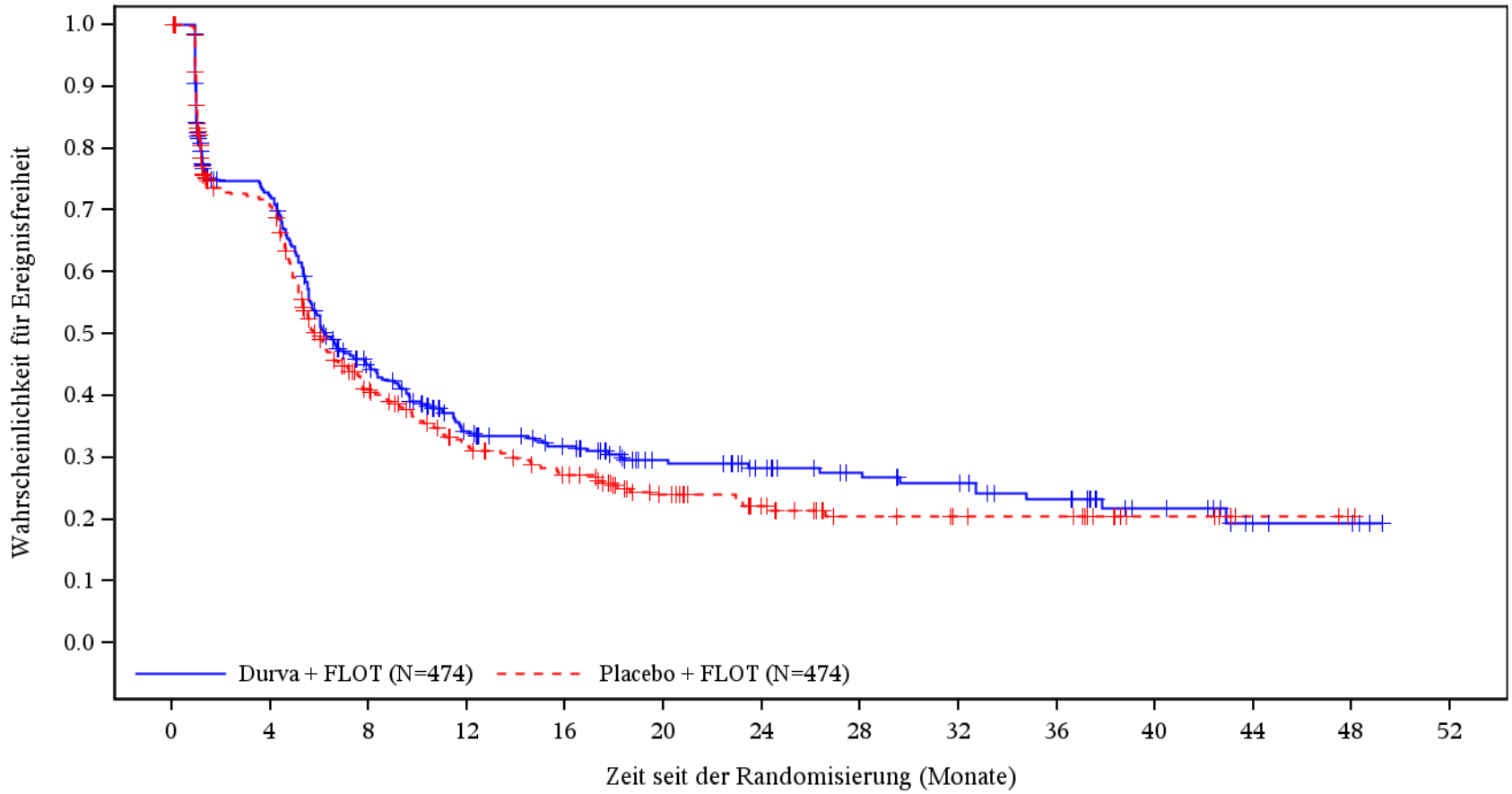
Anzahl im Risiko (Anzahl der zensierten Fälle)

474	199	78	51	37	28	20	17	17	13	8	2	2	0
(0)	(114)	(131)	(143)	(153)	(162)	(170)	(173)	(173)	(176)	(181)	(187)	(187)	(189)
474	182	85	58	40	29	18	15	13	11	6	3	2	0
(0)	(126)	(141)	(150)	(158)	(166)	(176)	(178)	(180)	(182)	(187)	(189)	(190)	(192)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttemainpr.sas gttemainpriag 29JUN2026:08:49 khcs324

Figure 3.2.9 Kaplan-Meier plot of EORTC QLQ-C30 Pain (Morbidity)
Full Analysis Set, DCO 01SEP2025

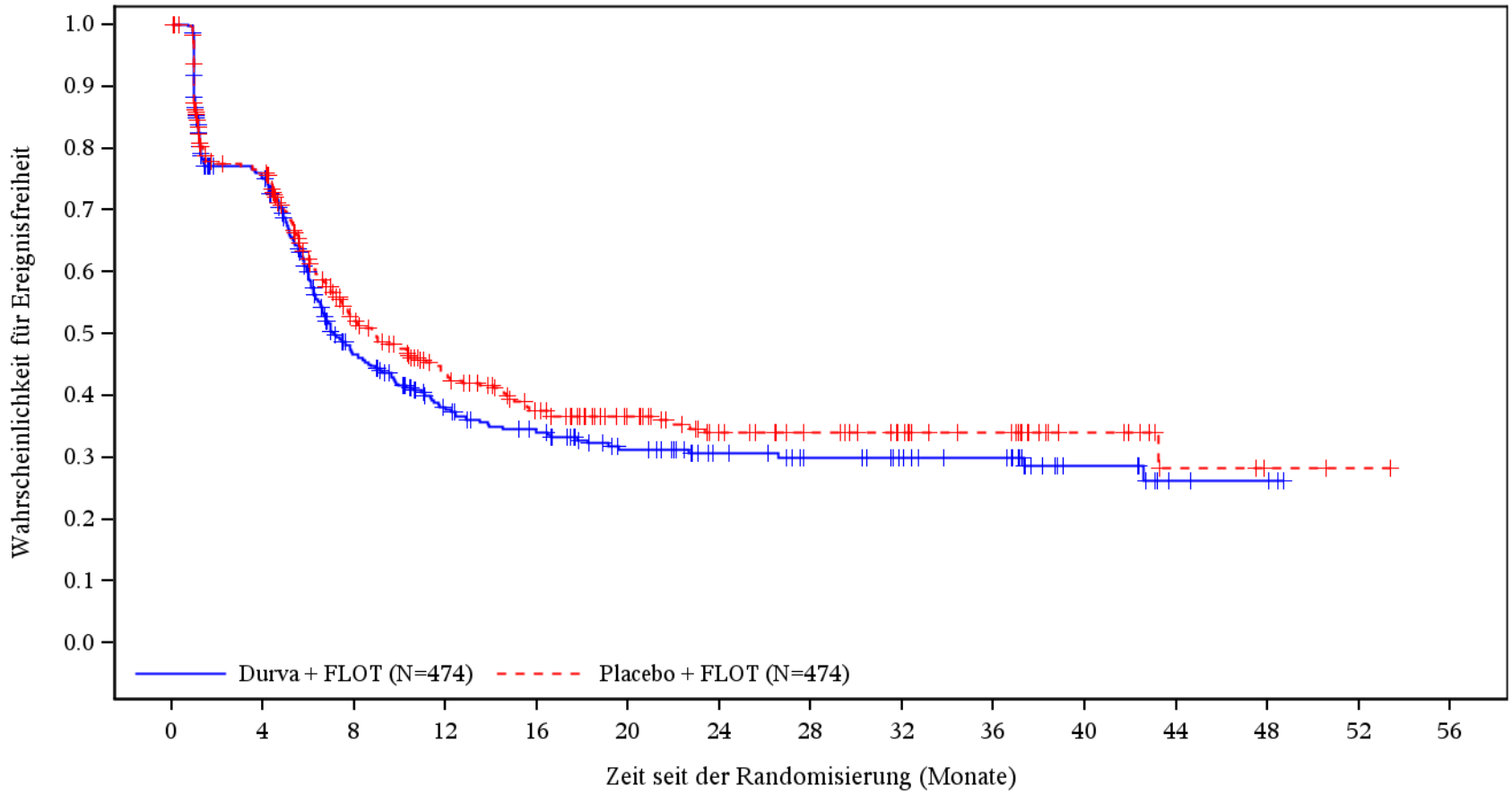


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	242	138	91	75	52	43	35	31	24	13	5	4	0
(0)	(127)	(141)	(157)	(167)	(185)	(192)	(199)	(201)	(205)	(215)	(222)	(223)	(227)
474	237	120	85	67	46	32	21	18	17	7	3	1	0
(0)	(127)	(148)	(158)	(164)	(178)	(189)	(198)	(201)	(202)	(212)	(216)	(218)	(219)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.2.10 Kaplan-Meier plot of EORTC QLQ-C30 Insomnia (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

474	251	138	97	80	61	45	38	33	29	14	6	5	0	0
(0)	(129)	(152)	(168)	(176)	(189)	(204)	(210)	(215)	(219)	(233)	(240)	(241)	(246)	(246)
474	246	145	107	82	61	44	36	28	22	11	4	2	1	0
(0)	(140)	(168)	(183)	(195)	(214)	(227)	(235)	(243)	(249)	(260)	(266)	(268)	(269)	(270)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttemainpr.sas gttemainpriai 29JUN2026:08:49 khcs324

Table 3.2.11 Summary of subgroup analysis of time to first EORTC QLQ-C30 Appetite Loss (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	59 [65,6]	4,8 [3,5; 5,7]	90	60 [66,7]	4,4 [1,2; 5,8]	0,98	[0,68; 1,40]	0,9013
Nicht-Asien	384	210 [54,7]	5,3 [4,7; 6,0]	384	196 [51,0]	5,7 [5,1; 6,5]	1,09	[0,90; 1,33]	0,3717
Interaktion p-Wert									0,5930
Klinischer Lymphknotenstatus									
Positiv	329	180 [54,7]	5,6 [4,9; 6,0]	330	176 [53,3]	5,6 [4,7; 6,4]	0,97	[0,78; 1,19]	0,7383
Negativ	145	89 [61,4]	4,0 [1,2; 5,1]	144	80 [55,6]	5,3 [4,2; 6,3]	1,36	[1,01; 1,85]	0,0437*
Interaktion p-Wert									0,0642
PD-L1-Status									
TAP >= 1%	426	236 [55,4]	5,3 [4,8; 5,7]	427	233 [54,6]	5,5 [4,7; 6,0]	1,01	[0,84; 1,21]	0,9414
TAP < 1%	48	33 [68,8]	1,9 [1,1; 6,0]	47	23 [48,9]	6,3 [1,4;26,2]	1,76	[1,04; 3,03]	0,0364*
Interaktion p-Wert									0,0507
Alter bei Randomisierung (Jahre)									
<65	291	167 [57,4]	5,3 [4,4; 6,0]	265	147 [55,5]	5,3 [4,6; 6,4]	1,00	[0,80; 1,25]	0,9799
>=65	183	102 [55,7]	5,1 [3,6; 5,8]	209	109 [52,2]	5,6 [4,7; 6,3]	1,19	[0,91; 1,56]	0,2102
Interaktion p-Wert									0,3246
Geschlecht									
Männlich	326	189 [58,0]	5,3 [4,6; 5,7]	356	201 [56,5]	5,5 [4,7; 6,0]	1,05	[0,86; 1,28]	0,6090
Weiblich	148	80 [54,1]	5,1 [4,0; 6,0]	118	55 [46,6]	5,6 [4,6; 8,0]	1,13	[0,80; 1,60]	0,4843
Interaktion p-Wert									0,7281
Tumorlokalisation									
GC	324	190 [58,6]	4,8 [3,5; 5,4]	316	176 [55,7]	5,1 [4,4; 6,0]	1,09	[0,89; 1,34]	0,4037
GEJC	150	79 [52,7]	5,6 [5,1; 6,4]	158	80 [50,6]	6,0 [5,1; 7,4]	1,01	[0,74; 1,38]	0,9532
Interaktion p-Wert									0,6814

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.12 Summary of subgroup analysis of time to first EORTC QLQ-C30 Constipation (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	36 [40,0]	15,2 [6,6; NE]	90	38 [42,2]	20,2 [7,6; NE]	0,98	[0,62; 1,54]	0,9190
Nicht-Asien	384	128 [33,3]	29,2 [14,6;38,4]	384	131 [34,1]	16,8 [10,2;37,1]	0,90	[0,70; 1,14]	0,3804
Interaktion p-Wert									0,7459
Klinischer Lymphknotenstatus									
Positiv	329	115 [35,0]	24,4 [12,2;38,4]	330	109 [33,0]	20,2 [11,0; NE]	0,97	[0,74; 1,26]	0,8003
Negativ	145	49 [33,8]	21,2 [8,0; NE]	144	60 [41,7]	12,5 [8,3;20,7]	0,82	[0,56; 1,20]	0,3095
Interaktion p-Wert									0,4907
PD-L1-Status									
TAP >= 1%	426	150 [35,2]	22,5 [12,2;37,2]	427	157 [36,8]	13,5 [9,9;22,3]	0,88	[0,71; 1,10]	0,2753
TAP < 1%	48	14 [29,2]	32,5 [6,0; NE]	47	12 [25,5]	NE [NE; NE]	1,29	[0,59; 2,84]	0,5189
Interaktion p-Wert									0,3554
Alter bei Randomisierung (Jahre)									
<65	291	110 [37,8]	22,5 [11,6;43,4]	265	99 [37,4]	19,2 [9,9;37,1]	0,94	[0,72; 1,23]	0,6529
>=65	183	54 [29,5]	32,0 [11,4; NE]	209	70 [33,5]	13,8 [9,0; NE]	0,86	[0,60; 1,22]	0,3888
Interaktion p-Wert									0,6823
Geschlecht									
Männlich	326	116 [35,6]	24,4 [12,2;37,2]	356	125 [35,1]	20,2 [11,3; NE]	0,99	[0,77; 1,27]	0,9362
Weiblich	148	48 [32,4]	32,0 [9,0; NE]	118	44 [37,3]	13,3 [7,1;28,0]	0,73	[0,48; 1,10]	0,1335
Interaktion p-Wert									0,2159
Tumorlokalisation									
GC	324	113 [34,9]	32,0 [14,6;38,4]	316	117 [37,0]	15,9 [9,5;28,0]	0,86	[0,66; 1,11]	0,2418
GEJC	150	51 [34,0]	15,2 [7,5; NE]	158	52 [32,9]	19,6 [9,7; NE]	1,06	[0,72; 1,56]	0,7669
Interaktion p-Wert									0,3695

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.13 Summary of subgroup analysis of time to first EORTC QLQ-C30 Diarrhea (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	63 [70,0]	4,2 [1,1; 5,1]	90	64 [71,1]	4,0 [1,2; 4,6]	1,13	[0,79; 1,60]	0,5035
Nicht-Asien	384	251 [65,4]	1,4 [1,3; 4,5]	384	229 [59,6]	4,9 [4,3; 5,3]	1,22	[1,02; 1,46]	0,0287*
Interaktion p-Wert									0,6845
Klinischer Lymphknotenstatus									
Positiv	329	218 [66,3]	4,3 [1,4; 4,8]	330	208 [63,0]	4,6 [3,9; 5,1]	1,12	[0,93; 1,36]	0,2296
Negativ	145	96 [66,2]	1,2 [1,1; 4,2]	144	85 [59,0]	4,9 [1,5; 5,4]	1,42	[1,06; 1,90]	0,0191*
Interaktion p-Wert									0,1910
PD-L1-Status									
TAP >= 1%	426	279 [65,5]	1,6 [1,3; 4,5]	427	262 [61,4]	4,7 [4,2; 5,1]	1,23	[1,04; 1,46]	0,0161*
TAP < 1%	48	35 [72,9]	1,9 [1,2; 5,4]	47	31 [66,0]	1,1 [1,0; 5,5]	0,96	[0,59; 1,57]	0,8793
Interaktion p-Wert									0,3504
Alter bei Randomisierung (Jahre)									
<65	291	206 [70,8]	1,4 [1,2; 4,3]	265	179 [67,5]	4,3 [1,4; 4,8]	1,17	[0,96; 1,43]	0,1305
>=65	183	108 [59,0]	4,4 [1,3; 5,5]	209	114 [54,5]	5,1 [4,2; 6,1]	1,22	[0,93; 1,58]	0,1462
Interaktion p-Wert									0,8071
Geschlecht									
Männlich	326	219 [67,2]	3,9 [1,3; 4,8]	356	224 [62,9]	4,7 [4,1; 5,1]	1,20	[0,995; 1,45]	0,0563
Weiblich	148	95 [64,2]	1,3 [1,2; 4,4]	118	69 [58,5]	4,2 [1,2; 5,3]	1,19	[0,87; 1,63]	0,2716
Interaktion p-Wert									0,9634
Tumorlokalisation									
GC	324	211 [65,1]	1,7 [1,3; 4,5]	316	188 [59,5]	4,9 [4,2; 5,4]	1,28	[1,05; 1,56]	0,0135*
GEJC	150	103 [68,7]	1,5 [1,2; 5,1]	158	105 [66,5]	3,5 [1,2; 4,7]	1,05	[0,80; 1,38]	0,7071
Interaktion p-Wert									0,2537

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.14 Summary of subgroup analysis of time to first EORTC QLQ-C30 Dyspnoea (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	47 [52,2]	6,6 [5,7;15,2]	90	58 [64,4]	6,5 [5,1;10,0]	0,88	[0,59; 1,29]	0,5068
Nicht-Asien	384	159 [41,4]	10,4 [7,6;15,4]	384	152 [39,6]	7,7 [7,0;10,8]	0,93	[0,74; 1,16]	0,4955
Interaktion p-Wert									0,8161
Klinischer Lymphknotenstatus									
Positiv	329	142 [43,2]	8,7 [7,2;15,4]	330	148 [44,8]	7,4 [6,3;10,0]	0,85	[0,67; 1,07]	0,1599
Negativ	145	64 [44,1]	9,0 [5,6;15,2]	144	62 [43,1]	8,9 [6,5;15,6]	1,06	[0,75; 1,51]	0,7255
Interaktion p-Wert									0,2859
PD-L1-Status									
TAP >= 1%	426	184 [43,2]	8,7 [7,4;15,2]	427	190 [44,5]	7,7 [7,0;10,4]	0,89	[0,73; 1,09]	0,2648
TAP < 1%	48	22 [45,8]	9,2 [1,9; NE]	47	20 [42,6]	6,6 [4,5; NE]	1,06	[0,58; 1,96]	0,8436
Interaktion p-Wert									0,5881
Alter bei Randomisierung (Jahre)									
<65	291	138 [47,4]	7,9 [6,6;13,4]	265	123 [46,4]	7,1 [6,0; 9,7]	0,93	[0,73; 1,19]	0,5741
>=65	183	68 [37,2]	12,9 [7,5;24,2]	209	87 [41,6]	8,1 [7,0;12,6]	0,85	[0,61; 1,16]	0,3011
Interaktion p-Wert									0,6337
Geschlecht									
Männlich	326	151 [46,3]	8,1 [6,5;11,8]	356	159 [44,7]	7,6 [6,7;10,0]	1,01	[0,81; 1,26]	0,9447
Weiblich	148	55 [37,2]	17,1 [7,6; NE]	118	51 [43,2]	7,8 [5,7;11,5]	0,70	[0,47; 1,02]	0,0634
Interaktion p-Wert									0,1006
Tumorlokalisation									
GC	324	131 [40,4]	12,4 [8,6;23,0]	316	133 [42,1]	9,3 [7,5;15,9]	0,90	[0,71; 1,15]	0,4058
GEJC	150	75 [50,0]	6,4 [5,7; 7,7]	158	77 [48,7]	6,1 [5,1; 7,1]	0,92	[0,67; 1,26]	0,5904
Interaktion p-Wert									0,9413

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.15 Summary of subgroup analysis of time to first EORTC QLQ-C30 Fatigue (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	65 [72,2]	4,5 [1,3; 5,3]	90	72 [80,0]	1,3 [1,1; 4,6]	0,86	[0,61; 1,20]	0,3769
Nicht-Asien	384	270 [70,3]	1,4 [1,2; 3,6]	384	250 [65,1]	1,5 [1,2; 4,4]	1,15	[0,97; 1,37]	0,1097
Interaktion p-Wert									0,1294
Klinischer Lymphknotenstatus									
Positiv	329	231 [70,2]	3,9 [1,3; 4,5]	330	221 [67,0]	1,7 [1,2; 4,5]	1,02	[0,85; 1,23]	0,8285
Negativ	145	104 [71,7]	1,2 [1,0; 3,6]	144	101 [70,1]	1,2 [1,2; 3,8]	1,27	[0,96; 1,67]	0,0900
Interaktion p-Wert									0,1984
PD-L1-Status									
TAP >= 1%	426	297 [69,7]	1,5 [1,2; 4,1]	427	288 [67,4]	1,5 [1,2; 4,4]	1,11	[0,94; 1,30]	0,2228
TAP < 1%	48	38 [79,2]	1,3 [1,0; 5,4]	47	34 [72,3]	1,1 [1,0; 4,4]	0,85	[0,54; 1,36]	0,4965
Interaktion p-Wert									0,2973
Alter bei Randomisierung (Jahre)									
<65	291	220 [75,6]	1,4 [1,2; 4,0]	265	186 [70,2]	1,3 [1,2; 4,4]	1,13	[0,93; 1,37]	0,2221
>=65	183	115 [62,8]	1,4 [1,2; 4,5]	209	136 [65,1]	2,0 [1,3; 4,6]	0,99	[0,77; 1,27]	0,9645
Interaktion p-Wert									0,4301
Geschlecht									
Männlich	326	233 [71,5]	1,4 [1,2; 3,9]	356	250 [70,2]	1,5 [1,2; 4,4]	1,09	[0,91; 1,30]	0,3505
Weiblich	148	102 [68,9]	3,9 [1,2; 4,5]	118	72 [61,0]	1,3 [1,2; 4,5]	1,05	[0,78; 1,43]	0,7468
Interaktion p-Wert									0,8429
Tumorlokalisation									
GC	324	226 [69,8]	3,7 [1,3; 4,3]	316	211 [66,8]	1,4 [1,2; 4,4]	1,07	[0,88; 1,29]	0,5020
GEJC	150	109 [72,7]	1,4 [1,1; 3,7]	158	111 [70,3]	1,5 [1,2; 4,7]	1,13	[0,87; 1,47]	0,3740
Interaktion p-Wert									0,7366

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.16 Summary of subgroup analysis of time to first EORTC QLQ-C30 Financial Difficulties (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	36 [40,0]	23,2 [8,8; NE]	90	42 [46,7]	8,7 [6,9; NE]	0,85	[0,54; 1,33]	0,4795
Nicht-Asien	384	139 [36,2]	12,0 [9,2;20,1]	384	146 [38,0]	10,2 [8,0;21,0]	0,97	[0,77; 1,22]	0,7801
Interaktion p-Wert									0,6190
Klinischer Lymphknotenstatus									
Positiv	329	119 [36,2]	14,5 [10,3; NE]	330	132 [40,0]	9,5 [7,4;20,2]	0,86	[0,67; 1,11]	0,2435
Negativ	145	56 [38,6]	11,1 [5,9;25,5]	144	56 [38,9]	9,4 [7,7; NE]	1,15	[0,79; 1,67]	0,4619
Interaktion p-Wert									0,2080
PD-L1-Status									
TAP >= 1%	426	158 [37,1]	12,2 [9,6;23,2]	427	176 [41,2]	9,2 [7,7;15,5]	0,90	[0,73; 1,12]	0,3555
TAP < 1%	48	17 [35,4]	26,3 [6,0; NE]	47	12 [25,5]	NE [NE; NE]	1,48	[0,71; 3,18]	0,2918
Interaktion p-Wert									0,2034
Alter bei Randomisierung (Jahre)									
<65	291	126 [43,3]	10,3 [7,4;15,5]	265	109 [41,1]	9,5 [7,7;21,8]	1,08	[0,84; 1,40]	0,5394
>=65	183	49 [26,8]	NE [NE; NE]	209	79 [37,8]	10,2 [7,4;26,8]	0,70	[0,49; 0,99997]	0,0500*
Interaktion p-Wert									0,0518
Geschlecht									
Männlich	326	117 [35,9]	15,2 [9,6; NE]	356	146 [41,0]	9,5 [7,8;18,7]	0,90	[0,71; 1,15]	0,4031
Weiblich	148	58 [39,2]	11,1 [7,4;21,4]	118	42 [35,6]	9,0 [6,4; NE]	1,03	[0,69; 1,54]	0,8908
Interaktion p-Wert									0,5796
Tumorlokalisation									
GC	324	118 [36,4]	15,5 [10,3; NE]	316	134 [42,4]	9,3 [7,5;17,5]	0,86	[0,67; 1,10]	0,2194

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.16 Summary of subgroup analysis of time to first EORTC QLQ-C30 Financial Difficulties (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
GEJC	150	57 [38,0]	11,2 [6,5; NE]	158	54 [34,2]	12,9 [7,7; NE]	1,16	[0,80; 1,69]	0,4290
Interaktion p-Wert									0,1809

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.17 Summary of subgroup analysis of time to first EORTC QLQ-C30 Nausea and Vomiting (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	59 [65,6]	5,0 [1,3; 5,5]	90	64 [71,1]	5,3 [3,8; 6,1]	1,01	[0,71; 1,44]	0,9417
Nicht-Asien	384	226 [58,9]	4,9 [4,2; 5,3]	384	218 [56,8]	4,5 [3,9; 5,2]	0,98	[0,82; 1,19]	0,8610
Interaktion p-Wert									0,8838
Klinischer Lymphknotenstatus									
Positiv	329	194 [59,0]	5,1 [4,4; 5,8]	330	189 [57,3]	4,8 [4,2; 5,6]	0,98	[0,81; 1,20]	0,8759
Negativ	145	91 [62,8]	4,1 [1,4; 5,3]	144	93 [64,6]	4,3 [1,3; 5,2]	1,02	[0,76; 1,36]	0,8850
Interaktion p-Wert									0,8354
PD-L1-Status									
TAP >= 1%	426	257 [60,3]	4,6 [4,1; 5,1]	427	255 [59,7]	4,7 [4,1; 5,2]	1,03	[0,87; 1,22]	0,7449
TAP < 1%	48	28 [58,3]	5,9 [3,4; 6,9]	47	27 [57,4]	4,3 [1,1; 6,5]	0,72	[0,42; 1,22]	0,2189
Interaktion p-Wert									0,2041
Alter bei Randomisierung (Jahre)									
<65	291	187 [64,3]	4,6 [4,1; 5,2]	265	171 [64,5]	4,0 [1,3; 4,8]	0,92	[0,75; 1,14]	0,4527
>=65	183	98 [53,6]	5,1 [4,0; 6,0]	209	111 [53,1]	5,2 [4,5; 6,2]	1,06	[0,81; 1,39]	0,6820
Interaktion p-Wert									0,4346
Geschlecht									
Männlich	326	188 [57,7]	5,1 [4,4; 5,7]	356	218 [61,2]	4,7 [4,2; 5,3]	0,92	[0,76; 1,12]	0,3923
Weiblich	148	97 [65,5]	4,2 [1,2; 4,9]	118	64 [54,2]	4,2 [1,3; 6,4]	1,17	[0,85; 1,60]	0,3409
Interaktion p-Wert									0,2074
Tumorlokalisation									
GC	324	204 [63,0]	4,2 [1,4; 5,0]	316	194 [61,4]	4,4 [1,5; 5,2]	1,03	[0,85; 1,26]	0,7622
GEJC	150	81 [54,0]	5,5 [4,9; 6,3]	158	88 [55,7]	5,1 [3,9; 6,1]	0,90	[0,67; 1,22]	0,5115
Interaktion p-Wert									0,4744

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.18 Summary of subgroup analysis of time to first EORTC QLQ-C30 Pain (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	54 [60,0]	5,7 [4,8; 7,3]	90	55 [61,1]	5,4 [4,6;12,1]	1,07	[0,73; 1,56]	0,7300
Nicht-Asien	384	193 [50,3]	6,7 [5,6; 9,1]	384	200 [52,1]	6,0 [5,3; 7,2]	0,87	[0,72; 1,07]	0,1854
Interaktion p-Wert									0,3563
Klinischer Lymphknotenstatus									
Positiv	329	165 [50,2]	6,7 [5,8; 9,3]	330	180 [54,5]	5,7 [5,1; 6,9]	0,83	[0,67; 1,03]	0,0906
Negativ	145	82 [56,6]	5,5 [4,7; 7,4]	144	75 [52,1]	6,4 [4,8; 9,2]	1,13	[0,83; 1,55]	0,4331
Interaktion p-Wert									0,1103
PD-L1-Status									
TAP >= 1%	426	218 [51,2]	6,6 [5,7; 8,3]	427	234 [54,8]	6,0 [5,2; 7,2]	0,89	[0,74; 1,07]	0,2196
TAP < 1%	48	29 [60,4]	5,3 [1,9; 9,5]	47	21 [44,7]	5,4 [4,3; NE]	1,16	[0,67; 2,06]	0,5989
Interaktion p-Wert									0,3760
Alter bei Randomisierung (Jahre)									
<65	291	170 [58,4]	5,8 [5,3; 6,7]	265	148 [55,8]	6,0 [5,2; 7,7]	1,03	[0,82; 1,28]	0,8103
>=65	183	77 [42,1]	8,3 [6,0;11,8]	209	107 [51,2]	5,7 [4,9; 7,2]	0,74	[0,55; 0,99]	0,0399*
Interaktion p-Wert									0,0747
Geschlecht									
Männlich	326	170 [52,1]	6,1 [5,6; 7,9]	356	194 [54,5]	6,0 [5,1; 7,7]	0,96	[0,78; 1,18]	0,6791
Weiblich	148	77 [52,0]	6,8 [5,3;11,0]	118	61 [51,7]	5,6 [4,8; 7,7]	0,79	[0,56; 1,11]	0,1692
Interaktion p-Wert									0,3365
Tumorlokalisation									
GC	324	167 [51,5]	6,8 [5,7; 9,1]	316	169 [53,5]	6,5 [5,3; 9,1]	0,97	[0,78; 1,20]	0,7547
GEJC	150	80 [53,3]	5,8 [5,4; 7,9]	158	86 [54,4]	5,4 [4,7; 6,0]	0,81	[0,59; 1,10]	0,1703
Interaktion p-Wert									0,3457

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.19 Summary of subgroup analysis of time to first EORTC QLQ-C30 Insomnia (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	52 [57,8]	6,3 [5,3; 8,1]	90	49 [54,4]	7,7 [5,3;12,2]	1,16	[0,79; 1,72]	0,4500
Nicht-Asien	384	176 [45,8]	7,8 [6,6; 9,8]	384	155 [40,4]	9,8 [7,5;12,7]	1,11	[0,90; 1,38]	0,3350
Interaktion p-Wert									0,8458
Klinischer Lymphknotenstatus									
Positiv	329	155 [47,1]	7,6 [6,5;10,9]	330	137 [41,5]	8,8 [7,2;11,8]	1,09	[0,87; 1,38]	0,4457
Negativ	145	73 [50,3]	6,6 [5,2; 8,9]	144	67 [46,5]	10,0 [5,9;14,5]	1,20	[0,86; 1,67]	0,2916
Interaktion p-Wert									0,6653
PD-L1-Status									
TAP >= 1%	426	202 [47,4]	7,1 [6,3; 9,1]	427	186 [43,6]	9,0 [7,4;11,8]	1,11	[0,91; 1,36]	0,3024
TAP < 1%	48	26 [54,2]	6,6 [4,2;16,0]	47	18 [38,3]	7,5 [1,3; NE]	1,20	[0,66; 2,22]	0,5565
Interaktion p-Wert									0,8167
Alter bei Randomisierung (Jahre)									
<65	291	151 [51,9]	6,7 [6,1; 9,1]	265	122 [46,0]	7,8 [6,5;10,3]	1,09	[0,86; 1,38]	0,4977
>=65	183	77 [42,1]	7,8 [6,2;11,4]	209	82 [39,2]	11,8 [7,4;16,5]	1,15	[0,84; 1,57]	0,3898
Interaktion p-Wert									0,7866
Geschlecht									
Männlich	326	158 [48,5]	7,6 [6,4; 9,6]	356	158 [44,4]	8,1 [7,0;11,3]	1,12	[0,89; 1,39]	0,3309
Weiblich	148	70 [47,3]	6,9 [5,8; 9,9]	118	46 [39,0]	10,4 [6,1;22,7]	1,13	[0,78; 1,66]	0,5048
Interaktion p-Wert									0,9397
Tumorlokalisation									
GC	324	161 [49,7]	6,9 [6,1; 8,7]	316	136 [43,0]	9,3 [6,7;13,5]	1,21	[0,96; 1,52]	0,0989
GEJC	150	67 [44,7]	8,1 [6,4;13,8]	158	68 [43,0]	7,9 [6,8;10,4]	0,95	[0,67; 1,33]	0,7450
Interaktion p-Wert									0,2331

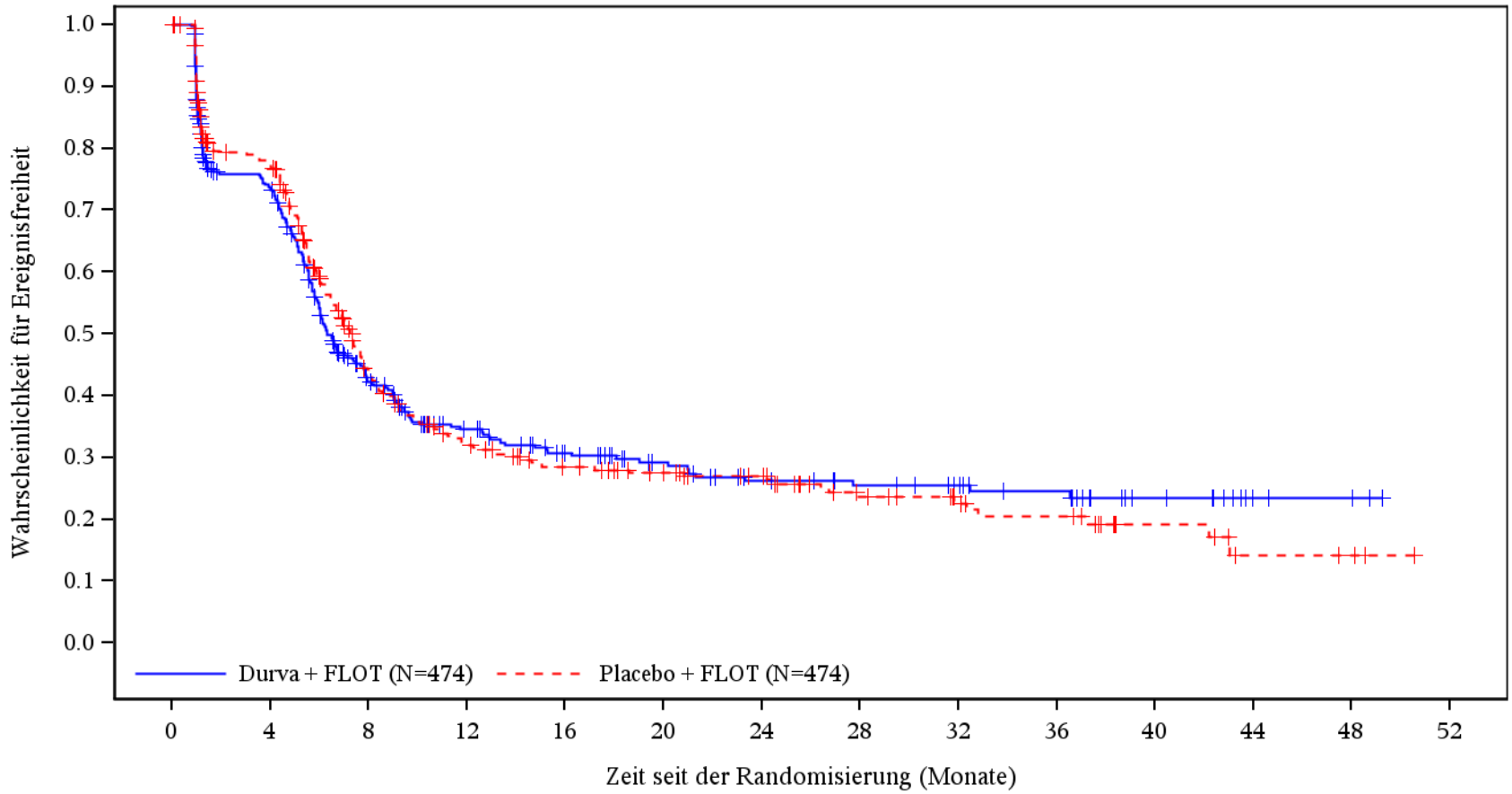
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.20 Summary of analysis of time to deterioration in EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
EORTC QLQ-C30 Kognitive Funktion	474	245 [51,7]	6,3 [5,9; 7,8]	474	243 [51,3]	7,2 [6,5; 7,8]	1,00	[0,84; 1,20]	0,9968
EORTC QLQ-C30 Emotionale Funktion	474	178 [37,6]	16,4 [11,7;29,2]	474	190 [40,1]	13,4 [10,0;17,4]	0,90	[0,73; 1,10]	0,3048
EORTC QLQ-C30 Körperliche Funktion	474	274 [57,8]	5,9 [5,4; 6,3]	474	279 [58,9]	5,5 [5,1; 6,0]	0,91	[0,77; 1,08]	0,2774
EORTC QLQ-C30 Allgemeine Lebensqualität/ Gesundheitsszustand	474	253 [53,4]	5,8 [5,1; 6,2]	474	259 [54,6]	5,4 [4,8; 5,8]	0,93	[0,78; 1,11]	0,4054
EORTC QLQ-C30 Rollenfunktion	474	286 [60,3]	5,1 [4,6; 5,6]	474	292 [61,6]	4,6 [4,1; 5,1]	0,91	[0,78; 1,08]	0,2815
EORTC QLQ-C30 Soziale Funktion	474	271 [57,2]	5,7 [4,9; 6,1]	474	262 [55,3]	5,6 [5,1; 6,3]	1,02	[0,86; 1,21]	0,8356

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 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 based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic region, clinical lymph node status and PD-L1 status
Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.2.21 Kaplan-Meier plot of EORTC QLQ-C30 Cognitive Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025

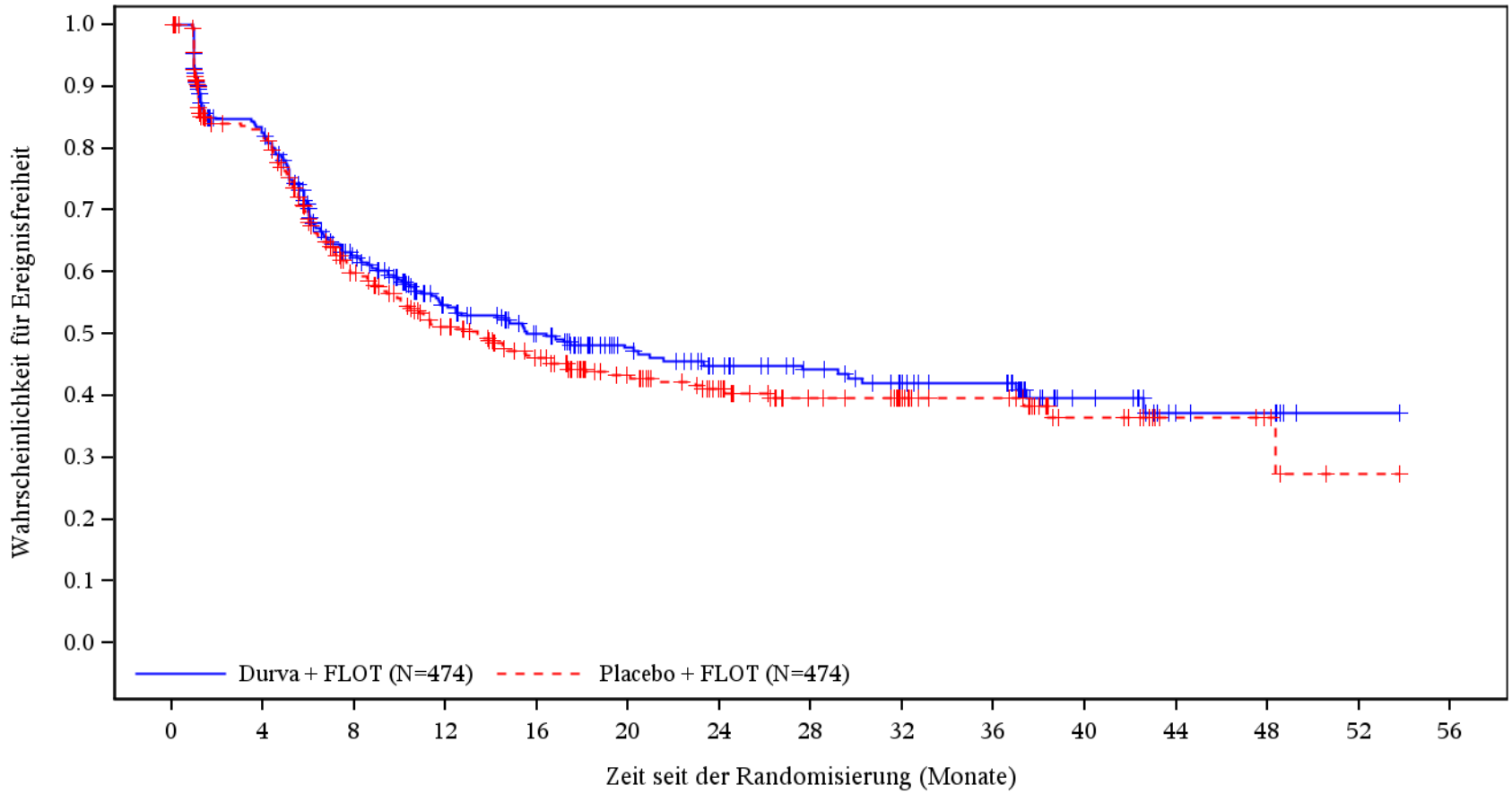


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	251	127	87	66	50	40	34	30	25	15	5	4	0
(0)	(123)	(144)	(162)	(174)	(187)	(192)	(197)	(201)	(205)	(214)	(224)	(225)	(229)
474	256	128	85	66	56	47	31	23	19	9	4	3	0
(0)	(136)	(160)	(169)	(179)	(187)	(195)	(206)	(213)	(215)	(224)	(227)	(228)	(231)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttemainpr.sas gttemainpriaj 29JUN2026:08:49 khcs324

Figure 3.2.22 Kaplan-Meier plot of EORTC QLQ-C30 Emotional functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025



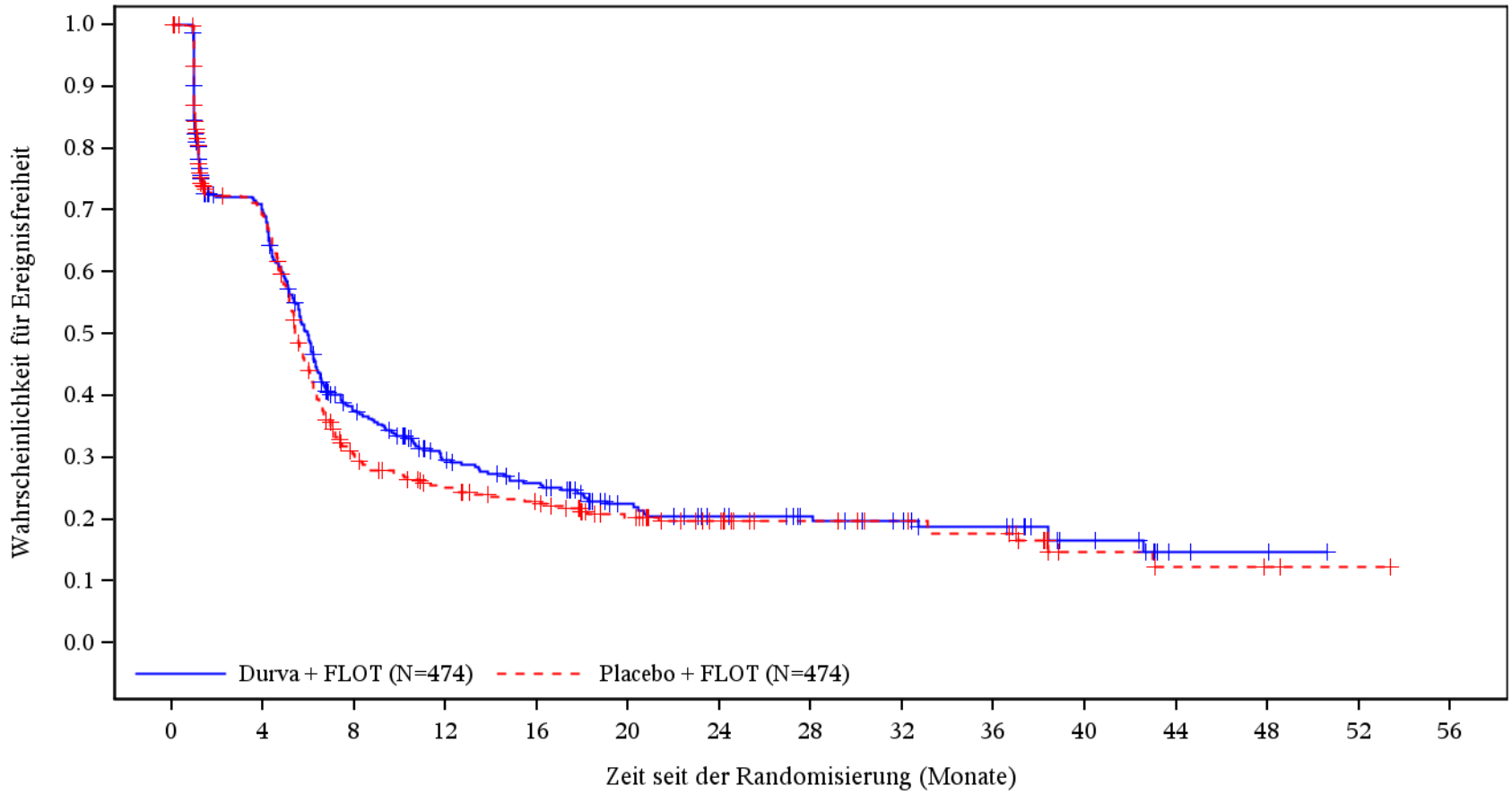
Anzahl im Risiko (Anzahl der zensierten Fälle)

474	273	186	138	114	87	72	62	52	47	22	8	7	1	0
(0)	(137)	(160)	(186)	(199)	(221)	(231)	(240)	(247)	(252)	(275)	(288)	(289)	(295)	(296)
474	274	179	139	111	83	66	49	39	32	17	7	5	1	0
(0)	(135)	(158)	(173)	(188)	(210)	(223)	(238)	(248)	(255)	(268)	(278)	(280)	(283)	(284)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttemainpr.sas gttemainpriak 29JUN2026:08:49 khcs324

Figure 3.2.23 Kaplan-Meier plot of EORTC QLQ-C30 Physical Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025



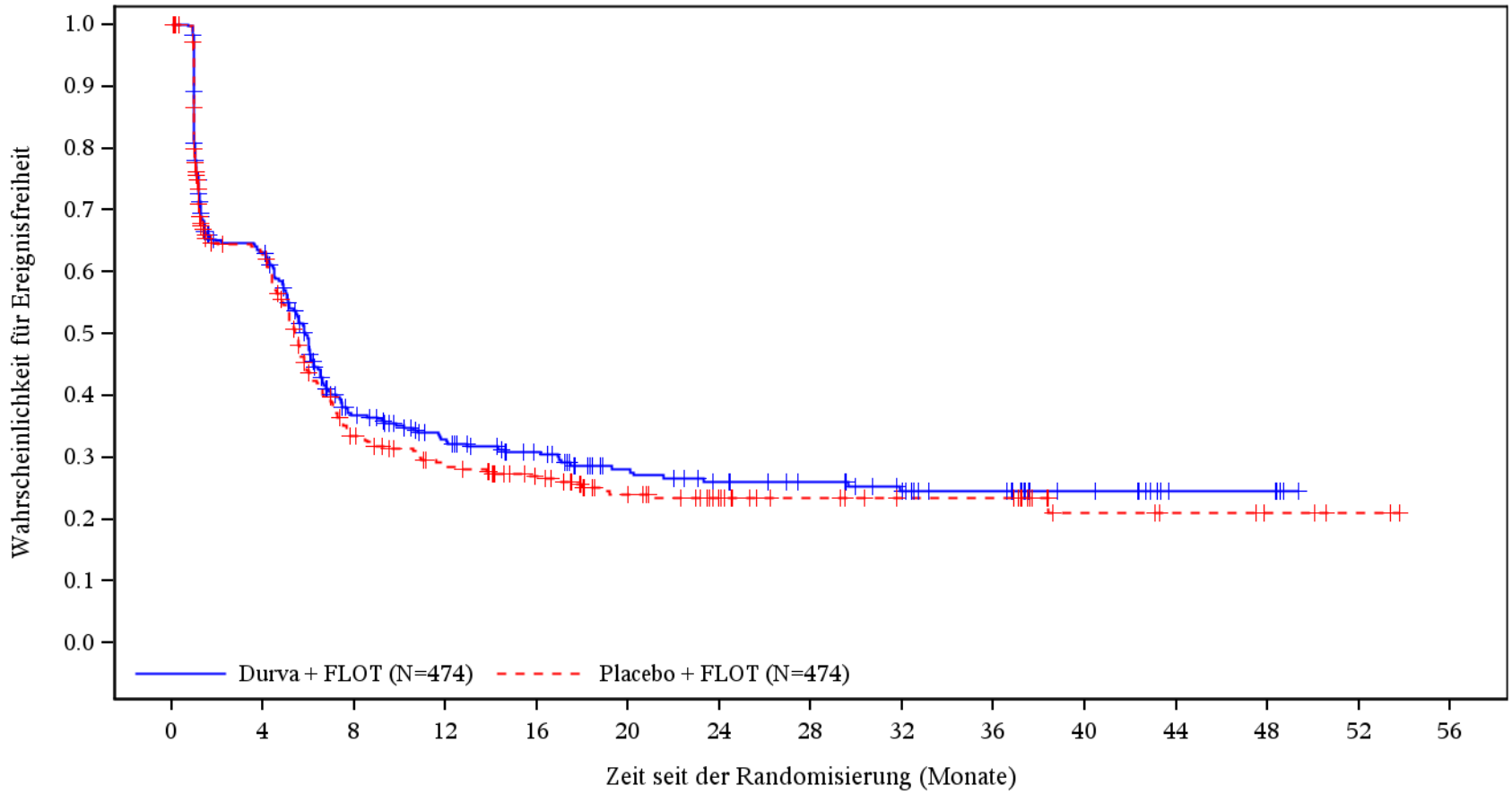
Anzahl im Risiko (Anzahl der zensierten Fälle)

474	237	119	82	66	44	35	29	25	21	12	3	2	0	0
(0)	(121)	(132)	(145)	(151)	(165)	(170)	(176)	(179)	(182)	(189)	(197)	(198)	(200)	(200)
474	236	92	71	60	42	30	23	20	17	6	3	2	1	0
(0)	(122)	(135)	(142)	(147)	(159)	(170)	(177)	(180)	(181)	(190)	(192)	(193)	(194)	(195)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.2.24 Kaplan-Meier plot of EORTC QLQ-C30 Global Health Status/QoL (hrQoL)
Full Analysis Set, DCO 01SEP2025



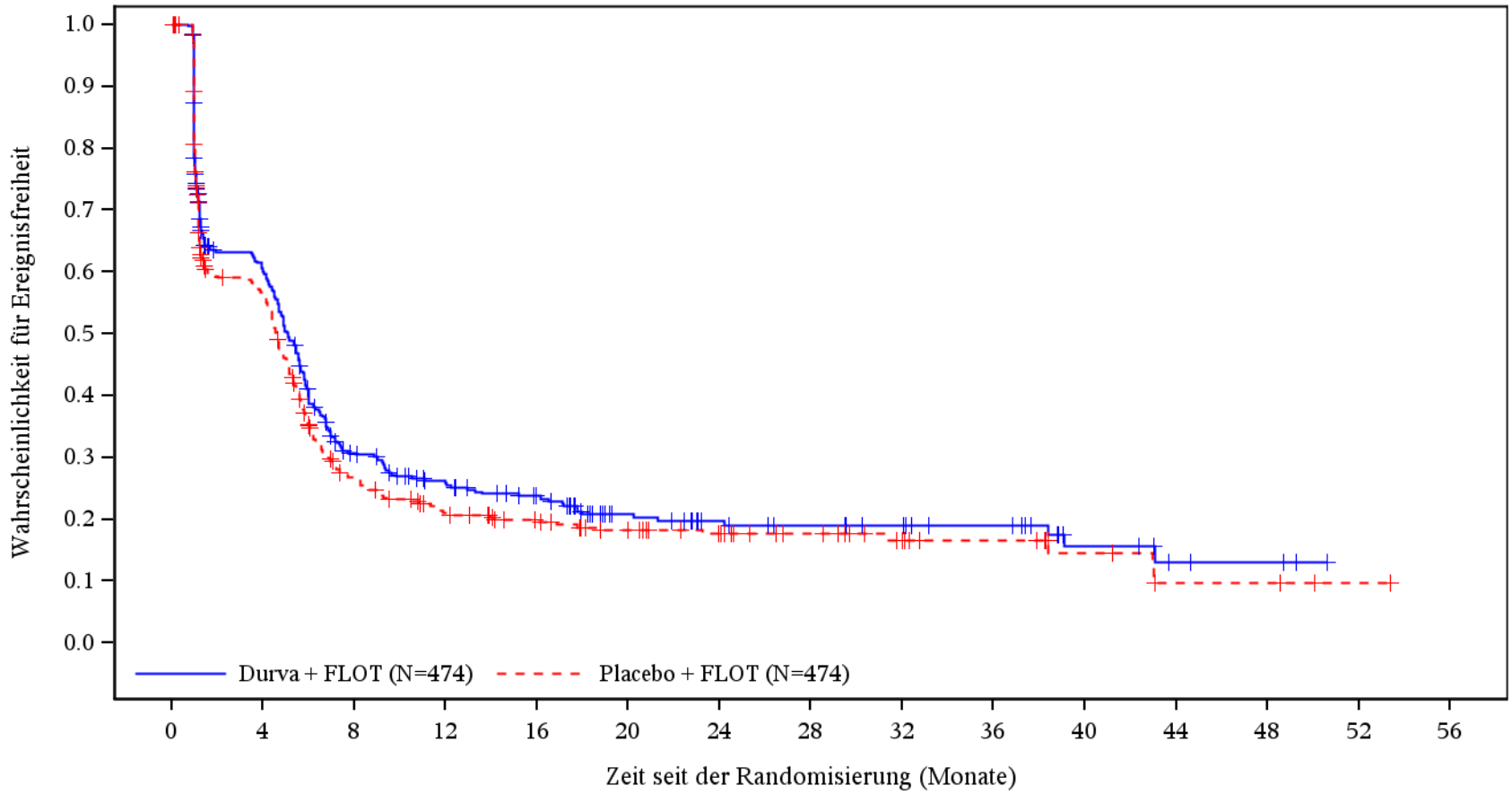
Anzahl im Risiko (Anzahl der zensierten Fälle)

474	216	111	87	71	53	44	39	32	26	14	5	5	0	0
(0)	(119)	(138)	(151)	(162)	(174)	(179)	(184)	(189)	(195)	(207)	(216)	(216)	(221)	(221)
474	206	99	77	62	42	31	24	19	19	8	6	4	2	0
(0)	(127)	(142)	(150)	(161)	(175)	(185)	(192)	(197)	(197)	(207)	(209)	(211)	(213)	(215)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.2.25 Kaplan-Meier plot of EORTC QLQ-C30 Role Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025

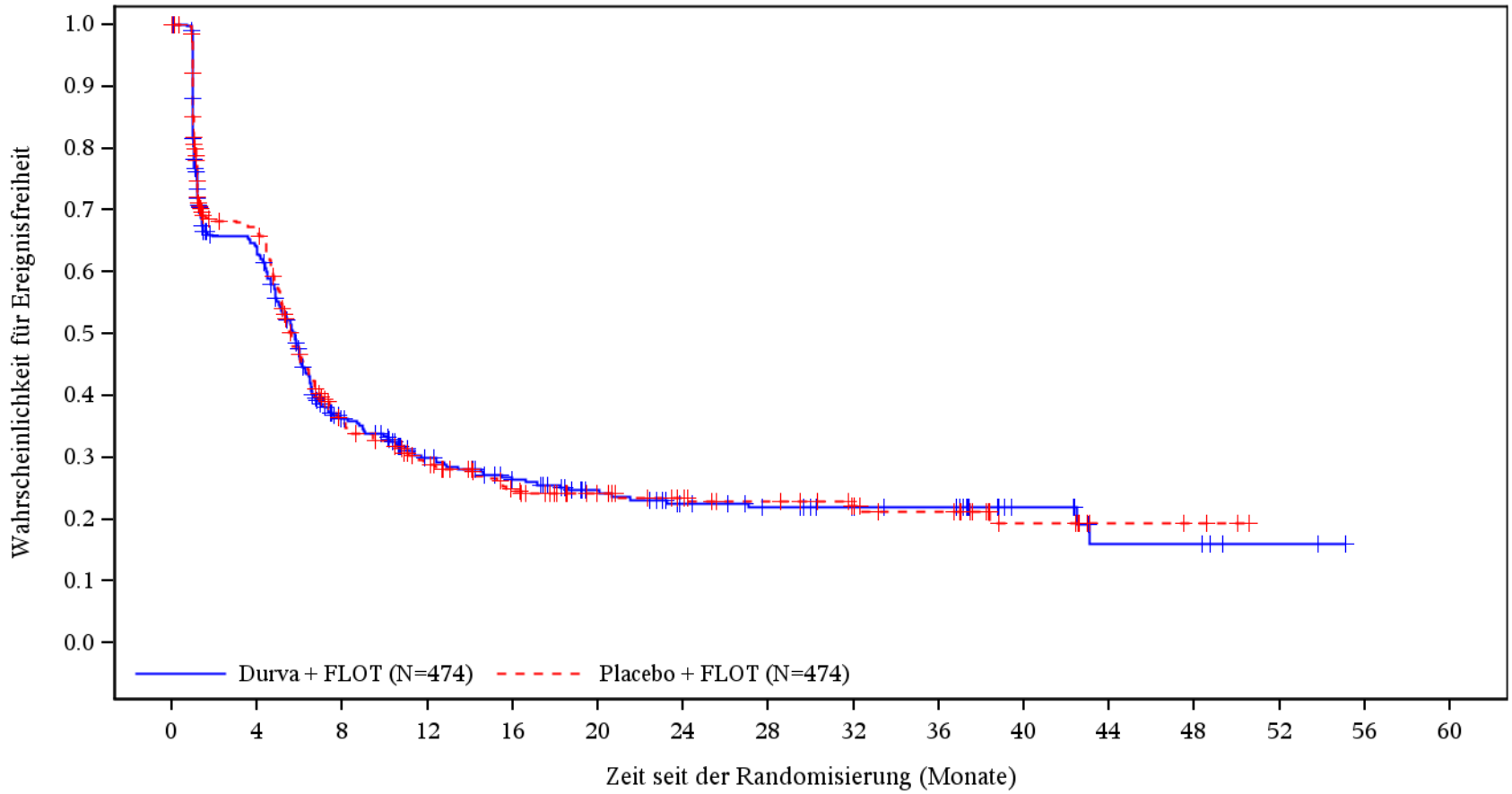


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	206	98	74	60	38	28	24	21	17	8	4	3	0	0
(0)	(115)	(124)	(133)	(141)	(156)	(164)	(167)	(170)	(174)	(181)	(184)	(185)	(188)	(188)
474	193	81	58	48	37	30	23	16	12	7	3	3	1	0
(0)	(116)	(129)	(135)	(143)	(150)	(156)	(163)	(169)	(173)	(177)	(179)	(179)	(181)	(182)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.2.26 Kaplan-Meier plot of EORTC QLQ-C30 Social Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

474	222	111	79	63	48	38	32	26	24	11	5	5	2	0	0
(0)	(111)	(130)	(144)	(151)	(162)	(168)	(173)	(179)	(181)	(194)	(198)	(198)	(201)	(203)	(203)
474	224	107	80	60	45	38	33	26	22	10	4	3	0	0	0
(0)	(125)	(142)	(149)	(159)	(172)	(178)	(182)	(188)	(191)	(202)	(208)	(209)	(212)	(212)	(212)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttemainpr.sas gttemainpriao 29JUN2026:08:49 khcs324

Table 3.2.27 Summary of subgroup analysis of time to first EORTC QLQ-C30 Cognitive Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	52 [57,8]	6,3 [5,5;11,4]	90	57 [63,3]	7,2 [5,5; 9,0]	0,95	[0,65; 1,39]	0,7951
Nicht-Asien	384	193 [50,3]	6,5 [5,8; 7,8]	384	186 [48,4]	7,4 [6,5; 8,1]	1,03	[0,84; 1,26]	0,8031
Interaktion p-Wert									0,7288
Klinischer Lymphknotenstatus									
Positiv	329	172 [52,3]	6,5 [5,8; 7,9]	330	162 [49,1]	7,4 [6,5; 8,4]	1,06	[0,86; 1,32]	0,5681
Negativ	145	73 [50,3]	6,3 [5,3; 8,7]	144	81 [56,3]	6,9 [5,6; 8,0]	0,90	[0,65; 1,23]	0,5103
Interaktion p-Wert									0,3868
PD-L1-Status									
TAP >= 1%	426	217 [50,9]	6,6 [5,9; 7,9]	427	222 [52,0]	7,2 [6,5; 7,8]	0,97	[0,80; 1,17]	0,7193
TAP < 1%	48	28 [58,3]	5,9 [5,1; 7,4]	47	21 [44,7]	9,4 [5,2;26,4]	1,51	[0,86; 2,69]	0,1533
Interaktion p-Wert									0,1421
Alter bei Randomisierung (Jahre)									
<65	291	164 [56,4]	6,1 [5,6; 6,8]	265	140 [52,8]	7,1 [6,0; 7,8]	1,06	[0,85; 1,33]	0,6085
>=65	183	81 [44,3]	7,5 [6,0; 9,1]	209	103 [49,3]	7,4 [6,2; 9,0]	0,92	[0,68; 1,22]	0,5566
Interaktion p-Wert									0,4363
Geschlecht									
Männlich	326	167 [51,2]	6,5 [6,0; 8,0]	356	191 [53,7]	7,4 [6,2; 8,1]	0,95	[0,77; 1,17]	0,6062
Weiblich	148	78 [52,7]	6,0 [5,0; 7,8]	118	52 [44,1]	7,1 [6,2; 9,0]	1,20	[0,85; 1,71]	0,3050
Interaktion p-Wert									0,2521
Tumorlokalisation									
GC	324	170 [52,5]	6,6 [5,9; 7,9]	316	159 [50,3]	7,7 [6,7; 8,7]	1,09	[0,88; 1,35]	0,4386
GEJC	150	75 [50,0]	6,1 [5,6; 8,1]	158	84 [53,2]	6,6 [5,7; 7,7]	0,86	[0,63; 1,17]	0,3364
Interaktion p-Wert									0,2181

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.28 Summary of subgroup analysis of time to first EORTC QLQ-C30 Emotional functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	29 [32,2]	NE [NE; NE]	90	42 [46,7]	21,2 [8,5; NE]	0,69	[0,42; 1,10]	0,1184
Nicht-Asien	384	149 [38,8]	14,3 [10,4;19,8]	384	148 [38,5]	11,3 [9,2;16,5]	0,98	[0,78; 1,22]	0,8295
Interaktion p-Wert									0,1904
Klinischer Lymphknotenstatus									
Positiv	329	120 [36,5]	20,9 [12,1;37,5]	330	135 [40,9]	13,4 [9,2;18,1]	0,82	[0,64; 1,05]	0,1131
Negativ	145	58 [40,0]	11,7 [7,0;19,8]	144	55 [38,2]	13,0 [7,7; NE]	1,18	[0,82; 1,71]	0,3740
Interaktion p-Wert									0,1059
PD-L1-Status									
TAP >= 1%	426	156 [36,6]	16,8 [11,7;30,2]	427	179 [41,9]	11,3 [9,2;15,6]	0,84	[0,68; 1,04]	0,1053
TAP < 1%	48	22 [45,8]	14,8 [5,3; NE]	47	11 [23,4]	NE [NE; NE]	2,23	[1,11; 4,79]	0,0246*
Interaktion p-Wert									0,0086*
Alter bei Randomisierung (Jahre)									
<65	291	122 [41,9]	14,8 [10,1;23,3]	265	103 [38,9]	16,5 [11,7;37,3]	1,08	[0,83; 1,41]	0,5647
>=65	183	56 [30,6]	29,2 [12,4; NE]	209	87 [41,6]	8,8 [6,6;13,4]	0,71	[0,50; 0,99]	0,0407*
Interaktion p-Wert									0,0498*
Geschlecht									
Männlich	326	125 [38,3]	15,4 [10,3;29,2]	356	152 [42,7]	11,1 [9,2;15,6]	0,89	[0,70; 1,13]	0,3447
Weiblich	148	53 [35,8]	19,8 [10,9; NE]	118	38 [32,2]	23,3 [9,0; NE]	1,03	[0,68; 1,58]	0,8756
Interaktion p-Wert									0,5462
Tumorlokalisation									
GC	324	121 [37,3]	19,8 [10,9;37,5]	316	128 [40,5]	14,5 [10,0;24,2]	0,92	[0,71; 1,18]	0,4955
GEJC	150	57 [38,0]	14,8 [9,0;27,6]	158	62 [39,2]	11,1 [7,8;19,2]	0,91	[0,63; 1,31]	0,6100
Interaktion p-Wert									0,9744

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.29 Summary of subgroup analysis of time to first EORTC QLQ-C30 Physical Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	57 [63,3]	6,1 [5,1; 6,5]	90	65 [72,2]	5,4 [4,9; 6,3]	0,92	[0,65; 1,32]	0,6645
Nicht-Asien	384	217 [56,5]	5,8 [5,2; 6,4]	384	214 [55,7]	5,5 [5,1; 6,0]	0,93	[0,77; 1,12]	0,4520
Interaktion p-Wert									0,9763
Klinischer Lymphknotenstatus									
Positiv	329	187 [56,8]	6,0 [5,6; 6,5]	330	189 [57,3]	5,5 [5,1; 6,1]	0,92	[0,75; 1,12]	0,4079
Negativ	145	87 [60,0]	5,6 [4,4; 7,0]	144	90 [62,5]	5,4 [5,1; 6,2]	0,96	[0,71; 1,29]	0,7838
Interaktion p-Wert									0,8089
PD-L1-Status									
TAP >= 1%	426	244 [57,3]	6,0 [5,4; 6,3]	427	255 [59,7]	5,5 [5,1; 6,0]	0,91	[0,76; 1,09]	0,2978
TAP < 1%	48	30 [62,5]	5,3 [1,9; 9,2]	47	24 [51,1]	5,3 [4,4; 7,1]	1,13	[0,66; 1,95]	0,6564
Interaktion p-Wert									0,4546
Alter bei Randomisierung (Jahre)									
<65	291	178 [61,2]	5,7 [5,1; 6,3]	265	157 [59,2]	5,5 [5,1; 6,0]	0,97	[0,78; 1,21]	0,7940
>=65	183	96 [52,5]	6,1 [5,1; 6,8]	209	122 [58,4]	5,4 [4,8; 6,3]	0,87	[0,67; 1,14]	0,3193
Interaktion p-Wert									0,5405
Geschlecht									
Männlich	326	182 [55,8]	6,4 [5,9; 7,6]	356	217 [61,0]	5,6 [5,1; 6,1]	0,84	[0,69; 1,03]	0,0870
Weiblich	148	92 [62,2]	4,7 [4,2; 5,4]	118	62 [52,5]	5,3 [4,6; 6,1]	1,17	[0,85; 1,62]	0,3401
Interaktion p-Wert									0,0871
Tumorlokalisation									
GC	324	187 [57,7]	6,0 [5,1; 6,5]	316	184 [58,2]	5,5 [5,1; 6,2]	0,97	[0,79; 1,19]	0,7624
GEJC	150	87 [58,0]	5,8 [5,4; 6,5]	158	95 [60,1]	5,4 [4,7; 5,8]	0,85	[0,64; 1,14]	0,2854
Interaktion p-Wert									0,4826

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttesubpr.sas gttesubpraal 02JUL2026:12:32 khcs324

Table 3.2.30 Summary of subgroup analysis of time to first EORTC QLQ-C30 Global Health Status/QoL (hrQoL)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	54 [60,0]	5,1 [3,7; 6,2]	90	58 [64,4]	4,2 [1,2; 5,4]	0,88	[0,61; 1,28]	0,5092
Nicht-Asien	384	199 [51,8]	6,0 [5,1; 6,6]	384	201 [52,3]	5,6 [5,1; 6,4]	0,93	[0,76; 1,13]	0,4658
Interaktion p-Wert									0,8085
Klinischer Lymphknotenstatus									
Positiv	329	173 [52,6]	6,1 [5,6; 6,7]	330	178 [53,9]	5,5 [4,8; 6,0]	0,90	[0,73; 1,10]	0,3044
Negativ	145	80 [55,2]	4,8 [4,0; 5,8]	144	81 [56,3]	5,2 [4,3; 6,0]	0,98	[0,72; 1,33]	0,8953
Interaktion p-Wert									0,6407
PD-L1-Status									
TAP >= 1%	426	227 [53,3]	5,9 [5,1; 6,5]	427	234 [54,8]	5,4 [4,8; 5,9]	0,92	[0,77; 1,11]	0,3988
TAP < 1%	48	26 [54,2]	5,1 [1,9;19,3]	47	25 [53,2]	5,2 [4,2; 7,8]	0,88	[0,51; 1,53]	0,6431
Interaktion p-Wert									0,8622
Alter bei Randomisierung (Jahre)									
<65	291	164 [56,4]	5,8 [4,9; 6,5]	265	153 [57,7]	5,4 [4,7; 5,9]	0,91	[0,73; 1,13]	0,3854
>=65	183	89 [48,6]	5,8 [5,0; 6,7]	209	106 [50,7]	5,6 [4,4; 7,0]	0,93	[0,70; 1,24]	0,6283
Interaktion p-Wert									0,8775
Geschlecht									
Männlich	326	171 [52,5]	6,0 [5,4; 6,6]	356	204 [57,3]	5,6 [4,8; 6,0]	0,88	[0,72; 1,07]	0,2066
Weiblich	148	82 [55,4]	5,0 [4,1; 6,2]	118	55 [46,6]	5,2 [2,0; 7,0]	1,03	[0,74; 1,46]	0,8553
Interaktion p-Wert									0,4215
Tumorlokalisation									
GC	324	179 [55,2]	5,5 [4,7; 6,2]	316	174 [55,1]	5,5 [4,4; 6,2]	0,97	[0,79; 1,20]	0,8082
GEJC	150	74 [49,3]	6,1 [5,4; 7,7]	158	85 [53,8]	5,3 [4,8; 6,0]	0,81	[0,59; 1,10]	0,1777
Interaktion p-Wert									0,3249

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.31 Summary of subgroup analysis of time to first EORTC QLQ-C30 Role Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	59 [65,6]	5,5 [3,6; 6,6]	90	68 [75,6]	4,1 [1,2; 5,2]	0,75	[0,53; 1,06]	0,1014
Nicht-Asien	384	227 [59,1]	5,1 [4,6; 5,6]	384	224 [58,3]	4,7 [4,2; 5,2]	0,95	[0,79; 1,14]	0,5975
Interaktion p-Wert									0,2302
Klinischer Lymphknotenstatus									
Positiv	329	193 [58,7]	5,7 [4,9; 6,0]	330	203 [61,5]	4,6 [4,2; 5,1]	0,81	[0,67; 0,99]	0,0369*
Negativ	145	93 [64,1]	4,3 [1,6; 4,9]	144	89 [61,8]	4,4 [1,7; 5,6]	1,18	[0,88; 1,58]	0,2633
Interaktion p-Wert									0,0361*
PD-L1-Status									
TAP >= 1%	426	255 [59,9]	5,1 [4,7; 5,7]	427	263 [61,6]	4,6 [4,1; 5,1]	0,89	[0,74; 1,05]	0,1651
TAP < 1%	48	31 [64,6]	4,2 [1,3; 5,8]	47	29 [61,7]	4,4 [1,3; 6,7]	1,07	[0,64; 1,78]	0,7902
Interaktion p-Wert									0,4844
Alter bei Randomisierung (Jahre)									
<65	291	184 [63,2]	5,1 [4,6; 5,7]	265	169 [63,8]	4,6 [3,9; 5,1]	0,90	[0,73; 1,11]	0,3234
>=65	183	102 [55,7]	4,9 [3,5; 5,9]	209	123 [58,9]	4,7 [3,5; 5,6]	0,90	[0,69; 1,18]	0,4523
Interaktion p-Wert									0,9774
Geschlecht									
Männlich	326	189 [58,0]	5,7 [4,9; 6,0]	356	226 [63,5]	4,7 [4,1; 5,2]	0,83	[0,69; 1,01]	0,0661
Weiblich	148	97 [65,5]	4,5 [1,3; 4,9]	118	66 [55,9]	4,4 [1,3; 5,2]	1,06	[0,78; 1,46]	0,7077
Interaktion p-Wert									0,1978
Tumorlokalisation									
GC	324	195 [60,2]	5,1 [4,6; 6,0]	316	192 [60,8]	4,9 [4,4; 5,5]	0,94	[0,77; 1,15]	0,5398
GEJC	150	91 [60,7]	5,1 [3,9; 5,6]	158	100 [63,3]	4,1 [1,2; 4,8]	0,83	[0,62; 1,10]	0,1981
Interaktion p-Wert									0,4831

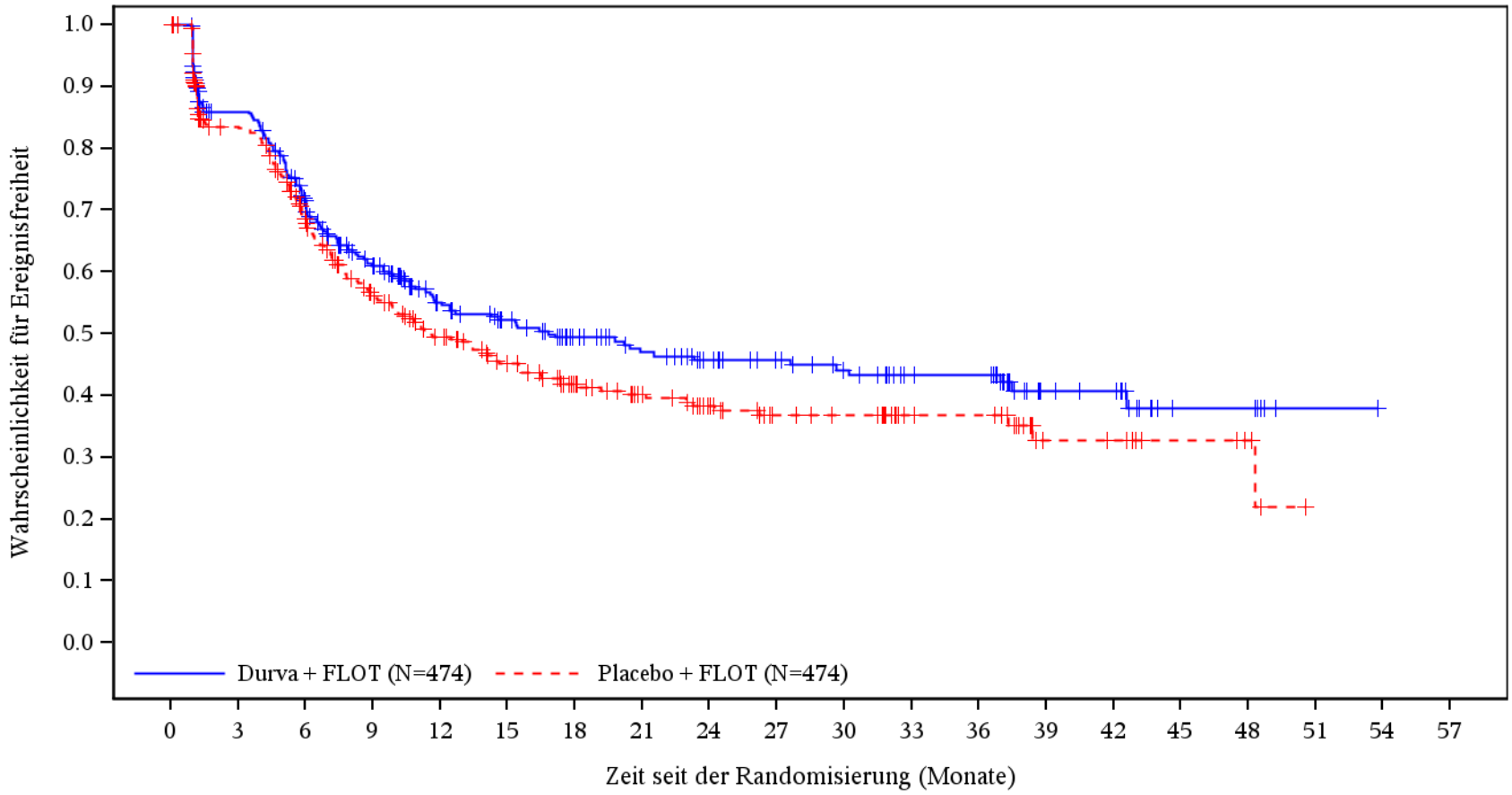
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.2.32 Summary of subgroup analysis of time to first EORTC QLQ-C30 Social Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	58 [64,4]	4,9 [3,7; 7,0]	90	52 [57,8]	6,3 [4,6;11,8]	1,24	[0,85; 1,80]	0,2650
Nicht-Asien	384	213 [55,5]	5,8 [5,1; 6,3]	384	210 [54,7]	5,5 [5,1; 6,1]	0,97	[0,80; 1,18]	0,7622
Interaktion p-Wert									0,2583
Klinischer Lymphknotenstatus									
Positiv	329	187 [56,8]	6,0 [5,4; 6,6]	330	181 [54,8]	5,5 [5,1; 6,3]	0,96	[0,79; 1,18]	0,7225
Negativ	145	84 [57,9]	4,8 [3,6; 5,8]	144	81 [56,3]	6,0 [4,7; 6,7]	1,20	[0,89; 1,63]	0,2387
Interaktion p-Wert									0,2394
PD-L1-Status									
TAP >= 1%	426	241 [56,6]	5,7 [4,9; 6,2]	427	240 [56,2]	5,6 [5,1; 6,3]	0,99	[0,83; 1,19]	0,9378
TAP < 1%	48	30 [62,5]	5,9 [3,9; 6,6]	47	22 [46,8]	6,2 [4,9; NE]	1,37	[0,79; 2,40]	0,2588
Interaktion p-Wert									0,2726
Alter bei Randomisierung (Jahre)									
<65	291	179 [61,5]	5,6 [4,8; 6,2]	265	153 [57,7]	5,9 [5,1; 6,7]	1,05	[0,85; 1,30]	0,6557
>=65	183	92 [50,3]	5,8 [4,9; 7,3]	209	109 [52,2]	5,3 [4,7; 6,3]	0,97	[0,74; 1,29]	0,8563
Interaktion p-Wert									0,6769
Geschlecht									
Männlich	326	181 [55,5]	6,0 [5,6; 6,6]	356	205 [57,6]	5,6 [5,2; 6,5]	0,96	[0,78; 1,17]	0,6787
Weiblich	148	90 [60,8]	4,8 [4,0; 5,8]	118	57 [48,3]	5,1 [4,5; 7,5]	1,18	[0,85; 1,65]	0,3223
Interaktion p-Wert									0,2887
Tumorlokalisation									
GC	324	178 [54,9]	6,0 [4,9; 6,8]	316	179 [56,6]	5,5 [5,0; 6,4]	0,95	[0,77; 1,17]	0,6284
GEJC	150	93 [62,0]	5,6 [4,1; 6,0]	158	83 [52,5]	5,6 [4,8; 6,5]	1,21	[0,90; 1,63]	0,2106
Interaktion p-Wert									0,1927

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.2.33 Subgroup Analysis: Kaplan-Meier plot of EORTC QLQ-C30 Emotional functioning for PD-L1 status: TAP >= 1% (hrQoL)
Full Analysis Set, DCO 01SEP2025



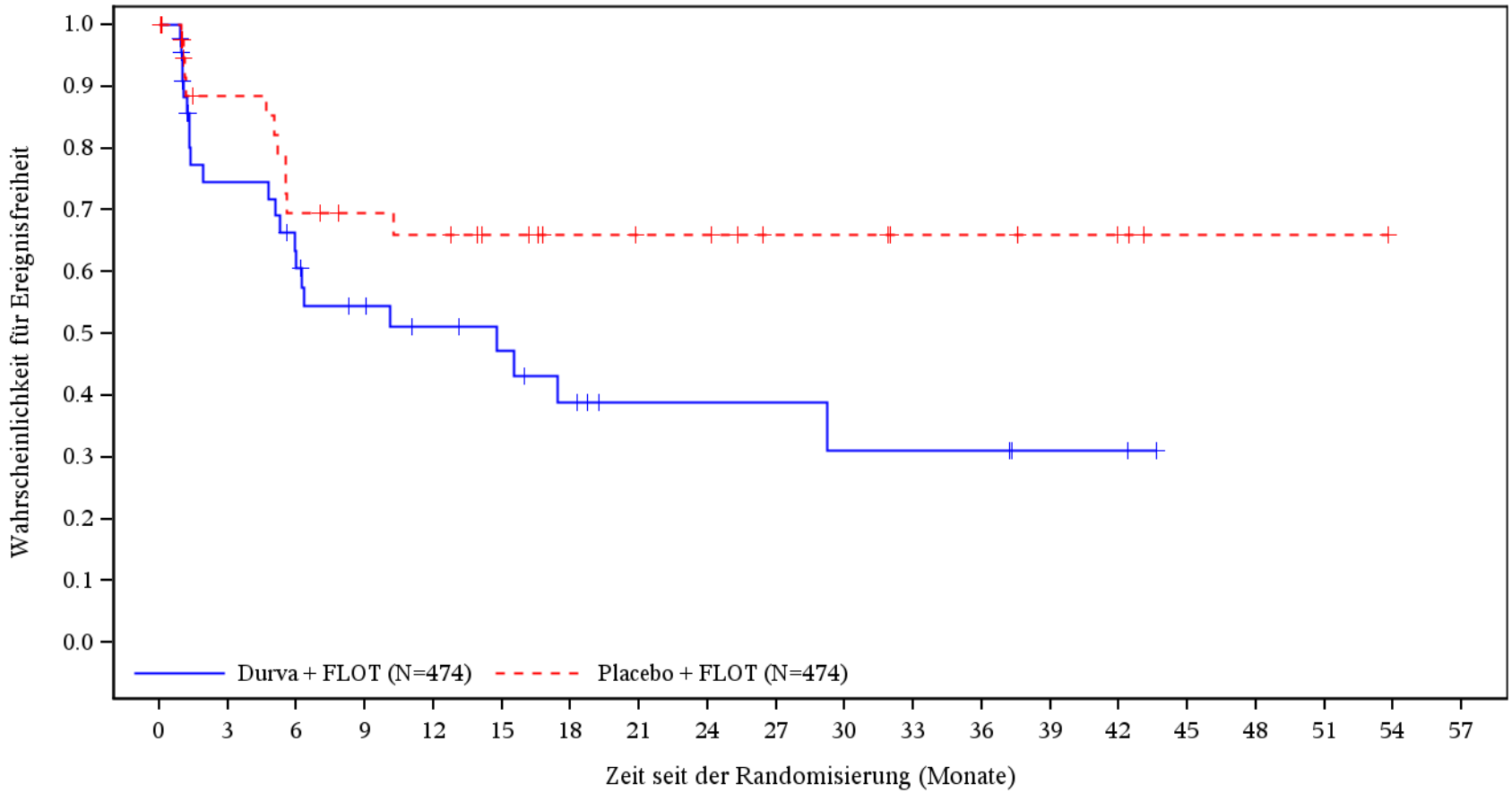
Anzahl im Risiko (Anzahl der zensierten Fälle)

426	253	201	159	124	109	91	78	67	60	53	44	43	21	19	7	7	1	0	0
(0)	(126)	(136)	(149)	(170)	(179)	(191)	(200)	(209)	(216)	(221)	(229)	(230)	(250)	(252)	(263)	(263)	(269)	(270)	(270)
427	251	195	148	120	100	80	64	54	42	38	27	26	12	11	6	4	0	0	0
(0)	(120)	(132)	(146)	(156)	(166)	(179)	(192)	(199)	(209)	(213)	(224)	(225)	(237)	(238)	(243)	(245)	(248)	(248)	(248)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.2.34 Subgroup Analysis: Kaplan-Meier plot of EORTC QLQ-C30 Emotional functioning for PD-L1 status: TAP < 1% (hrQoL)
Full Analysis Set, DCO 01SEP2025

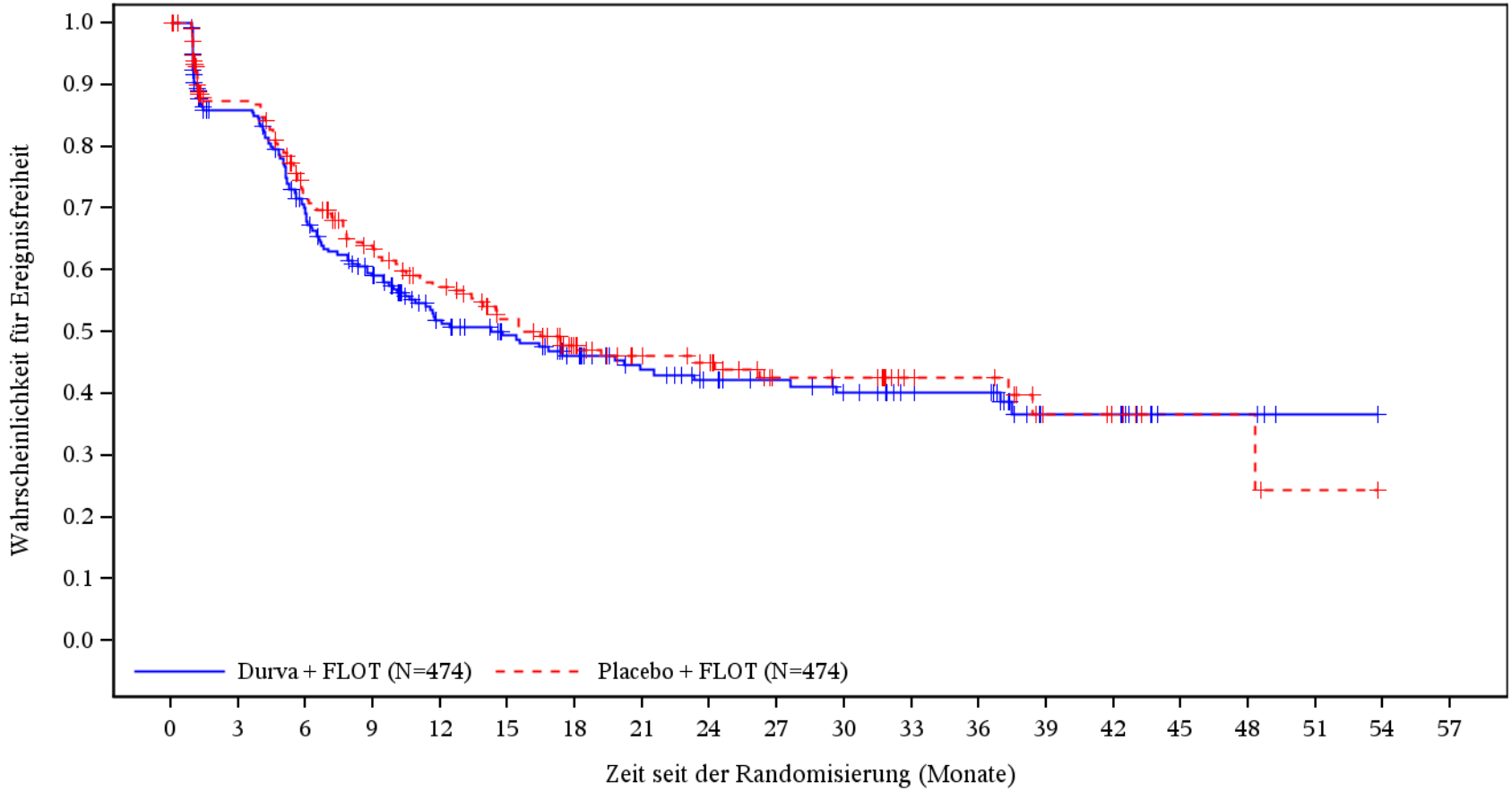


Anzahl im Risiko (Anzahl der zensierten Fälle)

48	27	21	17	14	12	9	5	5	5	4	4	4	2	2	0	0	0	0	0
(0)	(11)	(12)	(14)	(16)	(17)	(18)	(22)	(22)	(22)	(22)	(22)	(22)	(24)	(24)	(26)	(26)	(26)	(26)	(26)
47	28	22	20	19	16	13	12	12	8	8	6	6	5	4	1	1	1	0	0
(0)	(15)	(15)	(17)	(17)	(20)	(23)	(24)	(24)	(28)	(28)	(30)	(30)	(31)	(32)	(35)	(35)	(35)	(36)	(36)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.2.35 Subgroup Analysis: Kaplan-Meier plot of EORTC QLQ-C30 Emotional functioning for Age at randomisation (years): <65 (hrQoL)
Full Analysis Set, DCO 01SEP2025



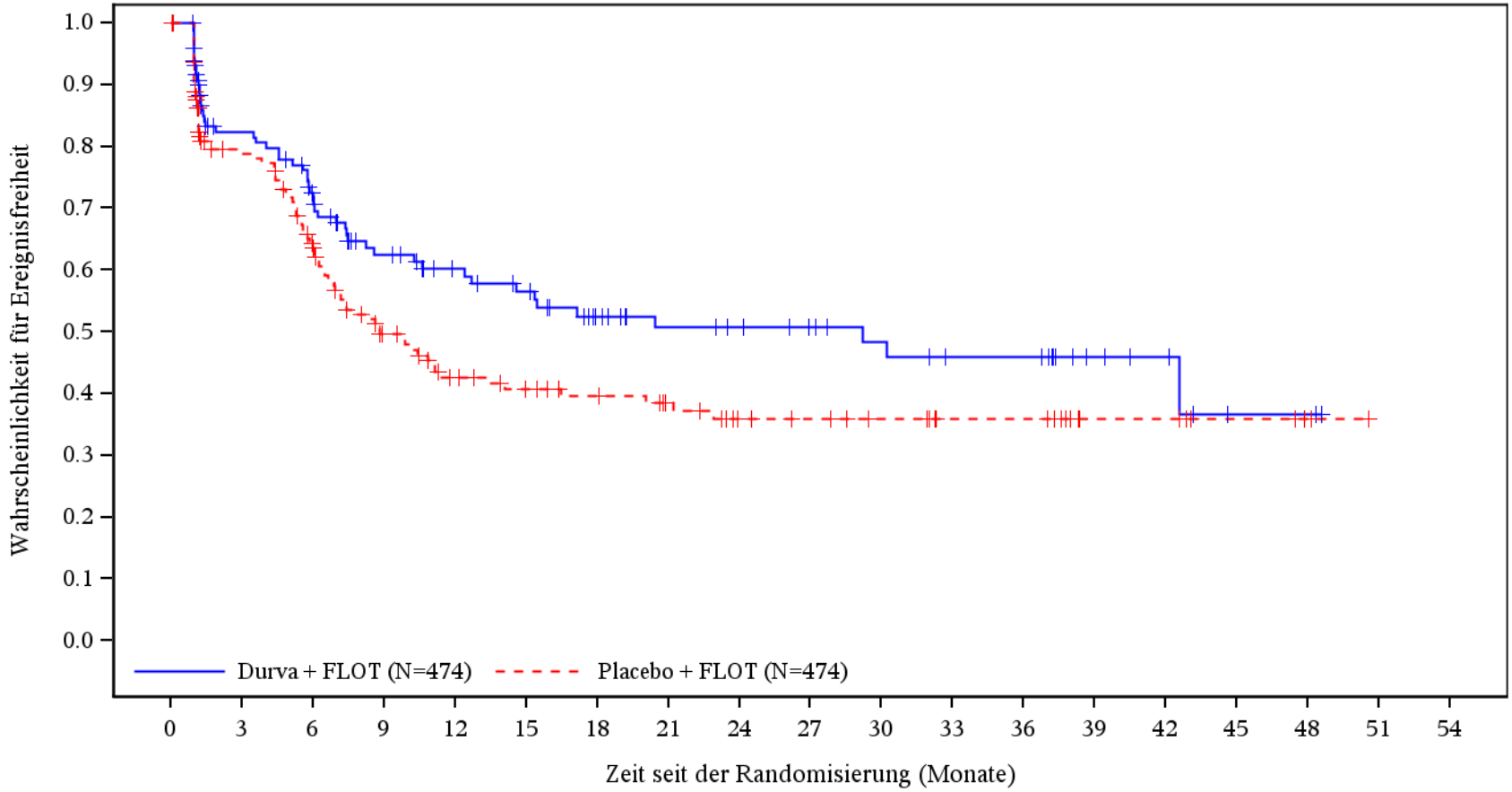
Anzahl im Risiko (Anzahl der zensierten Fälle)

291	187	146	118	89	77	66	55	46	42	37	31	30	15	15	5	5	1	0	0
(0)	(70)	(75)	(82)	(98)	(106)	(112)	(120)	(127)	(131)	(134)	(140)	(141)	(154)	(154)	(164)	(164)	(168)	(169)	(169)
265	167	131	109	93	76	57	45	42	28	27	18	17	9	7	3	3	1	0	0
(0)	(71)	(78)	(86)	(91)	(100)	(113)	(123)	(125)	(137)	(138)	(147)	(148)	(154)	(156)	(160)	(160)	(161)	(162)	(162)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.2.36 Subgroup Analysis: Kaplan-Meier plot of EORTC QLQ-C30 Emotional functioning for Age at randomisation (years): >=65 (hrQoL)
Full Analysis Set, DCO 01SEP2025

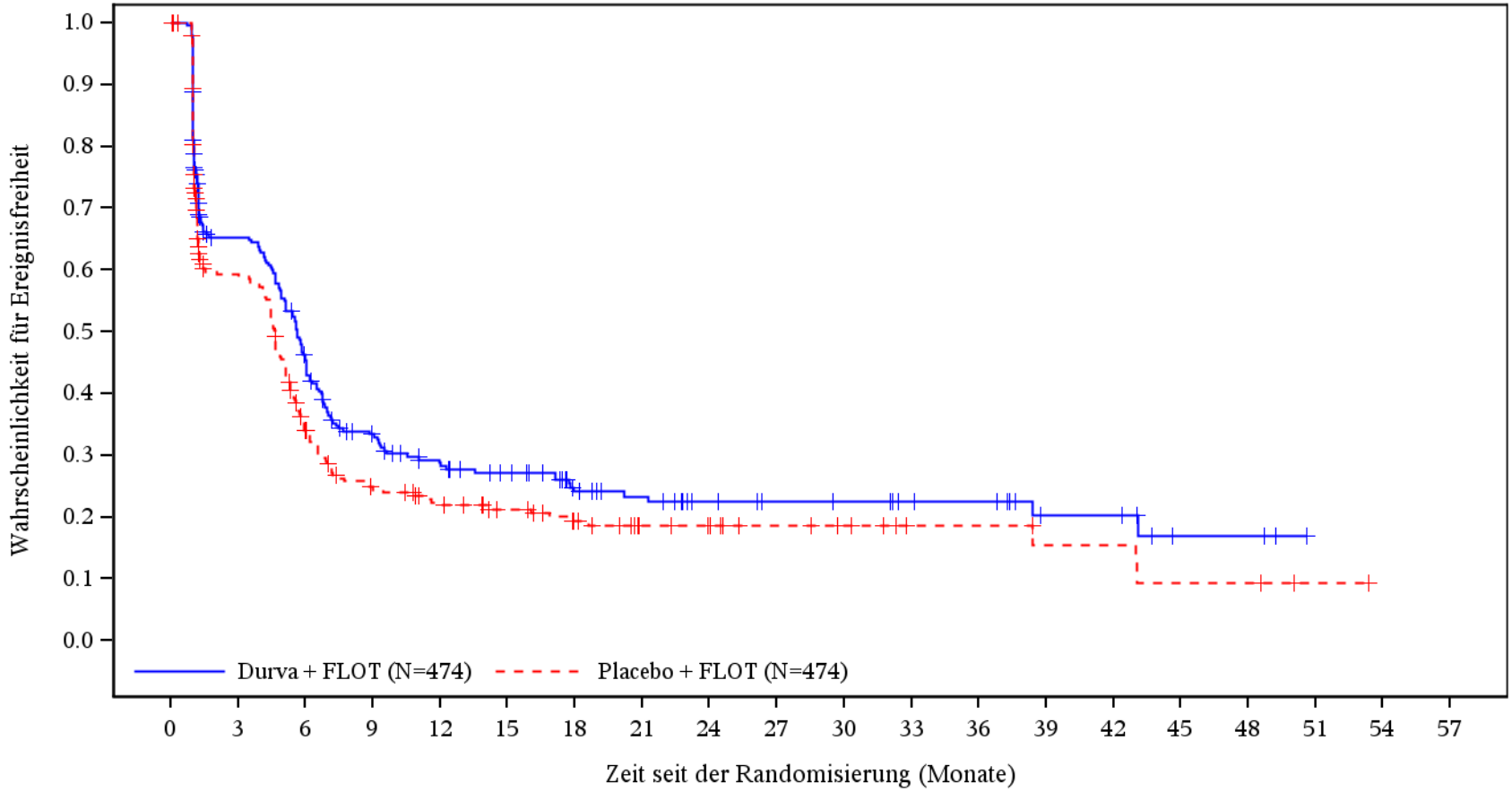


Anzahl im Risiko (Anzahl der zensierten Fälle)

183	93	76	58	49	44	34	28	26	23	20	17	17	8	6	2	2	0	0
(0)	(67)	(73)	(81)	(88)	(90)	(97)	(102)	(104)	(107)	(109)	(111)	(111)	(120)	(122)	(125)	(125)	(127)	(127)
209	112	86	59	46	40	36	31	24	22	19	15	15	8	8	4	2	0	0
(0)	(64)	(69)	(77)	(82)	(86)	(89)	(93)	(98)	(100)	(103)	(107)	(107)	(114)	(114)	(118)	(120)	(122)	(122)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.2.37 Subgroup Analysis: Kaplan-Meier plot of EORTC QLQ-C30 Role Functioning for Clinical lymph node status: Positive (hrQoL)
Full Analysis Set, DCO 01SEP2025

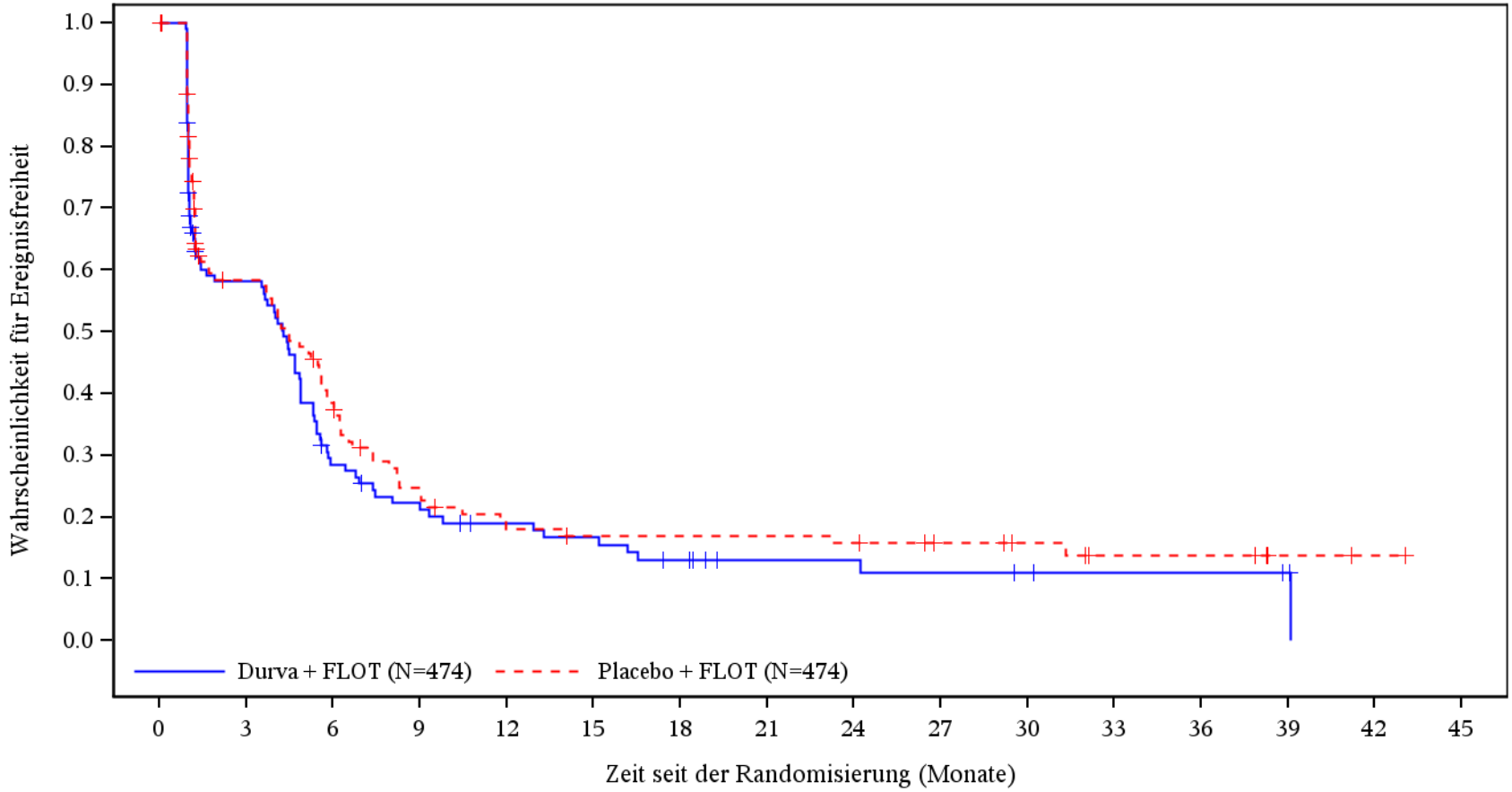


Anzahl im Risiko (Anzahl der zensierten Fälle)

329	158	108	73	58	50	36	31	22	19	18	15	14	8	8	3	3	0	0	0
(0)	(76)	(78)	(85)	(90)	(95)	(104)	(108)	(116)	(119)	(120)	(123)	(124)	(129)	(129)	(133)	(133)	(136)	(136)	(136)
330	143	77	52	42	35	27	19	17	13	11	7	7	5	5	3	3	1	0	0
(0)	(78)	(84)	(89)	(93)	(99)	(104)	(111)	(113)	(117)	(119)	(123)	(123)	(124)	(124)	(124)	(124)	(126)	(127)	(127)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.2.38 Subgroup Analysis: Kaplan-Meier plot of EORTC QLQ-C30 Role Functioning for Clinical lymph node status: Negative (hrQoL)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

145	59	28	21	16	14	10	6	6	5	4	3	3	2	0	0
(0)	(39)	(40)	(41)	(43)	(43)	(44)	(48)	(48)	(48)	(49)	(50)	(50)	(51)	(52)	(52)
144	59	38	23	16	14	14	14	13	10	8	5	5	2	1	0
(0)	(38)	(39)	(41)	(42)	(43)	(43)	(43)	(43)	(46)	(48)	(50)	(50)	(53)	(54)	(55)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

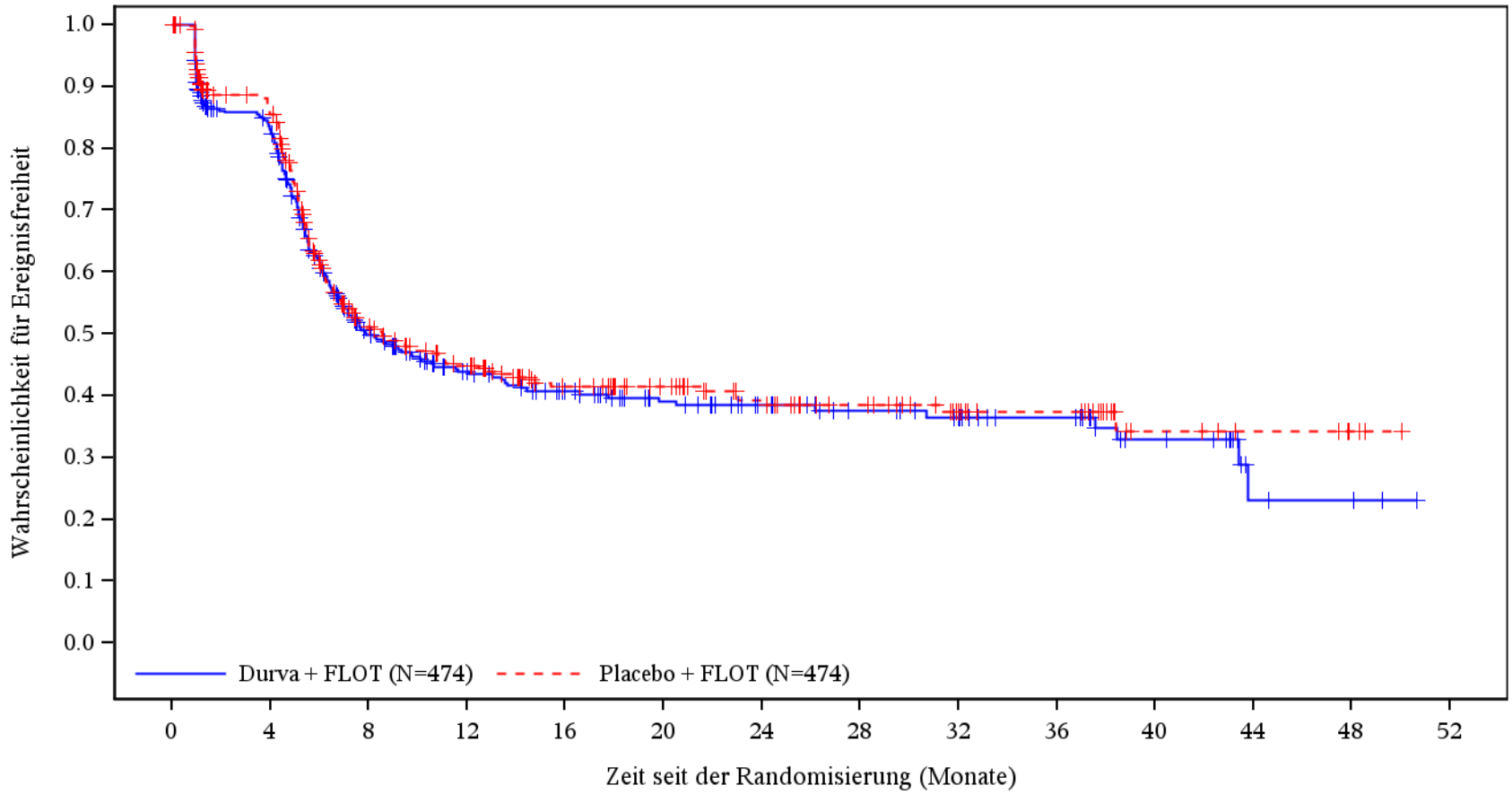
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Table 3.3.1 Summary of analysis of time to deterioration in EORTC QLQ-IL38 (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
EORTC IL38 Schwierigkeiten beim Schlucken	474	195 [41,1]	7,9 [6,9;11,5]	474	182 [38,4]	8,6 [6,8;12,9]	1,09	[0,89; 1,34]	0,3885
EORTC IL38 Gewichtsverlust	474	255 [53,8]	5,6 [5,2; 6,1]	474	248 [52,3]	5,5 [5,2; 6,0]	1,03	[0,86; 1,23]	0,7633

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 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 based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic region, clinical lymph node status and PD-L1 status
Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttemainpr.sas gttemainprcaa 29JUN2026:08:49 khcs324

Figure 3.3.2 Kaplan-Meier plot of EORTC IL38 Difficulty Swallowing (Morbidity)
Full Analysis Set, DCO 01SEP2025



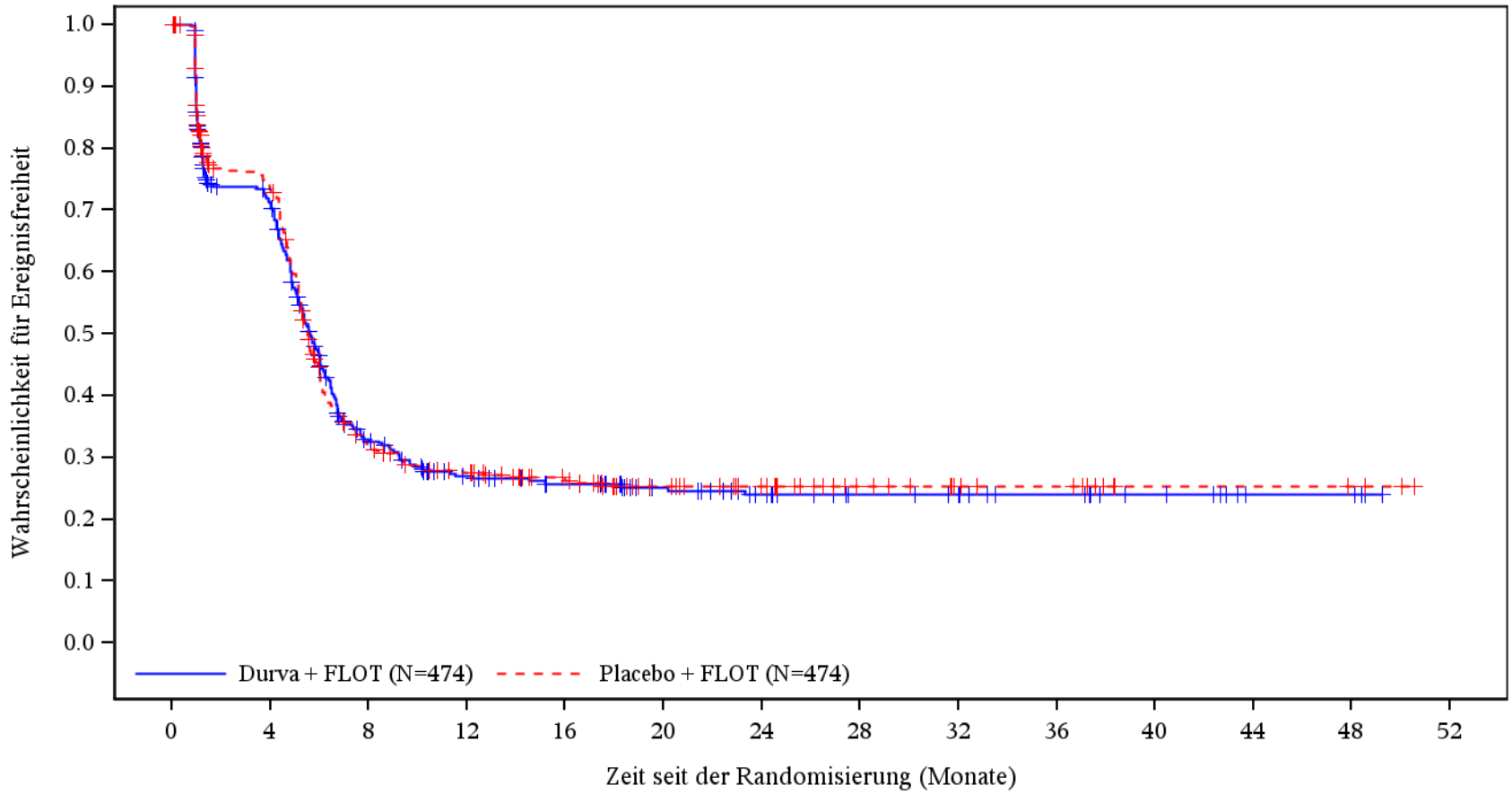
Anzahl im Risiko (Anzahl der zensierten Fälle)

474	266	136	103	82	62	48	39	34	27	16	4	3	0
(0)	(146)	(175)	(193)	(207)	(224)	(237)	(245)	(249)	(256)	(265)	(275)	(276)	(279)
474	267	135	108	81	64	50	40	29	24	9	6	3	0
(0)	(155)	(186)	(197)	(217)	(234)	(244)	(254)	(264)	(269)	(283)	(286)	(289)	(292)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.3.3 Kaplan-Meier plot of EORTC IL38 Weight Loss (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

474	240	98	69	58	43	33	24	22	16	11	4	4	0
(0)	(126)	(144)	(156)	(164)	(178)	(186)	(195)	(197)	(203)	(208)	(215)	(215)	(219)
474	241	96	76	60	44	33	22	16	14	5	5	4	0
(0)	(135)	(148)	(155)	(168)	(182)	(193)	(204)	(210)	(212)	(221)	(221)	(222)	(226)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.3.4 Summary of subgroup analysis of time to first EORTC IL38 Difficulty Swallowing (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	46 [51,1]	6,3 [5,3; 7,7]	90	45 [50,0]	6,1 [5,2;31,2]	1,17	[0,77; 1,76]	0,4635
Nicht-Asien	384	149 [38,8]	9,7 [7,1;13,6]	384	137 [35,7]	8,9 [7,3;13,4]	1,05	[0,83; 1,32]	0,7071
Interaktion p-Wert									0,6501
Klinischer Lymphknotenstatus									
Positiv	329	122 [37,1]	11,5 [7,9;37,6]	330	124 [37,6]	8,9 [6,7;14,8]	0,93	[0,72; 1,19]	0,5438
Negativ	145	73 [50,3]	5,6 [5,1; 6,9]	144	58 [40,3]	7,6 [6,2;15,4]	1,45	[1,03; 2,05]	0,0339*
Interaktion p-Wert									0,0383*
PD-L1-Status									
TAP >= 1%	426	172 [40,4]	8,3 [6,9;13,0]	427	164 [38,4]	8,6 [6,9;12,5]	1,05	[0,84; 1,30]	0,6795
TAP < 1%	48	23 [47,9]	6,3 [4,7; NE]	47	18 [38,3]	8,6 [4,9; NE]	1,26	[0,68; 2,36]	0,4671
Interaktion p-Wert									0,5818
Alter bei Randomisierung (Jahre)									
<65	291	127 [43,6]	8,3 [6,5;13,6]	265	110 [41,5]	7,4 [6,3;13,4]	1,02	[0,79; 1,31]	0,9032
>=65	183	68 [37,2]	7,4 [6,4;13,0]	209	72 [34,4]	10,8 [6,7;24,0]	1,15	[0,82; 1,60]	0,4087
Interaktion p-Wert									0,5614
Geschlecht									
Männlich	326	129 [39,6]	8,6 [6,8;13,6]	356	146 [41,0]	7,6 [6,4;11,1]	0,94	[0,74; 1,19]	0,6170
Weiblich	148	66 [44,6]	7,9 [5,8;13,6]	118	36 [30,5]	13,4 [6,5; NE]	1,52	[1,02; 2,31]	0,0389*
Interaktion p-Wert									0,0426*
Tumorlokalisation									
GC	324	156 [48,1]	6,5 [5,6; 7,7]	316	139 [44,0]	7,1 [6,1; 9,8]	1,13	[0,90; 1,42]	0,2873
GEJC	150	39 [26,0]	NE [NE; NE]	158	43 [27,2]	NE [NE; NE]	0,88	[0,57; 1,36]	0,5704
Interaktion p-Wert									0,3181

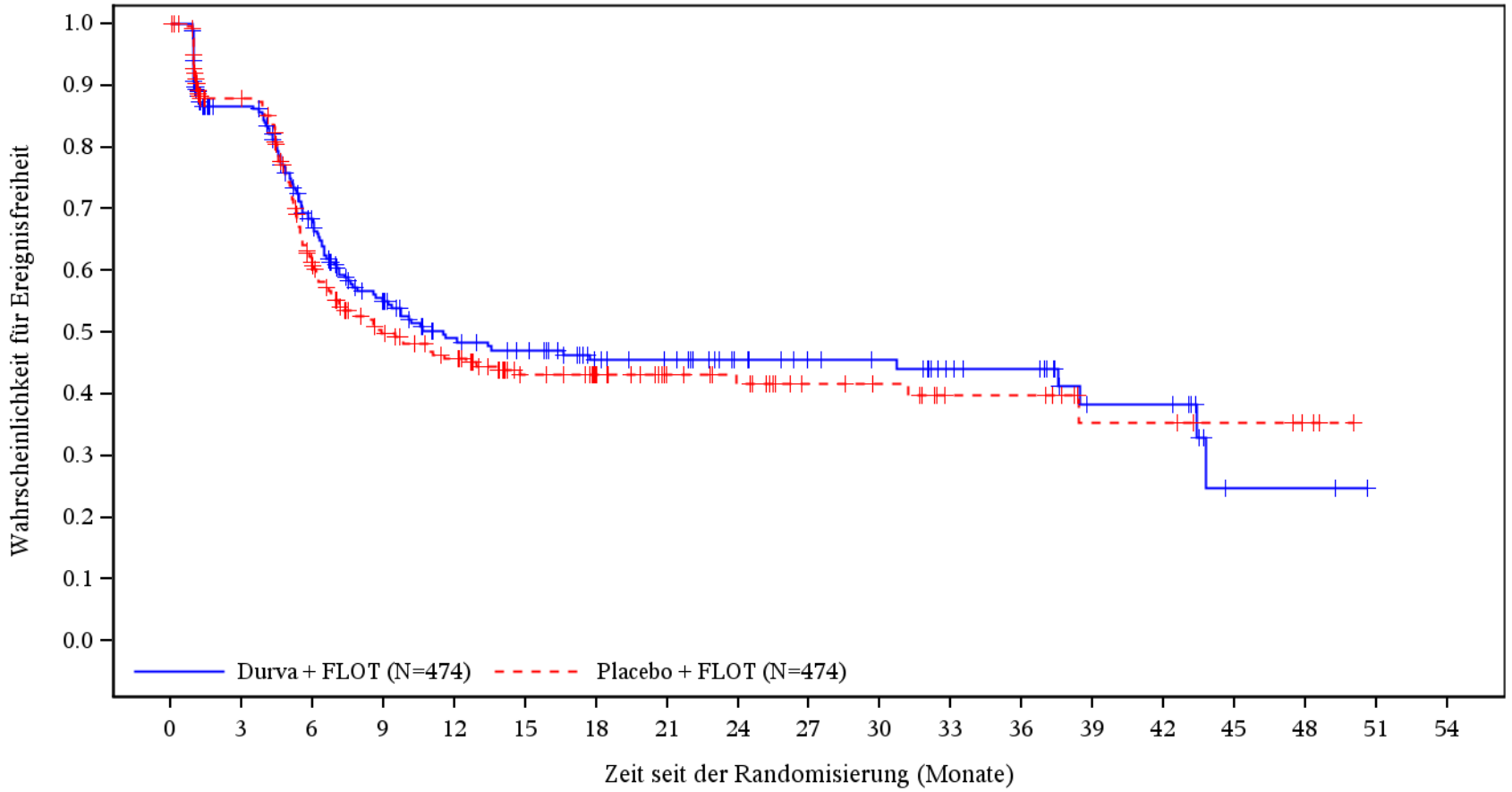
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.3.5 Summary of subgroup analysis of time to first EORTC IL38 Weight Loss (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	64 [71,1]	4,5 [4,0; 5,7]	90	61 [67,8]	5,1 [4,6; 5,8]	1,16	[0,81; 1,65]	0,4158
Nicht-Asien	384	191 [49,7]	5,9 [5,4; 6,5]	384	187 [48,7]	5,6 [5,3; 6,1]	0,98	[0,80; 1,20]	0,8689
Interaktion p-Wert									0,4308
Klinischer Lymphknotenstatus									
Positiv	329	173 [52,6]	6,0 [5,4; 6,5]	330	170 [51,5]	5,6 [5,2; 6,1]	0,94	[0,76; 1,16]	0,5400
Negativ	145	82 [56,6]	4,9 [4,0; 5,5]	144	78 [54,2]	5,3 [4,9; 6,0]	1,27	[0,93; 1,73]	0,1380
Interaktion p-Wert									0,1163
PD-L1-Status									
TAP >= 1%	426	229 [53,8]	5,6 [5,0; 6,1]	427	224 [52,5]	5,5 [5,2; 6,0]	1,03	[0,85; 1,23]	0,7777
TAP < 1%	48	26 [54,2]	6,0 [5,1; 9,0]	47	24 [51,1]	5,6 [4,5; 6,2]	0,93	[0,54; 1,64]	0,8119
Interaktion p-Wert									0,7530
Alter bei Randomisierung (Jahre)									
<65	291	170 [58,4]	5,3 [4,9; 5,9]	265	143 [54,0]	5,7 [5,1; 6,2]	1,11	[0,89; 1,39]	0,3462
>=65	183	85 [46,4]	6,4 [5,4; 6,9]	209	105 [50,2]	5,4 [4,9; 5,8]	0,87	[0,65; 1,16]	0,3471
Interaktion p-Wert									0,1867
Geschlecht									
Männlich	326	172 [52,8]	5,9 [5,3; 6,5]	356	196 [55,1]	5,5 [5,1; 5,8]	0,94	[0,77; 1,16]	0,5688
Weiblich	148	83 [56,1]	5,2 [4,7; 6,0]	118	52 [44,1]	6,0 [5,1; 6,8]	1,25	[0,89; 1,78]	0,2047
Interaktion p-Wert									0,1673
Tumorlokalisation									
GC	324	181 [55,9]	5,1 [4,8; 5,4]	316	167 [52,8]	5,3 [5,1; 6,0]	1,11	[0,90; 1,38]	0,3130
GEJC	150	74 [49,3]	6,7 [6,0; 8,4]	158	81 [51,3]	5,7 [5,3; 6,2]	0,84	[0,61; 1,15]	0,2790
Interaktion p-Wert									0,1442

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.3.6 Subgroup Analysis: Kaplan-Meier plot of EORTC IL38 Difficulty Swallowing for Clinical lymph node status: Positive (Morbidity)
Full Analysis Set, DCO 01SEP2025

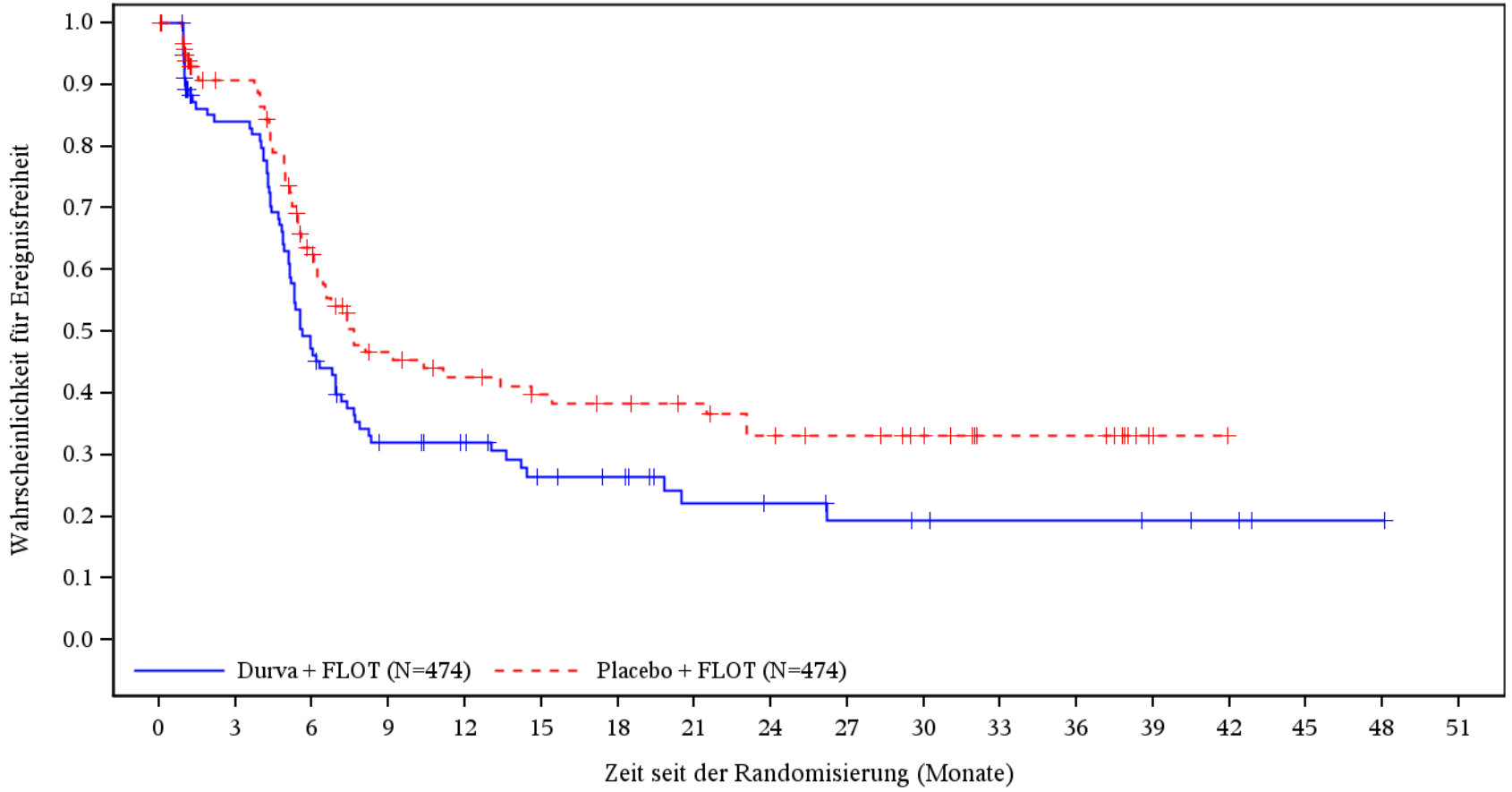


Anzahl im Risiko (Anzahl der zensierten Fälle)

329	196	140	98	78	70	55	48	39	34	31	24	22	12	12	2	2	0	0
(0)	(97)	(113)	(129)	(139)	(144)	(157)	(164)	(173)	(178)	(181)	(187)	(189)	(197)	(197)	(205)	(205)	(207)	(207)
330	193	123	90	77	56	46	35	31	23	21	15	15	8	8	6	3	0	0
(0)	(105)	(119)	(130)	(136)	(153)	(163)	(174)	(177)	(185)	(187)	(192)	(192)	(198)	(198)	(200)	(203)	(206)	(206)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.3.7 Subgroup Analysis: Kaplan-Meier plot of EORTC IL38 Difficulty Swallowing for Clinical lymph node status: Negative (Morbidity)
Full Analysis Set, DCO 01SEP2025

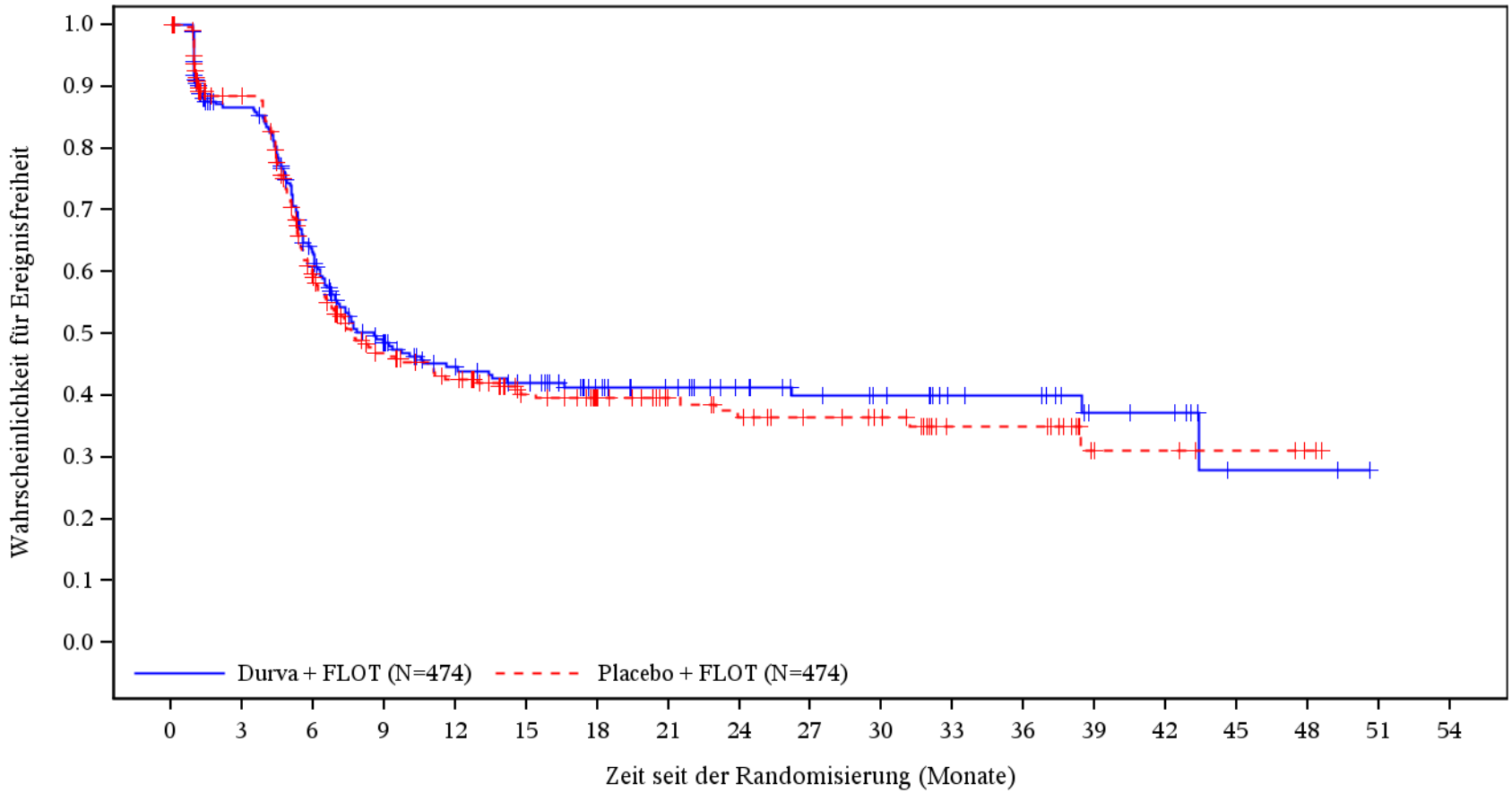


Anzahl im Risiko (Anzahl der zensierten Fälle)

145	80	45	28	25	18	16	10	9	7	6	5	5	4	3	1	1	0
(0)	(48)	(48)	(51)	(54)	(57)	(59)	(63)	(64)	(65)	(66)	(67)	(67)	(68)	(69)	(71)	(71)	(72)
144	85	55	36	31	27	25	23	19	17	14	9	9	1	0	0	0	0
(0)	(49)	(54)	(59)	(61)	(63)	(64)	(66)	(67)	(69)	(72)	(77)	(77)	(85)	(86)	(86)	(86)	(86)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.3.8 Subgroup Analysis: Kaplan-Meier plot of EORTC IL38 Difficulty Swallowing for Sex: Male (Morbidity)
Full Analysis Set, DCO 01SEP2025

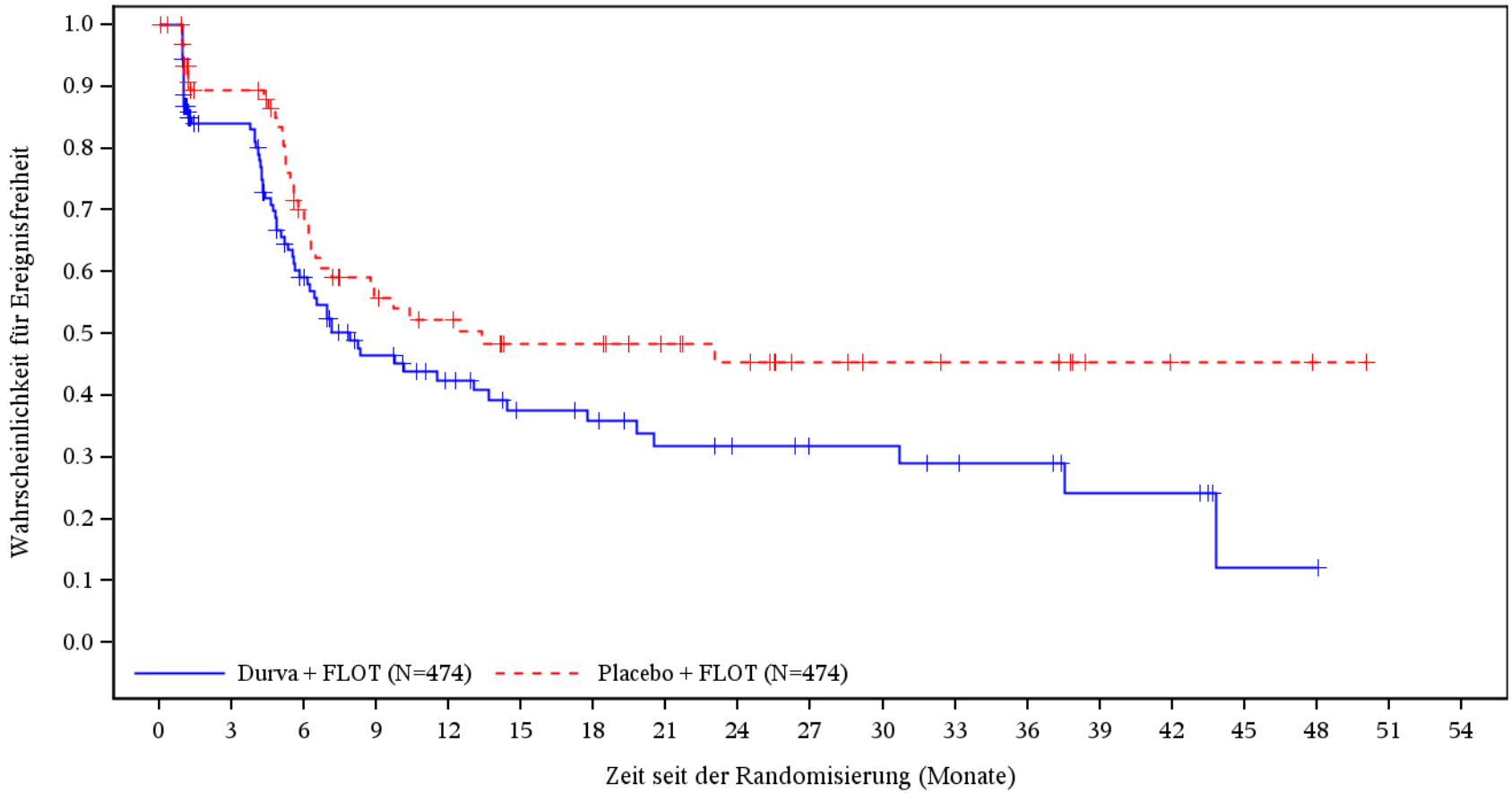


Anzahl im Risiko (Anzahl der zensierten Fälle)

326	192	132	89	74	66	51	42	35	30	26	20	19	11	10	2	2	0	0
(0)	(100)	(109)	(123)	(131)	(135)	(149)	(158)	(165)	(169)	(173)	(179)	(180)	(187)	(188)	(195)	(195)	(197)	(197)
356	215	133	93	80	61	49	40	35	30	27	17	17	6	6	4	2	0	0
(0)	(108)	(122)	(135)	(140)	(155)	(166)	(175)	(177)	(182)	(185)	(194)	(194)	(204)	(204)	(206)	(208)	(210)	(210)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.3.9 Subgroup Analysis: Kaplan-Meier plot of EORTC IL38 Difficulty Swallowing for Sex: Female (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

148	84	53	37	29	22	20	16	13	11	11	9	8	5	5	1	1	0	0
(0)	(45)	(52)	(57)	(62)	(66)	(67)	(69)	(72)	(74)	(74)	(75)	(76)	(78)	(78)	(81)	(81)	(82)	(82)
118	63	45	33	28	22	22	18	15	10	8	7	7	3	2	2	1	0	0
(0)	(46)	(51)	(54)	(57)	(61)	(61)	(65)	(67)	(72)	(74)	(75)	(75)	(79)	(80)	(80)	(81)	(82)	(82)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

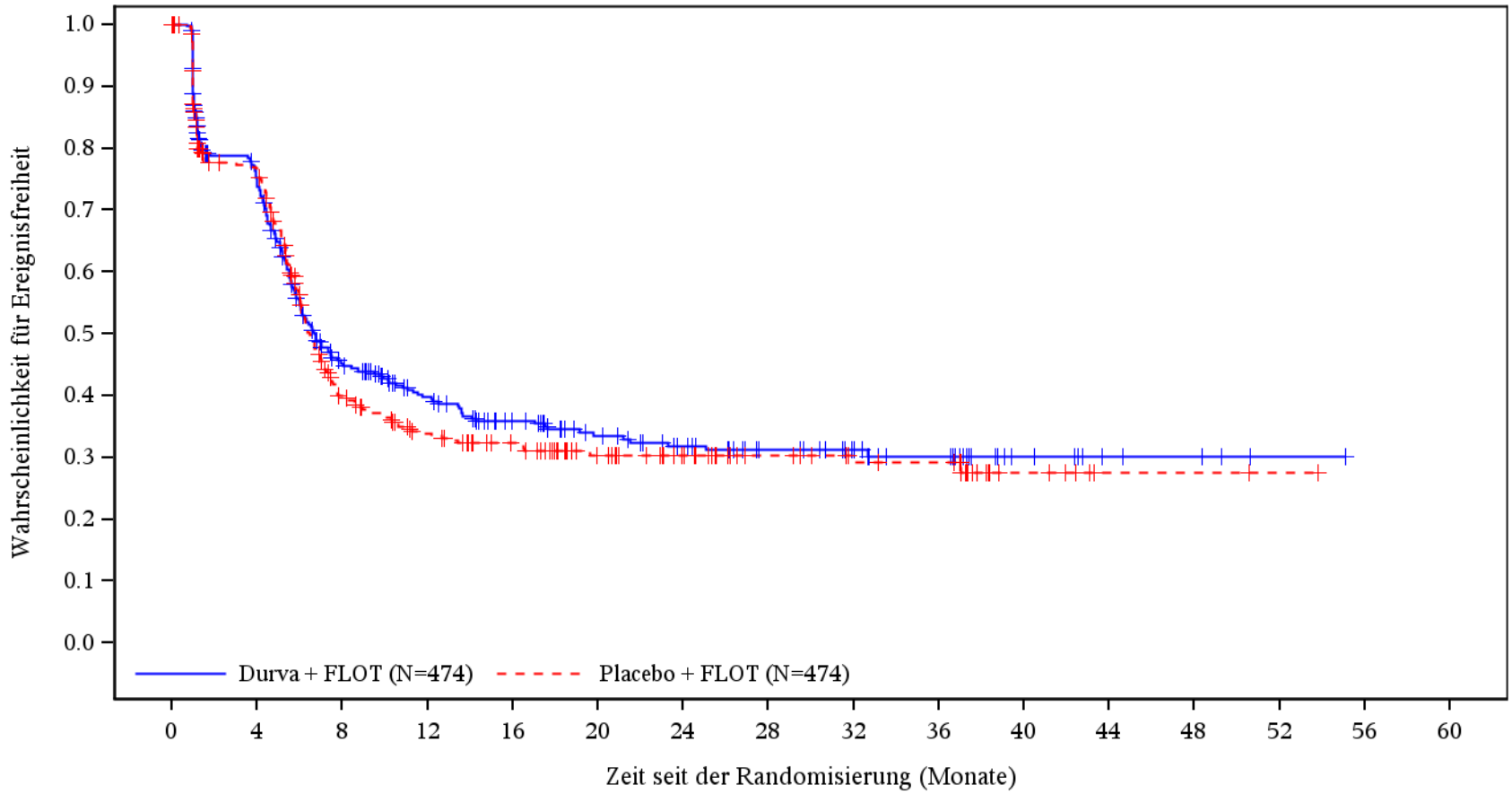
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Table 3.4.1 Summary of analysis of time to deterioration in EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
EORTC STO22 Angst	474	226 [47,7]	6,7 [6,0; 8,4]	474	230 [48,5]	6,5 [6,0; 7,1]	0,92	[0,77; 1,11]	0,4088
EORTC STO22 Körperbild	474	252 [53,2]	5,7 [5,1; 6,3]	474	228 [48,1]	6,1 [5,6; 7,7]	1,20	[0,9995; 1,43]	0,0624
EORTC STO22 Mundtrockenheit	474	265 [55,9]	5,1 [4,6; 5,6]	474	244 [51,5]	5,9 [5,2; 6,3]	1,21	[1,01; 1,44]	0,0393*
EORTC STO22 Dysphagie	474	253 [53,4]	5,8 [5,4; 6,2]	474	240 [50,6]	5,9 [5,3; 6,5]	1,09	[0,91; 1,30]	0,3470
EORTC STO22 Einschränkungen beim Essen	474	243 [51,3]	6,2 [5,6; 7,0]	474	231 [48,7]	5,8 [5,4; 6,3]	1,02	[0,85; 1,22]	0,8694
EORTC STO22 Haarverlust	474	377 [79,5]	1,1 [1,0; 1,1]	474	367 [77,4]	1,1 [1,0; 1,1]	1,09	[0,94; 1,26]	0,2879
EORTC STO22 Schmerzen	474	210 [44,3]	9,5 [7,7;11,4]	474	193 [40,7]	9,0 [7,0;12,1]	1,10	[0,90; 1,33]	0,3703
EORTC STO22 Reflux	474	257 [54,2]	5,8 [5,0; 6,5]	474	250 [52,7]	5,9 [5,3; 6,6]	1,08	[0,90; 1,28]	0,4270
EORTC STO22 Geschmacksstörungen	474	310 [65,4]	3,6 [1,3; 4,6]	474	278 [58,6]	4,3 [1,3; 5,3]	1,17	[0,9954; 1,38]	0,0606

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 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 based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic region, clinical lymph node status and PD-L1 status
Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.4.2 Kaplan-Meier plot of EORTC STO22 Anxiety (Morbidity)
Full Analysis Set, DCO 01SEP2025

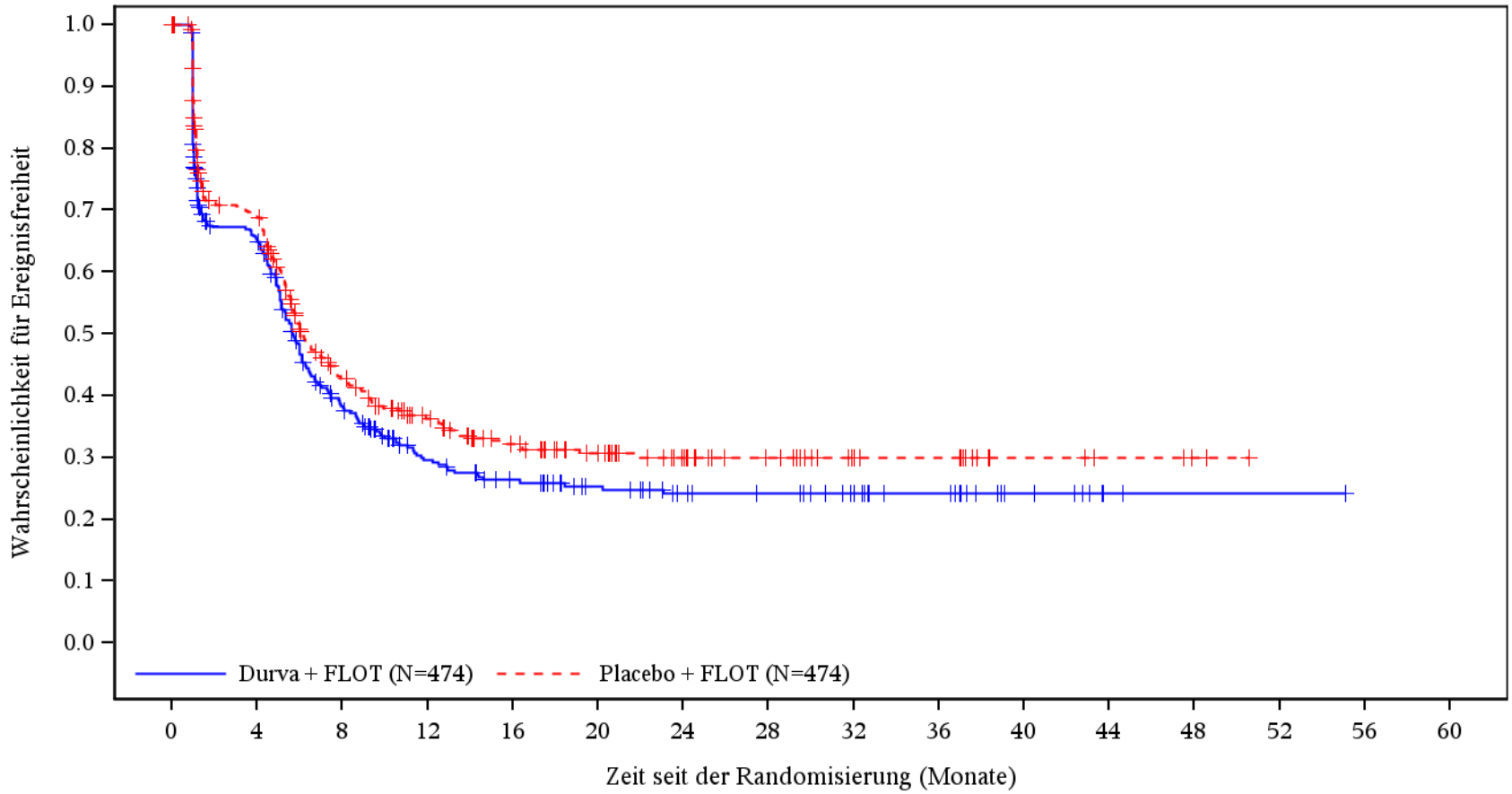


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	251	138	106	82	64	52	40	32	24	10	5	4	1	0	0
(0)	(127)	(145)	(162)	(176)	(189)	(198)	(209)	(217)	(224)	(238)	(243)	(244)	(247)	(248)	(248)
474	253	117	89	75	52	40	29	24	22	7	2	2	1	0	0
(0)	(132)	(154)	(165)	(175)	(194)	(206)	(217)	(221)	(223)	(237)	(242)	(242)	(243)	(244)	(244)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.4.3 Kaplan-Meier plot of EORTC STO22 Body Image (Morbidity)
Full Analysis Set, DCO 01SEP2025

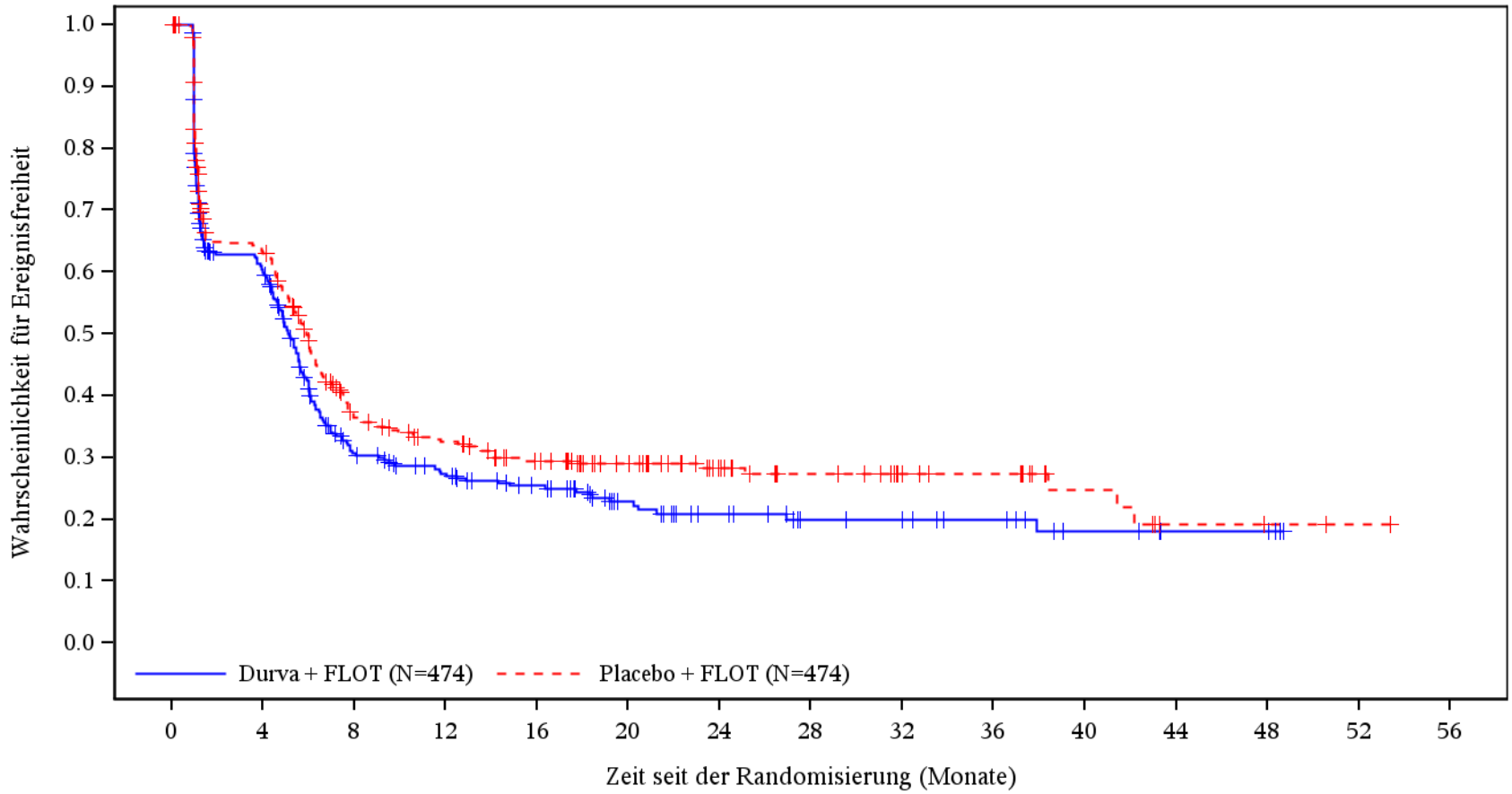


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	217	115	75	61	45	34	30	24	18	8	2	1	1	0	0
(0)	(126)	(143)	(159)	(165)	(179)	(188)	(192)	(198)	(204)	(214)	(220)	(221)	(221)	(222)	(222)
474	228	126	93	70	52	38	28	18	16	6	4	2	0	0	0
(0)	(132)	(152)	(167)	(180)	(195)	(208)	(218)	(228)	(230)	(240)	(242)	(244)	(246)	(246)	(246)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttemainpr.sas gttemainprias 29JUN2026:08:49 khcs324

Figure 3.4.4 Kaplan-Meier plot of EORTC STO22 Dry Mouth (Morbidity)
Full Analysis Set, DCO 01SEP2025

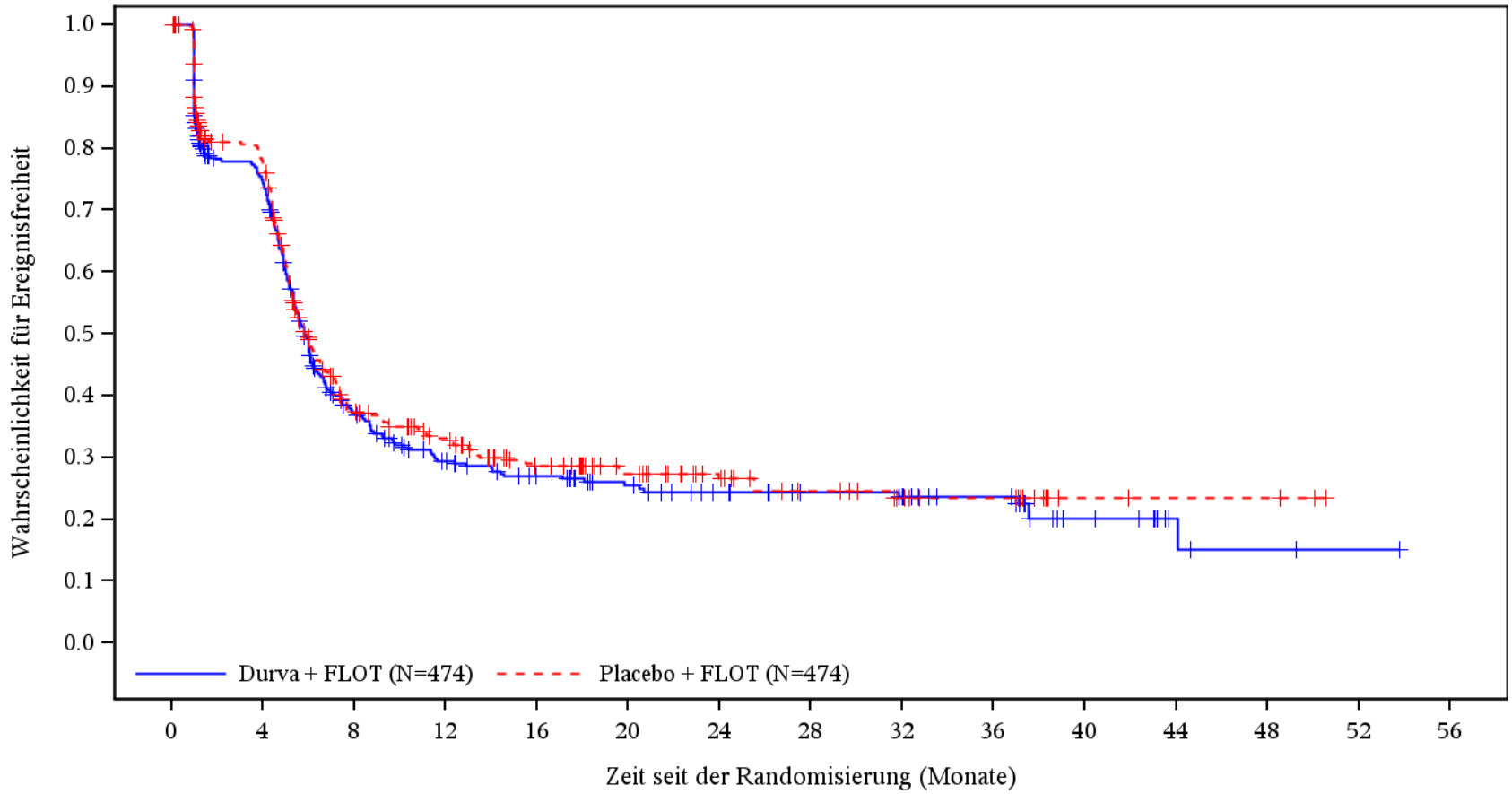


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	198	89	72	57	36	26	18	17	13	7	4	4	0	0
(0)	(126)	(144)	(152)	(162)	(178)	(185)	(192)	(193)	(197)	(202)	(205)	(205)	(209)	(209)
474	208	106	89	71	52	36	27	20	17	9	3	2	1	0
(0)	(131)	(149)	(155)	(165)	(183)	(198)	(206)	(213)	(216)	(223)	(227)	(228)	(229)	(230)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.4.5 Kaplan-Meier plot of EORTC STO22 Dysphagia (Morbidity)
Full Analysis Set, DCO 01SEP2025

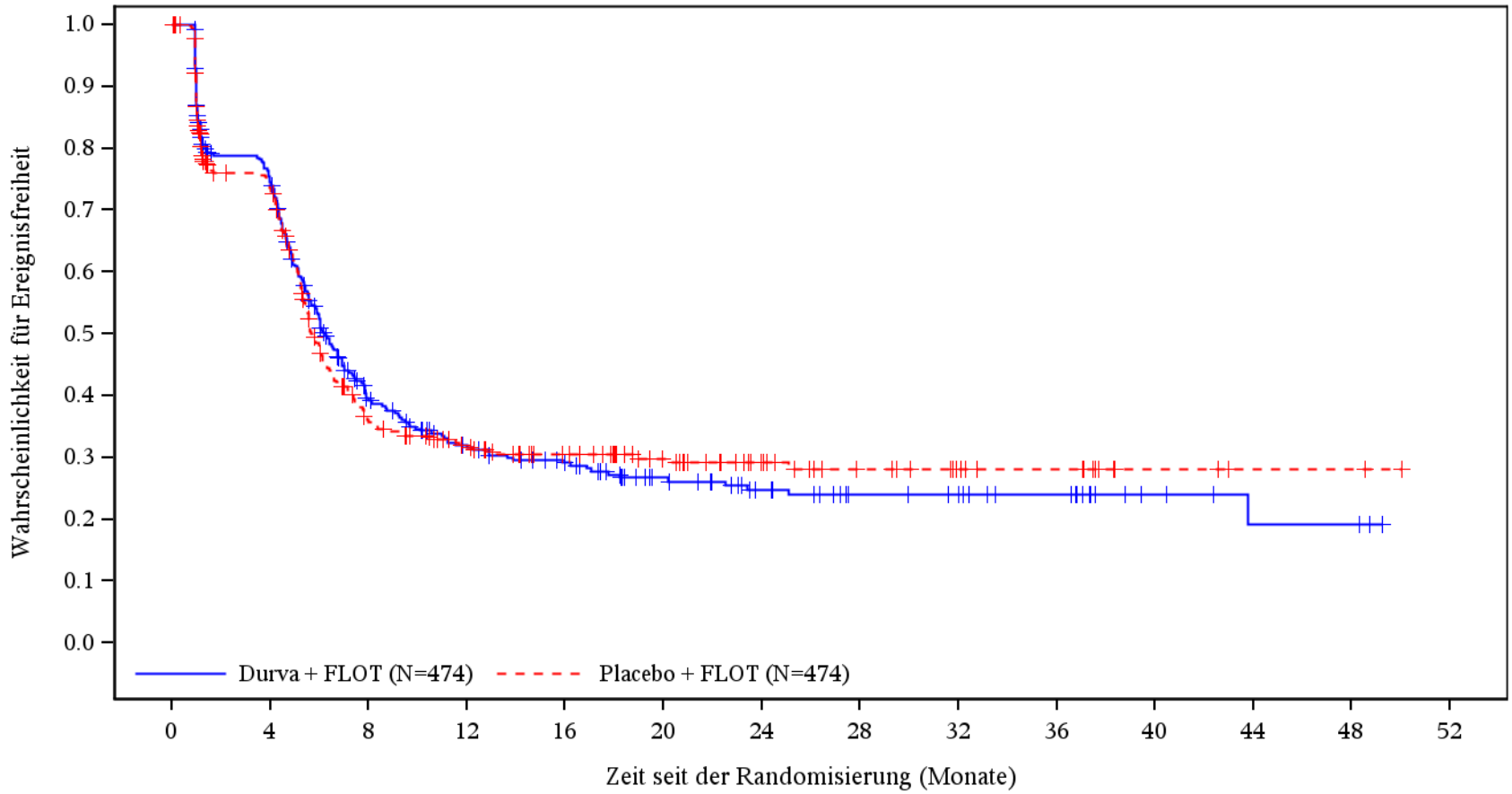


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	247	110	77	60	47	38	32	30	24	12	4	2	1	0
(0)	(131)	(149)	(160)	(171)	(181)	(188)	(194)	(195)	(201)	(210)	(218)	(219)	(220)	(221)
474	255	110	87	62	45	33	23	17	14	4	3	3	0	0
(0)	(132)	(153)	(164)	(178)	(193)	(204)	(212)	(217)	(220)	(230)	(231)	(231)	(234)	(234)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttemainpr.sas gttemainpriau 29JUN2026:08:49 khcs324

Figure 3.4.6 Kaplan-Meier plot of EORTC STO22 Eating Restrictions (Morbidity)
Full Analysis Set, DCO 01SEP2025

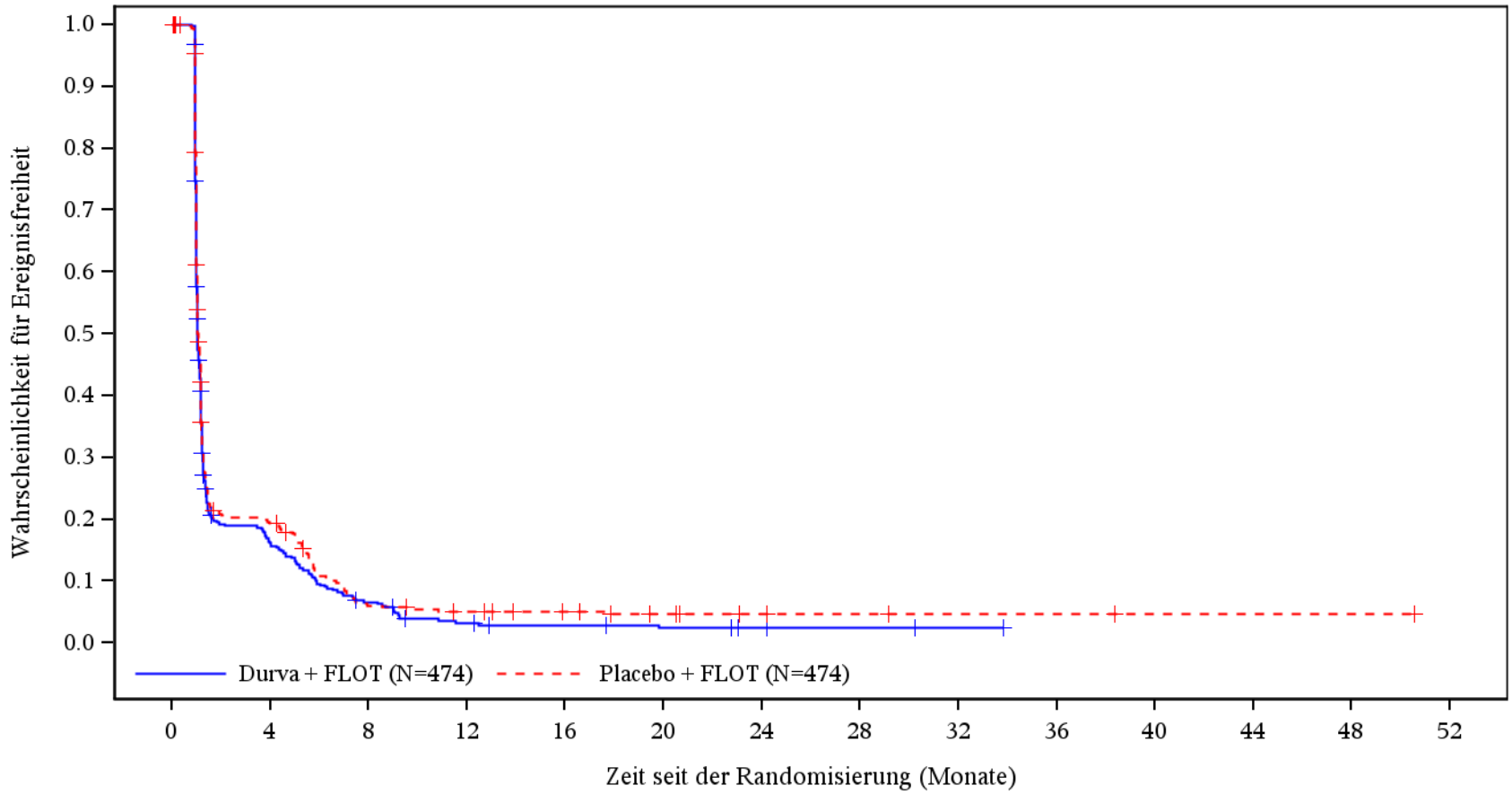


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	247	115	81	64	45	32	23	21	16	7	4	4	0
(0)	(133)	(154)	(167)	(177)	(191)	(201)	(209)	(211)	(216)	(225)	(227)	(227)	(231)
474	237	104	81	64	48	31	22	15	12	4	2	2	0
(0)	(140)	(157)	(168)	(182)	(197)	(213)	(221)	(228)	(231)	(239)	(241)	(241)	(243)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.4.7 Kaplan-Meier plot of EORTC STO22 Hair Loss (Morbidity)
Full Analysis Set, DCO 01SEP2025

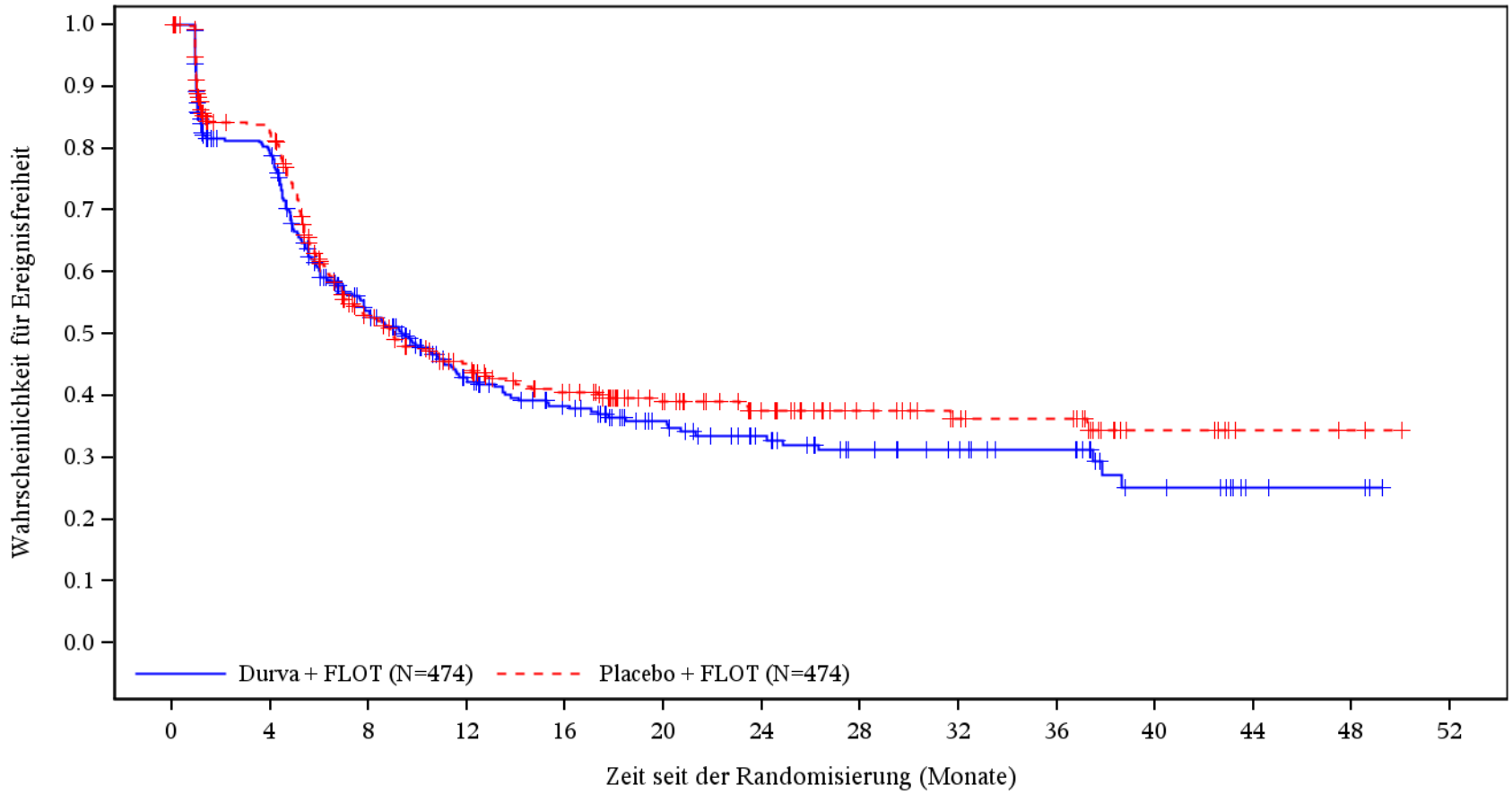


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	59	23	10	7	5	3	2	1	0	0	0	0	0
(0)	(86)	(87)	(89)	(91)	(92)	(94)	(95)	(96)	(97)	(97)	(97)	(97)	(97)
474	72	21	16	12	7	4	3	2	2	1	1	1	0
(0)	(86)	(90)	(92)	(96)	(100)	(103)	(104)	(105)	(105)	(106)	(106)	(106)	(107)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttemainpr.sas gttemainpriaw 29JUN2026:08:49 khcs324

Figure 3.4.8 Kaplan-Meier plot of EORTC STO22 Pain (Morbidity)
Full Analysis Set, DCO 01SEP2025



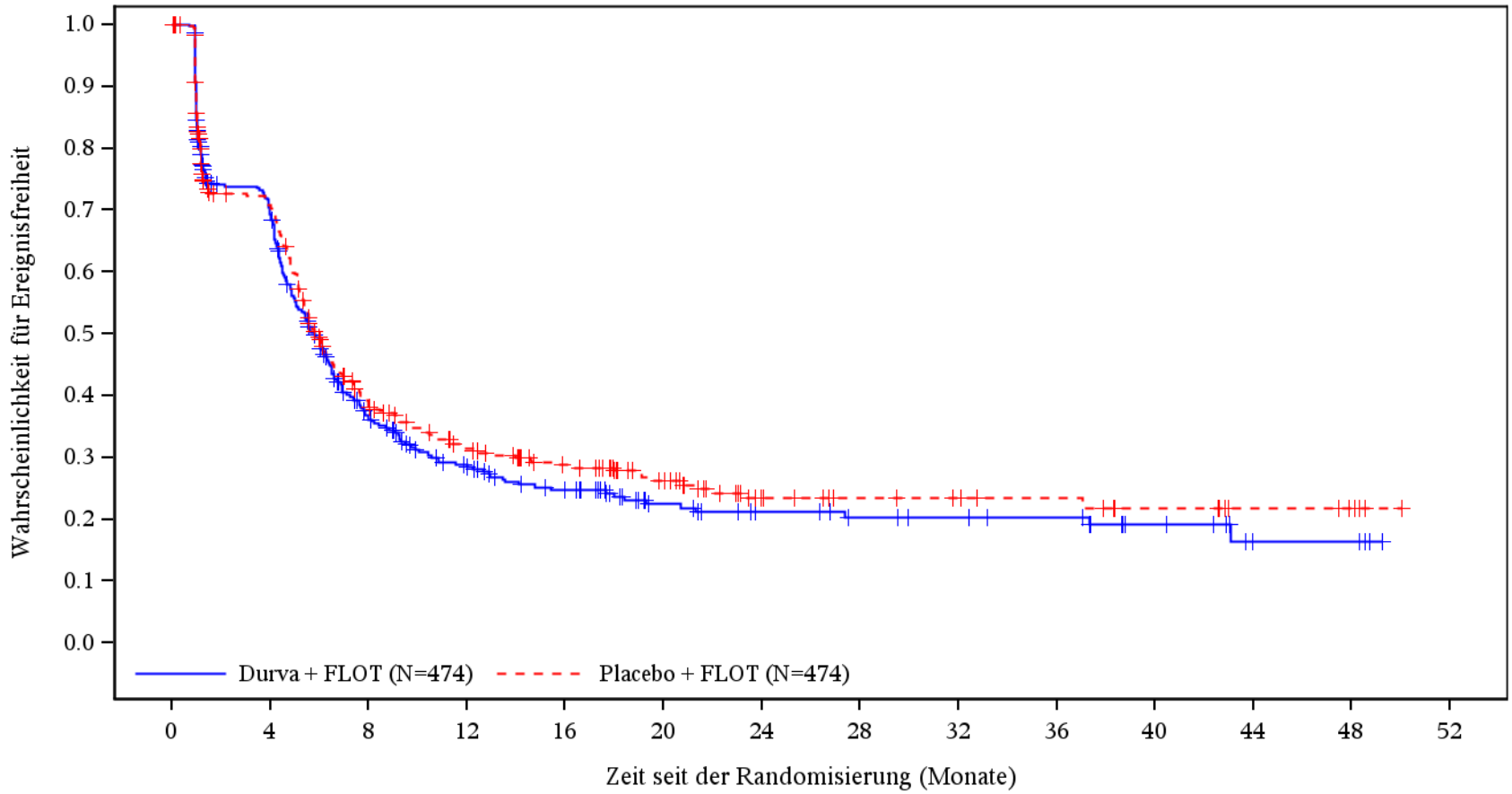
Anzahl im Risiko (Anzahl der zensierten Fälle)

474	255	152	105	84	62	46	34	28	23	11	4	3	0
(0)	(142)	(166)	(184)	(195)	(212)	(224)	(233)	(239)	(244)	(253)	(260)	(261)	(264)
474	263	147	112	90	65	48	35	26	24	8	3	2	0
(0)	(147)	(173)	(186)	(198)	(220)	(235)	(248)	(256)	(258)	(273)	(278)	(279)	(281)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.4.9 Kaplan-Meier plot of EORTC STO22 Reflux (Morbidity)
Full Analysis Set, DCO 01SEP2025

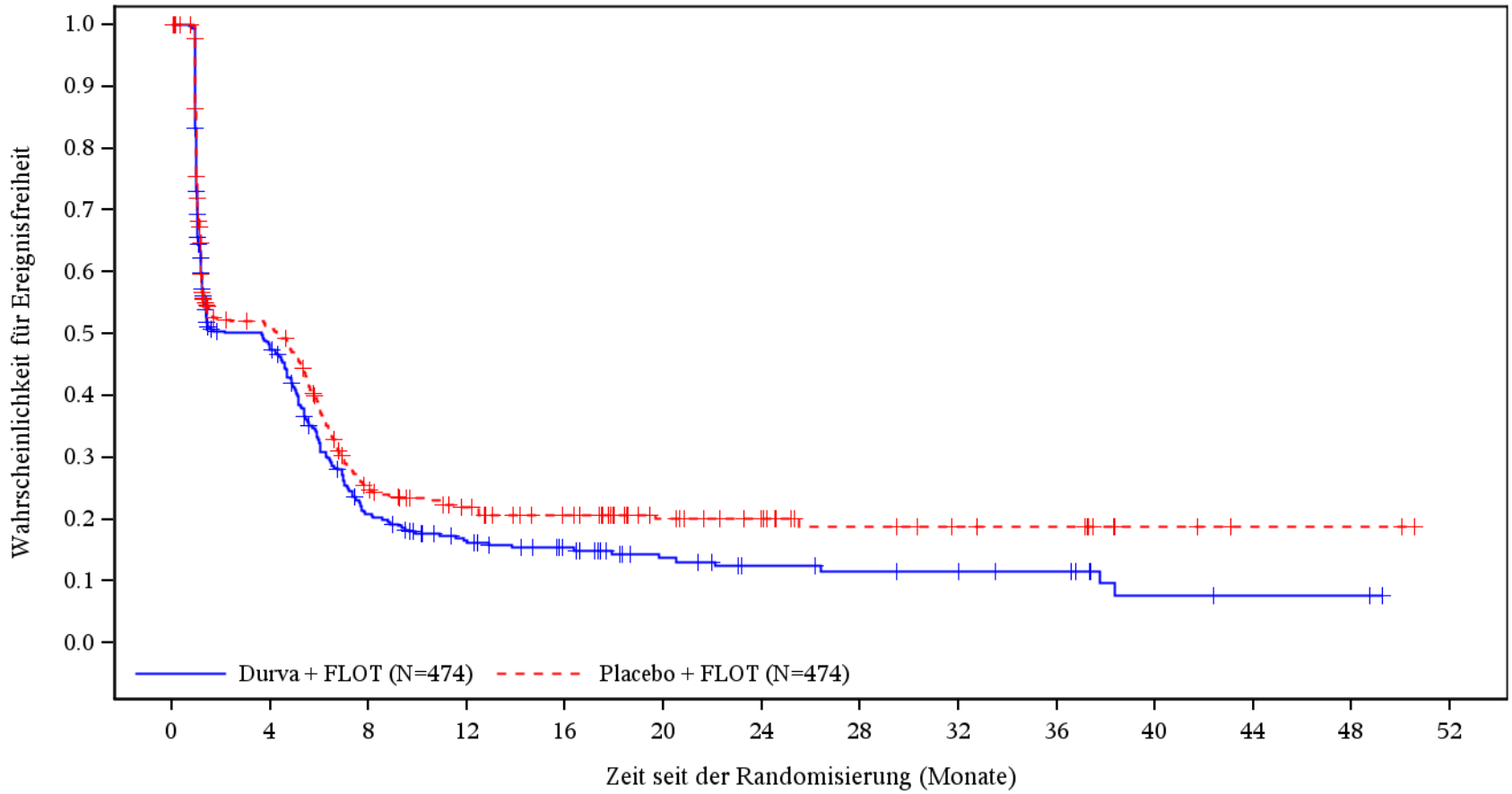


Anzahl im Risiko (Anzahl der zensierten Fälle)

474	228	107	74	55	35	27	23	21	19	11	4	4	0
(0)	(133)	(150)	(162)	(171)	(187)	(193)	(196)	(198)	(200)	(207)	(213)	(213)	(217)
474	235	116	86	68	47	25	19	16	14	10	6	4	0
(0)	(130)	(145)	(155)	(166)	(182)	(200)	(206)	(209)	(211)	(214)	(218)	(220)	(224)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/ttemainpr.sas gttemainpriay 29JUN2026:08:49 khcs324

Figure 3.4.10 Kaplan-Meier plot of EORTC STO22 Taste (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

474	160	66	45	34	22	16	14	13	11	4	2	2	0
(0)	(115)	(122)	(130)	(138)	(147)	(151)	(152)	(153)	(155)	(160)	(162)	(162)	(164)
474	169	74	57	44	29	22	15	12	11	4	2	2	0
(0)	(124)	(135)	(144)	(154)	(168)	(175)	(181)	(184)	(185)	(192)	(194)	(194)	(196)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Table 3.4.11 Summary of subgroup analysis of time to first EORTC STO22 Anxiety (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	54 [60,0]	5,8 [4,5; 7,5]	90	59 [65,6]	5,4 [4,4; 6,5]	0,85	[0,58; 1,23]	0,3792
Nicht-Asien	384	172 [44,8]	7,0 [6,0;10,2]	384	171 [44,5]	6,7 [6,2; 7,6]	0,97	[0,78; 1,20]	0,7709
Interaktion p-Wert									0,5367
Klinischer Lymphknotenstatus									
Positiv	329	157 [47,7]	6,6 [6,0; 9,9]	330	161 [48,8]	6,5 [5,9; 7,2]	0,92	[0,74; 1,15]	0,4605
Negativ	145	69 [47,6]	6,9 [5,2;10,5]	144	69 [47,9]	6,3 [5,5; 7,7]	0,98	[0,70; 1,37]	0,9170
Interaktion p-Wert									0,7497
PD-L1-Status									
TAP >= 1%	426	201 [47,2]	6,7 [6,0; 9,8]	427	210 [49,2]	6,3 [6,0; 7,1]	0,90	[0,74; 1,09]	0,2916
TAP < 1%	48	25 [52,1]	5,7 [4,7; 9,5]	47	20 [42,6]	8,0 [5,3; NE]	1,36	[0,76; 2,48]	0,3041
Interaktion p-Wert									0,1914
Alter bei Randomisierung (Jahre)									
<65	291	147 [50,5]	6,6 [5,7; 9,8]	265	137 [51,7]	7,0 [6,1; 7,7]	0,97	[0,77; 1,22]	0,7951
>=65	183	79 [43,2]	6,7 [5,6;11,3]	209	93 [44,5]	5,9 [5,3; 6,8]	0,89	[0,66; 1,20]	0,4524
Interaktion p-Wert									0,6644
Geschlecht									
Männlich	326	159 [48,8]	6,5 [5,5; 8,0]	356	181 [50,8]	6,3 [5,8; 7,0]	0,93	[0,75; 1,16]	0,5291
Weiblich	148	67 [45,3]	7,9 [5,8;13,6]	118	49 [41,5]	7,5 [6,0;11,1]	1,00	[0,69; 1,46]	0,9915
Interaktion p-Wert									0,7456
Tumorlokalisation									
GC	324	163 [50,3]	6,2 [5,5; 7,8]	316	152 [48,1]	6,3 [5,8; 7,4]	1,04	[0,83; 1,29]	0,7493
GEJC	150	63 [42,0]	8,7 [6,1;17,1]	158	78 [49,4]	6,7 [5,8; 7,7]	0,75	[0,54; 1,05]	0,0914
Interaktion p-Wert									0,1138

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.4.12 Summary of subgroup analysis of time to first EORTC STO22 Body Image (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	61 [67,8]	5,1 [3,7; 5,8]	90	60 [66,7]	4,0 [1,2; 5,3]	1,02	[0,71; 1,46]	0,9227
Nicht-Asien	384	191 [49,7]	6,0 [5,1; 7,0]	384	168 [43,8]	6,9 [5,9; 8,6]	1,24	[1,01; 1,52]	0,0435*
Interaktion p-Wert									0,3526
Klinischer Lymphknotenstatus									
Positiv	329	174 [52,9]	6,0 [5,3; 6,7]	330	150 [45,5]	6,8 [5,7; 9,2]	1,23	[0,99; 1,53]	0,0634
Negativ	145	78 [53,8]	4,9 [4,0; 6,3]	144	78 [54,2]	5,6 [4,7; 6,2]	1,10	[0,80; 1,51]	0,5521
Interaktion p-Wert									0,5685
PD-L1-Status									
TAP >= 1%	426	226 [53,1]	5,6 [5,1; 6,3]	427	206 [48,2]	6,2 [5,6; 7,7]	1,19	[0,99; 1,44]	0,0703
TAP < 1%	48	26 [54,2]	6,1 [1,4; 8,6]	47	22 [46,8]	5,3 [1,2; NE]	1,12	[0,64; 2,00]	0,6890
Interaktion p-Wert									0,8484
Alter bei Randomisierung (Jahre)									
<65	291	165 [56,7]	5,3 [4,6; 6,1]	265	144 [54,3]	5,9 [5,1; 7,4]	1,09	[0,87; 1,37]	0,4415
>=65	183	87 [47,5]	6,1 [5,3; 7,8]	209	84 [40,2]	7,0 [5,4;13,0]	1,30	[0,97; 1,76]	0,0833
Interaktion p-Wert									0,3525
Geschlecht									
Männlich	326	175 [53,7]	6,0 [5,4; 6,7]	356	167 [46,9]	6,2 [5,6; 8,3]	1,21	[0,98; 1,49]	0,0797
Weiblich	148	77 [52,0]	5,0 [1,4; 6,1]	118	61 [51,7]	5,3 [1,5; 7,8]	1,08	[0,77; 1,51]	0,6680
Interaktion p-Wert									0,5671
Tumorlokalisation									
GC	324	181 [55,9]	5,3 [4,6; 6,1]	316	157 [49,7]	6,0 [5,2; 7,7]	1,25	[1,01; 1,55]	0,0414*
GEJC	150	71 [47,3]	6,5 [5,6; 8,7]	158	71 [44,9]	6,5 [5,6; 8,7]	1,05	[0,75; 1,46]	0,7828
Interaktion p-Wert									0,3797

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.4.13 Summary of subgroup analysis of time to first EORTC STO22 Dry Mouth (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	58 [64,4]	5,6 [4,2; 6,4]	90	50 [55,6]	6,3 [4,2;10,6]	1,30	[0,89; 1,90]	0,1788
Nicht-Asien	384	207 [53,9]	4,9 [4,4; 5,6]	384	194 [50,5]	5,8 [5,1; 6,2]	1,16	[0,95; 1,41]	0,1490
Interaktion p-Wert									0,5967
Klinischer Lymphknotenstatus									
Positiv	329	175 [53,2]	5,7 [4,9; 6,4]	330	164 [49,7]	5,7 [4,7; 6,3]	1,05	[0,85; 1,30]	0,6775
Negativ	145	90 [62,1]	3,9 [1,2; 4,9]	144	80 [55,6]	6,0 [4,9; 7,7]	1,63	[1,20; 2,20]	0,0016*
Interaktion p-Wert									0,0191*
PD-L1-Status									
TAP >= 1%	426	235 [55,2]	5,3 [4,6; 5,7]	427	225 [52,7]	5,8 [5,2; 6,3]	1,14	[0,95; 1,37]	0,1586
TAP < 1%	48	30 [62,5]	4,8 [1,0; 6,0]	47	19 [40,4]	6,2 [1,1; NE]	1,70	[0,96; 3,07]	0,0668
Interaktion p-Wert									0,1907
Alter bei Randomisierung (Jahre)									
<65	291	174 [59,8]	4,9 [4,2; 5,6]	265	137 [51,7]	6,0 [5,3; 7,5]	1,34	[1,07; 1,67]	0,0112*
>=65	183	91 [49,7]	5,5 [4,4; 6,3]	209	107 [51,2]	5,6 [4,3; 6,3]	0,98	[0,74; 1,30]	0,8944
Interaktion p-Wert									0,0914
Geschlecht									
Männlich	326	179 [54,9]	5,3 [4,8; 6,0]	356	194 [54,5]	5,7 [4,8; 6,2]	1,09	[0,89; 1,33]	0,4255
Weiblich	148	86 [58,1]	4,6 [1,4; 5,7]	118	50 [42,4]	6,5 [5,2;10,6]	1,51	[1,07; 2,15]	0,0195*
Interaktion p-Wert									0,1098
Tumorlokalisation									
GC	324	182 [56,2]	5,3 [4,4; 5,9]	316	160 [50,6]	6,3 [5,4; 7,7]	1,25	[1,01; 1,55]	0,0364*
GEJC	150	83 [55,3]	4,8 [4,0; 5,6]	158	84 [53,2]	4,8 [1,5; 5,8]	1,05	[0,77; 1,42]	0,7548
Interaktion p-Wert									0,3455

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.4.14 Summary of subgroup analysis of time to first EORTC STO22 Dysphagia (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	56 [62,2]	5,0 [4,1; 5,7]	90	62 [68,9]	4,6 [4,1; 5,2]	0,91	[0,63; 1,31]	0,6073
Nicht-Asien	384	197 [51,3]	6,0 [5,5; 6,7]	384	178 [46,4]	6,5 [5,6; 7,4]	1,12	[0,92; 1,38]	0,2577
Interaktion p-Wert									0,3164
Klinischer Lymphknotenstatus									
Positiv	329	167 [50,8]	6,1 [5,7; 7,5]	330	160 [48,5]	6,1 [5,4; 7,2]	1,03	[0,83; 1,28]	0,8130
Negativ	145	86 [59,3]	4,9 [4,4; 5,9]	144	80 [55,6]	5,3 [5,0; 6,5]	1,18	[0,87; 1,60]	0,2824
Interaktion p-Wert									0,4606
PD-L1-Status									
TAP >= 1%	426	227 [53,3]	5,8 [5,4; 6,3]	427	214 [50,1]	6,0 [5,4; 7,1]	1,09	[0,91; 1,32]	0,3512
TAP < 1%	48	26 [54,2]	6,0 [4,4; 8,3]	47	26 [55,3]	4,9 [3,5; 6,2]	0,86	[0,50; 1,49]	0,5959
Interaktion p-Wert									0,4214
Alter bei Randomisierung (Jahre)									
<65	291	164 [56,4]	5,4 [5,0; 6,3]	265	147 [55,5]	5,8 [5,1; 6,7]	1,03	[0,82; 1,28]	0,8223
>=65	183	89 [48,6]	6,0 [5,6; 7,4]	209	93 [44,5]	6,0 [5,3; 7,7]	1,12	[0,84; 1,50]	0,4290
Interaktion p-Wert									0,6231
Geschlecht									
Männlich	326	164 [50,3]	6,0 [5,4; 6,6]	356	185 [52,0]	5,9 [5,2; 6,5]	0,96	[0,78; 1,18]	0,6957
Weiblich	148	89 [60,1]	5,4 [4,6; 6,1]	118	55 [46,6]	5,6 [5,2; 8,1]	1,36	[0,98; 1,92]	0,0692
Interaktion p-Wert									0,0814
Tumorlokalisation									
GC	324	196 [60,5]	5,2 [4,9; 5,8]	316	179 [56,6]	5,3 [5,0; 6,2]	1,11	[0,91; 1,36]	0,3103
GEJC	150	57 [38,0]	7,9 [6,1;31,8]	158	61 [38,6]	8,7 [5,6;19,6]	0,95	[0,66; 1,36]	0,7636
Interaktion p-Wert									0,4479

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.4.15 Summary of subgroup analysis of time to first EORTC STO22 Eating Restrictions (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	56 [62,2]	5,4 [4,2; 6,3]	90	59 [65,6]	4,7 [4,2; 5,8]	0,95	[0,66; 1,38]	0,8038
Nicht-Asien	384	187 [48,7]	6,6 [5,9; 7,9]	384	172 [44,8]	6,1 [5,6; 7,2]	1,02	[0,83; 1,25]	0,8719
Interaktion p-Wert									0,7675
Klinischer Lymphknotenstatus									
Positiv	329	161 [48,9]	6,7 [5,9; 8,1]	330	156 [47,3]	5,8 [5,4; 7,1]	0,94	[0,76; 1,18]	0,6026
Negativ	145	82 [56,6]	5,6 [4,5; 6,5]	144	75 [52,1]	5,6 [5,1; 6,5]	1,14	[0,83; 1,56]	0,4127
Interaktion p-Wert									0,3323
PD-L1-Status									
TAP >= 1%	426	218 [51,2]	6,2 [5,6; 7,0]	427	210 [49,2]	5,7 [5,3; 6,3]	0,99	[0,82; 1,20]	0,9255
TAP < 1%	48	25 [52,1]	6,8 [4,7; 9,6]	47	21 [44,7]	5,8 [4,4; NE]	1,07	[0,60; 1,94]	0,8088
Interaktion p-Wert									0,7956
Alter bei Randomisierung (Jahre)									
<65	291	158 [54,3]	6,0 [5,2; 7,0]	265	139 [52,5]	5,7 [5,3; 6,5]	0,98	[0,78; 1,23]	0,8550
>=65	183	85 [46,4]	6,6 [5,6; 8,0]	209	92 [44,0]	6,0 [5,3; 7,5]	1,02	[0,76; 1,37]	0,8962
Interaktion p-Wert									0,8298
Geschlecht									
Männlich	326	167 [51,2]	6,5 [5,6; 7,5]	356	181 [50,8]	5,8 [5,3; 6,4]	0,97	[0,79; 1,20]	0,8024
Weiblich	148	76 [51,4]	6,0 [4,7; 7,4]	118	50 [42,4]	5,6 [5,2; 7,7]	1,07	[0,75; 1,53]	0,7173
Interaktion p-Wert									0,6606
Tumorlokalisation									
GC	324	180 [55,6]	5,8 [4,9; 6,8]	316	162 [51,3]	5,4 [5,1; 6,1]	1,02	[0,83; 1,27]	0,8234
GEJC	150	63 [42,0]	6,9 [6,0; 9,7]	158	69 [43,7]	6,5 [5,6; 9,5]	0,92	[0,65; 1,29]	0,6109
Interaktion p-Wert									0,5824

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.4.16 Summary of subgroup analysis of time to first EORTC STO22 Hair Loss (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	82 [91,1]	1,1 [1,0; 1,1]	90	81 [90,0]	1,0 [1,0; 1,1]	1,15	[0,85; 1,57]	0,3639
Nicht-Asien	384	295 [76,8]	1,1 [1,0; 1,1]	384	286 [74,5]	1,1 [1,0; 1,1]	1,07	[0,91; 1,26]	0,4187
Interaktion p-Wert									0,6711
Klinischer Lymphknotenstatus									
Positiv	329	264 [80,2]	1,1 [1,1; 1,2]	330	253 [76,7]	1,1 [1,0; 1,1]	1,04	[0,87; 1,23]	0,6756
Negativ	145	113 [77,9]	1,0 [1,0; 1,0]	144	114 [79,2]	1,0 [1,0; 1,2]	1,21	[0,94; 1,58]	0,1439
Interaktion p-Wert									0,3234
PD-L1-Status									
TAP >= 1%	426	336 [78,9]	1,1 [1,0; 1,1]	427	331 [77,5]	1,1 [1,1; 1,1]	1,11	[0,96; 1,30]	0,1641
TAP < 1%	48	41 [85,4]	1,0 [1,0; 1,2]	47	36 [76,6]	1,0 [1,0; 1,1]	0,81	[0,52; 1,28]	0,3651
Interaktion p-Wert									0,1931
Alter bei Randomisierung (Jahre)									
<65	291	242 [83,2]	1,0 [1,0; 1,1]	265	210 [79,2]	1,1 [1,0; 1,1]	1,08	[0,90; 1,30]	0,4040
>=65	183	135 [73,8]	1,1 [1,1; 1,2]	209	157 [75,1]	1,1 [1,1; 1,2]	1,06	[0,84; 1,33]	0,6286
Interaktion p-Wert									0,8848
Geschlecht									
Männlich	326	257 [78,8]	1,1 [1,0; 1,1]	356	280 [78,7]	1,1 [1,0; 1,1]	1,05	[0,88; 1,24]	0,5944
Weiblich	148	120 [81,1]	1,0 [1,0; 1,1]	118	87 [73,7]	1,1 [1,0; 1,2]	1,13	[0,86; 1,50]	0,3686
Interaktion p-Wert									0,6271
Tumorlokalisation									
GC	324	261 [80,6]	1,1 [1,0; 1,1]	316	245 [77,5]	1,1 [1,0; 1,1]	1,08	[0,91; 1,29]	0,3891
GEJC	150	116 [77,3]	1,0 [1,0; 1,1]	158	122 [77,2]	1,1 [1,0; 1,1]	1,09	[0,84; 1,40]	0,5179
Interaktion p-Wert									0,9629

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.4.17 Summary of subgroup analysis of time to first EORTC STO22 Pain (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	46 [51,1]	5,8 [4,9;10,5]	90	43 [47,8]	9,1 [5,4; NE]	1,32	[0,87; 2,01]	0,1878
Nicht-Asien	384	164 [42,7]	9,8 [8,0;12,4]	384	150 [39,1]	9,0 [7,0;12,2]	1,06	[0,85; 1,32]	0,6027
Interaktion p-Wert									0,3587
Klinischer Lymphknotenstatus									
Positiv	329	139 [42,2]	10,5 [8,6;13,6]	330	136 [41,2]	9,0 [7,0;14,0]	1,01	[0,80; 1,28]	0,9230
Negativ	145	71 [49,0]	7,0 [4,9;10,0]	144	57 [39,6]	9,0 [6,2;12,9]	1,38	[0,97; 1,96]	0,0713
Interaktion p-Wert									0,1511
PD-L1-Status									
TAP >= 1%	426	183 [43,0]	10,0 [7,8;12,4]	427	176 [41,2]	9,0 [7,2;12,2]	1,07	[0,87; 1,31]	0,5451
TAP < 1%	48	27 [56,3]	6,0 [4,2; 9,2]	47	17 [36,2]	7,1 [4,5; NE]	1,56	[0,86; 2,91]	0,1488
Interaktion p-Wert									0,2441
Alter bei Randomisierung (Jahre)									
<65	291	141 [48,5]	8,0 [6,0;11,1]	265	110 [41,5]	8,3 [6,7;12,9]	1,19	[0,93; 1,53]	0,1649
>=65	183	69 [37,7]	11,3 [8,0;20,1]	209	83 [39,7]	9,0 [6,7;14,0]	0,98	[0,71; 1,34]	0,8887
Interaktion p-Wert									0,3352
Geschlecht									
Männlich	326	152 [46,6]	7,9 [6,0;10,4]	356	151 [42,4]	9,0 [7,0;12,7]	1,20	[0,96; 1,50]	0,1173
Weiblich	148	58 [39,2]	13,5 [9,5;24,2]	118	42 [35,6]	9,0 [5,6; NE]	0,94	[0,63; 1,41]	0,7597
Interaktion p-Wert									0,3007
Tumorlokalisation									
GC	324	151 [46,6]	8,5 [6,5;10,8]	316	129 [40,8]	10,4 [7,0;13,6]	1,23	[0,97; 1,56]	0,0823
GEJC	150	59 [39,3]	11,7 [7,0;20,7]	158	64 [40,5]	8,1 [6,0;14,0]	0,88	[0,62; 1,26]	0,4986
Interaktion p-Wert									0,1278

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.4.18 Summary of subgroup analysis of time to first EORTC STO22 Reflux (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	56 [62,2]	5,6 [4,5; 6,3]	90	44 [48,9]	9,7 [5,4; NE]	1,64	[1,11; 2,44]	0,0138*
Nicht-Asien	384	201 [52,3]	6,0 [5,0; 6,9]	384	206 [53,6]	5,6 [5,1; 6,2]	0,96	[0,79; 1,17]	0,6920
Interaktion p-Wert									0,0172*
Klinischer Lymphknotenstatus									
Positiv	329	183 [55,6]	6,0 [5,4; 6,9]	330	164 [49,7]	6,2 [5,5; 7,4]	1,12	[0,91; 1,38]	0,3008
Negativ	145	74 [51,0]	4,6 [4,2; 6,2]	144	86 [59,7]	5,4 [4,8; 6,1]	1,03	[0,75; 1,40]	0,8748
Interaktion p-Wert									0,6526
PD-L1-Status									
TAP >= 1%	426	234 [54,9]	5,6 [5,0; 6,3]	427	228 [53,4]	6,0 [5,4; 6,7]	1,11	[0,93; 1,33]	0,2542
TAP < 1%	48	23 [47,9]	6,9 [4,6;37,3]	47	22 [46,8]	5,6 [4,3; NE]	0,85	[0,47; 1,54]	0,5981
Interaktion p-Wert									0,3999
Alter bei Randomisierung (Jahre)									
<65	291	170 [58,4]	5,1 [4,5; 6,1]	265	147 [55,5]	5,5 [5,1; 6,4]	1,09	[0,88; 1,36]	0,4336
>=65	183	87 [47,5]	6,3 [5,6; 7,8]	209	103 [49,3]	6,3 [5,4; 8,0]	1,03	[0,78; 1,37]	0,8225
Interaktion p-Wert									0,7631
Geschlecht									
Männlich	326	180 [55,2]	6,0 [5,0; 6,6]	356	193 [54,2]	5,9 [5,2; 6,7]	1,08	[0,88; 1,32]	0,4532
Weiblich	148	77 [52,0]	5,6 [4,4; 7,4]	118	57 [48,3]	5,6 [5,1; 9,8]	1,09	[0,77; 1,54]	0,6333
Interaktion p-Wert									0,9788
Tumorlokalisation									
GC	324	175 [54,0]	5,6 [4,9; 6,5]	316	163 [51,6]	5,8 [5,2; 6,8]	1,09	[0,88; 1,36]	0,4049
GEJC	150	82 [54,7]	6,0 [4,6; 7,2]	158	87 [55,1]	6,1 [4,9; 7,4]	1,06	[0,78; 1,43]	0,7266
Interaktion p-Wert									0,8451

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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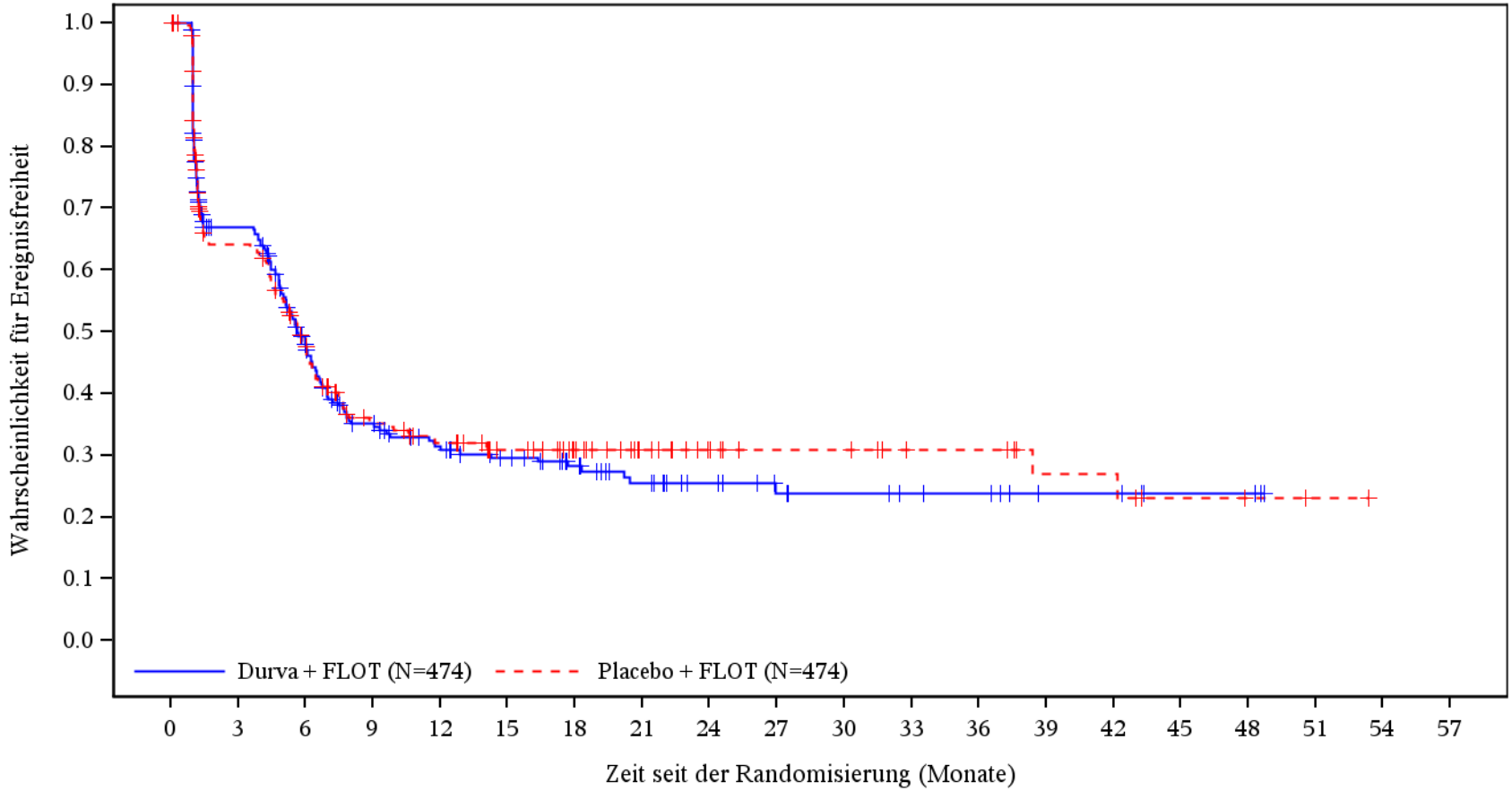
Table 3.4.19 Summary of subgroup analysis of time to first EORTC STO22 Taste (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	69 [76,7]	3,8 [1,2; 4,7]	90	65 [72,2]	1,4 [1,1; 4,4]	1,05	[0,75; 1,48]	0,7579
Nicht-Asien	384	241 [62,8]	2,2 [1,2; 4,7]	384	213 [55,5]	5,1 [1,4; 5,6]	1,20	[1,001; 1,45]	0,0483*
Interaktion p-Wert									0,5019
Klinischer Lymphknotenstatus									
Positiv	329	212 [64,4]	3,9 [1,3; 4,9]	330	192 [58,2]	1,7 [1,2; 5,1]	1,09	[0,90; 1,33]	0,3752
Negativ	145	98 [67,6]	1,4 [1,1; 4,7]	144	86 [59,7]	5,2 [1,5; 6,0]	1,38	[1,04; 1,85]	0,0281*
Interaktion p-Wert									0,1856
PD-L1-Status									
TAP >= 1%	426	277 [65,0]	3,6 [1,3; 4,6]	427	253 [59,3]	4,1 [1,2; 5,2]	1,16	[0,98; 1,38]	0,0806
TAP < 1%	48	33 [68,8]	2,2 [1,0; 5,8]	47	25 [53,2]	5,7 [1,1; 7,0]	1,23	[0,73; 2,08]	0,4385
Interaktion p-Wert									0,8499
Alter bei Randomisierung (Jahre)									
<65	291	194 [66,7]	3,7 [1,3; 4,7]	265	167 [63,0]	1,6 [1,2; 5,1]	1,03	[0,84; 1,27]	0,7783
>=65	183	116 [63,4]	1,4 [1,2; 4,8]	209	111 [53,1]	5,1 [1,5; 6,0]	1,41	[1,09; 1,83]	0,0098*
Interaktion p-Wert									0,0648
Geschlecht									
Männlich	326	212 [65,0]	4,3 [1,4; 4,9]	356	216 [60,7]	4,7 [1,5; 5,5]	1,12	[0,93; 1,35]	0,2384
Weiblich	148	98 [66,2]	1,2 [1,1; 3,8]	118	62 [52,5]	1,3 [1,2; 5,4]	1,28	[0,93; 1,77]	0,1251
Interaktion p-Wert									0,4804
Tumorlokalisation									
GC	324	214 [66,0]	3,7 [1,3; 4,7]	316	182 [57,6]	4,4 [1,2; 5,5]	1,23	[1,01; 1,50]	0,0422*
GEJC	150	96 [64,0]	2,2 [1,1; 5,2]	158	96 [60,8]	2,4 [1,2; 5,5]	1,06	[0,80; 1,41]	0,6840
Interaktion p-Wert									0,4077

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Nutzenbewertung nach AMNOG - MATTERHORN Seite 1 von 1

Figure 3.4.20 Subgroup Analysis: Kaplan-Meier plot of EORTC STO22 Dry Mouth for Clinical lymph node status: Positive (Morbidity)
Full Analysis Set, DCO 01SEP2025



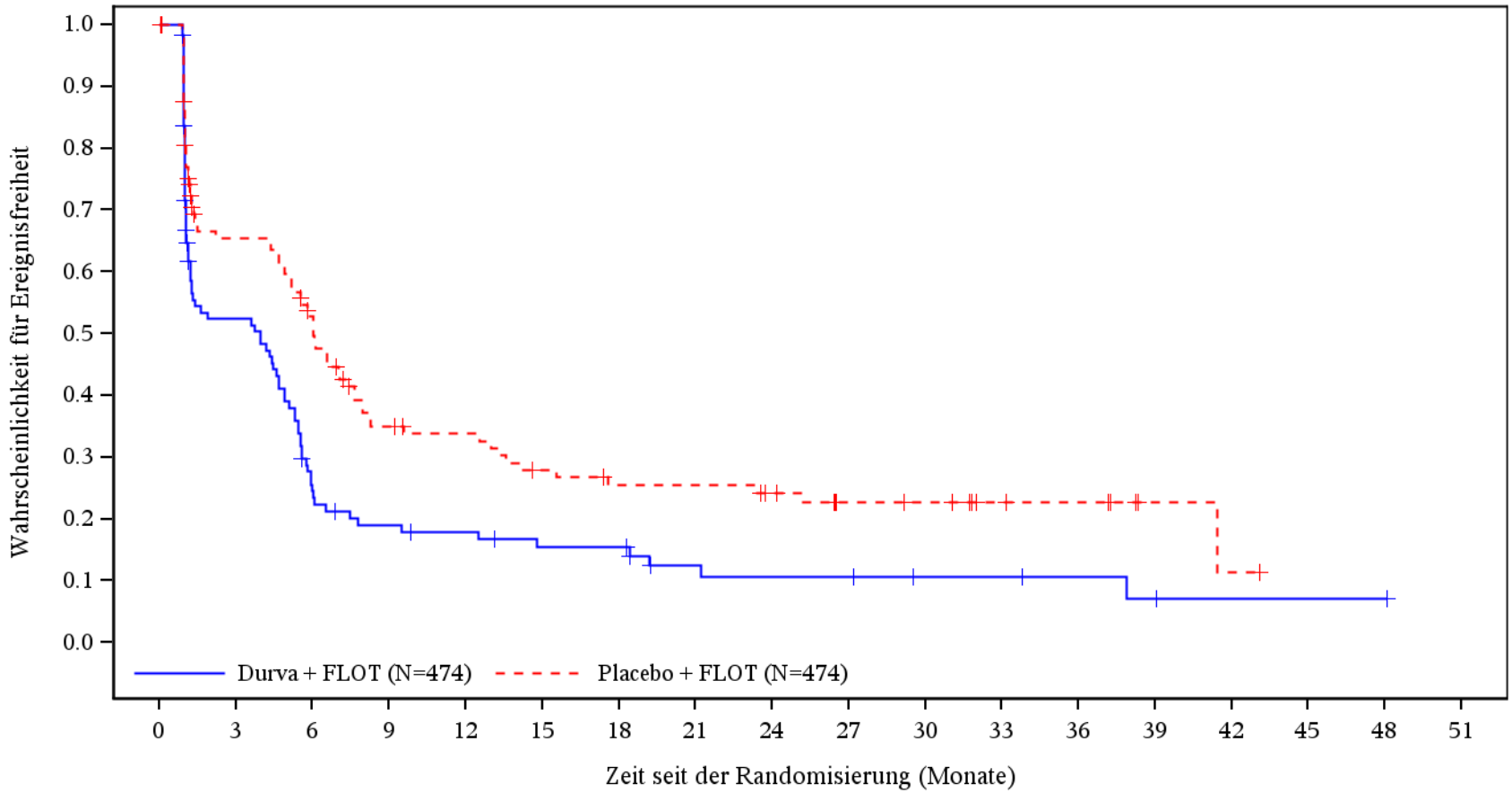
Anzahl im Risiko (Anzahl der zensierten Fälle)

329	157	103	70	57	48	37	27	20	15	13	11	10	6	6	3	3	0	0	0
(0)	(83)	(94)	(100)	(106)	(112)	(121)	(128)	(135)	(139)	(141)	(143)	(144)	(148)	(148)	(151)	(151)	(154)	(154)	(154)
330	146	104	70	60	50	38	26	19	15	15	11	11	7	7	3	2	1	0	0
(0)	(93)	(99)	(107)	(110)	(118)	(130)	(142)	(149)	(153)	(153)	(157)	(157)	(160)	(160)	(163)	(164)	(165)	(166)	(166)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.4.21 Subgroup Analysis: Kaplan-Meier plot of EORTC STO22 Dry Mouth for Clinical lymph node status: Negative (Morbidity)
Full Analysis Set, DCO 01SEP2025



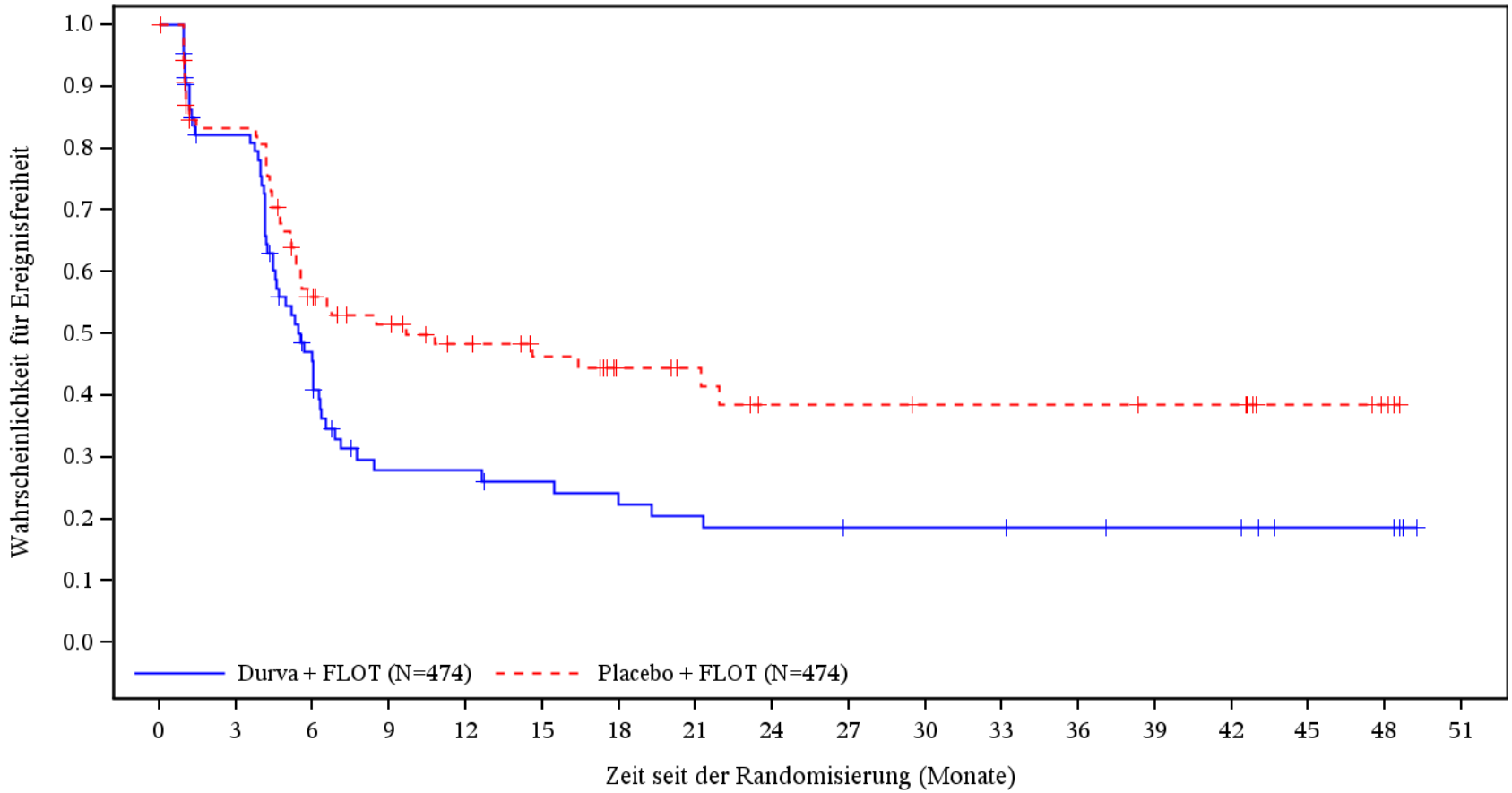
Anzahl im Risiko (Anzahl der zensierten Fälle)

145	51	23	17	15	12	12	7	6	6	4	4	3	2	1	1	1	0
(0)	(43)	(44)	(45)	(46)	(47)	(47)	(50)	(50)	(50)	(52)	(52)	(53)	(53)	(54)	(54)	(54)	(55)
144	67	52	32	29	23	20	20	17	12	11	7	6	2	1	0	0	0
(0)	(38)	(40)	(43)	(45)	(46)	(47)	(47)	(49)	(53)	(54)	(58)	(59)	(63)	(63)	(64)	(64)	(64)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.4.22 Subgroup Analysis: Kaplan-Meier plot of EORTC STO22 Reflux for Region: Asia (Morbidity)
Full Analysis Set, DCO 01SEP2025



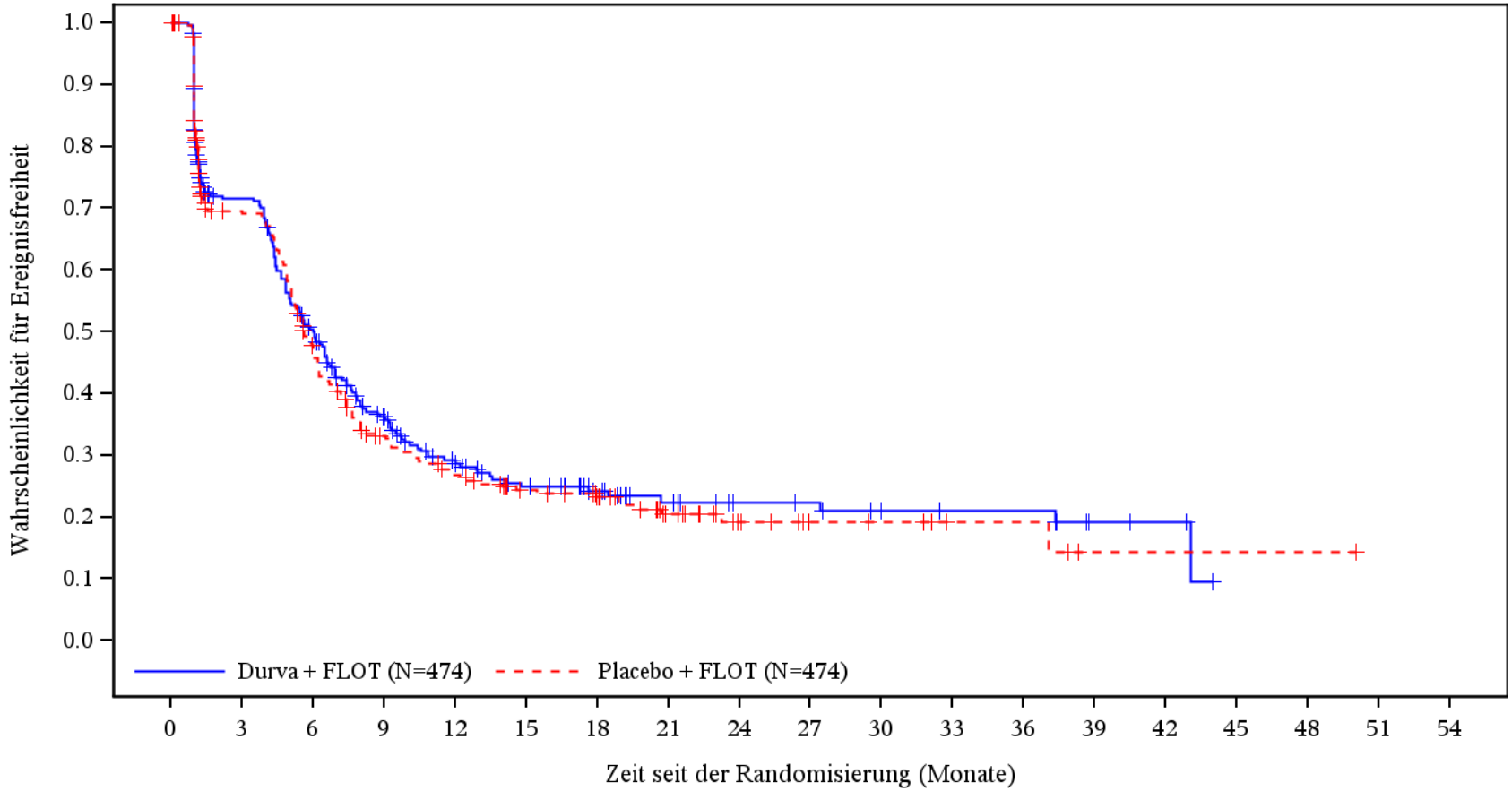
Anzahl im Risiko (Anzahl der zensierten Fälle)

90	60	30	16	16	14	12	11	10	9	9	9	8	7	7	4	4	0
(0)	(16)	(20)	(23)	(23)	(24)	(24)	(24)	(24)	(25)	(25)	(25)	(26)	(27)	(27)	(30)	(30)	(34)
90	65	41	34	28	24	17	15	11	11	10	10	10	9	9	5	3	0
(0)	(11)	(14)	(18)	(22)	(25)	(31)	(33)	(35)	(35)	(36)	(36)	(36)	(37)	(37)	(41)	(43)	(46)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.4.23 Subgroup Analysis: Kaplan-Meier plot of EORTC STO22 Reflux for Region: Non-Asia (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

384	183	126	82	58	44	32	23	17	16	12	11	11	4	3	0	0	0	0
(0)	(117)	(120)	(130)	(139)	(145)	(156)	(163)	(169)	(170)	(173)	(174)	(174)	(180)	(181)	(183)	(183)	(183)	(183)
384	176	116	74	58	46	38	24	14	8	7	4	4	1	1	1	1	0	0
(0)	(119)	(124)	(131)	(133)	(140)	(146)	(156)	(165)	(171)	(172)	(175)	(175)	(177)	(177)	(177)	(177)	(178)	(178)

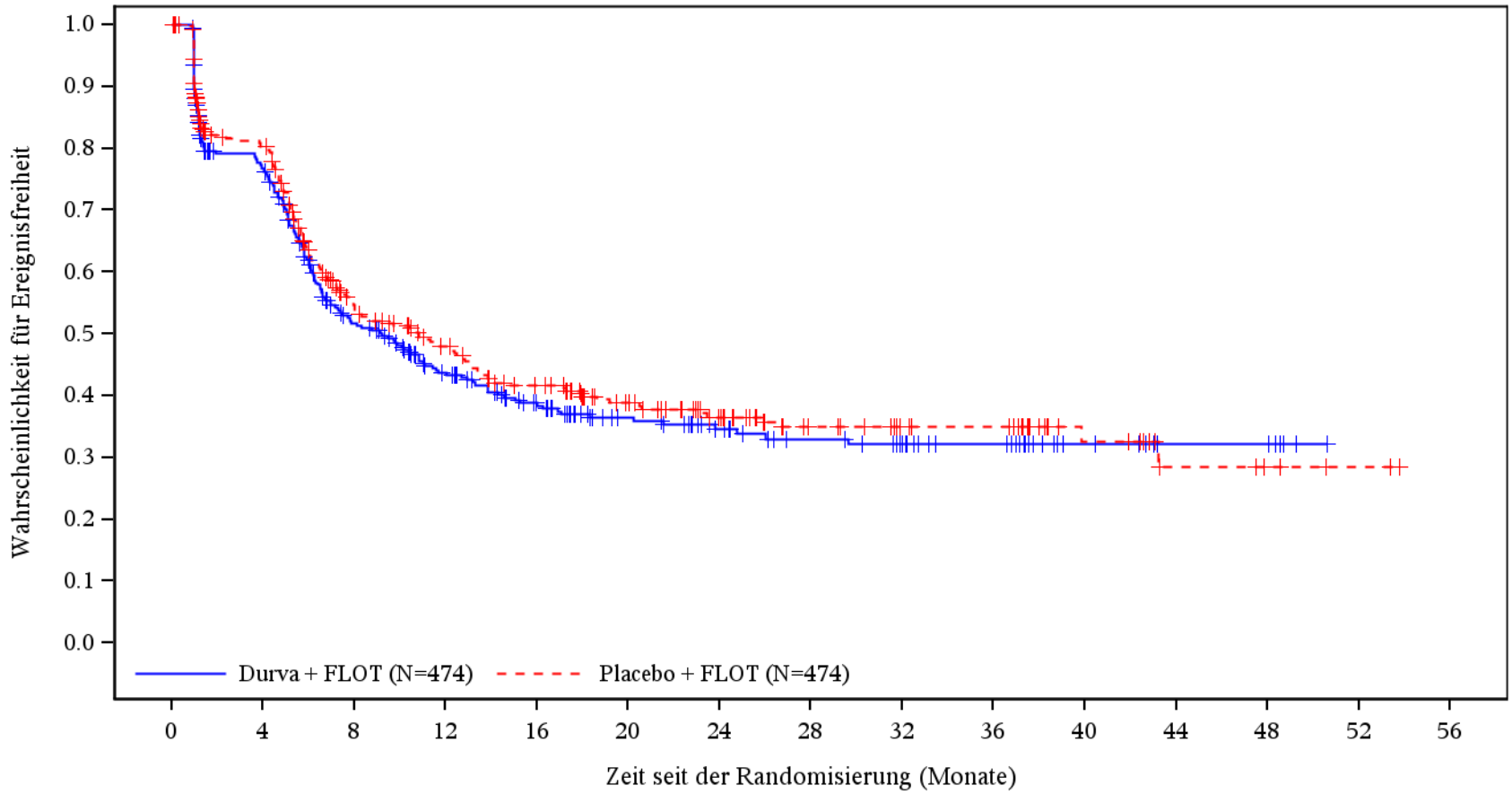
Kaplan-Meier plot is presented only if the interaction term in Cox regression model with treatment, subgroup and treatment-by-subgroup interaction is statistically significant at 5% level.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.5.1 Summary of analysis of time to deterioration in EQ-5D-5L Visual Analogue Scale (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
EQ-5D-5L Visuelle Analogskala	474	209 [44,1]	9,2 [6,7;11,4]	474	199 [42,0]	10,8 [7,9;13,1]	1,07	[0,88; 1,30]	0,5163

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 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 based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic region, clinical lymph node status and PD-L1 status
Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.5.2 Kaplan-Meier plot of EQ-5D-5L Visual Analogue Scale (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

474	252	152	114	86	62	48	38	32	23	11	6	6	0	0
(0)	(137)	(158)	(174)	(189)	(209)	(220)	(228)	(233)	(242)	(254)	(259)	(259)	(265)	(265)
474	260	151	124	100	75	57	38	31	29	14	6	4	2	0
(0)	(142)	(170)	(181)	(189)	(208)	(222)	(239)	(246)	(248)	(262)	(269)	(271)	(273)	(275)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.5.3 Summary of subgroup analysis of time to first EQ-5D-5L Visual Analogue Scale (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	47 [52,2]	6,7 [5,7;18,3]	90	45 [50,0]	13,1 [7,2;25,8]	1,26	[0,84; 1,90]	0,2711
Nicht-Asien	384	162 [42,2]	9,8 [7,1;12,0]	384	154 [40,1]	9,7 [7,2;13,0]	1,03	[0,83; 1,29]	0,7814
Interaktion p-Wert									0,4026
Klinischer Lymphknotenstatus									
Positiv	329	143 [43,5]	10,1 [7,3;12,9]	330	134 [40,6]	12,2 [8,0;17,9]	1,08	[0,85; 1,36]	0,5366
Negativ	145	66 [45,5]	6,2 [5,2;11,4]	144	65 [45,1]	8,0 [6,1;13,0]	1,10	[0,78; 1,55]	0,5870
Interaktion p-Wert									0,9225
PD-L1-Status									
TAP >= 1%	426	184 [43,2]	9,7 [6,9;12,7]	427	184 [43,1]	10,4 [7,5;13,1]	1,02	[0,83; 1,25]	0,8738
TAP < 1%	48	25 [52,1]	6,3 [4,6;10,8]	47	15 [31,9]	NE [NE; NE]	1,91	[1,02; 3,71]	0,0437*
Interaktion p-Wert									0,0619
Alter bei Randomisierung (Jahre)									
<65	291	146 [50,2]	7,5 [6,2;10,8]	265	120 [45,3]	8,0 [6,8;12,5]	1,15	[0,90; 1,46]	0,2676
>=65	183	63 [34,4]	11,1 [7,3; NE]	209	79 [37,8]	13,5 [10,4;25,8]	0,94	[0,67; 1,31]	0,7149
Interaktion p-Wert									0,3430
Geschlecht									
Männlich	326	136 [41,7]	10,4 [7,0;14,3]	356	152 [42,7]	10,8 [7,7;13,1]	1,02	[0,81; 1,28]	0,8762
Weiblich	148	73 [49,3]	7,8 [5,8;10,8]	118	47 [39,8]	11,6 [5,7;26,5]	1,21	[0,84; 1,76]	0,3032
Interaktion p-Wert									0,4326
Tumorlokalisation									
GC	324	148 [45,7]	8,3 [6,1;11,7]	316	134 [42,4]	12,2 [8,0;17,2]	1,17	[0,92; 1,48]	0,1929
GEJC	150	61 [40,7]	9,8 [6,6;16,0]	158	65 [41,1]	8,0 [6,0;12,7]	0,91	[0,64; 1,29]	0,5985
Interaktion p-Wert									0,2455

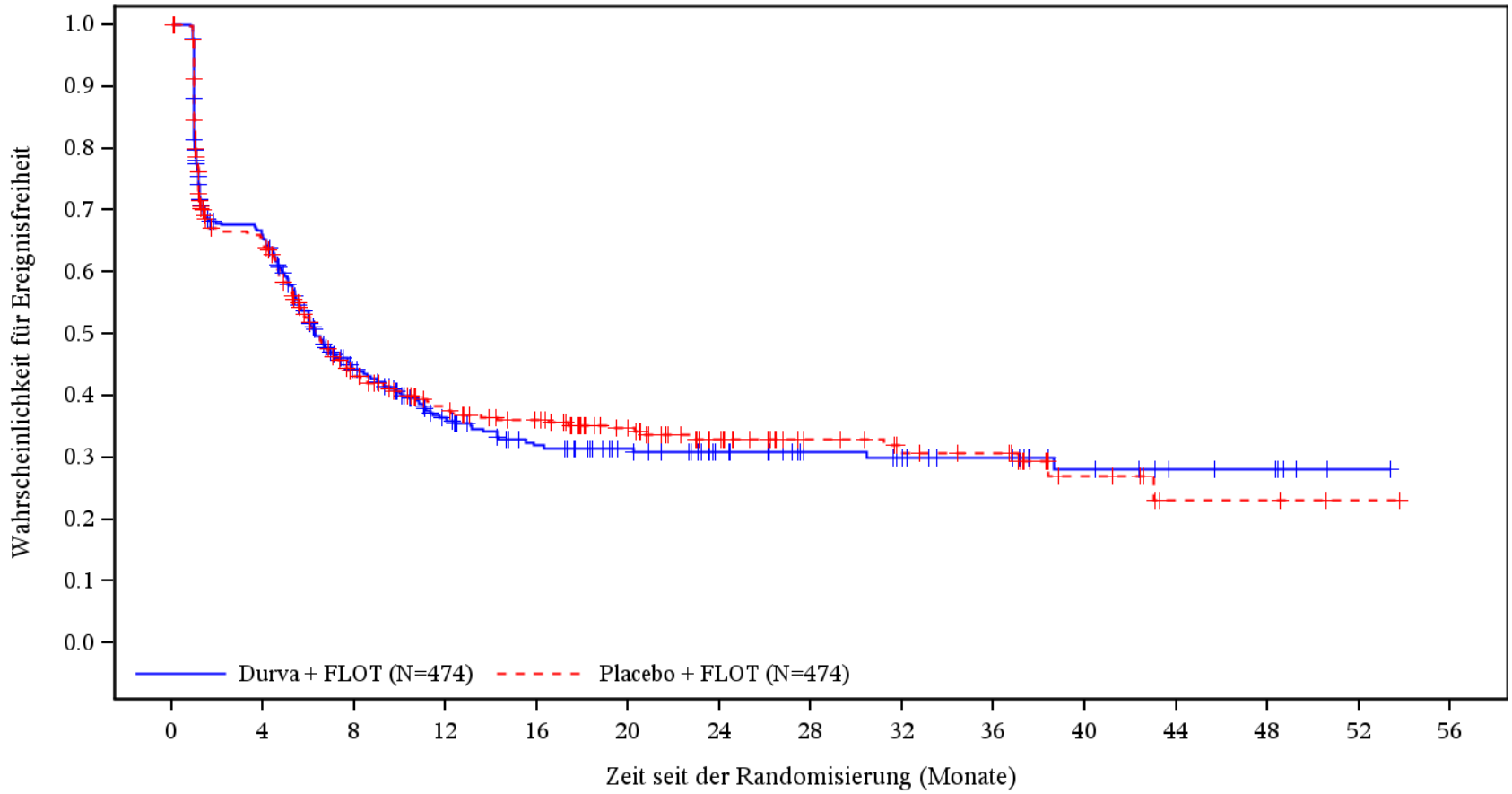
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.6.1 Summary of analysis of time to deterioration in Patient Global Impressions of Severity (PGIS) (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
Patient Global Impressions of Severity (PGIS)	474	228 [48,1]	6,3 [5,5; 7,9]	474	234 [49,4]	6,3 [5,5; 7,7]	1,02	[0,85; 1,23]	0,8193

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 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 based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic region, clinical lymph node status and PD-L1 status
Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.6.2 Kaplan-Meier plot of Patient Global Impressions of Severity (PGIS) (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

474	214	125	89	67	55	41	32	29	24	15	8	7	1	0
(0)	(133)	(156)	(171)	(183)	(194)	(207)	(216)	(218)	(223)	(231)	(238)	(239)	(245)	(246)
474	221	132	104	91	65	48	33	27	24	10	3	3	1	0
(0)	(121)	(139)	(151)	(160)	(183)	(197)	(212)	(216)	(219)	(231)	(237)	(237)	(239)	(240)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

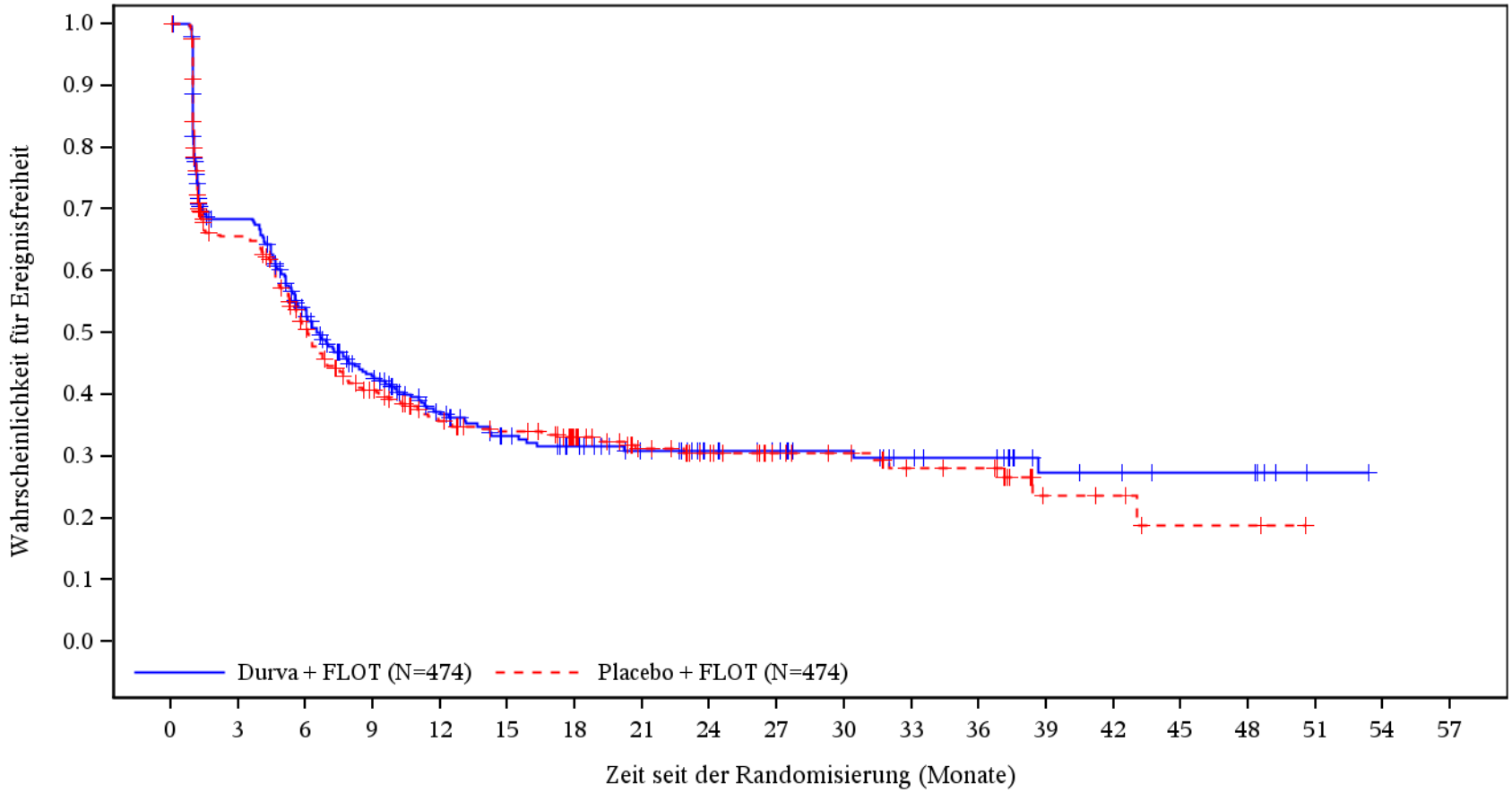
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Table 3.6.3 Summary of subgroup analysis of time to first Patient Global Impressions of Severity (PGIS) (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	54 [60,0]	5,6 [4,5; 6,7]	90	54 [60,0]	5,1 [4,2; 6,5]	1,02	[0,70; 1,49]	0,9186
Nicht-Asien	384	174 [45,3]	6,9 [5,5; 9,0]	384	180 [46,9]	6,9 [5,6; 8,2]	1,02	[0,83; 1,26]	0,8294
Interaktion p-Wert									0,9882
Klinischer Lymphknotenstatus									
Positiv	329	156 [47,4]	6,7 [5,7; 9,3]	330	159 [48,2]	6,8 [5,6; 9,5]	1,01	[0,81; 1,27]	0,9005
Negativ	145	72 [49,7]	5,3 [3,9; 8,7]	144	75 [52,1]	5,5 [4,1; 7,7]	1,05	[0,76; 1,45]	0,7727
Interaktion p-Wert									0,8666
PD-L1-Status									
TAP >= 1%	426	201 [47,2]	6,5 [5,5; 8,4]	427	218 [51,1]	6,1 [5,3; 7,3]	0,96	[0,79; 1,17]	0,7008
TAP < 1%	48	27 [56,3]	6,0 [1,4;10,8]	47	16 [34,0]	NE [NE; NE]	1,84	[1,005; 3,50]	0,0482*
Interaktion p-Wert									0,0456*
Alter bei Randomisierung (Jahre)									
<65	291	144 [49,5]	6,9 [5,5;10,0]	265	127 [47,9]	7,4 [6,1;10,6]	1,09	[0,86; 1,39]	0,4704
>=65	183	84 [45,9]	6,0 [4,9; 7,3]	209	107 [51,2]	5,3 [4,0; 6,3]	0,96	[0,72; 1,27]	0,7712
Interaktion p-Wert									0,4927
Geschlecht									
Männlich	326	146 [44,8]	7,3 [6,0; 9,6]	356	179 [50,3]	6,5 [5,6; 8,4]	0,94	[0,75; 1,17]	0,5669
Weiblich	148	82 [55,4]	4,6 [1,2; 6,7]	118	55 [46,6]	5,3 [4,1; 7,7]	1,18	[0,84; 1,67]	0,3431
Interaktion p-Wert									0,2683
Tumorlokalisation									
GC	324	173 [53,4]	5,3 [4,5; 6,6]	316	165 [52,2]	5,6 [4,7; 6,8]	1,08	[0,87; 1,33]	0,5051
GEJC	150	55 [36,7]	10,1 [6,6; NE]	158	69 [43,7]	7,7 [6,3;11,4]	0,88	[0,61; 1,25]	0,4664
Interaktion p-Wert									0,3330

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.6.4 Subgroup Analysis: Kaplan-Meier plot of Patient Global Impressions of Severity (PGIS) for PD-L1 status: TAP >= 1% (Morbidity)
Full Analysis Set, DCO 01SEP2025

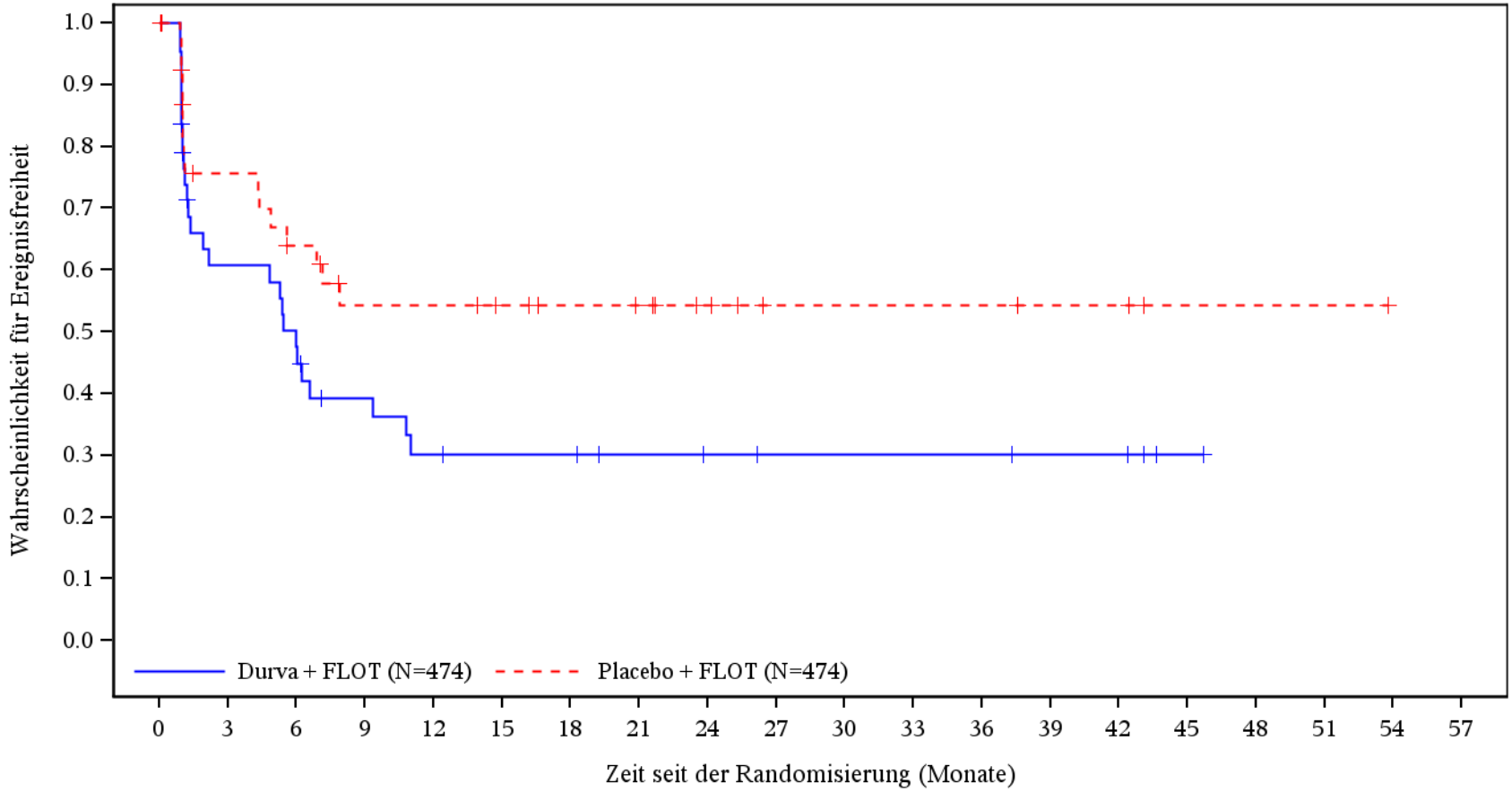


Anzahl im Risiko (Anzahl der zensierten Fälle)

426	198	146	106	79	63	53	44	35	31	27	21	19	11	10	7	7	1	0	0
(0)	(124)	(134)	(146)	(160)	(168)	(175)	(183)	(192)	(196)	(200)	(205)	(207)	(214)	(215)	(218)	(218)	(224)	(225)	(225)
427	201	149	110	88	78	63	47	40	31	28	21	20	7	6	2	2	0	0	0
(0)	(109)	(118)	(127)	(136)	(142)	(155)	(168)	(174)	(183)	(186)	(191)	(192)	(203)	(204)	(207)	(207)	(209)	(209)	(209)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.6.5 Subgroup Analysis: Kaplan-Meier plot of Patient Global Impressions of Severity (PGIS) for PD-L1 status: TAP < 1% (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

48	23	18	13	10	9	9	7	6	5	5	5	5	4	4	1	0	0	0	0
(0)	(9)	(9)	(11)	(11)	(12)	(12)	(14)	(15)	(16)	(16)	(16)	(16)	(17)	(17)	(20)	(21)	(21)	(21)	(21)
47	26	21	16	16	14	12	11	8	4	4	4	4	3	3	1	1	1	0	0
(0)	(12)	(13)	(15)	(15)	(17)	(19)	(20)	(23)	(27)	(27)	(27)	(27)	(28)	(28)	(30)	(30)	(30)	(31)	(31)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

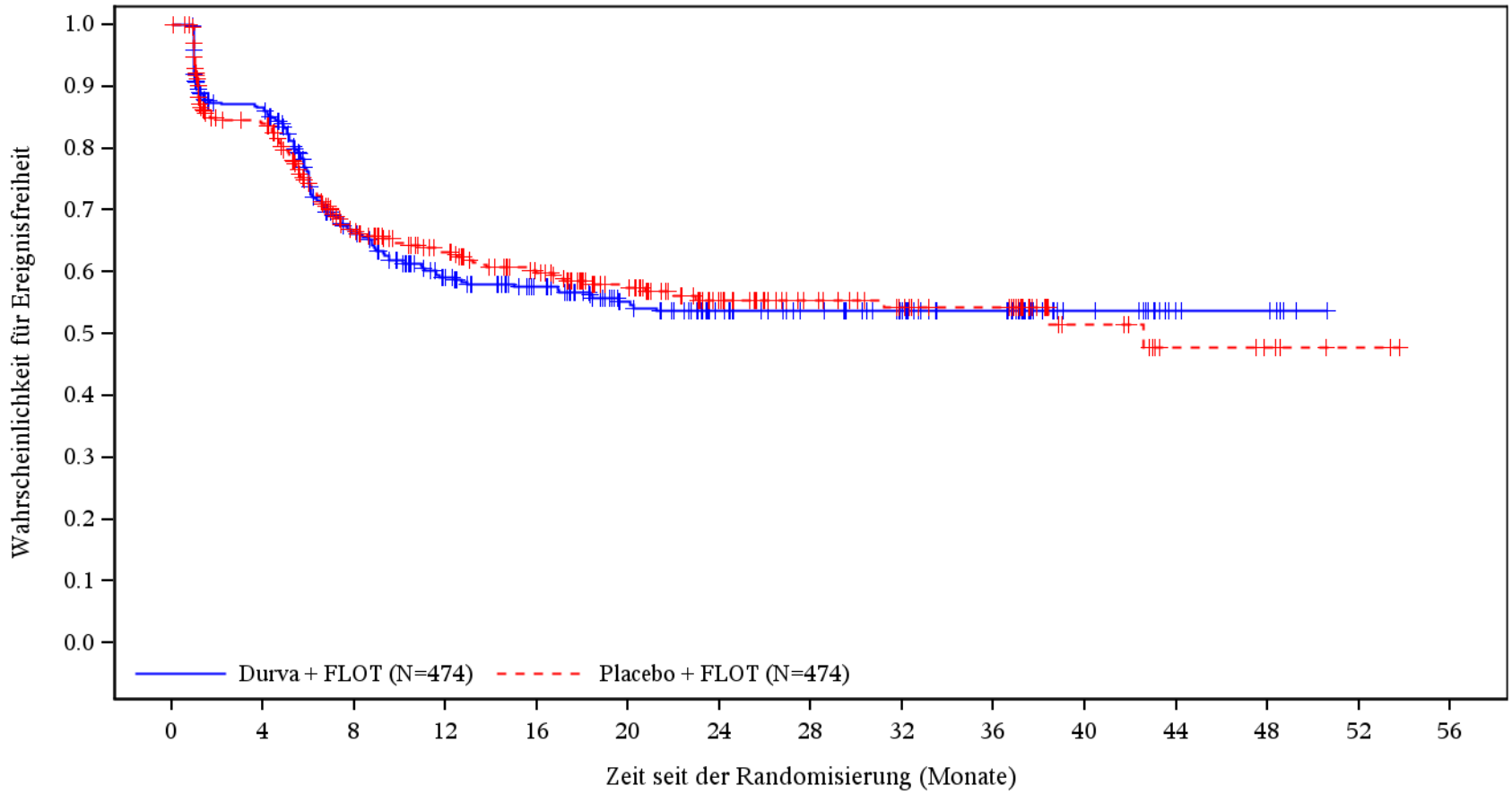
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Table 3.7.1 Summary of analysis of time to deterioration in Patient Global Impression of Change (PGIC) (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
Patient Global Impression of Change (PGIC)	474	155 [32,7]	NE [NE; NE]	474	143 [30,2]	42,5 [22,9; NE]	1,00	[0,80; 1,26]	0,9981

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 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 based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic region, clinical lymph node status and PD-L1 status
Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.7.2 Kaplan-Meier plot of Patient Global Impression of Change (PGIC) (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

474	308	204	161	133	105	80	68	57	46	23	9	8	0	0
(0)	(112)	(148)	(170)	(194)	(217)	(239)	(251)	(262)	(273)	(296)	(310)	(311)	(319)	(319)
474	280	190	161	135	104	72	54	44	39	16	8	5	2	0
(0)	(133)	(169)	(189)	(207)	(233)	(262)	(280)	(289)	(294)	(316)	(323)	(326)	(329)	(331)

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 date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Table 3.7.3 Summary of subgroup analysis of time to first Patient Global Impression of Change (PGIC) (Morbidity)
Full Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=474)			Placebo + FLOT (N=474)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	32 [35,6]	NE [NE; NE]	90	32 [35,6]	NE [NE; NE]	1,05	[0,64; 1,72]	0,8498
Nicht-Asien	384	123 [32,0]	NE [NE; NE]	384	111 [28,9]	38,4 [19,7; NE]	1,01	[0,78; 1,31]	0,9149
Interaktion p-Wert									0,9059
Klinischer Lymphknotenstatus									
Positiv	329	107 [32,5]	NE [NE; NE]	330	106 [32,1]	38,4 [16,9; NE]	0,90	[0,69; 1,18]	0,4664
Negativ	145	48 [33,1]	NE [NE; NE]	144	37 [25,7]	NE [NE; NE]	1,38	[0,90; 2,14]	0,1362
Interaktion p-Wert									0,0992
PD-L1-Status									
TAP >= 1%	426	139 [32,6]	NE [NE; NE]	427	134 [31,4]	38,4 [19,7; NE]	0,97	[0,77; 1,23]	0,8137
TAP < 1%	48	16 [33,3]	NE [NE; NE]	47	9 [19,1]	NE [NE; NE]	1,76	[0,79; 4,17]	0,1647
Interaktion p-Wert									0,1620
Alter bei Randomisierung (Jahre)									
<65	291	95 [32,6]	NE [NE; NE]	265	82 [30,9]	42,5 [21,9; NE]	0,98	[0,73; 1,31]	0,8677
>=65	183	60 [32,8]	21,3 [8,6; NE]	209	61 [29,2]	31,2 [13,5; NE]	1,12	[0,78; 1,60]	0,5458
Interaktion p-Wert									0,5678
Geschlecht									
Männlich	326	98 [30,1]	NE [NE; NE]	356	108 [30,3]	42,5 [22,9; NE]	0,94	[0,71; 1,23]	0,6479
Weiblich	148	57 [38,5]	20,1 [7,0; NE]	118	35 [29,7]	NE [NE; NE]	1,16	[0,77; 1,79]	0,4796
Interaktion p-Wert									0,4000
Tumorlokalisation									
GC	324	101 [31,2]	NE [NE; NE]	316	81 [25,6]	NE [NE; NE]	1,16	[0,86; 1,55]	0,3272
GEJC	150	54 [36,0]	18,4 [8,9; NE]	158	62 [39,2]	11,8 [7,4; NE]	0,85	[0,59; 1,22]	0,3768
Interaktion p-Wert									0,1929

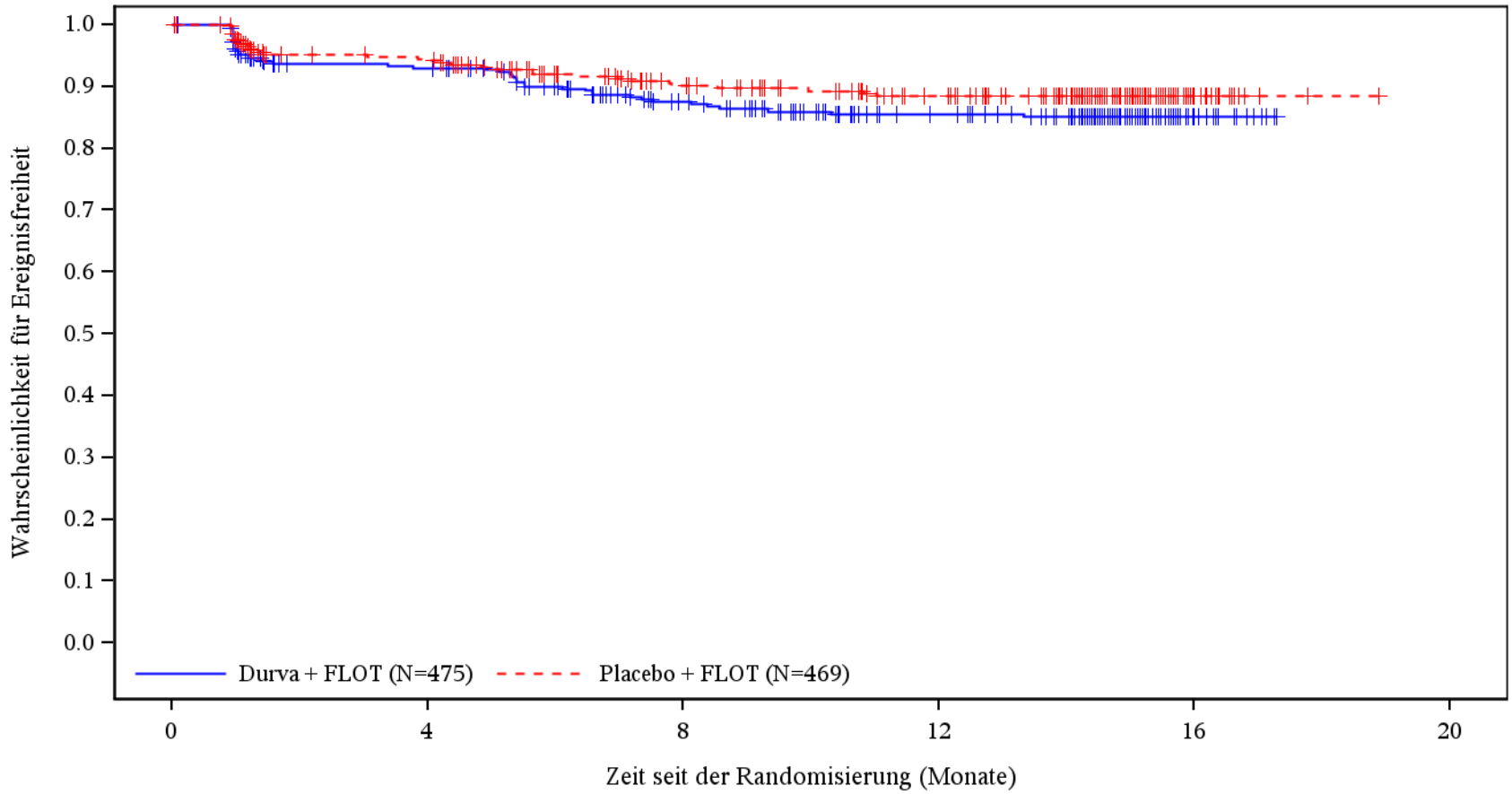
[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.8.1 Summary of analysis of time to deterioration in Patient Global Impression of Treatment Tolerability (PGITT) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)			Placebo + FLOT (N=469)					
	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (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]
Patient Global Impression of Treatment Tolerability (PGITT)	475	47 [9,9]	NE [NE; NE]	469	35 [7,5]	NE [NE; NE]	1,29	[0,84; 2,01]	0,2545

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 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 based on the Kaplan Meier estimate. NE = Not estimable as median (or 95% CLs) is not reached.
[b] Estimated from Cox proportional hazards model including treatment, geographic region, clinical lymph node status and PD-L1 status
Efron method for handling ties. 95% CI from profile likelihood estimation. Hazard ratio <1 favours Durva + FLOT.
[c] p-value is estimated using log-rank test stratified by same factors as part [b]. * p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.8.2 Kaplan-Meier plot of Patient Global Impression of Treatment Tolerability (PGITT) (Safety)
Safety Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

475	289	230	188	17	0
(0)	(161)	(204)	(241)	(411)	(428)
469	282	223	194	22	0
(0)	(167)	(215)	(240)	(412)	(434)

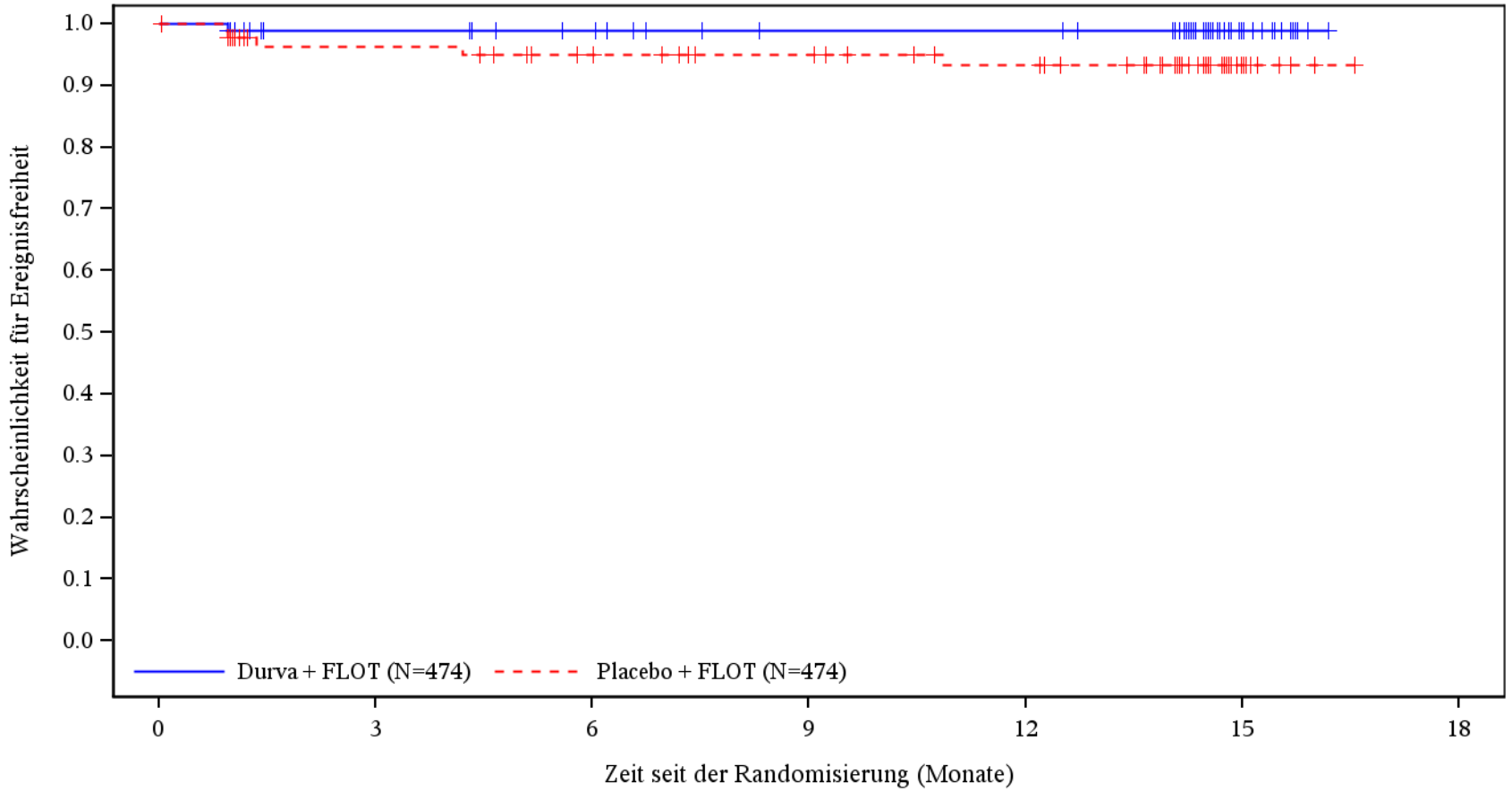
Time to first deterioration is defined as the time from randomization until the date of the first clinically meaningful worsening. Death is not considered an event. Patients with evaluable baseline data and no clinically important deterioration are censored at date of their last evaluable assessment. Patients with no evaluable baseline or post-baseline data will be censored at Day 1.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 3.8.3 Summary of subgroup analysis of time to first Patient Global Impression of Treatment Tolerability (PGITT) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)			Placebo + FLOT (N=469)					
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	n	Anzahl (%) der Patienten mit Ereignis	Mediane Zeit [95%-KI] (Monate) [a]	Hazard Ratio [b]	[95%-KI] [b]	2-seitiger p-Wert [b]
Region									
Asien	90	1 [1,1]	NE [NE; NE]	88	5 [5,7]	NE [NE; NE]	0,21	[0,01; 1,30]	0,0984
Nicht-Asien	385	46 [11,9]	NE [NE; NE]	381	30 [7,9]	NE [NE; NE]	1,49	[0,94; 2,38]	0,0876
Interaktion p-Wert									0,0410*
Klinischer Lymphknotenstatus									
Positiv	330	35 [10,6]	NE [NE; NE]	325	26 [8,0]	NE [NE; NE]	1,30	[0,78; 2,18]	0,3101
Negativ	145	12 [8,3]	NE [NE; NE]	144	9 [6,3]	NE [NE; NE]	1,39	[0,59; 3,40]	0,4535
Interaktion p-Wert									0,8954
PD-L1-Status									
TAP >= 1%	427	41 [9,6]	NE [NE; NE]	422	32 [7,6]	NE [NE; NE]	1,26	[0,80; 2,02]	0,3199
TAP < 1%	48	6 [12,5]	NE [NE; NE]	47	3 [6,4]	NE [NE; NE]	2,00	[0,53; 9,49]	0,3119
Interaktion p-Wert									0,5295
Alter bei Randomisierung (Jahre)									
<65	291	34 [11,7]	NE [NE; NE]	264	22 [8,3]	NE [NE; NE]	1,39	[0,82; 2,41]	0,2262
>=65	184	13 [7,1]	NE [NE; NE]	205	13 [6,3]	NE [NE; NE]	1,14	[0,53; 2,49]	0,7328
Interaktion p-Wert									0,6848
Geschlecht									
Männlich	327	30 [9,2]	NE [NE; NE]	351	31 [8,8]	NE [NE; NE]	1,07	[0,65; 1,78]	0,7783
Weiblich	148	17 [11,5]	NE [NE; NE]	118	4 [3,4]	NE [NE; NE]	3,05	[1,13; 10,60]	0,0266*
Interaktion p-Wert									0,0694
Tumorlokalisation									
GC	325	30 [9,2]	NE [NE; NE]	313	16 [5,1]	NE [NE; NE]	1,80	[0,996; 3,39]	0,0514
GEJC	150	17 [11,3]	NE [NE; NE]	156	19 [12,2]	NE [NE; NE]	0,94	[0,48; 1,81]	0,8511
Interaktion p-Wert									0,1496

[a] Median time to event based on the Kaplan Meier estimate. NE = not estimable as median (or 95% CLs) not reached.
[b] HR, 95% CIs and p-values are estimated using an unstratified Cox PH model with treatment, subgroup and treatment by subgroup interaction. The CIs are calculated using a profile likelihood approach. Treatment-by-subgroup interaction p-value was assessed by a likelihood ratio test comparing a model including treatment, subgroup and treatment-by-subgroup interaction with a reduced model without the interaction term. Efron method for handling ties. Note: An interaction model is only used when there are >=10 patients in each subgroup level, >=10 events in at least one subgroup level and >0 events in each treatment arm within a subgroup level. A subgroup level is removed from the analysis if insufficient data. If only one subgroup level then the model will include only treatment as a covariate. * Interaction p-value <0.05. HR <1 favours Durva + FLOT. NC = not calculable.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 3.8.4 Subgroup Analysis: Kaplan-Meier plot of Patient Global Impression of Treatment Tolerability (PGITT) for Region: Asia (Safety)
Safety Analysis Set, DCO 01SEP2025



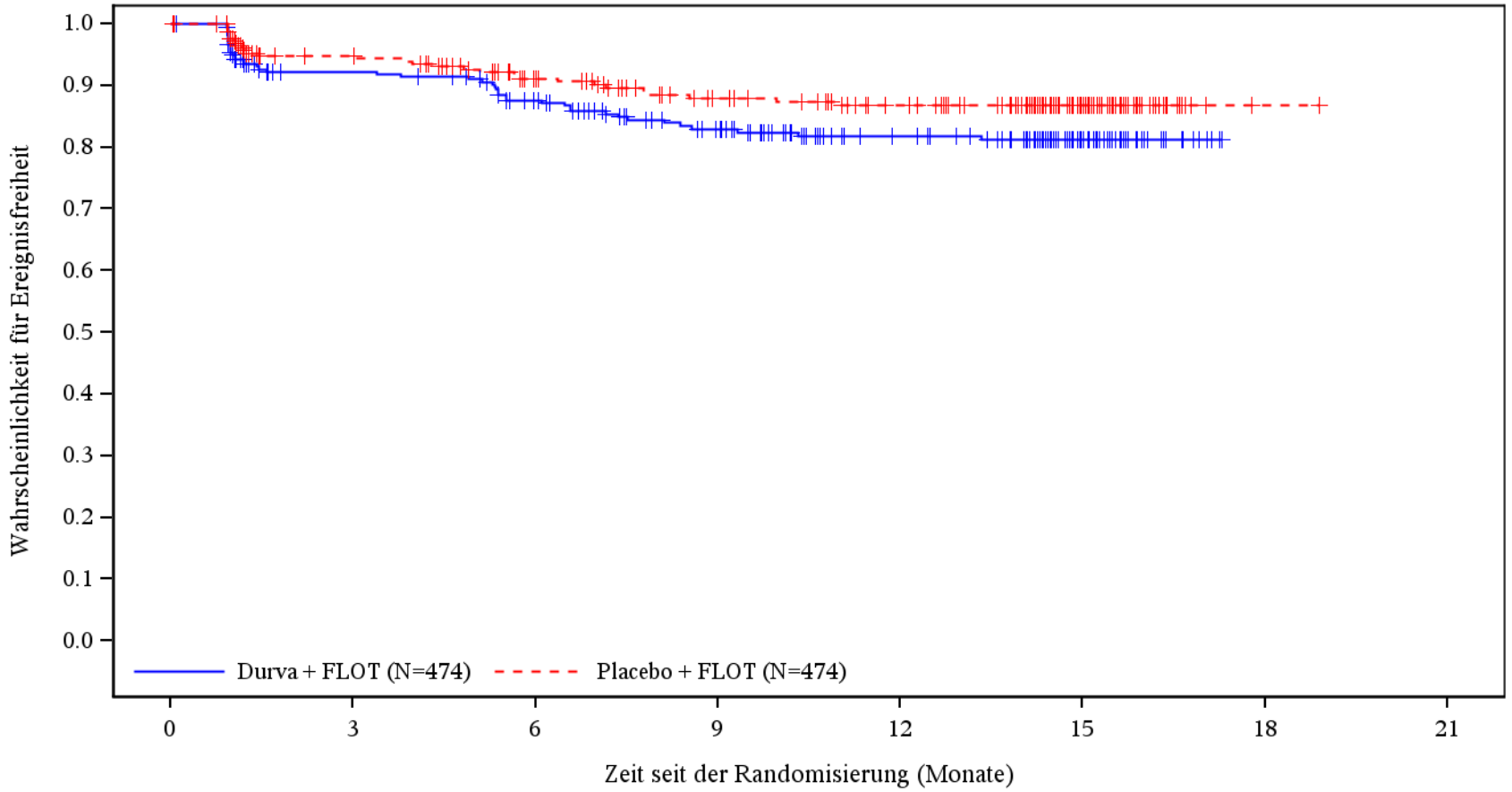
Anzahl im Risiko (Anzahl der zensierten Fälle)

90	66	62	56	56	18	0
(0)	(23)	(27)	(33)	(33)	(71)	(89)
88	72	65	60	54	10	0
(0)	(13)	(19)	(24)	(29)	(73)	(83)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Figure 3.8.5 Subgroup Analysis: Kaplan-Meier plot of Patient Global Impression of Treatment Tolerability (PGITT) for Region: Non-Asia (Safety)
Safety Analysis Set, DCO 01SEP2025



Anzahl im Risiko (Anzahl der zensierten Fälle)

385	225	200	164	132	58	0	0
(0)	(138)	(152)	(178)	(208)	(281)	(339)	(339)
381	214	182	156	140	65	1	0
(0)	(153)	(177)	(197)	(211)	(286)	(350)	(351)

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.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

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Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Appetitverlust	Durva + FLOT (N=474)	Baseline	425	21,25	28,786	0,0	0,00	100,0
		Zyklus 2, Tag 29	429	29,29	29,609	0,0	33,33	100,0
		Zyklus 3, Tag 1	293	26,96	30,676	0,0	33,33	100,0
		Zyklus 4, Tag 29	290	34,94	31,697	0,0	33,33	100,0
		Zyklus 5	262	33,46	31,359	0,0	33,33	100,0
		Zyklus 6	288	18,75	24,801	0,0	0,00	100,0
		Zyklus 7	283	16,84	23,881	0,0	0,00	100,0
		Zyklus 8	285	16,37	24,324	0,0	0,00	100,0
		Zyklus 9	268	16,29	22,986	0,0	0,00	100,0
		Zyklus 10	258	14,60	22,153	0,0	0,00	100,0
		Zyklus 11	258	14,47	22,140	0,0	0,00	100,0
		Zyklus 12	250	15,60	23,356	0,0	0,00	100,0
		Zyklus 13	236	11,72	20,376	0,0	0,00	100,0
		Zyklus 14	251	13,41	22,147	0,0	0,00	100,0
		Tag 30 Follow-up	248	14,65	22,951	0,0	0,00	100,0
		Monat 2 Follow-up	238	14,99	24,772	0,0	0,00	100,0
		Monat 3 Follow-up	252	14,29	22,827	0,0	0,00	100,0
		Monat 6 Follow-up	208	14,90	24,012	0,0	0,00	100,0
		Monat 9 Follow-up	198	11,78	20,047	0,0	0,00	100,0
		Monat 12 Follow-up	163	12,88	21,381	0,0	0,00	100,0
		Monat 15 Follow-up	85	9,41	16,755	0,0	0,00	66,7
		Monat 18 Follow-up	116	11,21	21,510	0,0	0,00	100,0
		Monat 21 Follow-up	77	10,39	17,320	0,0	0,00	66,7
		Monat 24 Follow-up	76	17,54	30,049	0,0	0,00	100,0
		Monat 30 Follow-up	86	11,63	21,552	0,0	0,00	100,0
		Monat 36 Follow-up	37	10,81	22,297	0,0	0,00	100,0
		Monat 42 Follow-up	6	11,11	17,213	0,0	0,00	33,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Appetitverlust	Placebo + FLOT (N=474)	Baseline	433	21,71	30,189	0,0	0,00	100,0
		Zyklus 2, Tag 29	410	26,67	28,434	0,0	33,33	100,0
		Zyklus 3, Tag 1	277	25,51	28,072	0,0	33,33	100,0
		Zyklus 4, Tag 29	278	31,29	29,568	0,0	33,33	100,0
		Zyklus 5	260	30,51	30,870	0,0	33,33	100,0
		Zyklus 6	276	18,60	25,747	0,0	0,00	100,0
		Zyklus 7	266	13,53	22,999	0,0	0,00	100,0
		Zyklus 8	268	13,18	22,167	0,0	0,00	100,0
		Zyklus 9	260	11,79	21,269	0,0	0,00	100,0
		Zyklus 10	257	14,14	22,513	0,0	0,00	100,0
		Zyklus 11	240	11,53	20,714	0,0	0,00	100,0
		Zyklus 12	233	10,30	20,265	0,0	0,00	100,0
		Zyklus 13	222	10,21	19,180	0,0	0,00	100,0
		Zyklus 14	232	9,05	19,603	0,0	0,00	100,0
		Tag 30 Follow-up	231	12,84	23,126	0,0	0,00	100,0
		Monat 2 Follow-up	239	12,41	23,055	0,0	0,00	100,0
		Monat 3 Follow-up	257	14,66	23,691	0,0	0,00	100,0
		Monat 6 Follow-up	186	14,16	23,690	0,0	0,00	100,0
		Monat 9 Follow-up	164	12,80	24,603	0,0	0,00	100,0
		Monat 12 Follow-up	120	12,78	24,515	0,0	0,00	100,0
		Monat 15 Follow-up	54	16,67	28,039	0,0	0,00	100,0
		Monat 18 Follow-up	99	12,46	21,074	0,0	0,00	66,7
		Monat 21 Follow-up	50	17,33	28,761	0,0	0,00	100,0
		Monat 24 Follow-up	65	12,82	21,804	0,0	0,00	100,0
		Monat 30 Follow-up	57	14,04	25,156	0,0	0,00	100,0
		Monat 36 Follow-up	21	12,70	19,653	0,0	0,00	66,7
		Monat 42 Follow-up	8	4,17	11,785	0,0	0,00	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Verstopfung	Durva + FLOT (N=474)	Baseline	425	17,02	26,708	0,0	0,00	100,0
		Zyklus 2, Tag 29	429	13,75	22,898	0,0	0,00	100,0
		Zyklus 3, Tag 1	293	11,15	21,299	0,0	0,00	100,0
		Zyklus 4, Tag 29	290	11,84	19,053	0,0	0,00	100,0
		Zyklus 5	262	11,32	19,657	0,0	0,00	66,7
		Zyklus 6	288	7,87	16,689	0,0	0,00	100,0
		Zyklus 7	283	6,60	15,236	0,0	0,00	100,0
		Zyklus 8	285	6,08	14,058	0,0	0,00	66,7
		Zyklus 9	268	5,72	15,005	0,0	0,00	66,7
		Zyklus 10	258	5,30	15,064	0,0	0,00	100,0
		Zyklus 11	258	6,07	15,895	0,0	0,00	100,0
		Zyklus 12	250	6,53	15,722	0,0	0,00	100,0
		Zyklus 13	236	5,08	13,493	0,0	0,00	66,7
		Zyklus 14	251	5,98	14,443	0,0	0,00	100,0
		Tag 30 Follow-up	248	6,32	15,885	0,0	0,00	100,0
		Monat 2 Follow-up	238	6,58	15,571	0,0	0,00	100,0
		Monat 3 Follow-up	252	5,82	16,067	0,0	0,00	100,0
		Monat 6 Follow-up	208	7,53	17,085	0,0	0,00	100,0
		Monat 9 Follow-up	198	7,91	17,100	0,0	0,00	100,0
		Monat 12 Follow-up	163	6,75	15,783	0,0	0,00	66,7
		Monat 15 Follow-up	85	7,06	15,511	0,0	0,00	66,7
		Monat 18 Follow-up	116	9,48	19,563	0,0	0,00	100,0
		Monat 21 Follow-up	77	9,52	19,389	0,0	0,00	66,7
		Monat 24 Follow-up	76	9,65	17,054	0,0	0,00	66,7
		Monat 30 Follow-up	86	10,85	21,354	0,0	0,00	100,0
		Monat 36 Follow-up	37	11,71	26,313	0,0	0,00	100,0
		Monat 42 Follow-up	6	11,11	17,213	0,0	0,00	33,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Verstopfung	Placebo + FLOT (N=474)	Baseline	433	16,40	26,265	0,0	0,00	100,0
		Zyklus 2, Tag 29	410	15,20	24,095	0,0	0,00	100,0
		Zyklus 3, Tag 1	277	11,55	21,113	0,0	0,00	100,0
		Zyklus 4, Tag 29	278	11,15	22,112	0,0	0,00	100,0
		Zyklus 5	260	10,00	20,357	0,0	0,00	100,0
		Zyklus 6	276	8,09	17,836	0,0	0,00	100,0
		Zyklus 7	266	7,02	15,889	0,0	0,00	100,0
		Zyklus 8	268	6,59	16,638	0,0	0,00	100,0
		Zyklus 9	260	5,38	13,297	0,0	0,00	66,7
		Zyklus 10	257	6,23	15,455	0,0	0,00	100,0
		Zyklus 11	240	6,67	15,903	0,0	0,00	100,0
		Zyklus 12	233	6,29	15,734	0,0	0,00	100,0
		Zyklus 13	222	5,26	14,089	0,0	0,00	100,0
		Zyklus 14	232	5,89	15,778	0,0	0,00	100,0
		Tag 30 Follow-up	231	6,64	15,043	0,0	0,00	66,7
		Monat 2 Follow-up	239	7,67	17,862	0,0	0,00	100,0
		Monat 3 Follow-up	257	8,04	18,755	0,0	0,00	100,0
		Monat 6 Follow-up	186	8,78	18,679	0,0	0,00	100,0
		Monat 9 Follow-up	164	8,54	19,051	0,0	0,00	100,0
		Monat 12 Follow-up	120	7,22	17,384	0,0	0,00	100,0
		Monat 15 Follow-up	54	9,88	23,012	0,0	0,00	100,0
		Monat 18 Follow-up	99	7,74	15,670	0,0	0,00	66,7
		Monat 21 Follow-up	50	8,67	19,989	0,0	0,00	100,0
		Monat 24 Follow-up	65	5,13	12,120	0,0	0,00	33,3
		Monat 30 Follow-up	57	10,53	23,703	0,0	0,00	100,0
		Monat 36 Follow-up	21	9,52	26,125	0,0	0,00	100,0
		Monat 42 Follow-up	8	4,17	11,785	0,0	0,00	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Diarrhö	Durva + FLOT (N=474)	Baseline	425	6,51	16,090	0,0	0,00	100,0
		Zyklus 2, Tag 29	429	25,87	27,651	0,0	33,33	100,0
		Zyklus 3, Tag 1	293	22,07	25,250	0,0	33,33	100,0
		Zyklus 4, Tag 29	290	31,95	29,182	0,0	33,33	100,0
		Zyklus 5	262	30,53	30,194	0,0	33,33	100,0
		Zyklus 6	288	19,91	25,142	0,0	0,00	100,0
		Zyklus 7	283	17,08	23,546	0,0	0,00	100,0
		Zyklus 8	285	15,32	20,819	0,0	0,00	100,0
		Zyklus 9	268	15,17	21,825	0,0	0,00	100,0
		Zyklus 10	258	14,86	20,131	0,0	0,00	100,0
		Zyklus 11	258	13,18	20,124	0,0	0,00	100,0
		Zyklus 12	250	13,47	20,283	0,0	0,00	66,7
		Zyklus 13	236	13,84	21,449	0,0	0,00	100,0
		Zyklus 14	251	13,94	20,771	0,0	0,00	100,0
		Tag 30 Follow-up	248	13,84	20,805	0,0	0,00	100,0
		Monat 2 Follow-up	238	14,15	21,450	0,0	0,00	100,0
		Monat 3 Follow-up	252	13,10	21,260	0,0	0,00	100,0
		Monat 6 Follow-up	208	12,34	21,297	0,0	0,00	100,0
		Monat 9 Follow-up	198	13,64	20,956	0,0	0,00	100,0
		Monat 12 Follow-up	163	11,04	19,265	0,0	0,00	100,0
		Monat 15 Follow-up	85	11,37	19,621	0,0	0,00	100,0
		Monat 18 Follow-up	116	8,33	16,374	0,0	0,00	66,7
		Monat 21 Follow-up	77	13,85	21,865	0,0	0,00	100,0
		Monat 24 Follow-up	76	10,96	17,544	0,0	0,00	66,7
		Monat 30 Follow-up	86	11,63	22,151	0,0	0,00	100,0
		Monat 36 Follow-up	37	15,32	26,753	0,0	0,00	100,0
		Monat 42 Follow-up	6	5,56	13,608	0,0	0,00	33,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Diarrhö	Placebo + FLOT (N=474)	Baseline	433	8,16	17,425	0,0	0,00	100,0
		Zyklus 2, Tag 29	410	24,15	28,731	0,0	33,33	100,0
		Zyklus 3, Tag 1	277	24,91	29,235	0,0	33,33	100,0
		Zyklus 4, Tag 29	278	34,29	32,280	0,0	33,33	100,0
		Zyklus 5	260	30,51	30,591	0,0	33,33	100,0
		Zyklus 6	276	22,46	27,462	0,0	0,00	100,0
		Zyklus 7	266	19,67	25,766	0,0	0,00	100,0
		Zyklus 8	268	16,54	23,169	0,0	0,00	100,0
		Zyklus 9	260	17,82	23,128	0,0	0,00	100,0
		Zyklus 10	257	18,42	24,610	0,0	0,00	100,0
		Zyklus 11	240	16,81	22,199	0,0	0,00	100,0
		Zyklus 12	233	16,17	22,973	0,0	0,00	100,0
		Zyklus 13	222	15,32	22,099	0,0	0,00	100,0
		Zyklus 14	232	14,22	21,573	0,0	0,00	100,0
		Tag 30 Follow-up	231	14,72	22,943	0,0	0,00	100,0
		Monat 2 Follow-up	239	14,09	22,279	0,0	0,00	100,0
		Monat 3 Follow-up	257	16,99	23,774	0,0	0,00	100,0
		Monat 6 Follow-up	186	15,77	23,807	0,0	0,00	100,0
		Monat 9 Follow-up	164	13,01	21,053	0,0	0,00	100,0
		Monat 12 Follow-up	120	14,44	21,052	0,0	0,00	100,0
		Monat 15 Follow-up	54	19,14	28,668	0,0	0,00	100,0
		Monat 18 Follow-up	99	17,17	23,017	0,0	0,00	66,7
		Monat 21 Follow-up	50	22,00	26,607	0,0	0,00	100,0
		Monat 24 Follow-up	65	20,51	28,070	0,0	0,00	100,0
		Monat 30 Follow-up	57	15,79	22,805	0,0	0,00	100,0
		Monat 36 Follow-up	21	11,11	21,943	0,0	0,00	66,7
		Monat 42 Follow-up	8	8,33	15,430	0,0	0,00	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Dyspnoe	Durva + FLOT (N=474)	Baseline	425	10,98	19,950	0,0	0,00	100,0
		Zyklus 2, Tag 29	429	11,03	18,721	0,0	0,00	100,0
		Zyklus 3, Tag 1	293	17,29	23,175	0,0	0,00	100,0
		Zyklus 4, Tag 29	290	16,55	22,399	0,0	0,00	100,0
		Zyklus 5	262	16,16	22,549	0,0	0,00	100,0
		Zyklus 6	288	15,28	22,391	0,0	0,00	100,0
		Zyklus 7	283	12,60	19,504	0,0	0,00	66,7
		Zyklus 8	285	12,16	18,977	0,0	0,00	66,7
		Zyklus 9	268	11,19	18,447	0,0	0,00	100,0
		Zyklus 10	258	10,59	18,119	0,0	0,00	100,0
		Zyklus 11	258	9,43	16,152	0,0	0,00	66,7
		Zyklus 12	250	9,47	17,779	0,0	0,00	100,0
		Zyklus 13	236	8,90	16,006	0,0	0,00	66,7
		Zyklus 14	251	8,50	16,287	0,0	0,00	66,7
		Tag 30 Follow-up	248	8,33	16,222	0,0	0,00	66,7
		Monat 2 Follow-up	238	10,22	19,197	0,0	0,00	100,0
		Monat 3 Follow-up	252	10,71	19,394	0,0	0,00	100,0
		Monat 6 Follow-up	208	9,94	18,172	0,0	0,00	100,0
		Monat 9 Follow-up	198	11,95	21,181	0,0	0,00	100,0
		Monat 12 Follow-up	163	10,43	18,711	0,0	0,00	100,0
		Monat 15 Follow-up	85	11,76	21,023	0,0	0,00	100,0
		Monat 18 Follow-up	116	10,63	20,897	0,0	0,00	100,0
		Monat 21 Follow-up	77	11,69	20,779	0,0	0,00	100,0
		Monat 24 Follow-up	76	9,65	20,233	0,0	0,00	100,0
		Monat 30 Follow-up	86	11,63	20,303	0,0	0,00	100,0
		Monat 36 Follow-up	37	16,22	27,913	0,0	0,00	100,0
		Monat 42 Follow-up	6	5,56	13,608	0,0	0,00	33,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Dyspnoe	Placebo + FLOT (N=474)	Baseline	433	9,39	19,220	0,0	0,00	100,0
		Zyklus 2, Tag 29	410	12,20	20,262	0,0	0,00	100,0
		Zyklus 3, Tag 1	277	16,37	22,453	0,0	0,00	100,0
		Zyklus 4, Tag 29	278	15,71	22,594	0,0	0,00	100,0
		Zyklus 5	260	17,18	24,589	0,0	0,00	100,0
		Zyklus 6	276	12,44	21,515	0,0	0,00	100,0
		Zyklus 7	266	10,03	18,760	0,0	0,00	100,0
		Zyklus 8	268	12,44	20,872	0,0	0,00	100,0
		Zyklus 9	260	10,51	19,223	0,0	0,00	100,0
		Zyklus 10	257	10,77	19,565	0,0	0,00	100,0
		Zyklus 11	240	10,83	19,122	0,0	0,00	100,0
		Zyklus 12	233	9,01	18,565	0,0	0,00	100,0
		Zyklus 13	222	7,36	15,565	0,0	0,00	100,0
		Zyklus 14	232	7,76	18,010	0,0	0,00	100,0
		Tag 30 Follow-up	231	10,25	19,803	0,0	0,00	100,0
		Monat 2 Follow-up	239	11,30	19,750	0,0	0,00	100,0
		Monat 3 Follow-up	257	13,49	23,746	0,0	0,00	100,0
		Monat 6 Follow-up	186	12,54	22,681	0,0	0,00	100,0
		Monat 9 Follow-up	164	9,96	19,945	0,0	0,00	100,0
		Monat 12 Follow-up	120	9,17	18,315	0,0	0,00	100,0
		Monat 15 Follow-up	54	10,49	23,188	0,0	0,00	100,0
		Monat 18 Follow-up	99	13,47	20,712	0,0	0,00	100,0
		Monat 21 Follow-up	50	14,67	26,221	0,0	0,00	100,0
		Monat 24 Follow-up	65	10,77	21,334	0,0	0,00	100,0
		Monat 30 Follow-up	57	12,28	22,389	0,0	0,00	100,0
		Monat 36 Follow-up	21	9,52	23,905	0,0	0,00	100,0
		Monat 42 Follow-up	8	8,33	15,430	0,0	0,00	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Fatigue	Durva + FLOT (N=474)	Baseline	425	24,39	21,858	0,0	22,22	100,0
		Zyklus 2, Tag 29	429	32,43	21,322	0,0	33,33	100,0
		Zyklus 3, Tag 1	293	34,51	21,971	0,0	33,33	100,0
		Zyklus 4, Tag 29	290	38,81	24,407	0,0	33,33	100,0
		Zyklus 5	262	38,08	23,667	0,0	33,33	100,0
		Zyklus 6	288	29,90	22,275	0,0	33,33	100,0
		Zyklus 7	283	27,33	20,758	0,0	22,22	100,0
		Zyklus 8	285	26,71	20,371	0,0	33,33	100,0
		Zyklus 9	268	25,79	19,946	0,0	22,22	100,0
		Zyklus 10	258	24,94	19,525	0,0	22,22	100,0
		Zyklus 11	258	23,08	18,370	0,0	22,22	88,9
		Zyklus 12	250	23,60	19,503	0,0	22,22	88,9
		Zyklus 13	236	21,66	18,781	0,0	22,22	77,8
		Zyklus 14	251	21,16	20,070	0,0	22,22	100,0
		Tag 30 Follow-up	248	21,95	20,268	0,0	22,22	88,9
		Monat 2 Follow-up	238	23,81	22,745	0,0	22,22	100,0
		Monat 3 Follow-up	252	24,38	21,724	0,0	22,22	100,0
		Monat 6 Follow-up	208	24,31	22,218	0,0	22,22	100,0
		Monat 9 Follow-up	198	23,46	22,018	0,0	22,22	100,0
		Monat 12 Follow-up	163	22,49	21,131	0,0	22,22	100,0
		Monat 15 Follow-up	85	21,83	19,806	0,0	22,22	88,9
		Monat 18 Follow-up	116	21,74	20,535	0,0	22,22	88,9
		Monat 21 Follow-up	77	23,23	20,005	0,0	22,22	88,9
		Monat 24 Follow-up	76	22,66	22,032	0,0	22,22	100,0
		Monat 30 Follow-up	86	23,51	23,457	0,0	22,22	100,0
		Monat 36 Follow-up	37	25,23	28,766	0,0	22,22	100,0
		Monat 42 Follow-up	6	31,48	28,473	0,0	22,22	66,7
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Fatigue	Placebo + FLOT (N=474)	Baseline	433	23,22	21,777	0,0	22,22	100,0
		Zyklus 2, Tag 29	410	32,01	23,004	0,0	33,33	100,0
		Zyklus 3, Tag 1	277	32,97	22,489	0,0	33,33	100,0
		Zyklus 4, Tag 29	278	35,57	24,280	0,0	33,33	100,0
		Zyklus 5	260	36,28	23,804	0,0	33,33	100,0
		Zyklus 6	276	28,66	22,516	0,0	33,33	100,0
		Zyklus 7	266	24,23	21,052	0,0	22,22	100,0
		Zyklus 8	268	23,96	21,604	0,0	22,22	100,0
		Zyklus 9	260	23,08	20,158	0,0	22,22	100,0
		Zyklus 10	257	21,92	21,300	0,0	22,22	100,0
		Zyklus 11	240	21,67	20,346	0,0	22,22	100,0
		Zyklus 12	233	20,22	19,850	0,0	22,22	100,0
		Zyklus 13	222	18,72	18,368	0,0	11,11	77,8
		Zyklus 14	232	20,02	19,872	0,0	22,22	100,0
		Tag 30 Follow-up	231	21,89	22,638	0,0	22,22	100,0
		Monat 2 Follow-up	239	21,90	21,008	0,0	22,22	100,0
		Monat 3 Follow-up	257	24,25	23,369	0,0	22,22	100,0
		Monat 6 Follow-up	186	23,66	23,576	0,0	22,22	100,0
		Monat 9 Follow-up	164	22,09	23,384	0,0	22,22	100,0
		Monat 12 Follow-up	120	19,72	19,722	0,0	16,67	100,0
		Monat 15 Follow-up	54	20,16	23,553	0,0	16,67	88,9
		Monat 18 Follow-up	99	23,01	22,123	0,0	22,22	100,0
		Monat 21 Follow-up	50	30,44	25,278	0,0	33,33	100,0
		Monat 24 Follow-up	65	23,93	21,981	0,0	22,22	100,0
		Monat 30 Follow-up	57	24,56	24,374	0,0	22,22	100,0
		Monat 36 Follow-up	21	22,75	22,076	0,0	22,22	88,9
		Monat 42 Follow-up	8	18,06	15,643	0,0	16,67	44,4

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Finanzielle Schwierigkeiten	Durva + FLOT (N=474)	Baseline	425	18,82	27,303	0,0	0,00	100,0
		Zyklus 2, Tag 29	429	16,47	25,129	0,0	0,00	100,0
		Zyklus 3, Tag 1	293	20,71	26,814	0,0	0,00	100,0
		Zyklus 4, Tag 29	290	19,08	25,337	0,0	0,00	100,0
		Zyklus 5	262	19,47	28,264	0,0	0,00	100,0
		Zyklus 6	288	16,55	26,251	0,0	0,00	100,0
		Zyklus 7	283	17,20	26,533	0,0	0,00	100,0
		Zyklus 8	285	17,54	26,170	0,0	0,00	100,0
		Zyklus 9	268	17,54	24,886	0,0	0,00	100,0
		Zyklus 10	258	17,57	25,996	0,0	0,00	100,0
		Zyklus 11	258	16,15	24,465	0,0	0,00	100,0
		Zyklus 12	250	15,73	25,725	0,0	0,00	100,0
		Zyklus 13	236	15,68	25,983	0,0	0,00	100,0
		Zyklus 14	251	15,41	25,507	0,0	0,00	100,0
		Tag 30 Follow-up	248	14,52	25,360	0,0	0,00	100,0
		Monat 2 Follow-up	238	17,23	28,679	0,0	0,00	100,0
		Monat 3 Follow-up	252	15,87	26,850	0,0	0,00	100,0
		Monat 6 Follow-up	208	15,38	26,180	0,0	0,00	100,0
		Monat 9 Follow-up	198	17,17	28,246	0,0	0,00	100,0
		Monat 12 Follow-up	163	14,11	25,091	0,0	0,00	100,0
		Monat 15 Follow-up	85	11,37	24,426	0,0	0,00	100,0
		Monat 18 Follow-up	116	12,64	22,265	0,0	0,00	100,0
		Monat 21 Follow-up	77	14,29	26,173	0,0	0,00	100,0
		Monat 24 Follow-up	76	12,28	23,628	0,0	0,00	100,0
		Monat 30 Follow-up	86	13,95	24,768	0,0	0,00	100,0
		Monat 36 Follow-up	37	9,01	21,729	0,0	0,00	100,0
		Monat 42 Follow-up	6	16,67	27,889	0,0	0,00	66,7
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Finanzielle Schwierigkeiten	Placebo + FLOT (N=474)	Baseline	433	17,17	25,567	0,0	0,00	100,0
		Zyklus 2, Tag 29	410	15,85	25,119	0,0	0,00	100,0
		Zyklus 3, Tag 1	277	18,41	26,655	0,0	0,00	100,0
		Zyklus 4, Tag 29	278	19,54	28,706	0,0	0,00	100,0
		Zyklus 5	260	19,23	28,054	0,0	0,00	100,0
		Zyklus 6	276	18,60	26,823	0,0	0,00	100,0
		Zyklus 7	266	17,04	26,735	0,0	0,00	100,0
		Zyklus 8	268	17,29	28,186	0,0	0,00	100,0
		Zyklus 9	260	16,67	27,556	0,0	0,00	100,0
		Zyklus 10	257	17,12	27,967	0,0	0,00	100,0
		Zyklus 11	240	16,81	27,273	0,0	0,00	100,0
		Zyklus 12	233	15,74	26,085	0,0	0,00	100,0
		Zyklus 13	222	14,11	24,786	0,0	0,00	100,0
		Zyklus 14	232	15,23	25,536	0,0	0,00	100,0
		Tag 30 Follow-up	231	17,60	27,590	0,0	0,00	100,0
		Monat 2 Follow-up	239	15,76	25,343	0,0	0,00	100,0
		Monat 3 Follow-up	257	17,51	28,419	0,0	0,00	100,0
		Monat 6 Follow-up	186	16,31	26,221	0,0	0,00	100,0
		Monat 9 Follow-up	164	14,63	26,676	0,0	0,00	100,0
		Monat 12 Follow-up	120	10,83	22,522	0,0	0,00	100,0
		Monat 15 Follow-up	54	12,96	27,023	0,0	0,00	100,0
		Monat 18 Follow-up	99	14,81	23,915	0,0	0,00	100,0
		Monat 21 Follow-up	50	17,33	31,037	0,0	0,00	100,0
		Monat 24 Follow-up	65	14,87	25,021	0,0	0,00	100,0
		Monat 30 Follow-up	57	14,04	24,355	0,0	0,00	100,0
		Monat 36 Follow-up	21	11,11	30,429	0,0	0,00	100,0
		Monat 42 Follow-up	8	4,17	11,785	0,0	0,00	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Übelkeit und Erbrechen	Durva + FLOT (N=474)	Baseline	425	10,47	19,979	0,0	0,00	100,0
		Zyklus 2, Tag 29	429	15,97	20,622	0,0	16,67	100,0
		Zyklus 3, Tag 1	293	12,34	17,401	0,0	0,00	100,0
		Zyklus 4, Tag 29	290	21,90	24,024	0,0	16,67	100,0
		Zyklus 5	262	16,48	21,417	0,0	16,67	100,0
		Zyklus 6	288	11,57	17,297	0,0	0,00	100,0
		Zyklus 7	283	10,07	16,950	0,0	0,00	83,3
		Zyklus 8	285	9,30	15,646	0,0	0,00	100,0
		Zyklus 9	268	9,08	15,349	0,0	0,00	83,3
		Zyklus 10	258	7,88	13,883	0,0	0,00	66,7
		Zyklus 11	258	7,36	13,053	0,0	0,00	66,7
		Zyklus 12	250	7,07	13,152	0,0	0,00	66,7
		Zyklus 13	236	7,49	14,108	0,0	0,00	100,0
		Zyklus 14	251	7,77	15,437	0,0	0,00	100,0
		Tag 30 Follow-up	248	7,46	14,514	0,0	0,00	100,0
		Monat 2 Follow-up	238	8,19	15,214	0,0	0,00	83,3
		Monat 3 Follow-up	252	8,07	14,072	0,0	0,00	100,0
		Monat 6 Follow-up	208	7,45	14,718	0,0	0,00	100,0
		Monat 9 Follow-up	198	7,15	13,669	0,0	0,00	66,7
		Monat 12 Follow-up	163	6,65	12,359	0,0	0,00	66,7
		Monat 15 Follow-up	85	5,88	13,290	0,0	0,00	66,7
		Monat 18 Follow-up	116	7,18	14,450	0,0	0,00	83,3
		Monat 21 Follow-up	77	7,14	12,220	0,0	0,00	50,0
		Monat 24 Follow-up	76	8,11	15,029	0,0	0,00	66,7
		Monat 30 Follow-up	86	7,17	12,404	0,0	0,00	50,0
		Monat 36 Follow-up	37	10,81	18,094	0,0	0,00	66,7
		Monat 42 Follow-up	6	11,11	17,213	0,0	0,00	33,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Übelkeit und Erbrechen	Placebo + FLOT (N=474)	Baseline	433	10,93	20,377	0,0	0,00	100,0
		Zyklus 2, Tag 29	410	17,40	22,678	0,0	16,67	100,0
		Zyklus 3, Tag 1	277	12,76	17,713	0,0	0,00	100,0
		Zyklus 4, Tag 29	278	18,71	23,396	0,0	16,67	100,0
		Zyklus 5	260	15,06	21,390	0,0	0,00	100,0
		Zyklus 6	276	9,00	16,409	0,0	0,00	100,0
		Zyklus 7	266	7,96	14,990	0,0	0,00	100,0
		Zyklus 8	268	7,46	13,309	0,0	0,00	66,7
		Zyklus 9	260	7,05	14,179	0,0	0,00	100,0
		Zyklus 10	257	7,91	16,407	0,0	0,00	100,0
		Zyklus 11	240	6,32	12,595	0,0	0,00	83,3
		Zyklus 12	233	6,87	14,780	0,0	0,00	100,0
		Zyklus 13	222	6,31	12,190	0,0	0,00	50,0
		Zyklus 14	232	6,25	13,267	0,0	0,00	66,7
		Tag 30 Follow-up	231	6,20	13,459	0,0	0,00	66,7
		Monat 2 Follow-up	239	6,97	16,318	0,0	0,00	100,0
		Monat 3 Follow-up	257	8,24	14,666	0,0	0,00	66,7
		Monat 6 Follow-up	186	7,08	15,179	0,0	0,00	100,0
		Monat 9 Follow-up	164	7,11	15,231	0,0	0,00	100,0
		Monat 12 Follow-up	120	5,97	12,374	0,0	0,00	50,0
		Monat 15 Follow-up	54	10,19	20,836	0,0	0,00	100,0
		Monat 18 Follow-up	99	7,24	15,089	0,0	0,00	83,3
		Monat 21 Follow-up	50	8,67	16,916	0,0	0,00	66,7
		Monat 24 Follow-up	65	6,67	15,811	0,0	0,00	66,7
		Monat 30 Follow-up	57	6,14	12,453	0,0	0,00	50,0
		Monat 36 Follow-up	21	8,73	22,742	0,0	0,00	100,0
		Monat 42 Follow-up	8	6,25	8,626	0,0	0,00	16,7

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Schmerzen	Durva + FLOT (N=474)	Baseline	425	19,41	22,929	0,0	16,67	100,0
		Zyklus 2, Tag 29	429	16,16	21,626	0,0	0,00	100,0
		Zyklus 3, Tag 1	293	20,02	21,035	0,0	16,67	100,0
		Zyklus 4, Tag 29	290	18,22	20,576	0,0	16,67	100,0
		Zyklus 5	262	16,41	20,734	0,0	16,67	100,0
		Zyklus 6	288	15,10	20,412	0,0	0,00	100,0
		Zyklus 7	283	13,90	18,333	0,0	0,00	100,0
		Zyklus 8	285	13,98	16,974	0,0	0,00	66,7
		Zyklus 9	268	14,05	19,229	0,0	0,00	83,3
		Zyklus 10	258	14,28	19,662	0,0	0,00	100,0
		Zyklus 11	258	13,18	19,020	0,0	0,00	83,3
		Zyklus 12	250	12,53	18,735	0,0	0,00	83,3
		Zyklus 13	236	11,94	17,798	0,0	0,00	83,3
		Zyklus 14	251	11,16	16,982	0,0	0,00	100,0
		Tag 30 Follow-up	248	12,37	20,875	0,0	0,00	100,0
		Monat 2 Follow-up	238	12,46	20,105	0,0	0,00	100,0
		Monat 3 Follow-up	252	12,63	19,911	0,0	0,00	100,0
		Monat 6 Follow-up	208	13,70	21,561	0,0	0,00	100,0
		Monat 9 Follow-up	198	11,28	18,824	0,0	0,00	100,0
		Monat 12 Follow-up	163	11,04	17,880	0,0	0,00	83,3
		Monat 15 Follow-up	85	10,78	17,195	0,0	0,00	83,3
		Monat 18 Follow-up	116	9,63	17,877	0,0	0,00	83,3
		Monat 21 Follow-up	77	13,85	20,662	0,0	0,00	100,0
		Monat 24 Follow-up	76	9,87	16,142	0,0	0,00	83,3
		Monat 30 Follow-up	86	12,40	22,020	0,0	0,00	100,0
		Monat 36 Follow-up	37	16,67	27,217	0,0	0,00	83,3
		Monat 42 Follow-up	6	13,89	26,701	0,0	0,00	66,7
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Schmerzen	Placebo + FLOT (N=474)	Baseline	433	19,67	22,933	0,0	16,67	100,0
		Zyklus 2, Tag 29	410	16,91	21,583	0,0	16,67	100,0
		Zyklus 3, Tag 1	277	21,78	23,632	0,0	16,67	100,0
		Zyklus 4, Tag 29	278	18,05	22,372	0,0	16,67	100,0
		Zyklus 5	260	15,06	20,362	0,0	0,00	100,0
		Zyklus 6	276	12,92	18,315	0,0	0,00	100,0
		Zyklus 7	266	12,16	19,277	0,0	0,00	100,0
		Zyklus 8	268	12,69	18,437	0,0	0,00	100,0
		Zyklus 9	260	12,05	17,577	0,0	0,00	100,0
		Zyklus 10	257	11,54	19,396	0,0	0,00	100,0
		Zyklus 11	240	11,87	18,141	0,0	0,00	83,3
		Zyklus 12	233	10,52	17,379	0,0	0,00	100,0
		Zyklus 13	222	11,56	18,049	0,0	0,00	100,0
		Zyklus 14	232	10,42	18,031	0,0	0,00	100,0
		Tag 30 Follow-up	231	12,34	21,208	0,0	0,00	100,0
		Monat 2 Follow-up	239	11,85	18,305	0,0	0,00	100,0
		Monat 3 Follow-up	257	15,11	21,894	0,0	0,00	100,0
		Monat 6 Follow-up	186	14,61	22,600	0,0	0,00	100,0
		Monat 9 Follow-up	164	11,18	18,927	0,0	0,00	100,0
		Monat 12 Follow-up	120	10,56	16,727	0,0	0,00	83,3
		Monat 15 Follow-up	54	17,59	25,579	0,0	0,00	100,0
		Monat 18 Follow-up	99	12,12	19,316	0,0	0,00	100,0
		Monat 21 Follow-up	50	16,00	27,962	0,0	0,00	100,0
		Monat 24 Follow-up	65	14,62	19,875	0,0	0,00	100,0
		Monat 30 Follow-up	57	14,04	22,667	0,0	0,00	100,0
		Monat 36 Follow-up	21	8,73	22,742	0,0	0,00	100,0
		Monat 42 Follow-up	8	14,58	16,517	0,0	8,33	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Schlaflosigkeit	Durva + FLOT (N=474)	Baseline	425	23,45	28,255	0,0	0,00	100,0
		Zyklus 2, Tag 29	429	23,39	27,048	0,0	33,33	100,0
		Zyklus 3, Tag 1	293	24,12	27,212	0,0	33,33	100,0
		Zyklus 4, Tag 29	290	26,55	27,098	0,0	33,33	100,0
		Zyklus 5	262	24,68	26,930	0,0	33,33	100,0
		Zyklus 6	288	21,30	26,431	0,0	0,00	100,0
		Zyklus 7	283	20,38	24,732	0,0	0,00	100,0
		Zyklus 8	285	20,35	25,772	0,0	0,00	100,0
		Zyklus 9	268	21,64	26,047	0,0	0,00	100,0
		Zyklus 10	258	19,12	24,523	0,0	0,00	100,0
		Zyklus 11	258	19,12	23,808	0,0	0,00	100,0
		Zyklus 12	250	19,07	24,744	0,0	0,00	100,0
		Zyklus 13	236	17,80	23,892	0,0	0,00	100,0
		Zyklus 14	251	17,26	23,349	0,0	0,00	100,0
		Tag 30 Follow-up	248	17,34	23,030	0,0	0,00	100,0
		Monat 2 Follow-up	238	20,87	27,019	0,0	0,00	100,0
		Monat 3 Follow-up	252	20,77	26,210	0,0	0,00	100,0
		Monat 6 Follow-up	208	17,79	24,711	0,0	0,00	100,0
		Monat 9 Follow-up	198	21,04	24,691	0,0	0,00	100,0
		Monat 12 Follow-up	163	18,61	25,418	0,0	0,00	100,0
		Monat 15 Follow-up	85	17,25	24,993	0,0	0,00	100,0
		Monat 18 Follow-up	116	16,95	24,275	0,0	0,00	100,0
		Monat 21 Follow-up	77	18,61	26,762	0,0	0,00	100,0
		Monat 24 Follow-up	76	21,93	26,417	0,0	0,00	100,0
		Monat 30 Follow-up	86	18,60	24,842	0,0	0,00	100,0
		Monat 36 Follow-up	37	19,82	30,892	0,0	0,00	100,0
		Monat 42 Follow-up	6	11,11	17,213	0,0	0,00	33,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.1 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Schlaflosigkeit	Placebo + FLOT (N=474)	Baseline	433	24,33	28,929	0,0	33,33	100,0
		Zyklus 2, Tag 29	410	23,50	26,947	0,0	33,33	100,0
		Zyklus 3, Tag 1	277	20,94	25,435	0,0	0,00	100,0
		Zyklus 4, Tag 29	278	22,18	26,562	0,0	0,00	100,0
		Zyklus 5	260	20,90	25,771	0,0	0,00	100,0
		Zyklus 6	276	16,91	23,526	0,0	0,00	100,0
		Zyklus 7	266	15,16	23,163	0,0	0,00	100,0
		Zyklus 8	268	15,55	23,142	0,0	0,00	100,0
		Zyklus 9	260	16,54	23,524	0,0	0,00	100,0
		Zyklus 10	257	14,66	24,055	0,0	0,00	100,0
		Zyklus 11	240	16,94	24,201	0,0	0,00	100,0
		Zyklus 12	233	15,74	23,167	0,0	0,00	100,0
		Zyklus 13	222	13,21	21,637	0,0	0,00	100,0
		Zyklus 14	232	14,80	22,715	0,0	0,00	100,0
		Tag 30 Follow-up	231	15,44	23,410	0,0	0,00	100,0
		Monat 2 Follow-up	239	17,15	24,796	0,0	0,00	100,0
		Monat 3 Follow-up	257	17,64	24,298	0,0	0,00	100,0
		Monat 6 Follow-up	186	18,64	26,149	0,0	0,00	100,0
		Monat 9 Follow-up	164	16,46	23,785	0,0	0,00	100,0
		Monat 12 Follow-up	120	18,06	26,249	0,0	0,00	100,0
		Monat 15 Follow-up	54	20,37	30,658	0,0	0,00	100,0
		Monat 18 Follow-up	99	16,16	22,010	0,0	0,00	66,7
		Monat 21 Follow-up	50	29,33	32,043	0,0	33,33	100,0
		Monat 24 Follow-up	65	20,00	22,669	0,0	33,33	100,0
		Monat 30 Follow-up	57	22,81	28,283	0,0	0,00	100,0
		Monat 36 Follow-up	21	11,11	24,343	0,0	0,00	100,0
		Monat 42 Follow-up	8	16,67	17,817	0,0	16,67	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraaa 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Kognitive Funktion	Durva + FLOT (N=474)	Baseline	425	88,08	17,890	0,0	100,00	100,0
		Zyklus 2, Tag 29	429	88,50	16,148	0,0	100,00	100,0
		Zyklus 3, Tag 1	293	86,35	18,491	0,0	100,00	100,0
		Zyklus 4, Tag 29	290	82,24	19,990	0,0	83,33	100,0
		Zyklus 5	262	83,59	18,510	0,0	83,33	100,0
		Zyklus 6	288	84,43	19,222	0,0	83,33	100,0
		Zyklus 7	283	85,69	18,471	0,0	100,00	100,0
		Zyklus 8	285	85,15	17,736	0,0	83,33	100,0
		Zyklus 9	268	84,20	18,953	0,0	83,33	100,0
		Zyklus 10	258	85,14	18,913	0,0	100,00	100,0
		Zyklus 11	258	86,11	16,823	16,7	100,00	100,0
		Zyklus 12	250	85,47	18,473	16,7	100,00	100,0
		Zyklus 13	236	86,65	17,451	16,7	100,00	100,0
		Zyklus 14	251	85,79	19,820	0,0	100,00	100,0
		Tag 30 Follow-up	248	87,10	19,010	0,0	100,00	100,0
		Monat 2 Follow-up	238	85,08	19,915	0,0	100,00	100,0
		Monat 3 Follow-up	252	85,65	20,239	0,0	100,00	100,0
		Monat 6 Follow-up	208	86,38	18,645	0,0	100,00	100,0
		Monat 9 Follow-up	198	86,36	18,065	16,7	100,00	100,0
		Monat 12 Follow-up	163	86,71	17,778	16,7	100,00	100,0
		Monat 15 Follow-up	85	85,69	19,442	0,0	100,00	100,0
		Monat 18 Follow-up	116	88,79	16,851	33,3	100,00	100,0
		Monat 21 Follow-up	77	85,71	21,240	0,0	100,00	100,0
		Monat 24 Follow-up	76	86,84	17,494	33,3	100,00	100,0
		Monat 30 Follow-up	86	88,37	19,979	16,7	100,00	100,0
		Monat 36 Follow-up	37	87,39	21,661	16,7	100,00	100,0
		Monat 42 Follow-up	6	86,11	22,153	50,0	100,00	100,0
		Monat 48 Follow-up	1	100,00	NC	100,0	100,00	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Kognitive Funktion	Placebo + FLOT (N=474)	Baseline	433	86,99	18,842	0,0	100,00	100,0
		Zyklus 2, Tag 29	410	87,80	17,099	16,7	100,00	100,0
		Zyklus 3, Tag 1	277	85,62	20,034	0,0	100,00	100,0
		Zyklus 4, Tag 29	278	83,51	20,497	0,0	83,33	100,0
		Zyklus 5	260	85,06	20,246	0,0	100,00	100,0
		Zyklus 6	276	83,82	20,640	0,0	83,33	100,0
		Zyklus 7	266	85,03	20,585	0,0	100,00	100,0
		Zyklus 8	268	84,64	20,383	0,0	100,00	100,0
		Zyklus 9	260	85,38	20,083	0,0	100,00	100,0
		Zyklus 10	257	85,15	20,701	0,0	100,00	100,0
		Zyklus 11	240	86,11	18,776	0,0	100,00	100,0
		Zyklus 12	233	86,70	18,425	0,0	100,00	100,0
		Zyklus 13	222	86,71	19,154	0,0	100,00	100,0
		Zyklus 14	232	86,21	19,154	0,0	100,00	100,0
		Tag 30 Follow-up	231	84,92	20,201	0,0	100,00	100,0
		Monat 2 Follow-up	239	86,33	19,121	0,0	100,00	100,0
		Monat 3 Follow-up	257	85,08	20,041	0,0	100,00	100,0
		Monat 6 Follow-up	186	84,68	22,588	0,0	100,00	100,0
		Monat 9 Follow-up	164	86,59	20,381	0,0	100,00	100,0
		Monat 12 Follow-up	120	85,42	21,232	0,0	100,00	100,0
		Monat 15 Follow-up	54	84,26	22,989	0,0	100,00	100,0
		Monat 18 Follow-up	99	84,01	20,192	16,7	100,00	100,0
		Monat 21 Follow-up	50	78,67	24,290	0,0	83,33	100,0
		Monat 24 Follow-up	65	82,31	22,414	0,0	83,33	100,0
		Monat 30 Follow-up	57	84,50	21,096	0,0	83,33	100,0
		Monat 36 Follow-up	21	85,71	25,973	0,0	100,00	100,0
		Monat 42 Follow-up	8	89,58	15,269	66,7	100,00	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Emotionale Funktion	Durva + FLOT (N=474)	Baseline	425	74,04	21,019	0,0	75,00	100,0
		Zyklus 2, Tag 29	429	80,52	18,738	0,0	83,33	100,0
		Zyklus 3, Tag 1	293	80,77	18,079	0,0	83,33	100,0
		Zyklus 4, Tag 29	290	78,05	20,040	0,0	83,33	100,0
		Zyklus 5	262	79,36	18,679	16,7	83,33	100,0
		Zyklus 6	288	82,03	18,614	16,7	83,33	100,0
		Zyklus 7	283	82,24	19,500	0,0	83,33	100,0
		Zyklus 8	285	83,07	17,319	16,7	83,33	100,0
		Zyklus 9	268	81,56	19,197	0,0	83,33	100,0
		Zyklus 10	258	82,59	18,503	16,7	91,67	100,0
		Zyklus 11	258	83,17	18,341	8,3	91,67	100,0
		Zyklus 12	250	82,37	19,009	0,0	87,50	100,0
		Zyklus 13	236	84,32	18,647	8,3	91,67	100,0
		Zyklus 14	251	83,80	19,041	0,0	91,67	100,0
		Tag 30 Follow-up	248	84,24	18,657	8,3	91,67	100,0
		Monat 2 Follow-up	238	82,49	20,352	0,0	83,33	100,0
		Monat 3 Follow-up	252	82,51	19,908	0,0	91,67	100,0
		Monat 6 Follow-up	208	82,37	20,635	0,0	91,67	100,0
		Monat 9 Follow-up	198	83,71	20,122	8,3	91,67	100,0
		Monat 12 Follow-up	163	85,48	17,038	25,0	91,67	100,0
		Monat 15 Follow-up	85	83,04	20,309	0,0	83,33	100,0
		Monat 18 Follow-up	116	84,05	18,926	0,0	91,67	100,0
		Monat 21 Follow-up	77	83,44	23,159	0,0	91,67	100,0
		Monat 24 Follow-up	76	83,88	18,526	25,0	91,67	100,0
		Monat 30 Follow-up	86	83,82	21,931	0,0	91,67	100,0
		Monat 36 Follow-up	37	80,18	27,383	8,3	100,00	100,0
		Monat 42 Follow-up	6	84,72	18,572	58,3	91,67	100,0
		Monat 48 Follow-up	1	100,00	NC	100,0	100,00	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Emotionale Funktion	Placebo + FLOT (N=474)	Baseline	433	75,67	20,671	0,0	75,00	100,0
		Zyklus 2, Tag 29	410	79,96	20,357	0,0	83,33	100,0
		Zyklus 3, Tag 1	277	79,09	21,617	0,0	83,33	100,0
		Zyklus 4, Tag 29	278	76,89	23,264	0,0	83,33	100,0
		Zyklus 5	260	79,78	21,423	0,0	83,33	100,0
		Zyklus 6	276	81,07	22,023	0,0	91,67	100,0
		Zyklus 7	266	82,83	20,030	0,0	91,67	100,0
		Zyklus 8	268	81,75	21,232	0,0	91,67	100,0
		Zyklus 9	260	82,21	20,946	0,0	91,67	100,0
		Zyklus 10	257	82,62	21,863	0,0	91,67	100,0
		Zyklus 11	240	83,06	21,193	0,0	91,67	100,0
		Zyklus 12	233	84,66	19,901	0,0	91,67	100,0
		Zyklus 13	222	84,50	19,472	0,0	91,67	100,0
		Zyklus 14	232	84,27	19,701	0,0	91,67	100,0
		Tag 30 Follow-up	231	82,94	20,193	0,0	91,67	100,0
		Monat 2 Follow-up	239	83,12	19,535	0,0	91,67	100,0
		Monat 3 Follow-up	257	81,49	21,197	0,0	91,67	100,0
		Monat 6 Follow-up	186	81,23	23,690	0,0	91,67	100,0
		Monat 9 Follow-up	164	84,35	19,468	0,0	91,67	100,0
		Monat 12 Follow-up	120	85,97	18,397	0,0	91,67	100,0
		Monat 15 Follow-up	54	82,72	26,395	0,0	95,83	100,0
		Monat 18 Follow-up	99	82,49	20,044	8,3	91,67	100,0
		Monat 21 Follow-up	50	81,00	22,964	0,0	87,50	100,0
		Monat 24 Follow-up	65	82,05	19,777	0,0	83,33	100,0
		Monat 30 Follow-up	57	84,94	21,388	0,0	100,00	100,0
		Monat 36 Follow-up	21	82,14	25,040	0,0	91,67	100,0
		Monat 42 Follow-up	8	88,54	17,216	58,3	100,00	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Körperliche Funktion	Durva + FLOT (N=474)	Baseline	425	87,59	15,085	20,0	93,33	100,0
		Zyklus 2, Tag 29	429	84,63	15,571	20,0	86,67	100,0
		Zyklus 3, Tag 1	293	81,55	16,562	20,0	86,67	100,0
		Zyklus 4, Tag 29	290	80,14	17,677	20,0	80,00	100,0
		Zyklus 5	262	79,72	19,083	0,0	86,67	100,0
		Zyklus 6	288	83,84	17,155	6,7	86,67	100,0
		Zyklus 7	283	85,35	15,725	20,0	86,67	100,0
		Zyklus 8	285	87,11	13,962	26,7	93,33	100,0
		Zyklus 9	268	86,67	15,450	6,7	90,00	100,0
		Zyklus 10	258	87,91	15,409	13,3	93,33	100,0
		Zyklus 11	258	88,55	14,444	20,0	93,33	100,0
		Zyklus 12	250	89,25	14,236	26,7	93,33	100,0
		Zyklus 13	236	90,06	12,937	26,7	93,33	100,0
		Zyklus 14	251	90,17	13,509	13,3	93,33	100,0
		Tag 30 Follow-up	248	89,49	14,783	26,7	93,33	100,0
		Monat 2 Follow-up	238	87,59	18,477	0,0	93,33	100,0
		Monat 3 Follow-up	252	88,62	17,321	0,0	93,33	100,0
		Monat 6 Follow-up	208	88,27	15,876	20,0	93,33	100,0
		Monat 9 Follow-up	198	88,92	16,025	20,0	93,33	100,0
		Monat 12 Follow-up	163	89,24	14,351	20,0	93,33	100,0
		Monat 15 Follow-up	85	88,94	14,997	20,0	93,33	100,0
		Monat 18 Follow-up	116	89,89	13,859	26,7	93,33	100,0
		Monat 21 Follow-up	77	88,74	18,646	13,3	93,33	100,0
		Monat 24 Follow-up	76	88,25	18,115	0,0	93,33	100,0
		Monat 30 Follow-up	86	88,68	16,837	20,0	93,33	100,0
		Monat 36 Follow-up	37	83,06	23,965	0,0	93,33	100,0
		Monat 42 Follow-up	6	84,44	21,773	53,3	96,67	100,0
		Monat 48 Follow-up	1	100,00	NC	100,0	100,00	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Körperliche Funktion	Placebo + FLOT (N=474)	Baseline	433	89,31	15,186	0,0	93,33	100,0
		Zyklus 2, Tag 29	410	85,24	16,728	6,7	86,67	100,0
		Zyklus 3, Tag 1	277	81,35	17,384	13,3	86,67	100,0
		Zyklus 4, Tag 29	278	81,41	18,773	13,3	86,67	100,0
		Zyklus 5	260	82,05	17,513	6,7	86,67	100,0
		Zyklus 6	276	84,83	16,871	0,0	86,67	100,0
		Zyklus 7	266	87,67	14,374	20,0	93,33	100,0
		Zyklus 8	268	88,13	14,767	13,3	93,33	100,0
		Zyklus 9	260	89,13	14,233	13,3	93,33	100,0
		Zyklus 10	257	89,03	14,390	26,7	93,33	100,0
		Zyklus 11	240	89,92	13,650	13,3	93,33	100,0
		Zyklus 12	233	90,73	13,372	6,7	93,33	100,0
		Zyklus 13	222	90,78	12,876	20,0	93,33	100,0
		Zyklus 14	232	91,44	13,065	6,7	93,33	100,0
		Tag 30 Follow-up	231	89,09	17,448	0,0	100,00	100,0
		Monat 2 Follow-up	239	89,43	14,857	0,0	93,33	100,0
		Monat 3 Follow-up	257	87,60	18,629	0,0	93,33	100,0
		Monat 6 Follow-up	186	88,32	17,893	0,0	93,33	100,0
		Monat 9 Follow-up	164	88,90	17,291	0,0	93,33	100,0
		Monat 12 Follow-up	120	91,00	14,961	0,0	93,33	100,0
		Monat 15 Follow-up	54	89,14	21,913	0,0	100,00	100,0
		Monat 18 Follow-up	99	88,01	18,344	13,3	93,33	100,0
		Monat 21 Follow-up	50	85,47	23,003	20,0	100,00	100,0
		Monat 24 Follow-up	65	89,23	15,032	33,3	93,33	100,0
		Monat 30 Follow-up	57	88,07	21,445	0,0	100,00	100,0
		Monat 36 Follow-up	21	87,94	24,731	6,7	100,00	100,0
		Monat 42 Follow-up	8	95,83	7,071	80,0	100,00	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Allgemeine Lebensqualität/Gesundheitszustand	Durva + FLOT (N=474)	Baseline	425	69,31	20,509	0,0	66,67	100,0
		Zyklus 2, Tag 29	429	64,59	18,972	0,0	66,67	100,0
		Zyklus 3, Tag 1	293	67,41	18,478	0,0	66,67	100,0
		Zyklus 4, Tag 29	290	61,29	19,830	0,0	66,67	100,0
		Zyklus 5	262	62,98	19,592	0,0	66,67	100,0
		Zyklus 6	288	68,61	18,375	0,0	66,67	100,0
		Zyklus 7	283	72,64	16,839	25,0	75,00	100,0
		Zyklus 8	285	72,51	15,883	25,0	75,00	100,0
		Zyklus 9	268	72,82	15,783	16,7	75,00	100,0
		Zyklus 10	258	73,68	16,638	16,7	75,00	100,0
		Zyklus 11	258	74,81	14,975	25,0	75,00	100,0
		Zyklus 12	250	74,90	17,088	16,7	83,33	100,0
		Zyklus 13	236	76,20	17,251	8,3	83,33	100,0
		Zyklus 14	251	76,59	16,856	0,0	83,33	100,0
		Tag 30 Follow-up	248	75,71	17,818	16,7	83,33	100,0
		Monat 2 Follow-up	238	74,82	19,221	0,0	83,33	100,0
		Monat 3 Follow-up	252	75,30	19,374	0,0	83,33	100,0
		Monat 6 Follow-up	208	74,64	19,766	0,0	83,33	100,0
		Monat 9 Follow-up	198	75,97	18,533	0,0	83,33	100,0
		Monat 12 Follow-up	163	77,71	15,819	16,7	83,33	100,0
		Monat 15 Follow-up	85	77,06	16,158	33,3	83,33	100,0
		Monat 18 Follow-up	116	79,24	16,972	16,7	83,33	100,0
		Monat 21 Follow-up	77	77,49	16,834	25,0	83,33	100,0
		Monat 24 Follow-up	76	76,64	17,744	0,0	83,33	100,0
		Monat 30 Follow-up	86	75,58	16,607	16,7	83,33	100,0
		Monat 36 Follow-up	37	71,62	16,604	25,0	83,33	100,0
		Monat 42 Follow-up	6	70,83	18,066	50,0	66,67	100,0
		Monat 48 Follow-up	1	83,33	NC	83,3	83,33	83,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Allgemeine Lebensqualität/Gesundheitszustand	Placebo + FLOT (N=474)	Baseline	433	70,90	19,585	0,0	75,00	100,0
		Zyklus 2, Tag 29	410	64,98	19,616	0,0	66,67	100,0
		Zyklus 3, Tag 1	277	66,34	17,293	16,7	66,67	100,0
		Zyklus 4, Tag 29	278	62,32	19,961	0,0	66,67	100,0
		Zyklus 5	260	64,39	20,159	0,0	66,67	100,0
		Zyklus 6	276	69,11	19,209	0,0	66,67	100,0
		Zyklus 7	266	72,56	18,451	0,0	75,00	100,0
		Zyklus 8	268	74,16	17,888	0,0	75,00	100,0
		Zyklus 9	260	76,47	16,826	0,0	83,33	100,0
		Zyklus 10	257	74,51	18,459	0,0	83,33	100,0
		Zyklus 11	240	75,49	17,887	0,0	83,33	100,0
		Zyklus 12	233	75,93	17,259	0,0	83,33	100,0
		Zyklus 13	222	77,40	17,328	16,7	83,33	100,0
		Zyklus 14	232	77,73	16,604	0,0	83,33	100,0
		Tag 30 Follow-up	231	75,94	19,835	0,0	83,33	100,0
		Monat 2 Follow-up	239	75,77	18,093	0,0	83,33	100,0
		Monat 3 Follow-up	257	73,12	20,472	0,0	83,33	100,0
		Monat 6 Follow-up	186	74,33	19,546	0,0	83,33	100,0
		Monat 9 Follow-up	164	76,52	18,024	0,0	83,33	100,0
		Monat 12 Follow-up	120	77,15	17,834	16,7	83,33	100,0
		Monat 15 Follow-up	54	74,54	21,804	16,7	83,33	100,0
		Monat 18 Follow-up	99	74,92	20,325	8,3	83,33	100,0
		Monat 21 Follow-up	50	74,50	26,535	0,0	83,33	100,0
		Monat 24 Follow-up	65	73,97	19,236	0,0	75,00	100,0
		Monat 30 Follow-up	57	75,73	20,790	0,0	83,33	100,0
		Monat 36 Follow-up	21	71,43	22,449	0,0	75,00	100,0
		Monat 42 Follow-up	8	79,17	14,773	50,0	83,33	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Rollenfunktion	Durva + FLOT (N=474)	Baseline	425	84,24	23,871	0,0	100,00	100,0
		Zyklus 2, Tag 29	429	78,59	25,056	0,0	83,33	100,0
		Zyklus 3, Tag 1	293	72,92	25,484	0,0	66,67	100,0
		Zyklus 4, Tag 29	290	71,90	26,461	0,0	66,67	100,0
		Zyklus 5	262	72,65	26,469	0,0	66,67	100,0
		Zyklus 6	288	78,24	24,320	0,0	83,33	100,0
		Zyklus 7	283	80,45	22,600	0,0	83,33	100,0
		Zyklus 8	285	81,46	21,496	0,0	83,33	100,0
		Zyklus 9	268	80,72	21,815	0,0	83,33	100,0
		Zyklus 10	258	83,27	21,980	0,0	100,00	100,0
		Zyklus 11	258	85,08	19,948	16,7	100,00	100,0
		Zyklus 12	250	83,33	21,124	16,7	100,00	100,0
		Zyklus 13	236	85,24	19,986	16,7	100,00	100,0
		Zyklus 14	251	85,92	20,302	0,0	100,00	100,0
		Tag 30 Follow-up	248	85,55	20,743	0,0	100,00	100,0
		Monat 2 Follow-up	238	82,91	24,493	0,0	100,00	100,0
		Monat 3 Follow-up	252	82,21	23,614	0,0	100,00	100,0
		Monat 6 Follow-up	208	83,49	24,077	0,0	100,00	100,0
		Monat 9 Follow-up	198	84,43	22,846	0,0	100,00	100,0
		Monat 12 Follow-up	163	84,46	20,962	0,0	100,00	100,0
		Monat 15 Follow-up	85	84,71	23,033	0,0	100,00	100,0
		Monat 18 Follow-up	116	87,07	18,002	33,3	100,00	100,0
		Monat 21 Follow-up	77	83,12	23,801	0,0	100,00	100,0
		Monat 24 Follow-up	76	87,06	20,656	0,0	100,00	100,0
		Monat 30 Follow-up	86	85,08	23,155	0,0	100,00	100,0
		Monat 36 Follow-up	37	83,78	25,905	0,0	100,00	100,0
		Monat 42 Follow-up	6	83,33	27,889	33,3	100,00	100,0
		Monat 48 Follow-up	1	100,00	NC	100,0	100,00	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Rollenfunktion	Placebo + FLOT (N=474)	Baseline	433	85,53	22,070	0,0	100,00	100,0
		Zyklus 2, Tag 29	410	79,35	23,376	0,0	83,33	100,0
		Zyklus 3, Tag 1	277	73,16	27,103	0,0	66,67	100,0
		Zyklus 4, Tag 29	278	71,70	26,845	0,0	66,67	100,0
		Zyklus 5	260	73,78	26,557	0,0	66,67	100,0
		Zyklus 6	276	78,99	23,596	0,0	83,33	100,0
		Zyklus 7	266	81,95	22,943	0,0	100,00	100,0
		Zyklus 8	268	83,27	22,509	0,0	100,00	100,0
		Zyklus 9	260	84,74	21,727	0,0	100,00	100,0
		Zyklus 10	257	84,18	22,495	0,0	100,00	100,0
		Zyklus 11	240	85,56	22,658	0,0	100,00	100,0
		Zyklus 12	233	86,41	21,191	0,0	100,00	100,0
		Zyklus 13	222	87,46	20,223	0,0	100,00	100,0
		Zyklus 14	232	88,07	20,375	0,0	100,00	100,0
		Tag 30 Follow-up	231	85,50	22,950	0,0	100,00	100,0
		Monat 2 Follow-up	239	84,94	21,736	0,0	100,00	100,0
		Monat 3 Follow-up	257	81,45	25,764	0,0	100,00	100,0
		Monat 6 Follow-up	186	85,22	24,280	0,0	100,00	100,0
		Monat 9 Follow-up	164	85,26	22,641	0,0	100,00	100,0
		Monat 12 Follow-up	120	88,19	19,850	0,0	100,00	100,0
		Monat 15 Follow-up	54	85,49	28,047	0,0	100,00	100,0
		Monat 18 Follow-up	99	84,18	24,208	0,0	100,00	100,0
		Monat 21 Follow-up	50	81,67	29,403	0,0	100,00	100,0
		Monat 24 Follow-up	65	85,13	22,268	0,0	100,00	100,0
		Monat 30 Follow-up	57	85,67	24,487	0,0	100,00	100,0
		Monat 36 Follow-up	21	85,71	27,531	0,0	100,00	100,0
		Monat 42 Follow-up	8	91,67	15,430	66,7	100,00	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Soziale Funktion	Durva + FLOT (N=474)	Baseline	425	79,25	24,317	0,0	83,33	100,0
		Zyklus 2, Tag 29	429	78,05	23,278	0,0	83,33	100,0
		Zyklus 3, Tag 1	293	75,88	24,216	0,0	83,33	100,0
		Zyklus 4, Tag 29	290	71,95	25,581	0,0	66,67	100,0
		Zyklus 5	262	74,75	25,089	0,0	83,33	100,0
		Zyklus 6	288	78,82	24,474	0,0	83,33	100,0
		Zyklus 7	283	79,39	23,426	0,0	83,33	100,0
		Zyklus 8	285	81,58	21,956	0,0	83,33	100,0
		Zyklus 9	268	81,09	20,682	0,0	83,33	100,0
		Zyklus 10	258	84,56	21,448	0,0	100,00	100,0
		Zyklus 11	258	84,75	20,109	0,0	100,00	100,0
		Zyklus 12	250	83,87	22,299	0,0	100,00	100,0
		Zyklus 13	236	85,59	21,571	0,0	100,00	100,0
		Zyklus 14	251	85,79	20,536	0,0	100,00	100,0
		Tag 30 Follow-up	248	86,36	20,477	0,0	100,00	100,0
		Monat 2 Follow-up	238	84,80	22,480	0,0	100,00	100,0
		Monat 3 Follow-up	252	85,52	22,084	0,0	100,00	100,0
		Monat 6 Follow-up	208	86,70	22,804	0,0	100,00	100,0
		Monat 9 Follow-up	198	85,61	21,153	0,0	100,00	100,0
		Monat 12 Follow-up	163	87,32	20,272	0,0	100,00	100,0
		Monat 15 Follow-up	85	88,24	22,687	0,0	100,00	100,0
		Monat 18 Follow-up	116	88,36	19,930	0,0	100,00	100,0
		Monat 21 Follow-up	77	85,71	24,589	0,0	100,00	100,0
		Monat 24 Follow-up	76	88,82	22,671	0,0	100,00	100,0
		Monat 30 Follow-up	86	89,15	21,507	0,0	100,00	100,0
		Monat 36 Follow-up	37	83,78	29,785	0,0	100,00	100,0
		Monat 42 Follow-up	6	83,33	25,820	50,0	100,00	100,0
		Monat 48 Follow-up	1	100,00	NC	100,0	100,00	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.2 Summary of absolute values across timepoints by treatment group for EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC QLQ-C30 Soziale Funktion	Placebo + FLOT (N=474)	Baseline	433	81,91	23,294	0,0	100,00	100,0
		Zyklus 2, Tag 29	410	78,58	24,608	0,0	83,33	100,0
		Zyklus 3, Tag 1	277	75,75	25,433	0,0	83,33	100,0
		Zyklus 4, Tag 29	278	73,20	27,356	0,0	66,67	100,0
		Zyklus 5	260	76,09	26,724	0,0	83,33	100,0
		Zyklus 6	276	79,05	26,944	0,0	83,33	100,0
		Zyklus 7	266	81,45	24,371	0,0	100,00	100,0
		Zyklus 8	268	83,08	23,832	0,0	100,00	100,0
		Zyklus 9	260	84,68	23,095	0,0	100,00	100,0
		Zyklus 10	257	83,92	24,221	0,0	100,00	100,0
		Zyklus 11	240	84,93	22,115	0,0	100,00	100,0
		Zyklus 12	233	85,62	22,361	0,0	100,00	100,0
		Zyklus 13	222	87,31	19,559	0,0	100,00	100,0
		Zyklus 14	232	86,06	21,871	0,0	100,00	100,0
		Tag 30 Follow-up	231	85,79	22,656	0,0	100,00	100,0
		Monat 2 Follow-up	239	86,47	20,796	0,0	100,00	100,0
		Monat 3 Follow-up	257	83,33	24,694	0,0	100,00	100,0
		Monat 6 Follow-up	186	83,15	24,260	0,0	100,00	100,0
		Monat 9 Follow-up	164	84,96	22,476	0,0	100,00	100,0
		Monat 12 Follow-up	120	87,50	20,753	0,0	100,00	100,0
		Monat 15 Follow-up	54	86,11	24,604	0,0	100,00	100,0
		Monat 18 Follow-up	99	83,67	26,404	0,0	100,00	100,0
		Monat 21 Follow-up	50	78,67	30,868	0,0	100,00	100,0
		Monat 24 Follow-up	65	85,38	22,343	0,0	100,00	100,0
		Monat 30 Follow-up	57	85,96	24,355	0,0	100,00	100,0
		Monat 36 Follow-up	21	91,27	24,506	0,0	100,00	100,0
		Monat 42 Follow-up	8	93,75	12,400	66,7	100,00	100,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraab 28JAN2026:09:31 khsk849

Table 4.1.3 Summary of absolute values across timepoints by treatment group for EORTC QLQ-IL38 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC IL38 Schwierigkeiten beim Schlucken	Durva + FLOT (N=474)	Baseline	423	20,25	31,416	0,0	0,00	100,0
		Zyklus 2, Tag 29	419	12,57	21,408	0,0	0,00	100,0
		Zyklus 3, Tag 1	285	21,40	26,647	0,0	0,00	100,0
		Zyklus 4, Tag 29	285	17,78	23,146	0,0	0,00	100,0
		Zyklus 5	257	17,64	21,654	0,0	0,00	100,0
		Zyklus 6	283	14,25	21,125	0,0	0,00	100,0
		Zyklus 7	279	12,19	19,660	0,0	0,00	100,0
		Zyklus 8	283	13,07	20,957	0,0	0,00	100,0
		Zyklus 9	267	13,48	20,874	0,0	0,00	100,0
		Zyklus 10	258	9,69	16,530	0,0	0,00	66,7
		Zyklus 11	256	10,16	18,226	0,0	0,00	100,0
		Zyklus 12	250	11,60	18,979	0,0	0,00	100,0
		Zyklus 13	232	10,06	18,723	0,0	0,00	100,0
		Zyklus 14	251	10,09	19,205	0,0	0,00	100,0
		Tag 30 Follow-up	245	10,75	20,415	0,0	0,00	100,0
		Monat 2 Follow-up	237	9,85	19,325	0,0	0,00	100,0
		Monat 3 Follow-up	252	10,45	18,846	0,0	0,00	100,0
		Monat 6 Follow-up	206	10,03	20,737	0,0	0,00	100,0
		Monat 9 Follow-up	198	8,08	17,830	0,0	0,00	100,0
		Monat 12 Follow-up	161	8,07	19,641	0,0	0,00	100,0
		Monat 15 Follow-up	83	8,84	18,831	0,0	0,00	100,0
		Monat 18 Follow-up	116	9,48	17,477	0,0	0,00	66,7
		Monat 21 Follow-up	76	8,77	16,661	0,0	0,00	66,7
		Monat 24 Follow-up	76	9,65	17,054	0,0	0,00	66,7
		Monat 30 Follow-up	86	10,47	17,159	0,0	0,00	66,7
		Monat 36 Follow-up	34	10,78	24,233	0,0	0,00	100,0
		Monat 42 Follow-up	6	11,11	27,217	0,0	0,00	66,7
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraac 28JAN2026:09:31 khsk849

Table 4.1.3 Summary of absolute values across timepoints by treatment group for EORTC QLQ-IL38 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC IL38 Schwierigkeiten beim Schlucken	Placebo + FLOT (N=474)	Baseline	430	19,30	29,623	0,0	0,00	100,0
		Zyklus 2, Tag 29	406	12,64	23,046	0,0	0,00	100,0
		Zyklus 3, Tag 1	272	22,79	29,119	0,0	0,00	100,0
		Zyklus 4, Tag 29	276	16,91	24,203	0,0	0,00	100,0
		Zyklus 5	259	15,83	24,430	0,0	0,00	100,0
		Zyklus 6	273	14,53	22,967	0,0	0,00	100,0
		Zyklus 7	266	13,03	23,287	0,0	0,00	100,0
		Zyklus 8	268	13,31	22,186	0,0	0,00	100,0
		Zyklus 9	259	12,87	21,506	0,0	0,00	100,0
		Zyklus 10	257	9,99	19,312	0,0	0,00	100,0
		Zyklus 11	240	10,97	19,878	0,0	0,00	100,0
		Zyklus 12	232	10,63	19,169	0,0	0,00	100,0
		Zyklus 13	220	10,91	18,904	0,0	0,00	100,0
		Zyklus 14	232	10,63	19,169	0,0	0,00	100,0
		Tag 30 Follow-up	231	10,10	18,492	0,0	0,00	100,0
		Monat 2 Follow-up	237	10,83	19,885	0,0	0,00	100,0
		Monat 3 Follow-up	254	12,47	21,725	0,0	0,00	100,0
		Monat 6 Follow-up	185	11,17	20,445	0,0	0,00	100,0
		Monat 9 Follow-up	162	10,49	20,169	0,0	0,00	100,0
		Monat 12 Follow-up	117	9,12	21,274	0,0	0,00	100,0
		Monat 15 Follow-up	54	9,88	21,111	0,0	0,00	100,0
		Monat 18 Follow-up	98	10,20	19,970	0,0	0,00	100,0
		Monat 21 Follow-up	50	13,33	26,082	0,0	0,00	100,0
		Monat 24 Follow-up	65	7,69	15,331	0,0	0,00	66,7
		Monat 30 Follow-up	55	11,52	24,189	0,0	0,00	100,0
		Monat 36 Follow-up	21	7,94	23,345	0,0	0,00	100,0
		Monat 42 Follow-up	7	4,76	12,599	0,0	0,00	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraac 28JAN2026:09:31 khsk849

Table 4.1.3 Summary of absolute values across timepoints by treatment group for EORTC QLQ-IL38 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC IL38 Gewichtsverlust	Durva + FLOT (N=474)	Baseline	423	27,34	32,386	0,0	33,33	100,0
		Zyklus 2, Tag 29	419	23,79	28,033	0,0	33,33	100,0
		Zyklus 3, Tag 1	285	39,53	32,690	0,0	33,33	100,0
		Zyklus 4, Tag 29	285	34,74	31,863	0,0	33,33	100,0
		Zyklus 5	257	38,52	33,319	0,0	33,33	100,0
		Zyklus 6	283	24,38	30,207	0,0	0,00	100,0
		Zyklus 7	279	17,92	26,774	0,0	0,00	100,0
		Zyklus 8	283	18,26	25,273	0,0	0,00	100,0
		Zyklus 9	267	17,35	25,415	0,0	0,00	100,0
		Zyklus 10	258	14,34	23,455	0,0	0,00	100,0
		Zyklus 11	256	14,06	23,285	0,0	0,00	100,0
		Zyklus 12	250	14,67	24,233	0,0	0,00	100,0
		Zyklus 13	232	14,51	22,901	0,0	0,00	100,0
		Zyklus 14	251	13,28	22,916	0,0	0,00	100,0
		Tag 30 Follow-up	245	13,61	20,152	0,0	0,00	100,0
		Monat 2 Follow-up	237	14,77	24,595	0,0	0,00	100,0
		Monat 3 Follow-up	252	15,48	24,417	0,0	0,00	100,0
		Monat 6 Follow-up	206	13,27	24,346	0,0	0,00	100,0
		Monat 9 Follow-up	198	9,76	18,550	0,0	0,00	100,0
		Monat 12 Follow-up	161	9,94	18,946	0,0	0,00	100,0
		Monat 15 Follow-up	83	8,84	18,097	0,0	0,00	66,7
		Monat 18 Follow-up	116	8,33	17,515	0,0	0,00	100,0
		Monat 21 Follow-up	76	7,02	15,697	0,0	0,00	66,7
		Monat 24 Follow-up	76	14,47	23,935	0,0	0,00	100,0
		Monat 30 Follow-up	86	7,75	18,908	0,0	0,00	100,0
		Monat 36 Follow-up	34	5,88	12,898	0,0	0,00	33,3
		Monat 42 Follow-up	6	11,11	17,213	0,0	0,00	33,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraac 28JAN2026:09:31 khsk849

Table 4.1.3 Summary of absolute values across timepoints by treatment group for EORTC QLQ-IL38 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC IL38 Gewichtsverlust	Placebo + FLOT (N=474)	Baseline	430	25,89	31,395	0,0	16,67	100,0
		Zyklus 2, Tag 29	406	21,51	26,028	0,0	0,00	100,0
		Zyklus 3, Tag 1	272	39,22	33,854	0,0	33,33	100,0
		Zyklus 4, Tag 29	276	37,68	31,354	0,0	33,33	100,0
		Zyklus 5	259	33,20	31,813	0,0	33,33	100,0
		Zyklus 6	273	25,76	31,436	0,0	0,00	100,0
		Zyklus 7	266	17,92	26,392	0,0	0,00	100,0
		Zyklus 8	268	20,90	29,328	0,0	0,00	100,0
		Zyklus 9	259	16,47	25,139	0,0	0,00	100,0
		Zyklus 10	257	14,79	25,806	0,0	0,00	100,0
		Zyklus 11	240	15,14	24,154	0,0	0,00	100,0
		Zyklus 12	232	12,64	23,067	0,0	0,00	100,0
		Zyklus 13	220	12,42	21,773	0,0	0,00	100,0
		Zyklus 14	232	12,79	23,708	0,0	0,00	100,0
		Tag 30 Follow-up	231	14,00	25,468	0,0	0,00	100,0
		Monat 2 Follow-up	237	14,35	24,172	0,0	0,00	100,0
		Monat 3 Follow-up	254	17,06	26,957	0,0	0,00	100,0
		Monat 6 Follow-up	185	15,32	25,531	0,0	0,00	100,0
		Monat 9 Follow-up	162	12,35	22,868	0,0	0,00	100,0
		Monat 12 Follow-up	117	12,82	22,252	0,0	0,00	100,0
		Monat 15 Follow-up	54	11,11	21,476	0,0	0,00	100,0
		Monat 18 Follow-up	98	11,90	18,691	0,0	0,00	66,7
		Monat 21 Follow-up	50	8,67	21,093	0,0	0,00	100,0
		Monat 24 Follow-up	65	10,77	19,639	0,0	0,00	66,7
		Monat 30 Follow-up	55	6,67	13,456	0,0	0,00	33,3
		Monat 36 Follow-up	21	17,46	27,119	0,0	0,00	100,0
		Monat 42 Follow-up	7	0,00	0,000	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraac 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Angst	Durva + FLOT (N=474)	Baseline	423	43,53	26,075	0,0	44,44	100,0
		Zyklus 2, Tag 29	419	34,58	23,874	0,0	33,33	100,0
		Zyklus 3, Tag 1	285	39,45	25,591	0,0	33,33	100,0
		Zyklus 4, Tag 29	285	38,99	26,776	0,0	33,33	100,0
		Zyklus 5	257	39,90	26,825	0,0	33,33	100,0
		Zyklus 6	283	34,39	25,475	0,0	33,33	100,0
		Zyklus 7	279	33,45	24,836	0,0	33,33	100,0
		Zyklus 8	283	31,84	24,193	0,0	33,33	100,0
		Zyklus 9	267	31,34	25,302	0,0	33,33	100,0
		Zyklus 10	258	28,98	24,243	0,0	22,22	100,0
		Zyklus 11	256	29,51	23,242	0,0	33,33	100,0
		Zyklus 12	250	28,76	25,491	0,0	22,22	100,0
		Zyklus 13	232	26,92	24,341	0,0	22,22	100,0
		Zyklus 14	251	25,32	23,586	0,0	22,22	100,0
		Tag 30 Follow-up	245	26,98	22,961	0,0	22,22	100,0
		Monat 2 Follow-up	237	27,71	24,348	0,0	22,22	100,0
		Monat 3 Follow-up	252	27,20	23,704	0,0	22,22	100,0
		Monat 6 Follow-up	206	27,62	23,326	0,0	22,22	100,0
		Monat 9 Follow-up	198	24,97	22,515	0,0	22,22	100,0
		Monat 12 Follow-up	161	23,19	18,978	0,0	22,22	100,0
		Monat 15 Follow-up	83	25,17	22,228	0,0	22,22	100,0
		Monat 18 Follow-up	116	23,28	22,173	0,0	22,22	100,0
		Monat 21 Follow-up	76	21,64	18,583	0,0	22,22	77,8
		Monat 24 Follow-up	76	24,71	24,384	0,0	22,22	100,0
		Monat 30 Follow-up	86	19,51	22,153	0,0	11,11	100,0
		Monat 36 Follow-up	34	19,28	24,816	0,0	11,11	100,0
		Monat 42 Follow-up	6	22,22	21,082	0,0	22,22	55,6
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Angst	Placebo + FLOT (N=474)	Baseline	430	42,30	24,152	0,0	44,44	100,0
		Zyklus 2, Tag 29	406	34,46	23,727	0,0	33,33	100,0
		Zyklus 3, Tag 1	272	37,13	25,139	0,0	33,33	100,0
		Zyklus 4, Tag 29	276	37,88	26,163	0,0	33,33	100,0
		Zyklus 5	259	35,14	26,515	0,0	33,33	100,0
		Zyklus 6	273	33,54	26,205	0,0	33,33	100,0
		Zyklus 7	266	29,20	24,230	0,0	22,22	100,0
		Zyklus 8	268	29,98	26,515	0,0	22,22	100,0
		Zyklus 9	259	28,06	25,119	0,0	22,22	100,0
		Zyklus 10	257	27,84	26,555	0,0	22,22	100,0
		Zyklus 11	240	26,94	26,079	0,0	22,22	100,0
		Zyklus 12	232	24,76	24,476	0,0	22,22	100,0
		Zyklus 13	220	24,49	24,419	0,0	22,22	100,0
		Zyklus 14	232	24,62	23,905	0,0	22,22	100,0
		Tag 30 Follow-up	231	25,16	25,368	0,0	22,22	100,0
		Monat 2 Follow-up	237	25,22	25,456	0,0	22,22	100,0
		Monat 3 Follow-up	254	27,56	26,796	0,0	22,22	100,0
		Monat 6 Follow-up	185	28,65	27,082	0,0	22,22	100,0
		Monat 9 Follow-up	162	23,32	23,274	0,0	22,22	100,0
		Monat 12 Follow-up	117	21,84	21,686	0,0	22,22	100,0
		Monat 15 Follow-up	54	24,69	27,016	0,0	16,67	100,0
		Monat 18 Follow-up	98	26,08	23,345	0,0	22,22	100,0
		Monat 21 Follow-up	50	25,33	25,598	0,0	22,22	100,0
		Monat 24 Follow-up	65	25,13	22,929	0,0	22,22	88,9
		Monat 30 Follow-up	55	20,00	23,850	0,0	11,11	100,0
		Monat 36 Follow-up	21	30,16	27,475	0,0	22,22	100,0
		Monat 42 Follow-up	7	12,70	16,265	0,0	0,00	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Körperbild	Durva + FLOT (N=474)	Baseline	423	18,05	27,586	0,0	0,00	100,0
		Zyklus 2, Tag 29	419	24,50	28,872	0,0	33,33	100,0
		Zyklus 3, Tag 1	285	23,74	27,861	0,0	33,33	100,0
		Zyklus 4, Tag 29	285	30,18	31,051	0,0	33,33	100,0
		Zyklus 5	257	28,92	31,006	0,0	33,33	100,0
		Zyklus 6	283	26,97	30,084	0,0	33,33	100,0
		Zyklus 7	279	24,97	27,877	0,0	33,33	100,0
		Zyklus 8	283	22,97	27,118	0,0	33,33	100,0
		Zyklus 9	267	22,47	25,580	0,0	33,33	100,0
		Zyklus 10	258	20,03	26,618	0,0	0,00	100,0
		Zyklus 11	256	18,62	25,661	0,0	0,00	100,0
		Zyklus 12	250	18,67	25,837	0,0	0,00	100,0
		Zyklus 13	232	17,24	24,806	0,0	0,00	100,0
		Zyklus 14	251	17,13	24,828	0,0	0,00	100,0
		Tag 30 Follow-up	245	16,46	23,497	0,0	0,00	100,0
		Monat 2 Follow-up	237	17,58	24,841	0,0	0,00	100,0
		Monat 3 Follow-up	252	18,65	25,778	0,0	0,00	100,0
		Monat 6 Follow-up	206	18,45	27,041	0,0	0,00	100,0
		Monat 9 Follow-up	198	17,34	24,614	0,0	0,00	100,0
		Monat 12 Follow-up	161	16,36	24,186	0,0	0,00	100,0
		Monat 15 Follow-up	83	12,45	19,276	0,0	0,00	66,7
		Monat 18 Follow-up	116	16,38	25,441	0,0	0,00	100,0
		Monat 21 Follow-up	76	15,79	25,224	0,0	0,00	100,0
		Monat 24 Follow-up	76	17,98	26,910	0,0	0,00	100,0
		Monat 30 Follow-up	86	13,57	23,082	0,0	0,00	100,0
		Monat 36 Follow-up	34	14,71	27,452	0,0	0,00	100,0
		Monat 42 Follow-up	6	11,11	27,217	0,0	0,00	66,7
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Körperbild	Placebo + FLOT (N=474)	Baseline	430	16,43	25,521	0,0	0,00	100,0
		Zyklus 2, Tag 29	406	21,18	27,420	0,0	0,00	100,0
		Zyklus 3, Tag 1	272	24,63	28,237	0,0	33,33	100,0
		Zyklus 4, Tag 29	276	26,09	28,917	0,0	33,33	100,0
		Zyklus 5	259	26,38	31,660	0,0	33,33	100,0
		Zyklus 6	273	24,30	29,005	0,0	0,00	100,0
		Zyklus 7	266	20,43	26,152	0,0	0,00	100,0
		Zyklus 8	268	20,27	28,109	0,0	0,00	100,0
		Zyklus 9	259	19,05	25,705	0,0	0,00	100,0
		Zyklus 10	257	19,71	27,803	0,0	0,00	100,0
		Zyklus 11	240	18,61	26,511	0,0	0,00	100,0
		Zyklus 12	232	17,39	25,754	0,0	0,00	100,0
		Zyklus 13	220	17,27	25,773	0,0	0,00	100,0
		Zyklus 14	232	15,95	24,996	0,0	0,00	100,0
		Tag 30 Follow-up	231	17,17	25,604	0,0	0,00	100,0
		Monat 2 Follow-up	237	15,75	25,404	0,0	0,00	100,0
		Monat 3 Follow-up	254	18,64	27,212	0,0	0,00	100,0
		Monat 6 Follow-up	185	18,20	28,218	0,0	0,00	100,0
		Monat 9 Follow-up	162	14,20	23,440	0,0	0,00	100,0
		Monat 12 Follow-up	117	14,81	23,750	0,0	0,00	100,0
		Monat 15 Follow-up	54	15,43	28,011	0,0	0,00	100,0
		Monat 18 Follow-up	98	18,37	24,463	0,0	0,00	100,0
		Monat 21 Follow-up	50	20,67	28,484	0,0	0,00	100,0
		Monat 24 Follow-up	65	14,87	22,845	0,0	0,00	100,0
		Monat 30 Follow-up	55	13,94	22,853	0,0	0,00	100,0
		Monat 36 Follow-up	21	14,29	24,881	0,0	0,00	100,0
		Monat 42 Follow-up	7	9,52	16,265	0,0	0,00	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Mundtrockenheit	Durva + FLOT (N=474)	Baseline	423	16,00	25,325	0,0	0,00	100,0
		Zyklus 2, Tag 29	419	26,33	28,591	0,0	33,33	100,0
		Zyklus 3, Tag 1	285	21,87	25,812	0,0	0,00	100,0
		Zyklus 4, Tag 29	285	29,47	27,915	0,0	33,33	100,0
		Zyklus 5	257	29,70	30,115	0,0	33,33	100,0
		Zyklus 6	283	22,14	25,351	0,0	33,33	100,0
		Zyklus 7	279	19,35	23,818	0,0	0,00	100,0
		Zyklus 8	283	18,37	24,311	0,0	0,00	100,0
		Zyklus 9	267	18,60	26,001	0,0	0,00	100,0
		Zyklus 10	258	17,57	23,736	0,0	0,00	100,0
		Zyklus 11	256	16,28	24,340	0,0	0,00	100,0
		Zyklus 12	250	16,53	23,380	0,0	0,00	100,0
		Zyklus 13	232	14,66	22,914	0,0	0,00	100,0
		Zyklus 14	251	14,87	23,288	0,0	0,00	100,0
		Tag 30 Follow-up	245	15,65	24,796	0,0	0,00	100,0
		Monat 2 Follow-up	237	17,44	25,035	0,0	0,00	100,0
		Monat 3 Follow-up	252	17,20	23,891	0,0	0,00	100,0
		Monat 6 Follow-up	206	19,42	27,947	0,0	0,00	100,0
		Monat 9 Follow-up	198	17,68	23,186	0,0	0,00	100,0
		Monat 12 Follow-up	161	15,32	23,272	0,0	0,00	100,0
		Monat 15 Follow-up	83	14,06	23,351	0,0	0,00	100,0
		Monat 18 Follow-up	116	14,66	22,106	0,0	0,00	100,0
		Monat 21 Follow-up	76	20,61	26,087	0,0	0,00	100,0
		Monat 24 Follow-up	76	16,23	24,642	0,0	0,00	100,0
		Monat 30 Follow-up	86	14,34	22,602	0,0	0,00	100,0
		Monat 36 Follow-up	34	17,65	28,704	0,0	0,00	100,0
		Monat 42 Follow-up	6	22,22	17,213	0,0	33,33	33,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Mundtrockenheit	Placebo + FLOT (N=474)	Baseline	430	18,76	26,630	0,0	0,00	100,0
		Zyklus 2, Tag 29	406	27,01	30,016	0,0	33,33	100,0
		Zyklus 3, Tag 1	272	17,77	23,588	0,0	0,00	100,0
		Zyklus 4, Tag 29	276	28,74	29,043	0,0	33,33	100,0
		Zyklus 5	259	28,19	28,892	0,0	33,33	100,0
		Zyklus 6	273	20,51	26,089	0,0	0,00	100,0
		Zyklus 7	266	15,66	24,423	0,0	0,00	100,0
		Zyklus 8	268	16,92	24,900	0,0	0,00	100,0
		Zyklus 9	259	14,67	21,945	0,0	0,00	100,0
		Zyklus 10	257	14,53	22,745	0,0	0,00	100,0
		Zyklus 11	240	15,14	23,172	0,0	0,00	100,0
		Zyklus 12	232	15,80	24,009	0,0	0,00	100,0
		Zyklus 13	220	12,42	20,820	0,0	0,00	100,0
		Zyklus 14	232	13,79	21,519	0,0	0,00	100,0
		Tag 30 Follow-up	231	14,72	22,731	0,0	0,00	100,0
		Monat 2 Follow-up	237	16,17	23,289	0,0	0,00	100,0
		Monat 3 Follow-up	254	14,70	22,436	0,0	0,00	100,0
		Monat 6 Follow-up	185	17,12	25,086	0,0	0,00	100,0
		Monat 9 Follow-up	162	14,40	21,941	0,0	0,00	100,0
		Monat 12 Follow-up	117	14,53	22,904	0,0	0,00	100,0
		Monat 15 Follow-up	54	16,67	26,501	0,0	0,00	100,0
		Monat 18 Follow-up	98	18,03	24,948	0,0	0,00	100,0
		Monat 21 Follow-up	50	20,67	26,845	0,0	0,00	100,0
		Monat 24 Follow-up	65	16,92	25,085	0,0	0,00	100,0
		Monat 30 Follow-up	55	18,18	29,270	0,0	0,00	100,0
		Monat 36 Follow-up	21	17,46	30,946	0,0	0,00	100,0
		Monat 42 Follow-up	7	14,29	17,817	0,0	0,00	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Dysphagie	Durva + FLOT (N=474)	Baseline	423	16,55	23,920	0,0	11,11	100,0
		Zyklus 2, Tag 29	419	10,82	17,915	0,0	0,00	100,0
		Zyklus 3, Tag 1	285	17,62	19,054	0,0	11,11	100,0
		Zyklus 4, Tag 29	285	15,44	18,505	0,0	11,11	100,0
		Zyklus 5	257	14,27	17,267	0,0	11,11	77,8
		Zyklus 6	283	12,01	16,032	0,0	11,11	100,0
		Zyklus 7	279	10,47	14,059	0,0	0,00	77,8
		Zyklus 8	283	10,68	14,863	0,0	0,00	100,0
		Zyklus 9	267	10,99	15,279	0,0	0,00	77,8
		Zyklus 10	258	9,47	14,177	0,0	0,00	77,8
		Zyklus 11	256	8,85	14,882	0,0	0,00	88,9
		Zyklus 12	250	8,89	13,726	0,0	0,00	66,7
		Zyklus 13	232	7,76	13,014	0,0	0,00	66,7
		Zyklus 14	251	8,76	14,226	0,0	0,00	77,8
		Tag 30 Follow-up	245	8,39	14,977	0,0	0,00	100,0
		Monat 2 Follow-up	237	9,24	17,256	0,0	0,00	100,0
		Monat 3 Follow-up	252	8,25	13,567	0,0	0,00	66,7
		Monat 6 Follow-up	206	8,79	14,725	0,0	0,00	100,0
		Monat 9 Follow-up	198	7,86	13,916	0,0	0,00	77,8
		Monat 12 Follow-up	161	7,80	14,585	0,0	0,00	100,0
		Monat 15 Follow-up	83	5,62	10,465	0,0	0,00	44,4
		Monat 18 Follow-up	116	6,90	12,052	0,0	0,00	55,6
		Monat 21 Follow-up	76	8,04	13,159	0,0	0,00	55,6
		Monat 24 Follow-up	76	9,65	13,498	0,0	0,00	44,4
		Monat 30 Follow-up	86	9,04	13,367	0,0	0,00	55,6
		Monat 36 Follow-up	34	9,15	15,099	0,0	0,00	44,4
		Monat 42 Follow-up	6	7,41	13,456	0,0	0,00	33,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Dysphagie	Placebo + FLOT (N=474)	Baseline	430	16,33	22,893	0,0	11,11	100,0
		Zyklus 2, Tag 29	406	11,66	19,513	0,0	0,00	100,0
		Zyklus 3, Tag 1	272	19,20	21,849	0,0	11,11	100,0
		Zyklus 4, Tag 29	276	14,86	18,852	0,0	11,11	100,0
		Zyklus 5	259	12,40	17,092	0,0	0,00	77,8
		Zyklus 6	273	11,76	16,978	0,0	11,11	100,0
		Zyklus 7	266	8,77	14,058	0,0	0,00	100,0
		Zyklus 8	268	9,91	15,474	0,0	0,00	100,0
		Zyklus 9	259	8,41	14,035	0,0	0,00	88,9
		Zyklus 10	257	8,95	16,261	0,0	0,00	100,0
		Zyklus 11	240	8,56	14,346	0,0	0,00	88,9
		Zyklus 12	232	8,05	14,295	0,0	0,00	77,8
		Zyklus 13	220	8,33	13,075	0,0	0,00	77,8
		Zyklus 14	232	8,00	14,115	0,0	0,00	100,0
		Tag 30 Follow-up	231	8,71	16,071	0,0	0,00	100,0
		Monat 2 Follow-up	237	8,25	15,702	0,0	0,00	100,0
		Monat 3 Follow-up	254	10,94	18,215	0,0	0,00	100,0
		Monat 6 Follow-up	185	9,43	16,213	0,0	0,00	100,0
		Monat 9 Follow-up	162	8,50	15,789	0,0	0,00	77,8
		Monat 12 Follow-up	117	7,22	15,667	0,0	0,00	100,0
		Monat 15 Follow-up	54	6,58	14,401	0,0	0,00	66,7
		Monat 18 Follow-up	98	9,18	15,388	0,0	0,00	77,8
		Monat 21 Follow-up	50	10,22	22,653	0,0	0,00	88,9
		Monat 24 Follow-up	65	8,89	13,205	0,0	0,00	55,6
		Monat 30 Follow-up	55	9,09	19,492	0,0	0,00	100,0
		Monat 36 Follow-up	21	4,76	17,417	0,0	0,00	77,8
		Monat 42 Follow-up	7	0,00	0,000	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Einschränkungen beim Essen	Durva + FLOT (N=474)	Baseline	423	21,24	23,857	0,0	16,67	100,0
		Zyklus 2, Tag 29	419	18,04	18,748	0,0	16,67	100,0
		Zyklus 3, Tag 1	285	26,99	19,642	0,0	25,00	100,0
		Zyklus 4, Tag 29	285	25,44	20,687	0,0	25,00	100,0
		Zyklus 5	257	25,45	20,381	0,0	25,00	91,7
		Zyklus 6	283	20,41	18,515	0,0	16,67	91,7
		Zyklus 7	279	19,35	18,411	0,0	16,67	91,7
		Zyklus 8	283	18,82	19,027	0,0	16,67	100,0
		Zyklus 9	267	18,54	19,081	0,0	16,67	100,0
		Zyklus 10	258	17,96	18,784	0,0	16,67	91,7
		Zyklus 11	256	16,70	17,994	0,0	16,67	91,7
		Zyklus 12	250	17,10	19,506	0,0	8,33	100,0
		Zyklus 13	232	15,59	18,497	0,0	8,33	91,7
		Zyklus 14	251	15,64	19,215	0,0	8,33	91,7
		Tag 30 Follow-up	245	16,09	19,600	0,0	8,33	100,0
		Monat 2 Follow-up	237	16,21	19,425	0,0	8,33	100,0
		Monat 3 Follow-up	252	15,41	18,717	0,0	8,33	83,3
		Monat 6 Follow-up	206	16,26	19,387	0,0	8,33	100,0
		Monat 9 Follow-up	198	15,03	17,904	0,0	8,33	100,0
		Monat 12 Follow-up	161	15,01	18,536	0,0	8,33	91,7
		Monat 15 Follow-up	83	13,76	17,336	0,0	8,33	83,3
		Monat 18 Follow-up	116	14,58	18,253	0,0	8,33	75,0
		Monat 21 Follow-up	76	14,14	16,444	0,0	8,33	66,7
		Monat 24 Follow-up	76	14,47	18,021	0,0	8,33	75,0
		Monat 30 Follow-up	86	14,73	19,118	0,0	8,33	83,3
		Monat 36 Follow-up	34	14,95	20,493	0,0	8,33	66,7
		Monat 42 Follow-up	6	15,28	24,954	0,0	0,00	58,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Einschränkungen beim Essen	Placebo + FLOT (N=474)	Baseline	430	21,05	23,138	0,0	16,67	100,0
		Zyklus 2, Tag 29	406	18,80	20,300	0,0	16,67	100,0
		Zyklus 3, Tag 1	272	26,99	22,827	0,0	25,00	100,0
		Zyklus 4, Tag 29	276	25,54	22,489	0,0	25,00	100,0
		Zyklus 5	259	23,07	21,580	0,0	16,67	100,0
		Zyklus 6	273	19,47	19,445	0,0	16,67	100,0
		Zyklus 7	266	16,60	18,343	0,0	8,33	100,0
		Zyklus 8	268	16,54	18,529	0,0	8,33	100,0
		Zyklus 9	259	16,02	17,840	0,0	8,33	83,3
		Zyklus 10	257	14,62	17,918	0,0	8,33	91,7
		Zyklus 11	240	14,55	17,295	0,0	8,33	100,0
		Zyklus 12	232	13,86	18,199	0,0	8,33	100,0
		Zyklus 13	220	12,80	16,034	0,0	8,33	91,7
		Zyklus 14	232	13,33	16,933	0,0	8,33	100,0
		Tag 30 Follow-up	231	13,92	18,016	0,0	8,33	100,0
		Monat 2 Follow-up	237	13,96	18,024	0,0	8,33	100,0
		Monat 3 Follow-up	254	16,63	19,943	0,0	8,33	100,0
		Monat 6 Follow-up	185	15,99	20,484	0,0	8,33	100,0
		Monat 9 Follow-up	162	15,12	19,860	0,0	8,33	100,0
		Monat 12 Follow-up	117	13,89	19,696	0,0	8,33	100,0
		Monat 15 Follow-up	54	17,44	23,418	0,0	8,33	100,0
		Monat 18 Follow-up	98	17,35	21,023	0,0	8,33	75,0
		Monat 21 Follow-up	50	17,83	22,900	0,0	8,33	100,0
		Monat 24 Follow-up	65	16,67	19,037	0,0	8,33	91,7
		Monat 30 Follow-up	55	13,48	20,879	0,0	8,33	100,0
		Monat 36 Follow-up	21	12,70	22,457	0,0	8,33	100,0
		Monat 42 Follow-up	7	4,76	6,557	0,0	0,00	16,7

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Haarverlust	Durva + FLOT (N=474)	Baseline	423	3,70	12,546	0,0	0,00	100,0
		Zyklus 2, Tag 29	419	45,47	30,184	0,0	50,00	100,0
		Zyklus 3, Tag 1	285	28,07	33,239	0,0	16,67	100,0
		Zyklus 4, Tag 29	285	34,50	27,983	0,0	33,33	100,0
		Zyklus 5	257	31,06	29,504	0,0	33,33	100,0
		Zyklus 6	283	28,80	30,430	0,0	16,67	100,0
		Zyklus 7	279	21,21	28,225	0,0	0,00	100,0
		Zyklus 8	283	14,19	23,565	0,0	0,00	100,0
		Zyklus 9	267	11,49	23,285	0,0	0,00	100,0
		Zyklus 10	258	9,50	21,640	0,0	0,00	100,0
		Zyklus 11	256	9,90	22,281	0,0	0,00	100,0
		Zyklus 12	250	8,60	21,346	0,0	0,00	100,0
		Zyklus 13	232	6,82	18,287	0,0	0,00	100,0
		Zyklus 14	251	6,31	17,545	0,0	0,00	100,0
		Tag 30 Follow-up	245	5,92	17,208	0,0	0,00	100,0
		Monat 2 Follow-up	237	7,17	18,286	0,0	0,00	100,0
		Monat 3 Follow-up	252	7,94	18,785	0,0	0,00	100,0
		Monat 6 Follow-up	206	7,52	18,369	0,0	0,00	100,0
		Monat 9 Follow-up	198	7,41	15,971	0,0	0,00	66,7
		Monat 12 Follow-up	161	6,31	16,131	0,0	0,00	100,0
		Monat 15 Follow-up	83	4,82	14,616	0,0	0,00	83,3
		Monat 18 Follow-up	116	6,18	16,231	0,0	0,00	83,3
		Monat 21 Follow-up	76	6,36	17,631	0,0	0,00	100,0
		Monat 24 Follow-up	76	9,87	22,473	0,0	0,00	100,0
		Monat 30 Follow-up	86	6,78	17,597	0,0	0,00	83,3
		Monat 36 Follow-up	34	7,84	16,532	0,0	0,00	50,0
		Monat 42 Follow-up	6	2,78	6,804	0,0	0,00	16,7
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Haarverlust	Placebo + FLOT (N=474)	Baseline	430	4,07	13,449	0,0	0,00	100,0
		Zyklus 2, Tag 29	406	40,52	29,252	0,0	33,33	100,0
		Zyklus 3, Tag 1	272	28,00	30,695	0,0	16,67	100,0
		Zyklus 4, Tag 29	276	30,86	27,394	0,0	33,33	100,0
		Zyklus 5	259	30,05	28,661	0,0	33,33	100,0
		Zyklus 6	273	26,56	28,437	0,0	16,67	100,0
		Zyklus 7	266	20,74	27,187	0,0	0,00	100,0
		Zyklus 8	268	14,93	24,203	0,0	0,00	100,0
		Zyklus 9	259	9,27	19,631	0,0	0,00	100,0
		Zyklus 10	257	8,56	19,715	0,0	0,00	100,0
		Zyklus 11	240	8,61	19,935	0,0	0,00	100,0
		Zyklus 12	232	7,26	18,318	0,0	0,00	100,0
		Zyklus 13	220	6,52	18,519	0,0	0,00	100,0
		Zyklus 14	232	7,90	19,916	0,0	0,00	100,0
		Tag 30 Follow-up	231	9,02	19,944	0,0	0,00	100,0
		Monat 2 Follow-up	237	8,16	19,262	0,0	0,00	100,0
		Monat 3 Follow-up	254	9,97	20,667	0,0	0,00	100,0
		Monat 6 Follow-up	185	9,46	20,092	0,0	0,00	100,0
		Monat 9 Follow-up	162	7,10	15,850	0,0	0,00	100,0
		Monat 12 Follow-up	117	8,97	17,851	0,0	0,00	100,0
		Monat 15 Follow-up	54	6,79	22,552	0,0	0,00	100,0
		Monat 18 Follow-up	98	8,33	17,627	0,0	0,00	83,3
		Monat 21 Follow-up	50	4,00	15,635	0,0	0,00	100,0
		Monat 24 Follow-up	65	11,79	21,393	0,0	0,00	83,3
		Monat 30 Follow-up	55	7,27	17,790	0,0	0,00	100,0
		Monat 36 Follow-up	21	6,35	22,655	0,0	0,00	100,0
		Monat 42 Follow-up	7	0,00	0,000	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Schmerzen	Durva + FLOT (N=474)	Baseline	423	22,40	21,144	0,0	16,67	100,0
		Zyklus 2, Tag 29	419	17,92	17,811	0,0	16,67	100,0
		Zyklus 3, Tag 1	285	24,09	19,378	0,0	25,00	100,0
		Zyklus 4, Tag 29	285	20,09	17,165	0,0	16,67	91,7
		Zyklus 5	257	19,36	16,991	0,0	16,67	100,0
		Zyklus 6	283	18,20	17,562	0,0	16,67	91,7
		Zyklus 7	279	17,47	17,201	0,0	16,67	83,3
		Zyklus 8	283	16,99	16,478	0,0	16,67	100,0
		Zyklus 9	267	17,92	18,280	0,0	16,67	100,0
		Zyklus 10	258	16,44	17,137	0,0	16,67	100,0
		Zyklus 11	256	15,20	16,445	0,0	8,33	83,3
		Zyklus 12	250	15,37	16,724	0,0	8,33	100,0
		Zyklus 13	232	13,65	16,609	0,0	8,33	91,7
		Zyklus 14	251	13,28	16,112	0,0	8,33	100,0
		Tag 30 Follow-up	245	15,48	17,645	0,0	8,33	100,0
		Monat 2 Follow-up	237	15,23	17,493	0,0	8,33	91,7
		Monat 3 Follow-up	252	14,29	17,023	0,0	8,33	100,0
		Monat 6 Follow-up	206	15,70	19,349	0,0	8,33	100,0
		Monat 9 Follow-up	198	15,15	17,202	0,0	8,33	83,3
		Monat 12 Follow-up	161	14,23	17,742	0,0	8,33	100,0
		Monat 15 Follow-up	83	15,46	16,262	0,0	16,67	66,7
		Monat 18 Follow-up	116	13,29	17,822	0,0	8,33	91,7
		Monat 21 Follow-up	76	16,67	18,559	0,0	8,33	83,3
		Monat 24 Follow-up	76	15,68	19,483	0,0	8,33	83,3
		Monat 30 Follow-up	86	16,57	18,938	0,0	8,33	100,0
		Monat 36 Follow-up	34	17,16	23,743	0,0	8,33	83,3
		Monat 42 Follow-up	6	15,28	23,224	0,0	4,17	58,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Schmerzen	Placebo + FLOT (N=474)	Baseline	430	23,82	21,623	0,0	16,67	100,0
		Zyklus 2, Tag 29	406	19,05	18,624	0,0	16,67	100,0
		Zyklus 3, Tag 1	272	24,02	20,502	0,0	25,00	100,0
		Zyklus 4, Tag 29	276	23,07	20,543	0,0	25,00	100,0
		Zyklus 5	259	19,66	17,682	0,0	16,67	100,0
		Zyklus 6	273	19,14	18,434	0,0	16,67	91,7
		Zyklus 7	266	16,73	16,588	0,0	16,67	83,3
		Zyklus 8	268	16,67	17,068	0,0	8,33	83,3
		Zyklus 9	259	16,15	15,830	0,0	16,67	75,0
		Zyklus 10	257	15,30	16,918	0,0	8,33	100,0
		Zyklus 11	240	14,69	16,887	0,0	8,33	83,3
		Zyklus 12	232	13,54	16,724	0,0	8,33	100,0
		Zyklus 13	220	14,09	16,523	0,0	8,33	100,0
		Zyklus 14	232	13,61	16,429	0,0	8,33	100,0
		Tag 30 Follow-up	231	14,29	17,576	0,0	8,33	91,7
		Monat 2 Follow-up	237	14,70	16,081	0,0	8,33	100,0
		Monat 3 Follow-up	254	17,45	18,297	0,0	12,50	100,0
		Monat 6 Follow-up	185	15,72	17,426	0,0	8,33	100,0
		Monat 9 Follow-up	162	13,94	17,322	0,0	8,33	100,0
		Monat 12 Follow-up	117	13,68	16,791	0,0	8,33	100,0
		Monat 15 Follow-up	54	17,44	21,061	0,0	12,50	100,0
		Monat 18 Follow-up	98	15,48	16,880	0,0	8,33	75,0
		Monat 21 Follow-up	50	16,33	20,686	0,0	8,33	100,0
		Monat 24 Follow-up	65	15,26	13,386	0,0	16,67	50,0
		Monat 30 Follow-up	55	13,48	21,185	0,0	0,00	100,0
		Monat 36 Follow-up	21	15,08	22,764	0,0	8,33	100,0
		Monat 42 Follow-up	7	13,10	15,105	0,0	8,33	33,3

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Reflux	Durva + FLOT (N=474)	Baseline	423	16,31	20,477	0,0	11,11	100,0
		Zyklus 2, Tag 29	419	13,58	17,663	0,0	11,11	100,0
		Zyklus 3, Tag 1	285	17,66	19,052	0,0	11,11	100,0
		Zyklus 4, Tag 29	285	17,86	18,272	0,0	11,11	100,0
		Zyklus 5	257	18,07	18,842	0,0	11,11	100,0
		Zyklus 6	283	14,84	15,645	0,0	11,11	100,0
		Zyklus 7	279	14,77	16,615	0,0	11,11	77,8
		Zyklus 8	283	14,17	16,850	0,0	11,11	100,0
		Zyklus 9	267	14,90	17,099	0,0	11,11	100,0
		Zyklus 10	258	15,20	19,107	0,0	11,11	100,0
		Zyklus 11	256	12,24	17,035	0,0	0,00	100,0
		Zyklus 12	250	14,00	18,228	0,0	11,11	100,0
		Zyklus 13	232	11,49	16,310	0,0	0,00	88,9
		Zyklus 14	251	11,69	16,485	0,0	0,00	100,0
		Tag 30 Follow-up	245	13,38	18,216	0,0	11,11	100,0
		Monat 2 Follow-up	237	12,05	16,403	0,0	0,00	88,9
		Monat 3 Follow-up	252	12,61	17,483	0,0	0,00	100,0
		Monat 6 Follow-up	206	13,16	16,770	0,0	11,11	100,0
		Monat 9 Follow-up	198	13,19	16,720	0,0	11,11	88,9
		Monat 12 Follow-up	161	13,87	18,046	0,0	11,11	88,9
		Monat 15 Follow-up	83	14,19	18,715	0,0	11,11	100,0
		Monat 18 Follow-up	116	11,78	15,596	0,0	0,00	66,7
		Monat 21 Follow-up	76	16,52	20,806	0,0	11,11	88,9
		Monat 24 Follow-up	76	12,57	15,433	0,0	11,11	66,7
		Monat 30 Follow-up	86	15,89	19,988	0,0	11,11	100,0
		Monat 36 Follow-up	34	19,28	23,260	0,0	11,11	100,0
		Monat 42 Follow-up	6	12,96	20,387	0,0	0,00	44,4
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Reflux	Placebo + FLOT (N=474)	Baseline	430	16,59	19,338	0,0	11,11	100,0
		Zyklus 2, Tag 29	406	15,08	18,911	0,0	11,11	100,0
		Zyklus 3, Tag 1	272	17,20	19,438	0,0	11,11	100,0
		Zyklus 4, Tag 29	276	17,11	19,633	0,0	11,11	100,0
		Zyklus 5	259	15,27	17,834	0,0	11,11	77,8
		Zyklus 6	273	13,06	16,496	0,0	11,11	77,8
		Zyklus 7	266	11,90	14,886	0,0	11,11	77,8
		Zyklus 8	268	13,47	16,779	0,0	11,11	77,8
		Zyklus 9	259	12,14	16,337	0,0	0,00	100,0
		Zyklus 10	257	11,89	16,590	0,0	0,00	88,9
		Zyklus 11	240	11,30	15,547	0,0	0,00	66,7
		Zyklus 12	232	10,73	15,013	0,0	0,00	66,7
		Zyklus 13	220	10,10	14,831	0,0	0,00	88,9
		Zyklus 14	232	10,82	15,227	0,0	0,00	66,7
		Tag 30 Follow-up	231	9,48	13,369	0,0	0,00	66,7
		Monat 2 Follow-up	237	11,06	16,445	0,0	0,00	100,0
		Monat 3 Follow-up	254	12,55	15,631	0,0	11,11	77,8
		Monat 6 Follow-up	185	12,49	16,949	0,0	11,11	100,0
		Monat 9 Follow-up	162	12,48	15,653	0,0	11,11	77,8
		Monat 12 Follow-up	117	11,68	17,800	0,0	0,00	88,9
		Monat 15 Follow-up	54	12,35	18,651	0,0	0,00	100,0
		Monat 18 Follow-up	98	13,27	17,232	0,0	11,11	66,7
		Monat 21 Follow-up	50	16,00	21,782	0,0	11,11	100,0
		Monat 24 Follow-up	65	11,62	14,755	0,0	0,00	66,7
		Monat 30 Follow-up	55	12,93	17,341	0,0	0,00	66,7
		Monat 36 Follow-up	21	12,70	19,653	0,0	0,00	77,8
		Monat 42 Follow-up	7	12,70	17,484	0,0	0,00	44,4

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Geschmacksstörungen	Durva + FLOT (N=474)	Baseline	423	9,54	21,305	0,0	0,00	100,0
		Zyklus 2, Tag 29	419	32,46	33,993	0,0	33,33	100,0
		Zyklus 3, Tag 1	285	18,48	28,001	0,0	0,00	100,0
		Zyklus 4, Tag 29	285	33,92	31,456	0,0	33,33	100,0
		Zyklus 5	257	36,06	32,628	0,0	33,33	100,0
		Zyklus 6	283	22,50	27,368	0,0	0,00	100,0
		Zyklus 7	279	16,61	23,802	0,0	0,00	100,0
		Zyklus 8	283	14,25	22,393	0,0	0,00	100,0
		Zyklus 9	267	14,98	23,129	0,0	0,00	100,0
		Zyklus 10	258	13,31	22,955	0,0	0,00	100,0
		Zyklus 11	256	11,20	19,482	0,0	0,00	100,0
		Zyklus 12	250	10,40	19,778	0,0	0,00	100,0
		Zyklus 13	232	9,34	19,219	0,0	0,00	100,0
		Zyklus 14	251	9,16	19,326	0,0	0,00	100,0
		Tag 30 Follow-up	245	10,34	21,385	0,0	0,00	100,0
		Monat 2 Follow-up	237	10,13	21,494	0,0	0,00	100,0
		Monat 3 Follow-up	252	11,90	22,252	0,0	0,00	100,0
		Monat 6 Follow-up	206	10,84	21,741	0,0	0,00	100,0
		Monat 9 Follow-up	198	8,59	17,103	0,0	0,00	100,0
		Monat 12 Follow-up	161	9,11	17,475	0,0	0,00	100,0
		Monat 15 Follow-up	83	8,43	23,190	0,0	0,00	100,0
		Monat 18 Follow-up	116	8,33	16,954	0,0	0,00	100,0
		Monat 21 Follow-up	76	8,33	17,321	0,0	0,00	100,0
		Monat 24 Follow-up	76	10,09	21,096	0,0	0,00	100,0
		Monat 30 Follow-up	86	10,47	19,975	0,0	0,00	100,0
		Monat 36 Follow-up	34	8,82	20,612	0,0	0,00	66,7
		Monat 42 Follow-up	6	5,56	13,608	0,0	0,00	33,3
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.4 Summary of absolute values across timepoints by treatment group for EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EORTC STO22 Geschmacksstörungen	Placebo + FLOT (N=474)	Baseline	430	10,39	21,606	0,0	0,00	100,0
		Zyklus 2, Tag 29	406	28,98	32,376	0,0	33,33	100,0
		Zyklus 3, Tag 1	272	19,00	28,252	0,0	0,00	100,0
		Zyklus 4, Tag 29	276	33,09	33,150	0,0	33,33	100,0
		Zyklus 5	259	33,46	33,782	0,0	33,33	100,0
		Zyklus 6	273	21,49	28,334	0,0	0,00	100,0
		Zyklus 7	266	14,54	24,003	0,0	0,00	100,0
		Zyklus 8	268	12,06	20,793	0,0	0,00	100,0
		Zyklus 9	259	11,45	21,002	0,0	0,00	100,0
		Zyklus 10	257	10,89	22,101	0,0	0,00	100,0
		Zyklus 11	240	10,14	20,770	0,0	0,00	100,0
		Zyklus 12	232	9,77	19,378	0,0	0,00	100,0
		Zyklus 13	220	8,18	17,842	0,0	0,00	100,0
		Zyklus 14	232	8,91	19,048	0,0	0,00	100,0
		Tag 30 Follow-up	231	10,39	19,849	0,0	0,00	100,0
		Monat 2 Follow-up	237	10,13	19,902	0,0	0,00	100,0
		Monat 3 Follow-up	254	11,94	21,412	0,0	0,00	100,0
		Monat 6 Follow-up	185	11,53	23,807	0,0	0,00	100,0
		Monat 9 Follow-up	162	8,64	20,198	0,0	0,00	100,0
		Monat 12 Follow-up	117	10,54	22,167	0,0	0,00	100,0
		Monat 15 Follow-up	54	8,64	20,665	0,0	0,00	100,0
		Monat 18 Follow-up	98	11,22	23,905	0,0	0,00	100,0
		Monat 21 Follow-up	50	12,00	24,981	0,0	0,00	100,0
		Monat 24 Follow-up	65	12,31	20,043	0,0	0,00	66,7
		Monat 30 Follow-up	55	10,30	21,153	0,0	0,00	100,0
		Monat 36 Follow-up	21	11,11	26,527	0,0	0,00	100,0
		Monat 42 Follow-up	7	0,00	0,000	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraad 28JAN2026:09:31 khsk849

Table 4.1.5 Summary of absolute values across timepoints by treatment group for EQ-5D-5L Visual Analogue Scale (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EQ-5D-5L Visuelle Analogskala	Durva + FLOT (N=474)	Baseline	423	73,70	19,259	0,0	80,00	100,0
		Zyklus 2, Tag 29	416	73,16	15,389	19,0	76,50	100,0
		Zyklus 3, Tag 1	282	73,93	15,555	0,0	76,50	100,0
		Zyklus 4, Tag 29	285	69,97	18,238	0,0	73,00	100,0
		Zyklus 5	255	70,39	18,147	0,0	71,00	100,0
		Zyklus 6	282	75,25	15,768	20,0	79,00	100,0
		Zyklus 7	278	76,61	15,217	19,0	80,00	100,0
		Zyklus 8	283	77,33	13,888	30,0	80,00	100,0
		Zyklus 9	266	75,97	14,776	29,0	79,00	100,0
		Zyklus 10	257	77,95	14,599	30,0	80,00	100,0
		Zyklus 11	256	78,30	13,827	35,0	80,00	100,0
		Zyklus 12	250	77,89	15,599	20,0	80,50	100,0
		Zyklus 13	232	78,56	16,146	0,0	80,50	100,0
		Zyklus 14	249	80,51	14,332	19,0	83,00	100,0
		Tag 30 Follow-up	245	79,16	15,728	21,0	81,00	100,0
		Monat 2 Follow-up	237	78,84	17,101	9,0	82,00	100,0
		Monat 3 Follow-up	252	78,79	16,237	15,0	81,00	100,0
		Monat 6 Follow-up	206	77,43	18,068	1,0	81,00	100,0
		Monat 9 Follow-up	195	78,89	15,893	12,0	83,00	100,0
		Monat 12 Follow-up	161	80,98	13,964	20,0	84,00	100,0
		Monat 15 Follow-up	82	82,05	11,186	50,0	82,50	100,0
		Monat 18 Follow-up	116	81,29	14,176	20,0	85,00	100,0
		Monat 21 Follow-up	76	80,30	14,667	33,0	84,00	100,0
		Monat 24 Follow-up	76	77,78	16,782	0,0	81,00	100,0
		Monat 30 Follow-up	86	79,55	14,317	30,0	81,50	100,0
		Monat 36 Follow-up	34	78,15	13,822	44,0	80,00	95,0
		Monat 42 Follow-up	6	80,67	16,170	50,0	89,00	91,0
		Monat 48 Follow-up	1	90,00	NC	90,0	90,00	90,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraae 28JAN2026:09:31 khsk849

Table 4.1.5 Summary of absolute values across timepoints by treatment group for EQ-5D-5L Visual Analogue Scale (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
EQ-5D-5L Visuelle Analogskala	Placebo + FLOT (N=474)	Baseline	429	75,10	17,721	10,0	80,00	100,0
		Zyklus 2, Tag 29	405	73,32	17,821	2,0	79,00	100,0
		Zyklus 3, Tag 1	270	72,23	16,626	10,0	74,00	100,0
		Zyklus 4, Tag 29	275	71,07	18,001	0,0	74,00	100,0
		Zyklus 5	259	72,97	16,888	1,0	75,00	100,0
		Zyklus 6	271	75,14	15,661	10,0	78,00	100,0
		Zyklus 7	266	77,03	15,485	0,0	80,00	100,0
		Zyklus 8	267	77,75	16,472	10,0	80,00	100,0
		Zyklus 9	258	79,03	14,428	30,0	80,00	100,0
		Zyklus 10	256	79,24	15,133	1,0	81,00	100,0
		Zyklus 11	240	79,23	15,344	9,0	81,00	100,0
		Zyklus 12	232	79,93	15,369	8,0	82,50	100,0
		Zyklus 13	219	79,83	15,549	13,0	84,00	100,0
		Zyklus 14	232	80,77	14,720	2,0	83,00	100,0
		Tag 30 Follow-up	230	78,88	17,147	11,0	81,00	100,0
		Monat 2 Follow-up	237	78,17	17,151	1,0	82,00	100,0
		Monat 3 Follow-up	253	76,62	18,693	0,0	80,00	100,0
		Monat 6 Follow-up	185	78,64	17,697	3,0	81,00	100,0
		Monat 9 Follow-up	161	79,34	15,911	2,0	82,00	100,0
		Monat 12 Follow-up	117	79,97	14,605	30,0	83,00	100,0
		Monat 15 Follow-up	54	77,43	20,095	7,0	82,00	100,0
		Monat 18 Follow-up	97	76,89	17,317	15,0	80,00	99,0
		Monat 21 Follow-up	50	75,30	23,189	0,0	80,00	100,0
		Monat 24 Follow-up	65	78,80	16,335	20,0	80,00	100,0
		Monat 30 Follow-up	55	78,36	19,840	1,0	82,00	100,0
		Monat 36 Follow-up	21	79,19	19,740	11,0	82,00	100,0
		Monat 42 Follow-up	7	75,71	15,478	48,0	82,00	88,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/smeanpr.sas gsmeanpraae 28JAN2026:09:31 khsk849

Table 4.1.6 Summary of absolute values across timepoints by treatment group for Patient Global Impressions of Severity (PGIS) (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
Patient Global Impressions of Severity (PGIS)	Durva + FLOT (N=474)	Baseline	421	1,18	1,266	0,0	1,00	5,0
		Zyklus 2, Tag 29	412	1,19	1,127	0,0	1,00	5,0
		Zyklus 3, Tag 1	281	0,78	1,036	0,0	0,00	4,0
		Zyklus 4, Tag 29	282	0,93	1,116	0,0	1,00	5,0
		Zyklus 5	250	0,94	1,066	0,0	1,00	4,0
		Zyklus 6	279	0,68	0,987	0,0	0,00	4,0
		Zyklus 7	275	0,65	0,921	0,0	0,00	3,0
		Zyklus 8	280	0,74	1,005	0,0	0,00	4,0
		Zyklus 9	264	0,63	0,926	0,0	0,00	4,0
		Zyklus 10	257	0,55	0,799	0,0	0,00	4,0
		Zyklus 11	256	0,52	0,858	0,0	0,00	4,0
		Zyklus 12	248	0,53	0,853	0,0	0,00	5,0
		Zyklus 13	231	0,45	0,847	0,0	0,00	5,0
		Zyklus 14	249	0,41	0,747	0,0	0,00	4,0
		Tag 30 Follow-up	243	0,52	0,911	0,0	0,00	4,0
		Monat 2 Follow-up	237	0,53	1,006	0,0	0,00	5,0
		Monat 3 Follow-up	250	0,59	0,995	0,0	0,00	4,0
		Monat 6 Follow-up	205	0,48	0,921	0,0	0,00	4,0
		Monat 9 Follow-up	193	0,39	0,778	0,0	0,00	3,0
		Monat 12 Follow-up	161	0,46	0,822	0,0	0,00	4,0
		Monat 15 Follow-up	81	0,32	0,566	0,0	0,00	2,0
		Monat 18 Follow-up	116	0,38	0,841	0,0	0,00	4,0
		Monat 21 Follow-up	76	0,49	0,931	0,0	0,00	4,0
		Monat 24 Follow-up	75	0,37	0,882	0,0	0,00	5,0
		Monat 30 Follow-up	86	0,43	0,875	0,0	0,00	5,0
		Monat 36 Follow-up	34	0,35	0,774	0,0	0,00	3,0
		Monat 42 Follow-up	6	0,67	1,211	0,0	0,00	3,0
		Monat 48 Follow-up	1	0,00	NC	0,0	0,00	0,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.1.6 Summary of absolute values across timepoints by treatment group for Patient Global Impressions of Severity (PGIS) (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
Patient Global Impressions of Severity (PGIS)	Placebo + FLOT (N=474)	Baseline	427	1,18	1,236	0,0	1,00	5,0
		Zyklus 2, Tag 29	404	1,22	1,136	0,0	1,00	5,0
		Zyklus 3, Tag 1	268	0,83	1,055	0,0	0,00	5,0
		Zyklus 4, Tag 29	273	0,99	1,216	0,0	1,00	5,0
		Zyklus 5	258	0,81	1,072	0,0	0,00	5,0
		Zyklus 6	269	0,74	0,972	0,0	0,00	5,0
		Zyklus 7	266	0,63	0,971	0,0	0,00	5,0
		Zyklus 8	263	0,67	0,978	0,0	0,00	5,0
		Zyklus 9	258	0,60	0,946	0,0	0,00	5,0
		Zyklus 10	255	0,58	0,973	0,0	0,00	5,0
		Zyklus 11	240	0,51	0,853	0,0	0,00	5,0
		Zyklus 12	231	0,42	0,814	0,0	0,00	5,0
		Zyklus 13	219	0,40	0,803	0,0	0,00	5,0
		Zyklus 14	232	0,41	0,837	0,0	0,00	5,0
		Tag 30 Follow-up	230	0,49	0,910	0,0	0,00	5,0
		Monat 2 Follow-up	233	0,57	0,972	0,0	0,00	5,0
		Monat 3 Follow-up	252	0,70	1,109	0,0	0,00	5,0
		Monat 6 Follow-up	182	0,65	1,050	0,0	0,00	5,0
		Monat 9 Follow-up	160	0,43	0,858	0,0	0,00	5,0
		Monat 12 Follow-up	117	0,38	0,807	0,0	0,00	5,0
		Monat 15 Follow-up	54	0,56	1,127	0,0	0,00	5,0
		Monat 18 Follow-up	97	0,53	0,879	0,0	0,00	3,0
		Monat 21 Follow-up	50	0,62	1,067	0,0	0,00	5,0
		Monat 24 Follow-up	65	0,35	0,837	0,0	0,00	5,0
		Monat 30 Follow-up	55	0,44	0,958	0,0	0,00	5,0
		Monat 36 Follow-up	21	0,67	1,238	0,0	0,00	5,0
		Monat 42 Follow-up	7	0,57	0,787	0,0	0,00	2,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.1.7 Summary of absolute values across timepoints by treatment group for Patient Global Impression of Change (PGIC) (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
Patient Global Impression of Change (PGIC)	Durva + FLOT (N=474)	Baseline	1	4,00	NC	4,0	4,00	4,0
		Zyklus 2, Tag 29	408	3,06	1,439	1,0	3,00	7,0
		Zyklus 3, Tag 1	280	2,51	1,437	1,0	2,00	7,0
		Zyklus 4, Tag 29	281	2,69	1,611	1,0	2,00	7,0
		Zyklus 5	252	2,54	1,492	1,0	2,00	7,0
		Zyklus 6	279	2,25	1,368	1,0	2,00	7,0
		Zyklus 7	276	2,07	1,260	1,0	2,00	7,0
		Zyklus 8	282	2,05	1,211	1,0	2,00	7,0
		Zyklus 9	265	2,09	1,234	1,0	2,00	6,0
		Zyklus 10	257	1,91	1,181	1,0	2,00	7,0
		Zyklus 11	256	1,89	1,162	1,0	2,00	6,0
		Zyklus 12	248	1,87	1,152	1,0	1,00	6,0
		Zyklus 13	232	1,85	1,220	1,0	1,00	7,0
		Zyklus 14	249	1,83	1,145	1,0	1,00	7,0
		Tag 30 Follow-up	243	1,96	1,309	1,0	1,00	7,0
		Monat 2 Follow-up	237	2,02	1,410	1,0	1,00	7,0
		Monat 3 Follow-up	252	1,96	1,334	1,0	1,00	7,0
		Monat 6 Follow-up	205	1,87	1,346	1,0	1,00	7,0
		Monat 9 Follow-up	195	1,81	1,245	1,0	1,00	6,0
		Monat 12 Follow-up	161	1,76	1,148	1,0	1,00	6,0
		Monat 15 Follow-up	82	1,66	0,892	1,0	1,00	4,0
		Monat 18 Follow-up	116	1,67	1,156	1,0	1,00	7,0
		Monat 21 Follow-up	76	1,68	1,235	1,0	1,00	7,0
		Monat 24 Follow-up	75	1,84	1,252	1,0	1,00	7,0
		Monat 30 Follow-up	86	1,66	1,013	1,0	1,00	6,0
		Monat 36 Follow-up	34	2,21	1,533	1,0	1,50	7,0
		Monat 42 Follow-up	6	2,17	1,835	1,0	1,00	5,0
		Monat 48 Follow-up	1	1,00	NC	1,0	1,00	1,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.1.7 Summary of absolute values across timepoints by treatment group for Patient Global Impression of Change (PGIC) (Morbidity)
Full Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
Patient Global Impression of Change (PGIC)	Placebo + FLOT (N=474)	Zyklus 2, Tag 29	400	3,20	1,415	1,0	3,00	7,0
		Zyklus 3, Tag 1	269	2,61	1,433	1,0	2,00	7,0
		Zyklus 4, Tag 29	273	2,71	1,596	1,0	2,00	7,0
		Zyklus 5	259	2,46	1,495	1,0	2,00	7,0
		Zyklus 6	269	2,17	1,269	1,0	2,00	7,0
		Zyklus 7	266	2,04	1,276	1,0	2,00	7,0
		Zyklus 8	263	1,90	1,127	1,0	2,00	7,0
		Zyklus 9	258	1,75	1,025	1,0	1,00	5,0
		Zyklus 10	255	1,89	1,172	1,0	1,00	7,0
		Zyklus 11	240	1,85	1,116	1,0	1,00	6,0
		Zyklus 12	232	1,80	1,145	1,0	1,00	7,0
		Zyklus 13	219	1,82	1,096	1,0	1,00	6,0
		Zyklus 14	232	1,67	1,060	1,0	1,00	7,0
		Tag 30 Follow-up	230	1,86	1,368	1,0	1,00	7,0
		Monat 2 Follow-up	234	1,82	1,247	1,0	1,00	7,0
		Monat 3 Follow-up	252	2,07	1,500	1,0	1,00	7,0
		Monat 6 Follow-up	185	2,03	1,489	1,0	1,00	7,0
		Monat 9 Follow-up	160	1,83	1,255	1,0	1,00	7,0
		Monat 12 Follow-up	117	1,80	1,240	1,0	1,00	7,0
		Monat 15 Follow-up	54	1,59	1,296	1,0	1,00	7,0
		Monat 18 Follow-up	97	2,01	1,319	1,0	2,00	7,0
		Monat 21 Follow-up	50	2,00	1,629	1,0	1,00	7,0
		Monat 24 Follow-up	65	1,83	1,206	1,0	1,00	7,0
		Monat 30 Follow-up	55	1,69	1,275	1,0	1,00	7,0
		Monat 36 Follow-up	21	1,95	1,499	1,0	1,00	7,0
		Monat 42 Follow-up	7	1,71	1,496	1,0	1,00	5,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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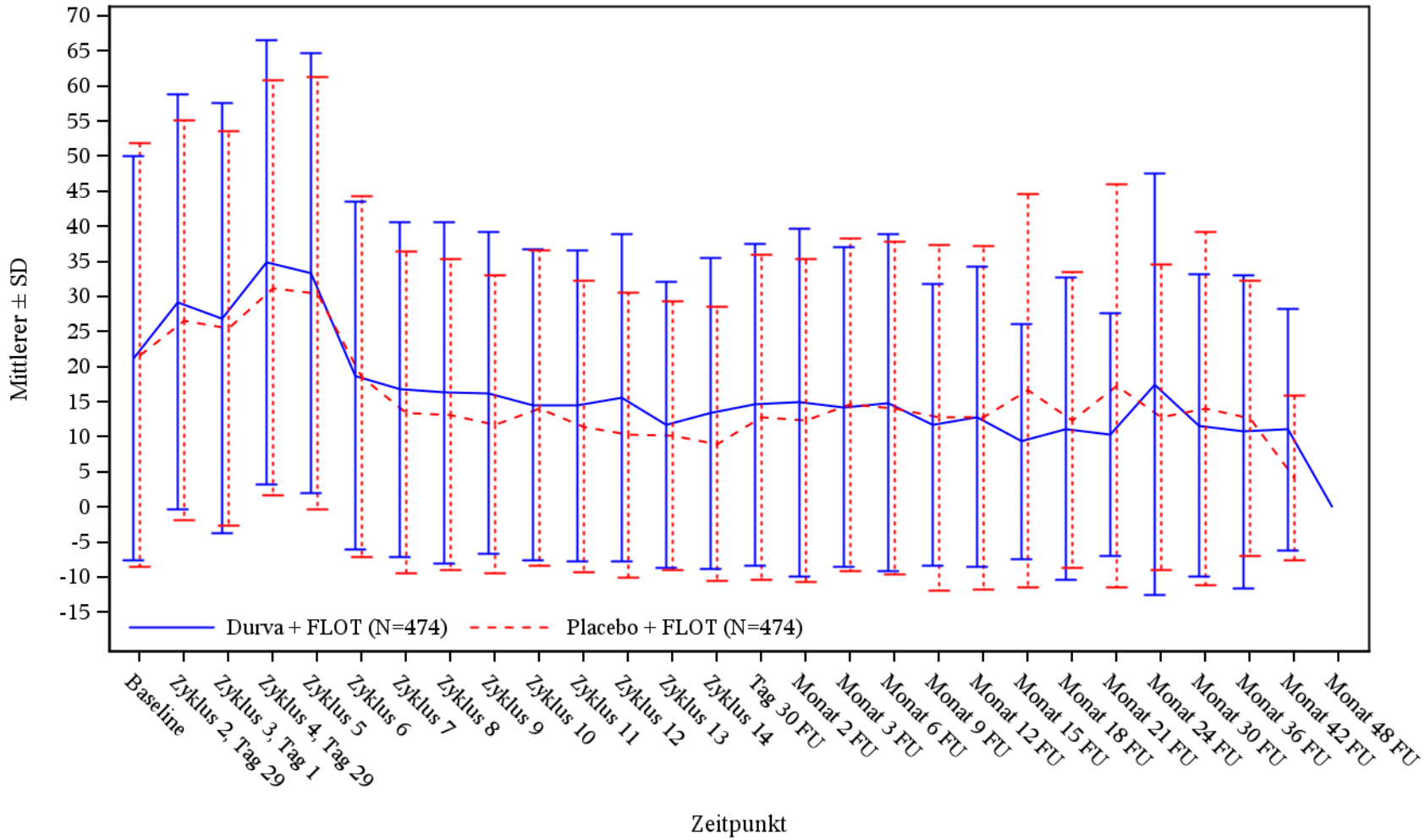
Table 4.1.8 Summary of absolute values across timepoints by treatment group for Patient Global Impression of Treatment Tolerability (PGITT) (Safety)
Safety Analysis Set, DCO 01SEP2025

			Absolute Werte					
Parameter	Gruppe	Zeitpunkt	n	Mittelwert	SD	Min	Mediane	Max
Patient Global Impression of Treatment Tolerability (PGITT)	Durva + FLOT (N=475)	Baseline	422	1,25	0,682	1,0	1,00	5,0
		Zyklus 2, Tag 29	413	2,38	0,986	1,0	2,00	5,0
		Zyklus 3, Tag 1	280	1,72	0,861	1,0	2,00	5,0
		Zyklus 4, Tag 29	283	2,41	1,076	1,0	2,00	5,0
		Zyklus 5	251	2,35	1,076	1,0	2,00	5,0
		Zyklus 6	280	1,87	0,928	1,0	2,00	5,0
		Zyklus 7	276	1,71	0,872	1,0	1,00	5,0
		Zyklus 8	280	1,68	0,861	1,0	1,00	5,0
		Zyklus 9	265	1,67	0,809	1,0	1,00	4,0
		Zyklus 10	257	1,56	0,832	1,0	1,00	5,0
		Zyklus 11	255	1,56	0,765	1,0	1,00	4,0
		Zyklus 12	248	1,54	0,789	1,0	1,00	4,0
		Zyklus 13	231	1,53	0,801	1,0	1,00	5,0
		Zyklus 14	250	1,46	0,734	1,0	1,00	5,0
	Placebo + FLOT (N=469)	Baseline	426	1,25	0,684	1,0	1,00	5,0
		Zyklus 2, Tag 29	403	2,32	1,064	1,0	2,00	5,0
		Zyklus 3, Tag 1	267	1,83	0,980	1,0	2,00	5,0
		Zyklus 4, Tag 29	269	2,37	1,087	1,0	2,00	5,0
		Zyklus 5	256	2,24	1,065	1,0	2,00	5,0
		Zyklus 6	268	1,83	0,947	1,0	2,00	5,0
		Zyklus 7	265	1,63	0,817	1,0	1,00	5,0
		Zyklus 8	262	1,60	0,873	1,0	1,00	5,0
		Zyklus 9	257	1,54	0,809	1,0	1,00	5,0
		Zyklus 10	254	1,52	0,828	1,0	1,00	5,0
		Zyklus 11	237	1,55	0,860	1,0	1,00	5,0
		Zyklus 12	229	1,45	0,715	1,0	1,00	5,0
		Zyklus 13	218	1,43	0,742	1,0	1,00	4,0
		Zyklus 14	231	1,42	0,711	1,0	1,00	5,0

SD = standard deviation; Min = minimum ; Max = maximum; NC = not calculated.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.1 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Appetite Loss (Morbidity)
Full Analysis Set, DCO 01SEP2025

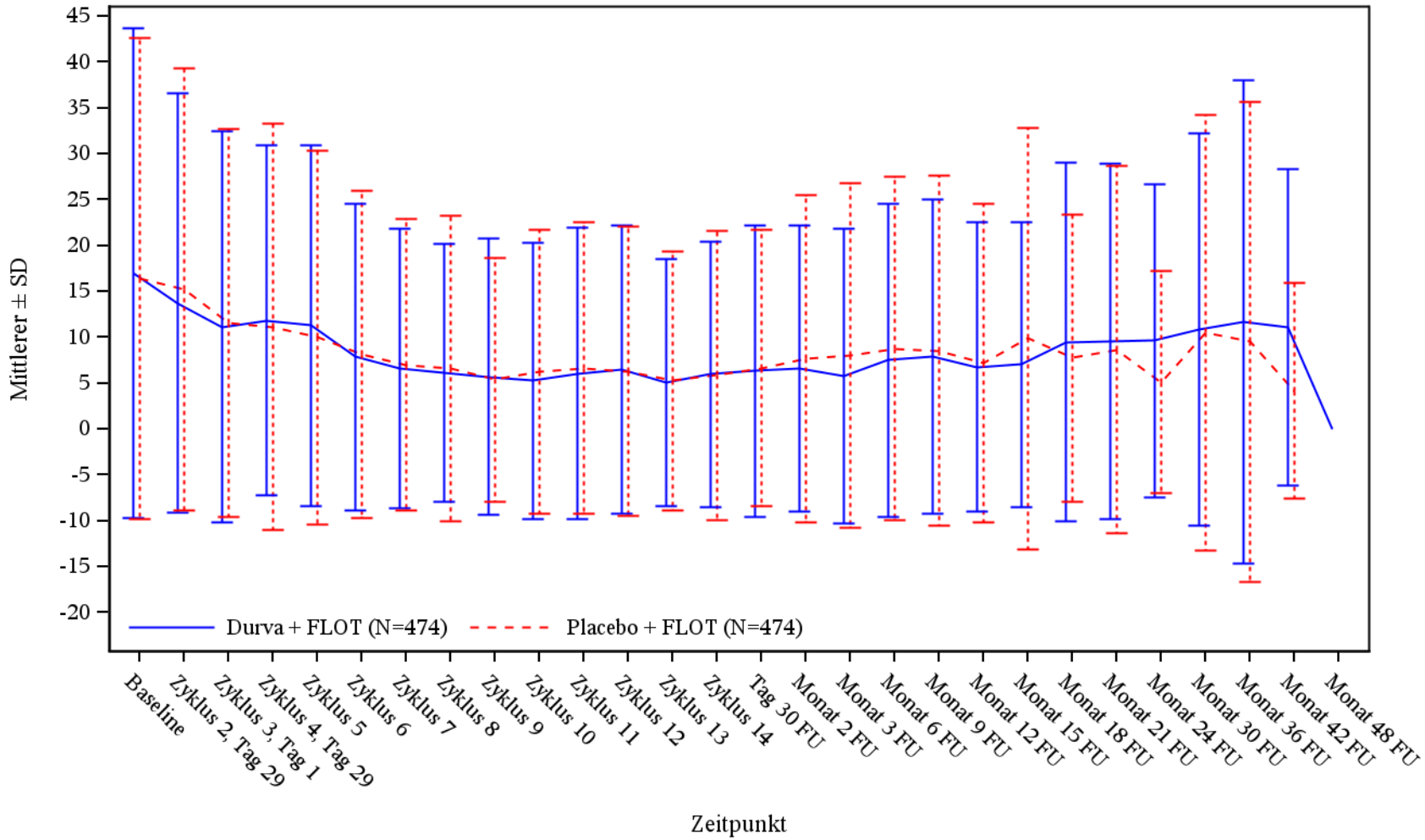


Anzahl an Patienten

Durva + FLOT	425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
Placebo + FLOT	433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.2 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Constipation (Morbidity)
Full Analysis Set, DCO 01SEP2025



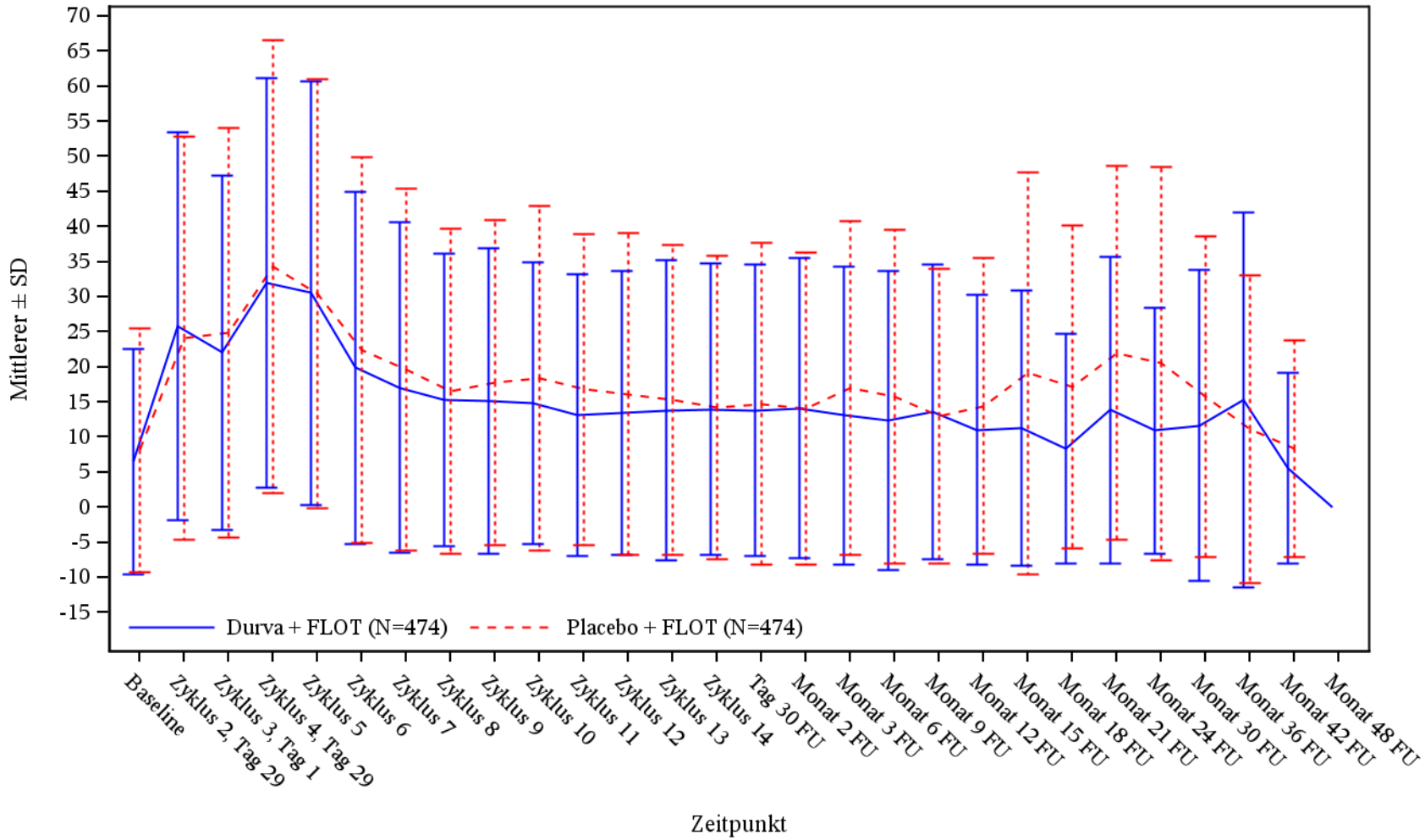
Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.3 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Diarrhea (Morbidity)
Full Analysis Set, DCO 01SEP2025



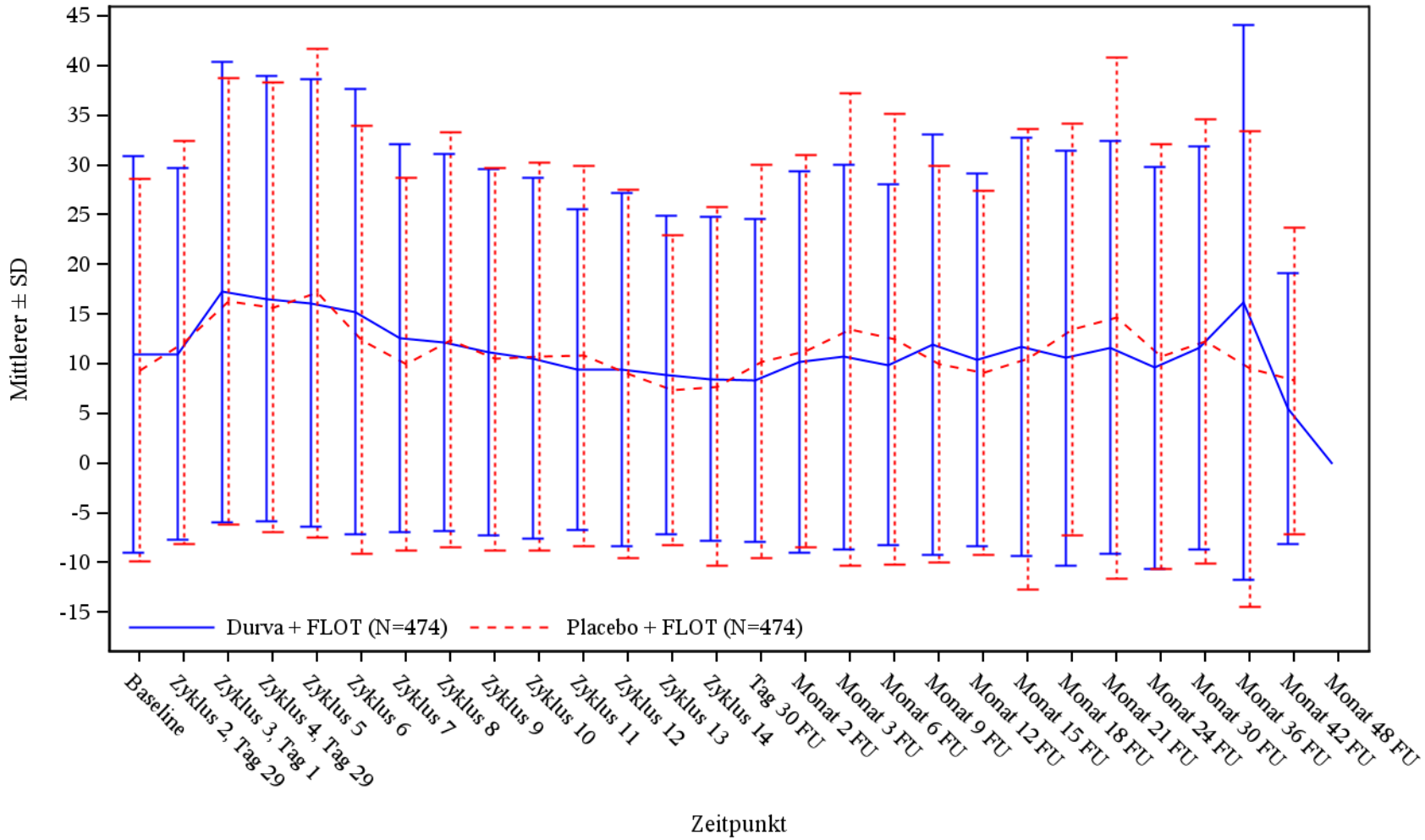
Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraac 28JAN2026:09:28 khsk849

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Figure 4.2.4 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Dyspnoea (Morbidity)
Full Analysis Set, DCO 01SEP2025

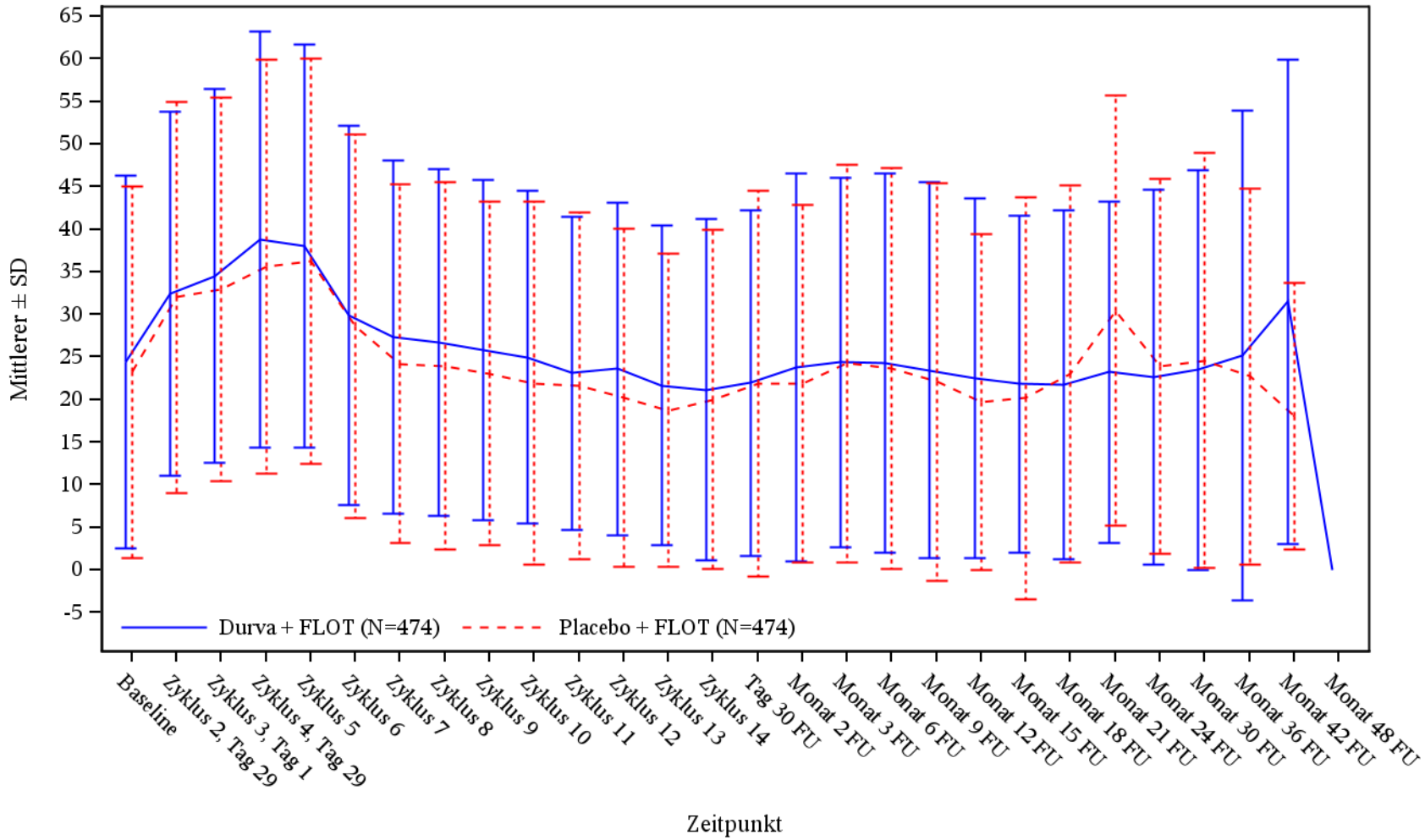


Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraad 28JAN2026:09:28 khsk849

Figure 4.2.5 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Fatigue (Morbidity)
Full Analysis Set, DCO 01SEP2025

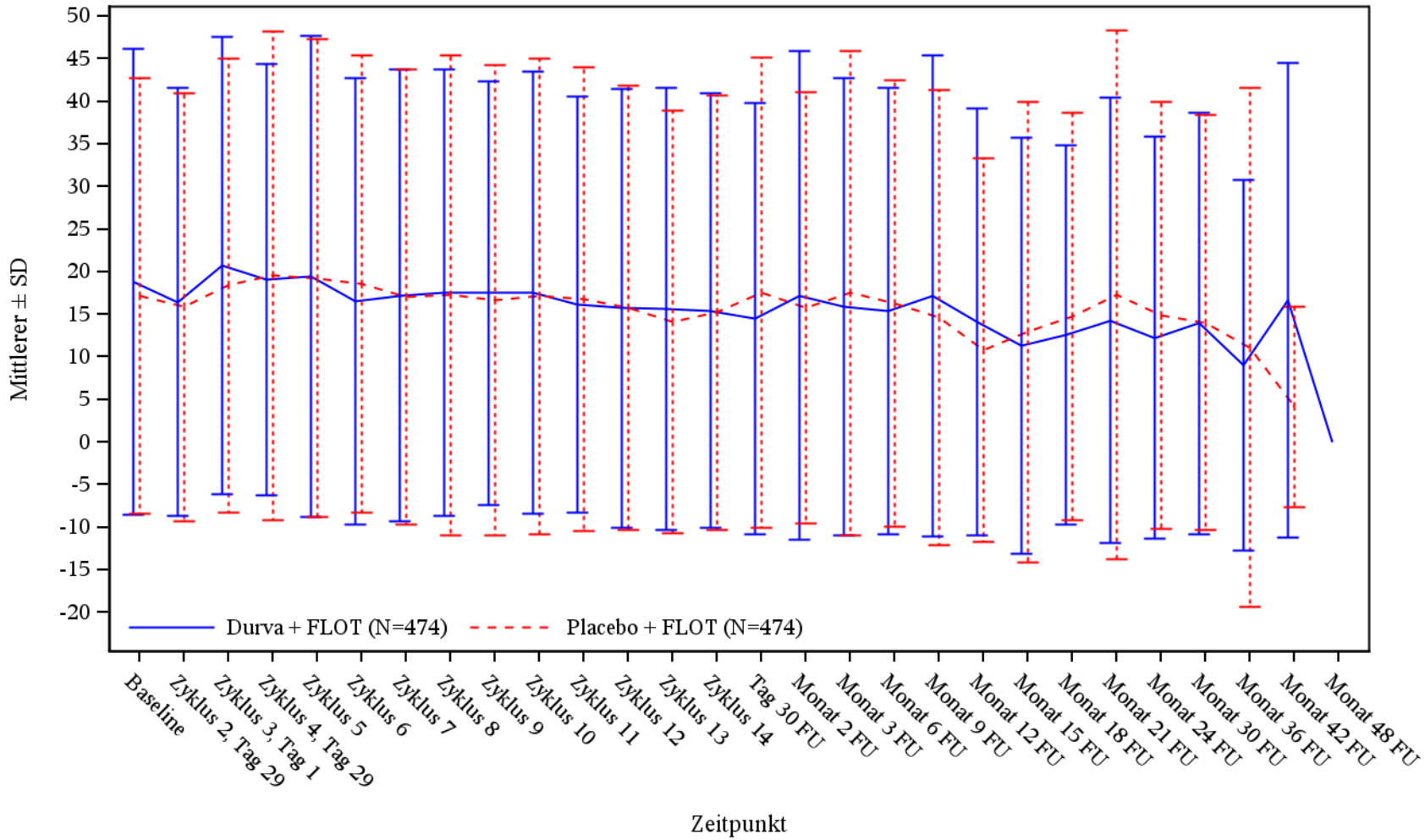


Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraae 28JAN2026:09:28 khsk849

Figure 4.2.6 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Financial Difficulties (Morbidity)
Full Analysis Set, DCO 01SEP2025



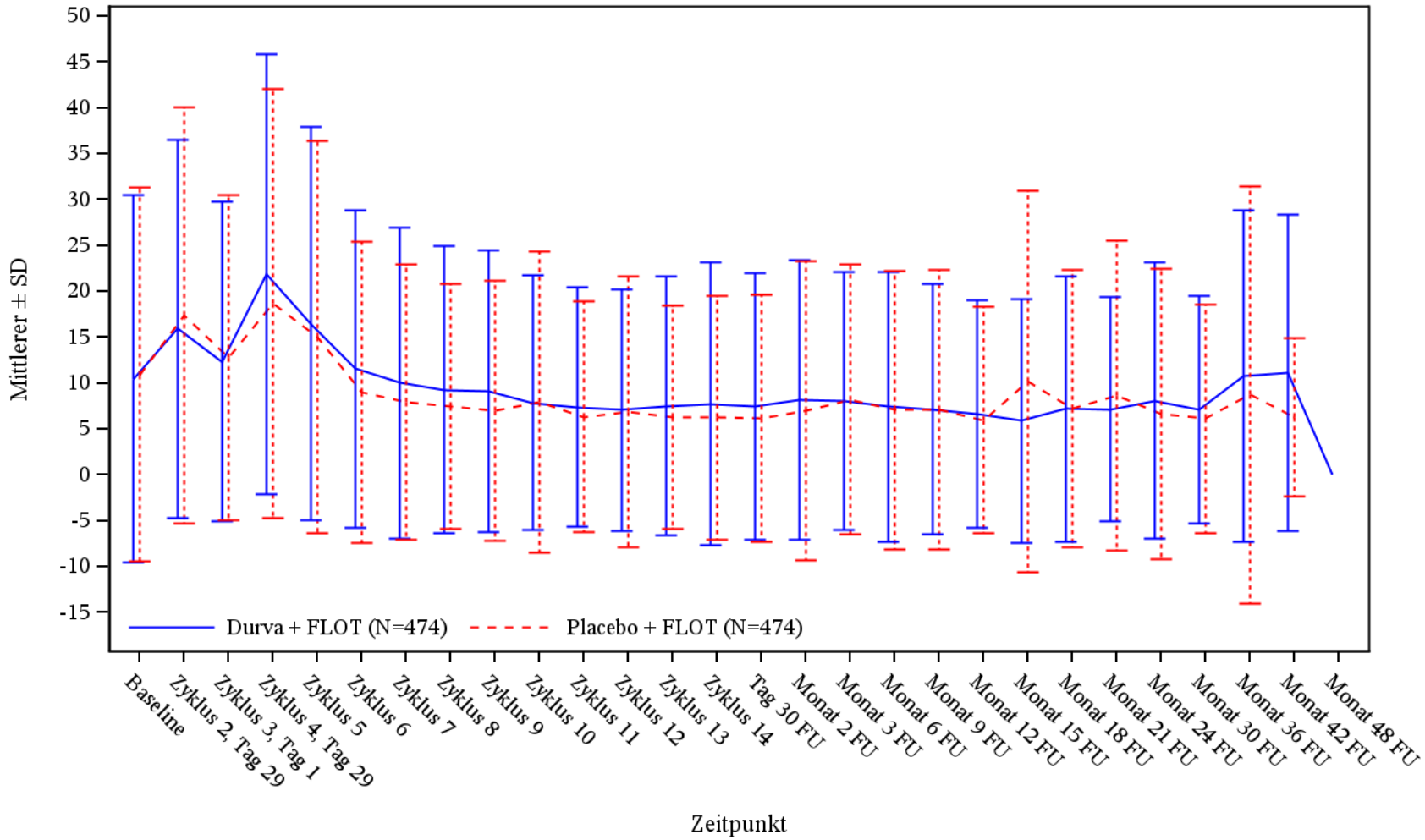
Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraaf 28JAN2026:09:28 khsk849

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Figure 4.2.7 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Nausea and Vomiting (Morbidity)
Full Analysis Set, DCO 01SEP2025

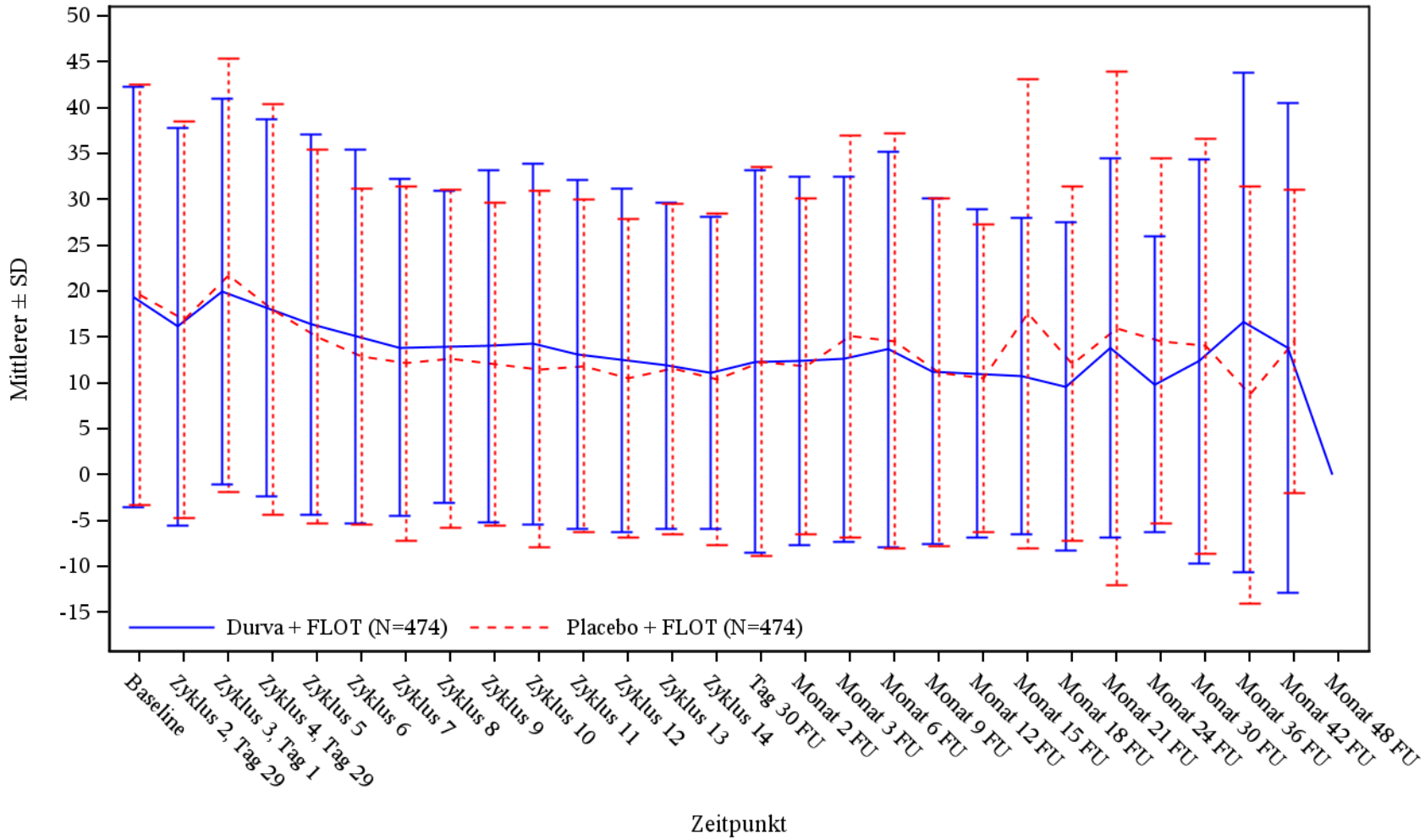


Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraag 28JAN2026:09:28 khsk849

Figure 4.2.8 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Pain (Morbidity)
Full Analysis Set, DCO 01SEP2025



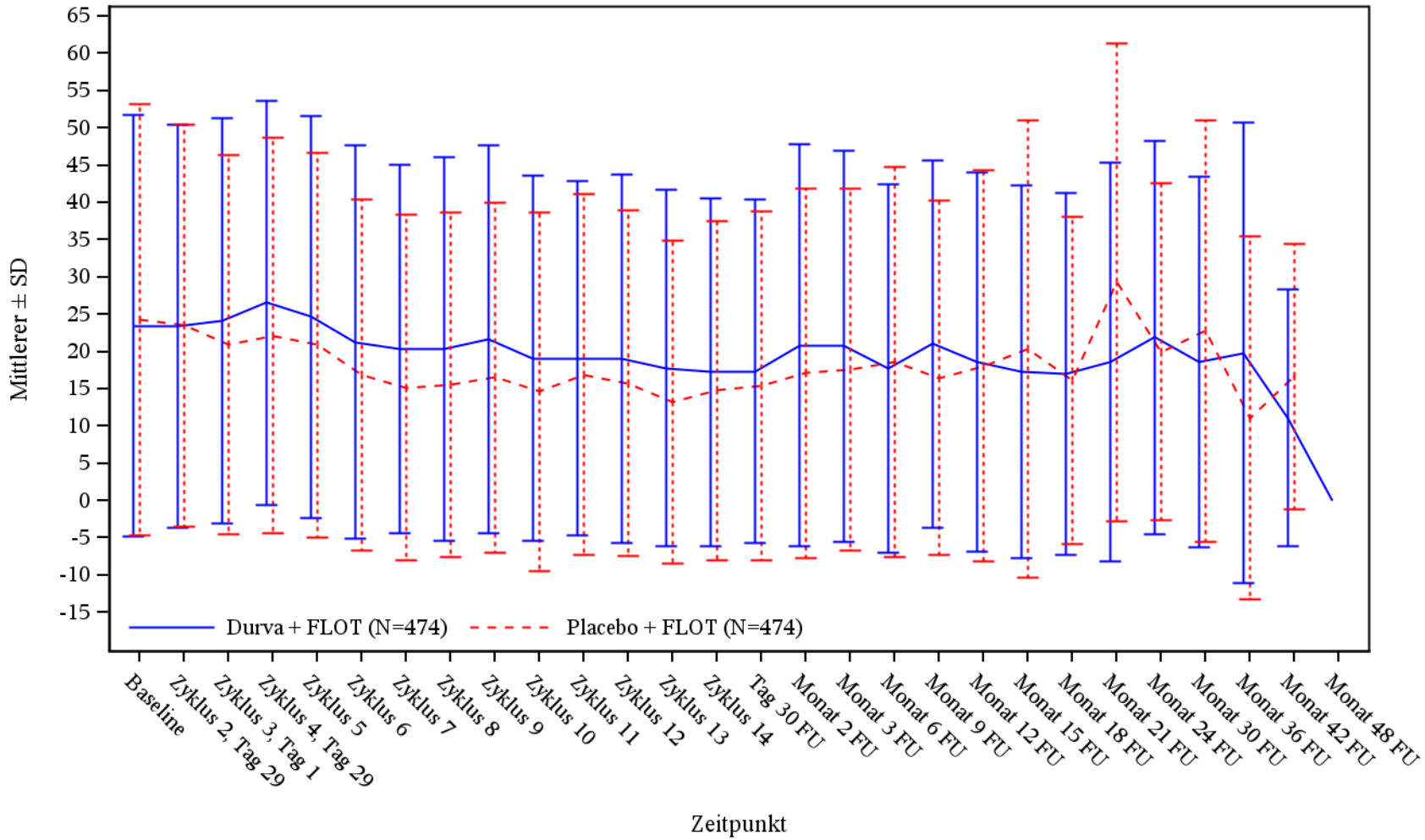
Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.9 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Insomnia (Morbidity)
Full Analysis Set, DCO 01SEP2025

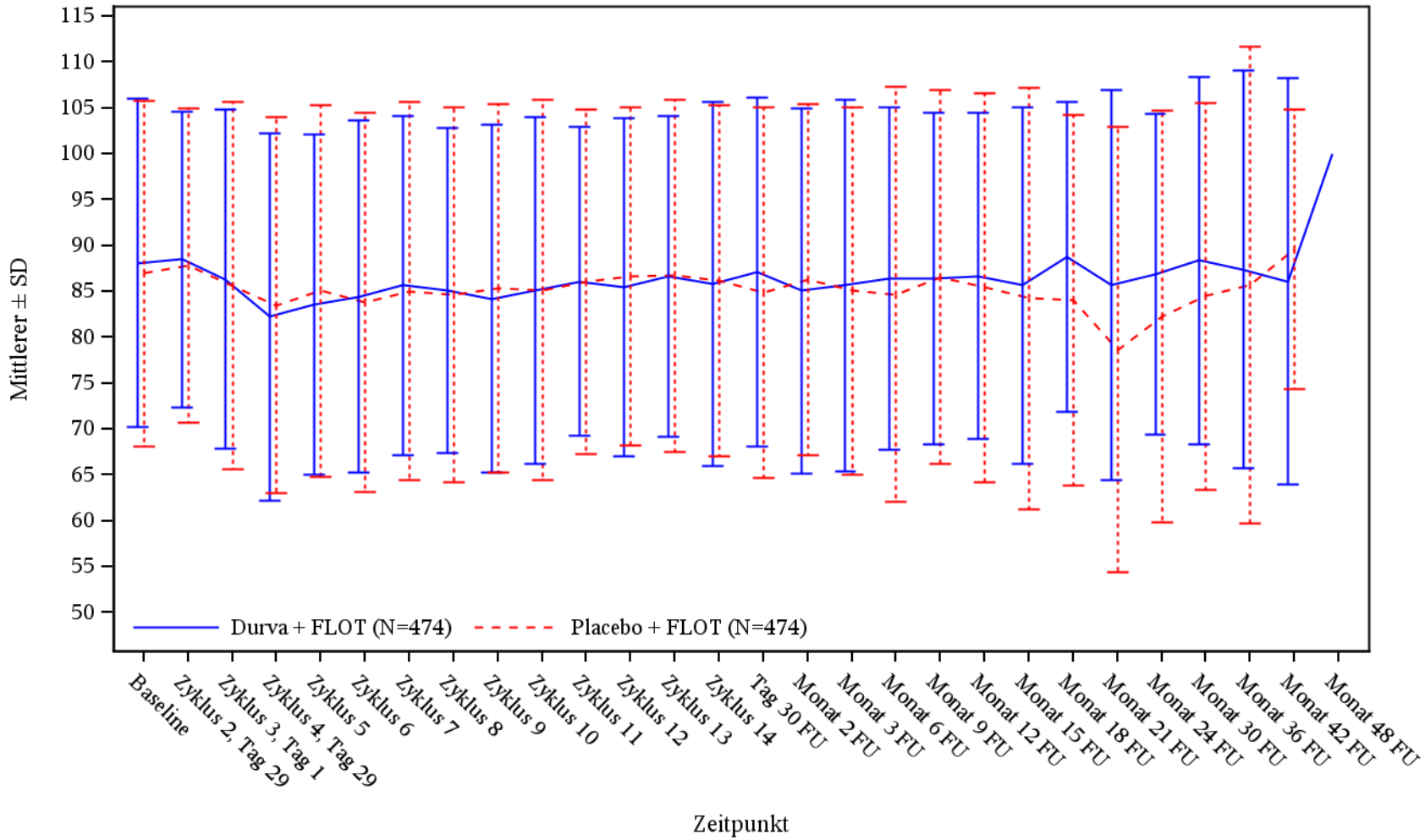


Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.10 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Cognitive Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025

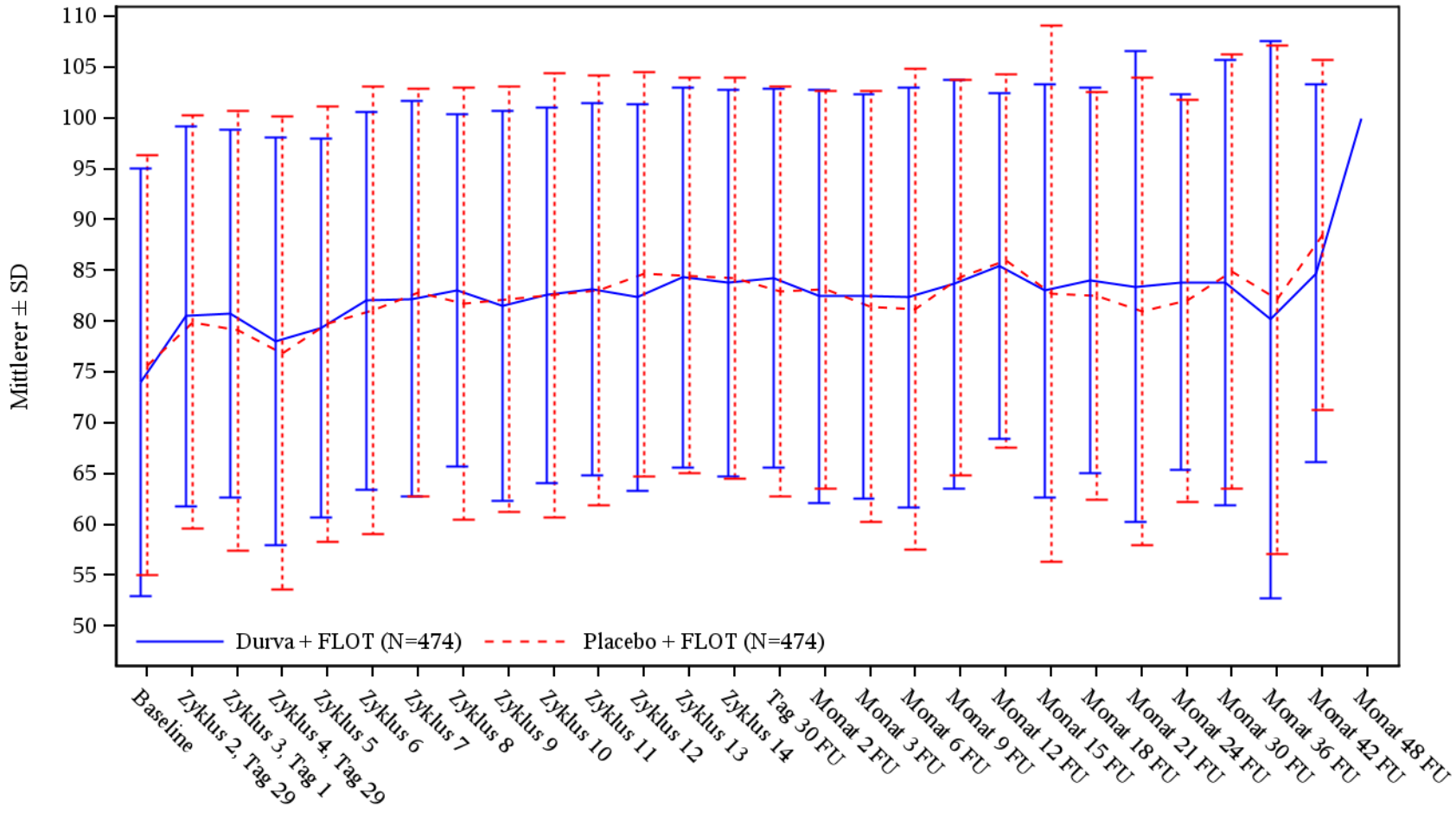


Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraaj 28JAN2026:09:28 khsk849

Figure 4.2.11 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Emotional functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025

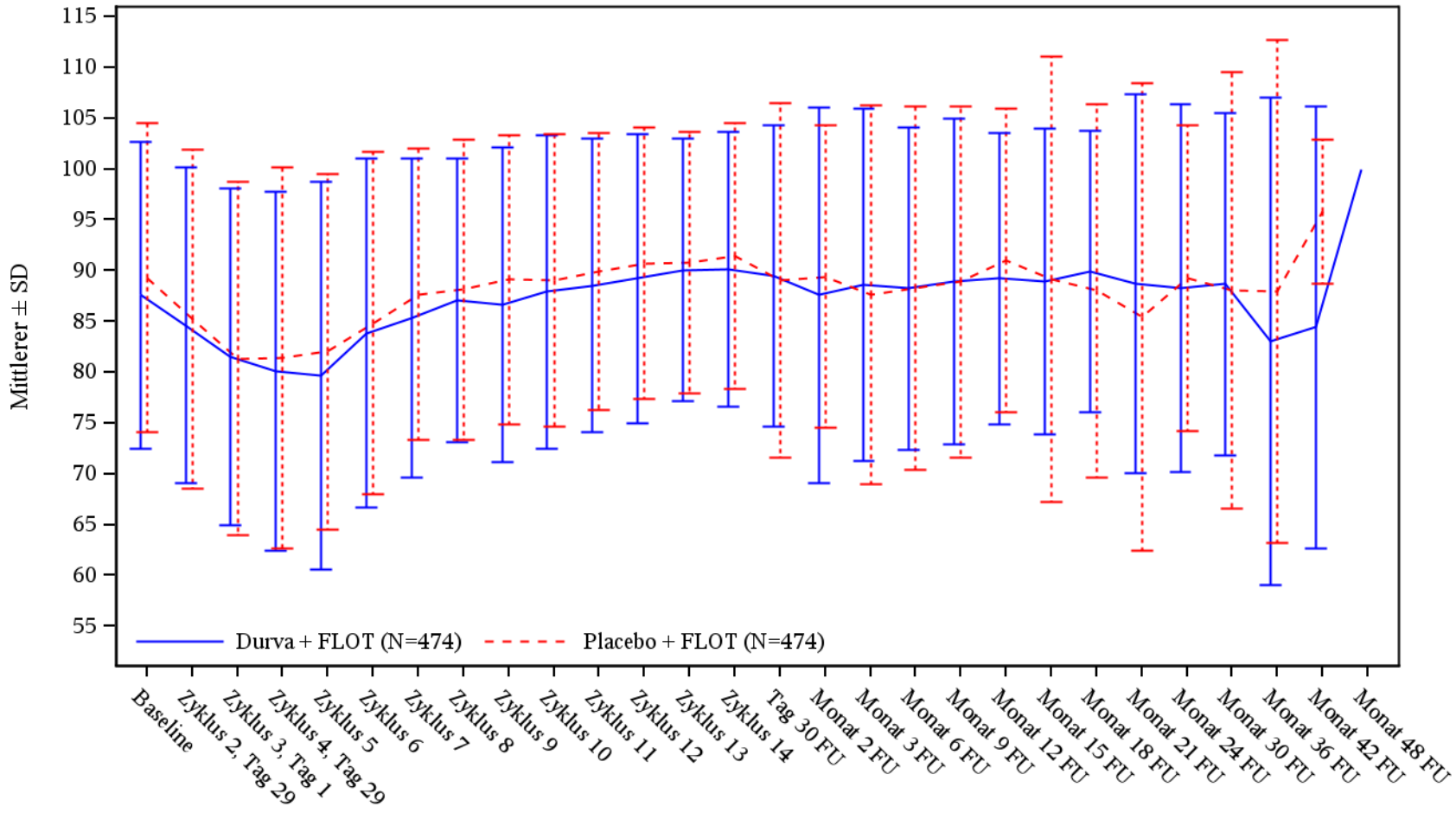


Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.12 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Physical Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025



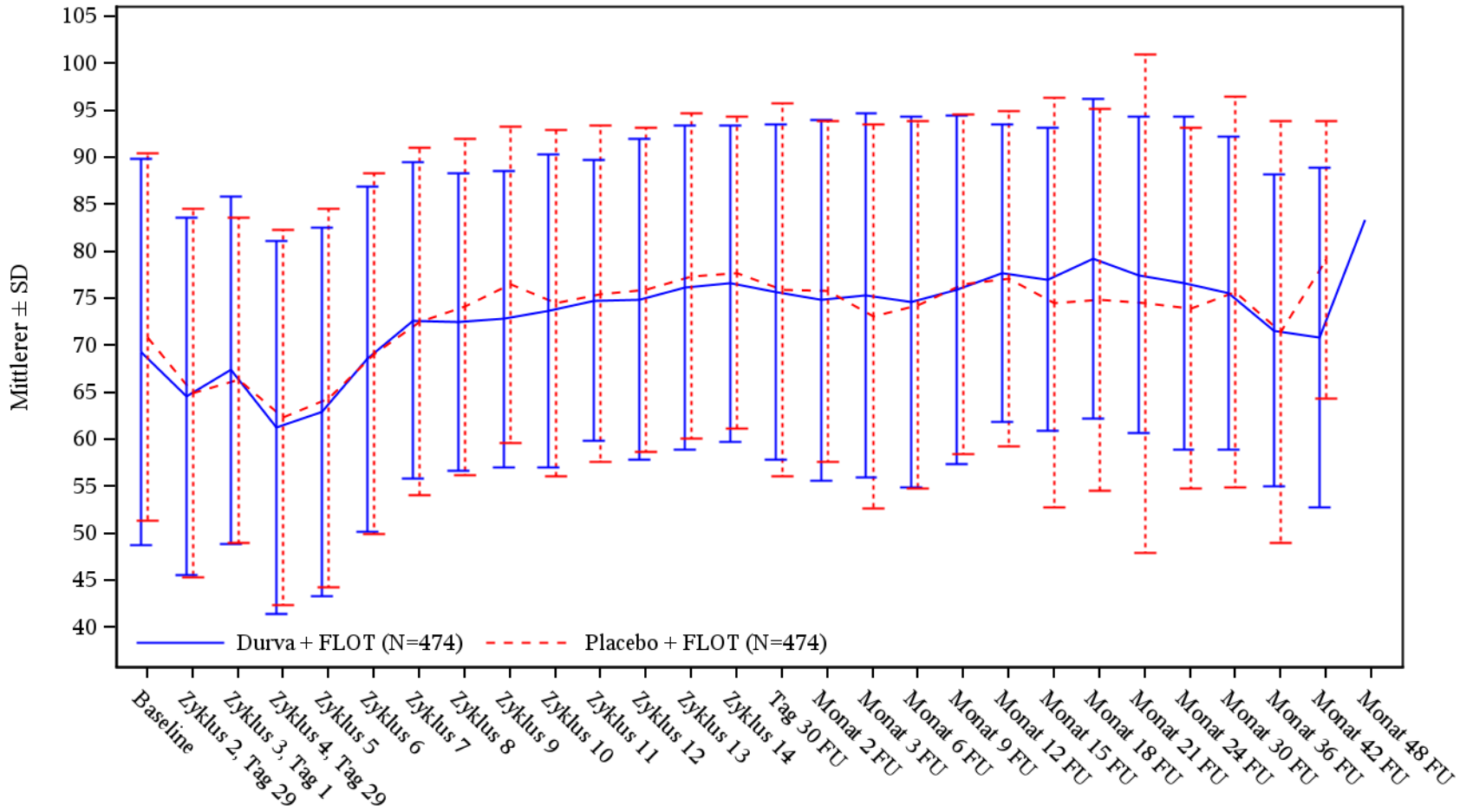
Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.13 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Global Health Status/QoL (hrQoL)
Full Analysis Set, DCO 01SEP2025

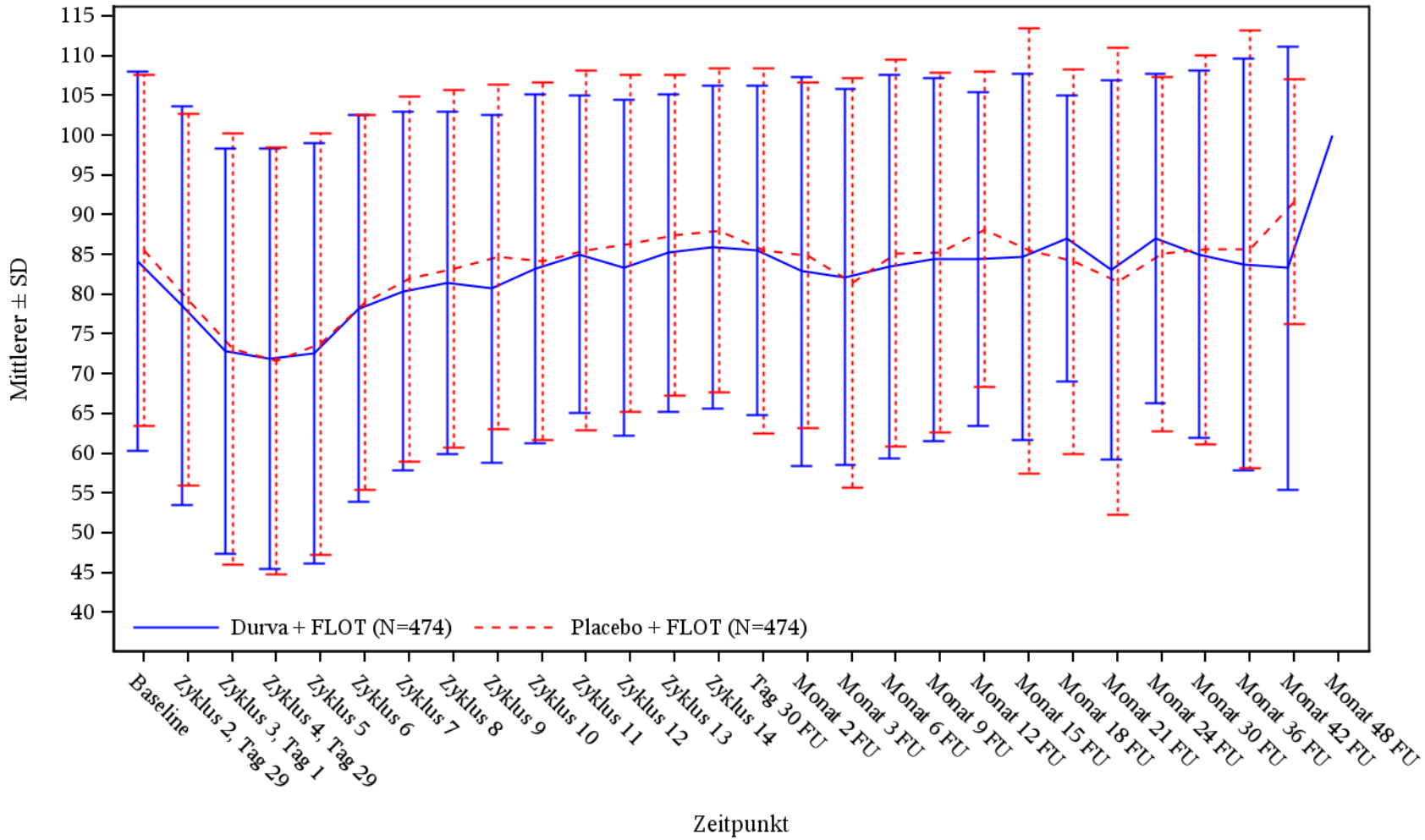


Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraam 28JAN2026:09:28 khsk849

Figure 4.2.14 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Role Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025



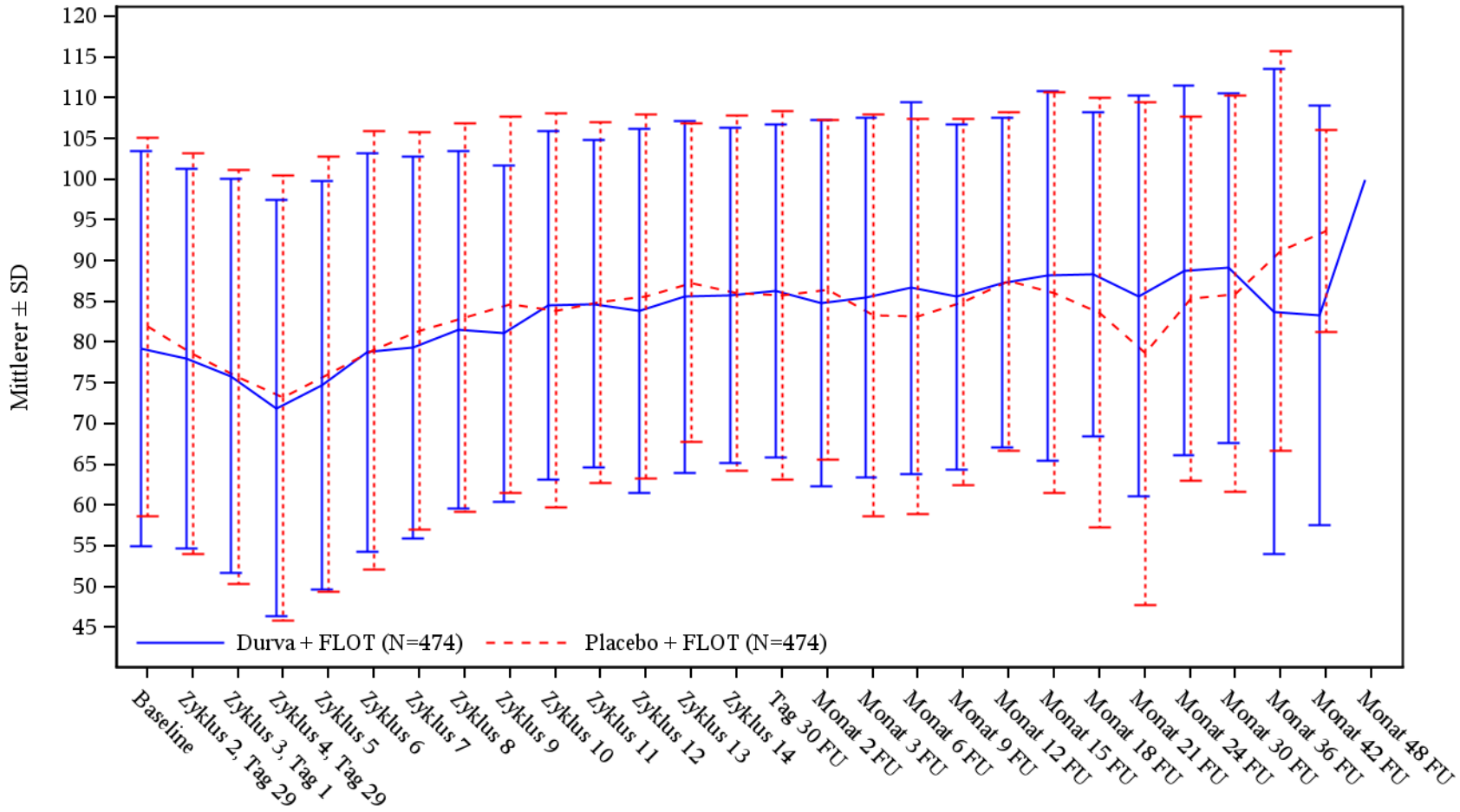
Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.15 Mean (+/- SD) across timepoint, by treatment group for EORTC QLQ-C30 Social Functioning (hrQoL)
Full Analysis Set, DCO 01SEP2025

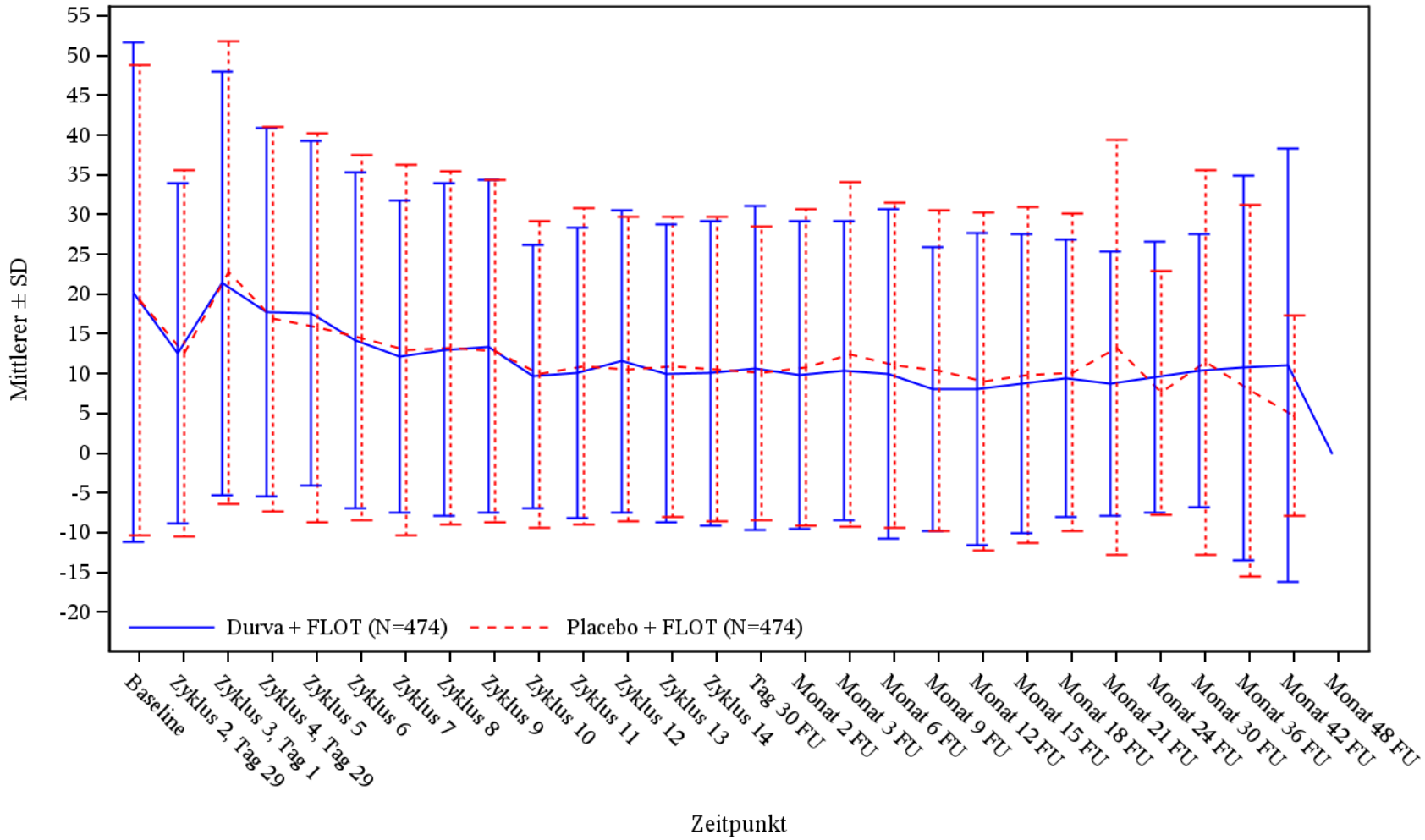


Anzahl an Patienten

425	429	293	290	262	288	283	285	268	258	258	250	236	251	248	238	252	208	198	163	85	116	77	76	86	37	6	1
433	410	277	278	260	276	266	268	260	257	240	233	222	232	231	239	257	186	164	120	54	99	50	65	57	21	8	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraao 28JAN2026:09:28 khsk849

Figure 4.2.16 Mean (+/- SD) across timepoint, by treatment group for EORTC IL38 Difficulty Swallowing (Morbidity)
Full Analysis Set, DCO 01SEP2025



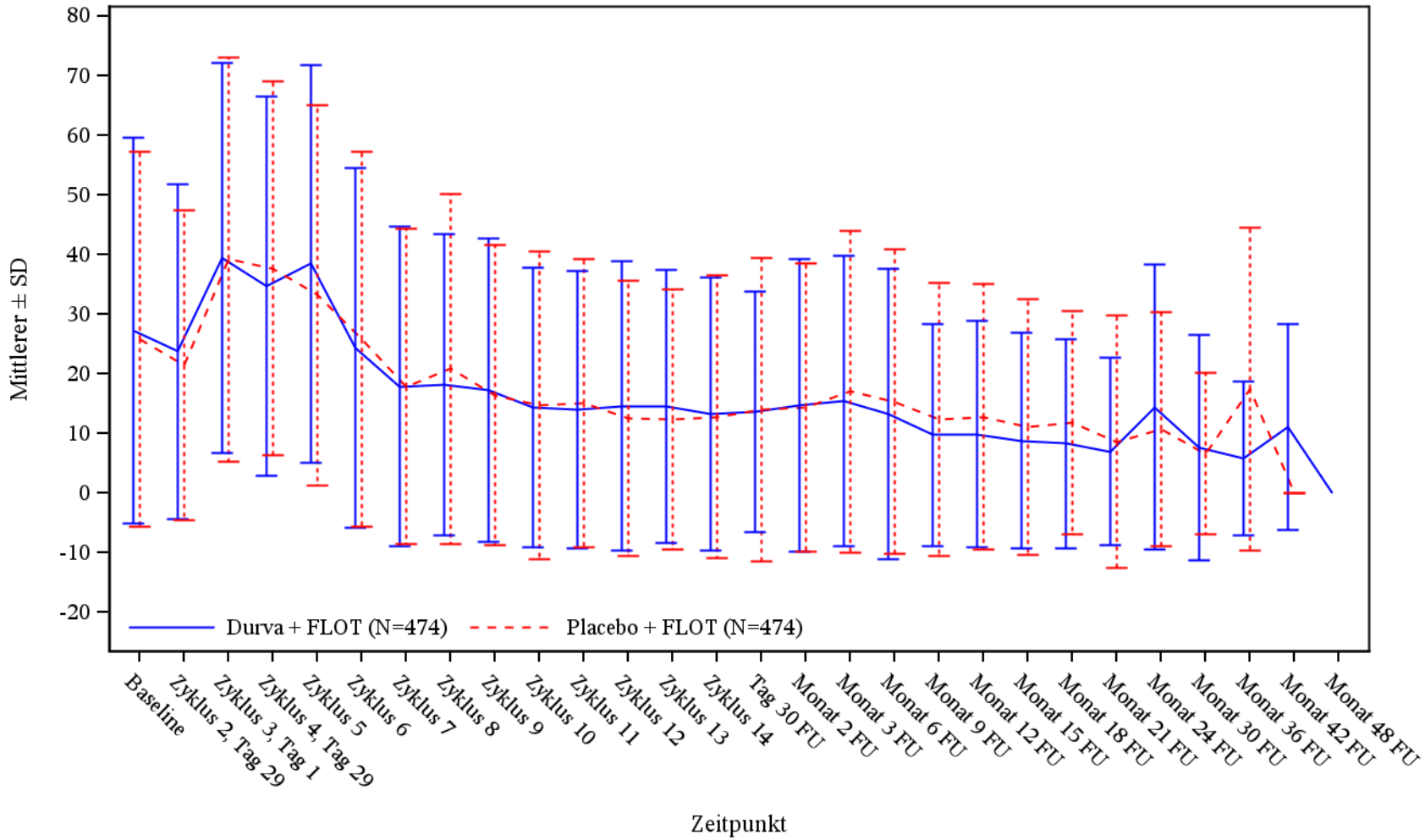
Anzahl an Patienten

423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraap 28JAN2026:09:28 khsk849

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Figure 4.2.17 Mean (+/- SD) across timepoint, by treatment group for EORTC IL38 Weight Loss (Morbidity)
Full Analysis Set, DCO 01SEP2025

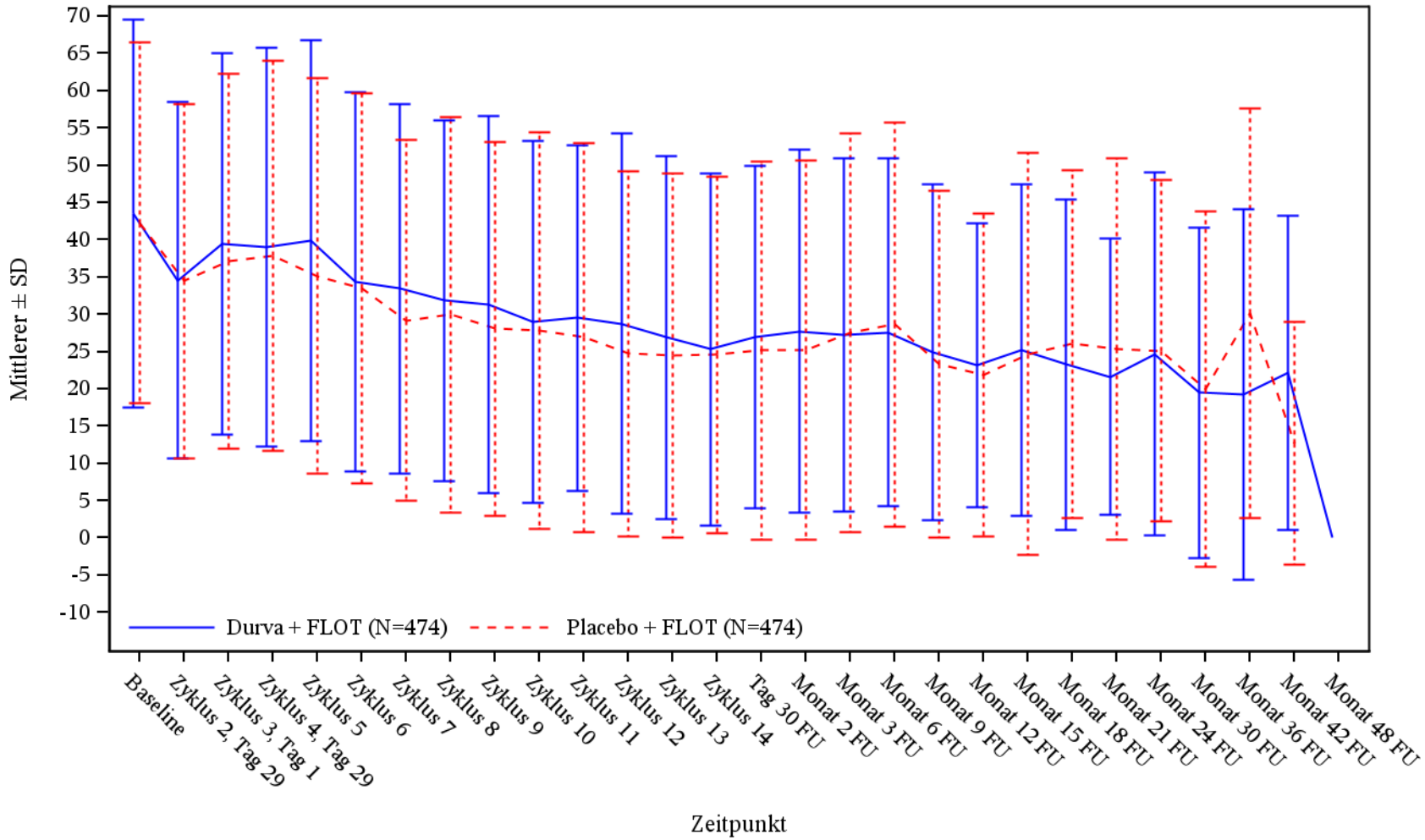


Anzahl an Patienten

423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraaq 28JAN2026:09:28 khsk849

Figure 4.2.18 Mean (+/- SD) across timepoint, by treatment group for EORTC STO22 Anxiety (Morbidity)
Full Analysis Set, DCO 01SEP2025

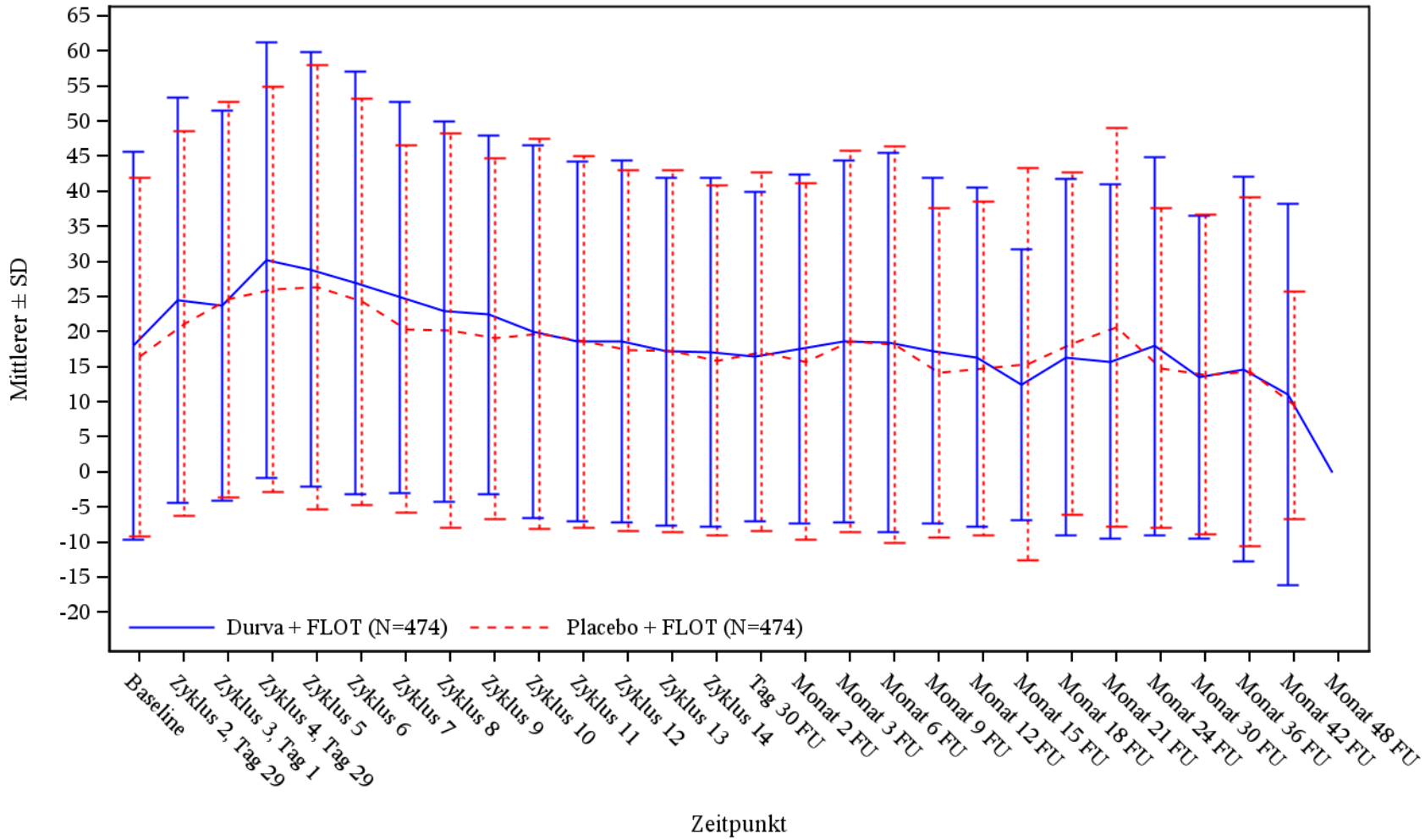


Anzahl an Patienten

423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraar 28JAN2026:09:28 khsk849

Figure 4.2.19 Mean (+/- SD) across timepoint, by treatment group for EORTC STO22 Body Image (Morbidity)
Full Analysis Set, DCO 01SEP2025

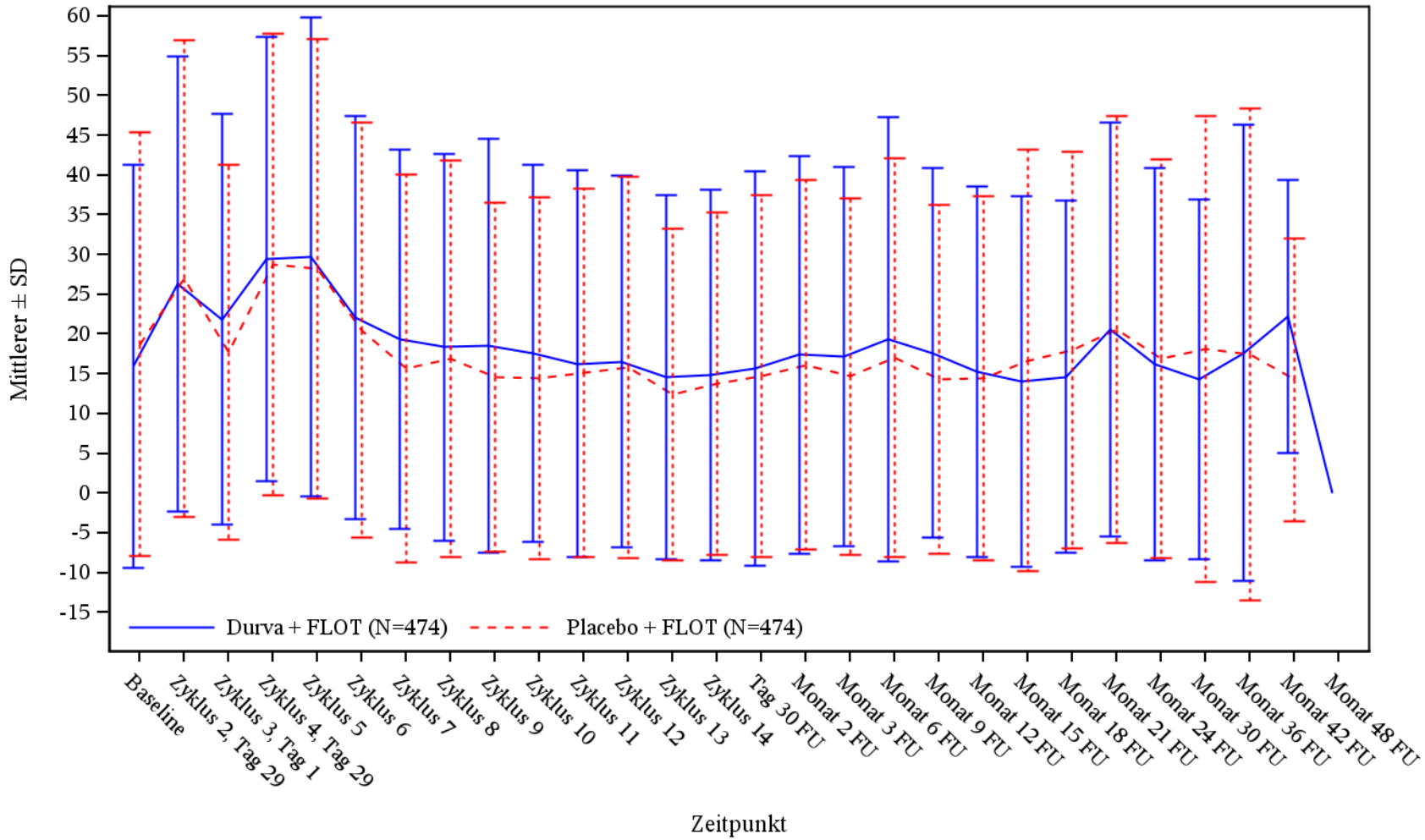


Anzahl an Patienten

423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.20 Mean (+/- SD) across timepoint, by treatment group for EORTC STO22 Dry Mouth (Morbidity)
Full Analysis Set, DCO 01SEP2025



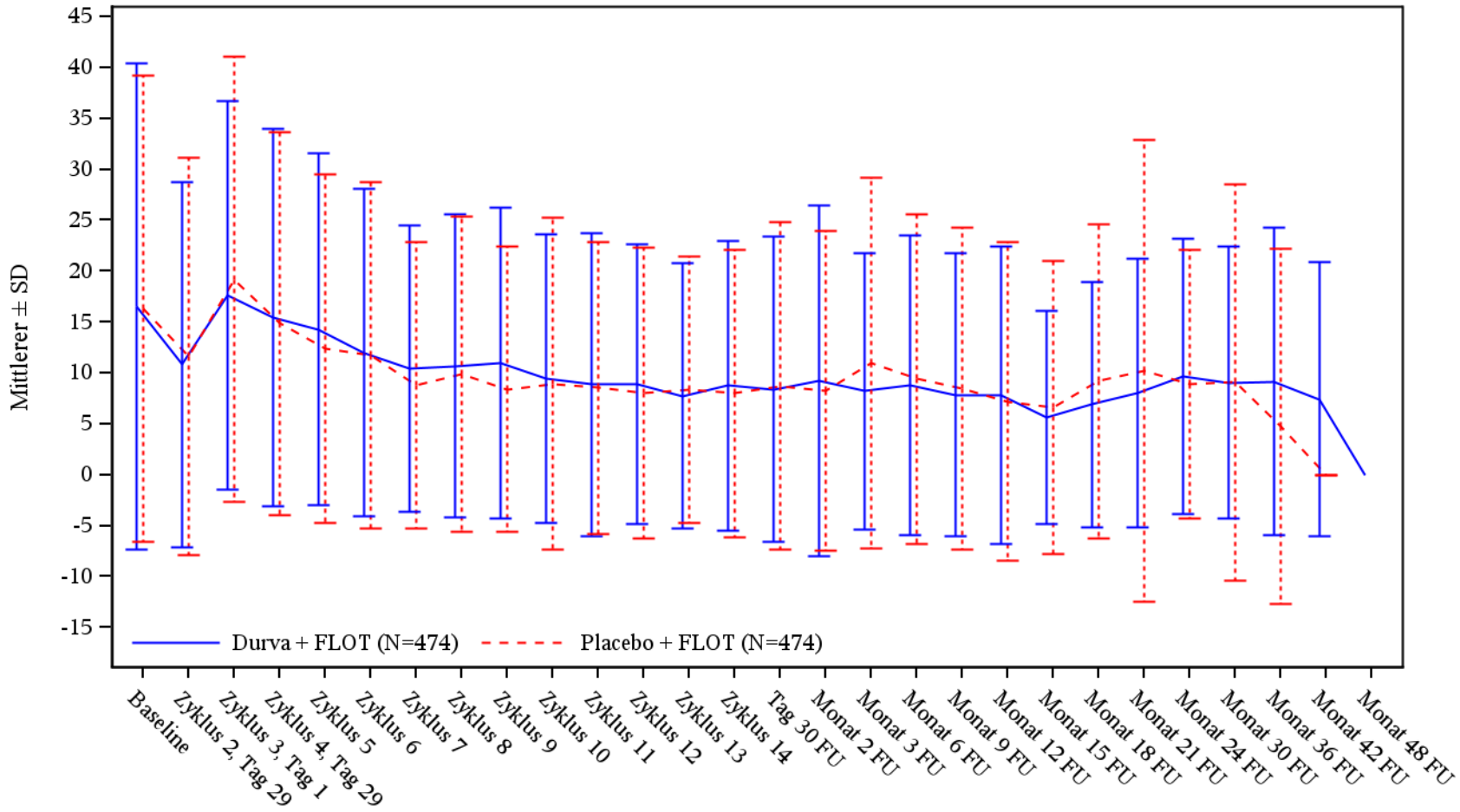
Anzahl an Patienten

423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.21 Mean (+/- SD) across timepoint, by treatment group for EORTC STO22 Dysphagia (Morbidity)
Full Analysis Set, DCO 01SEP2025

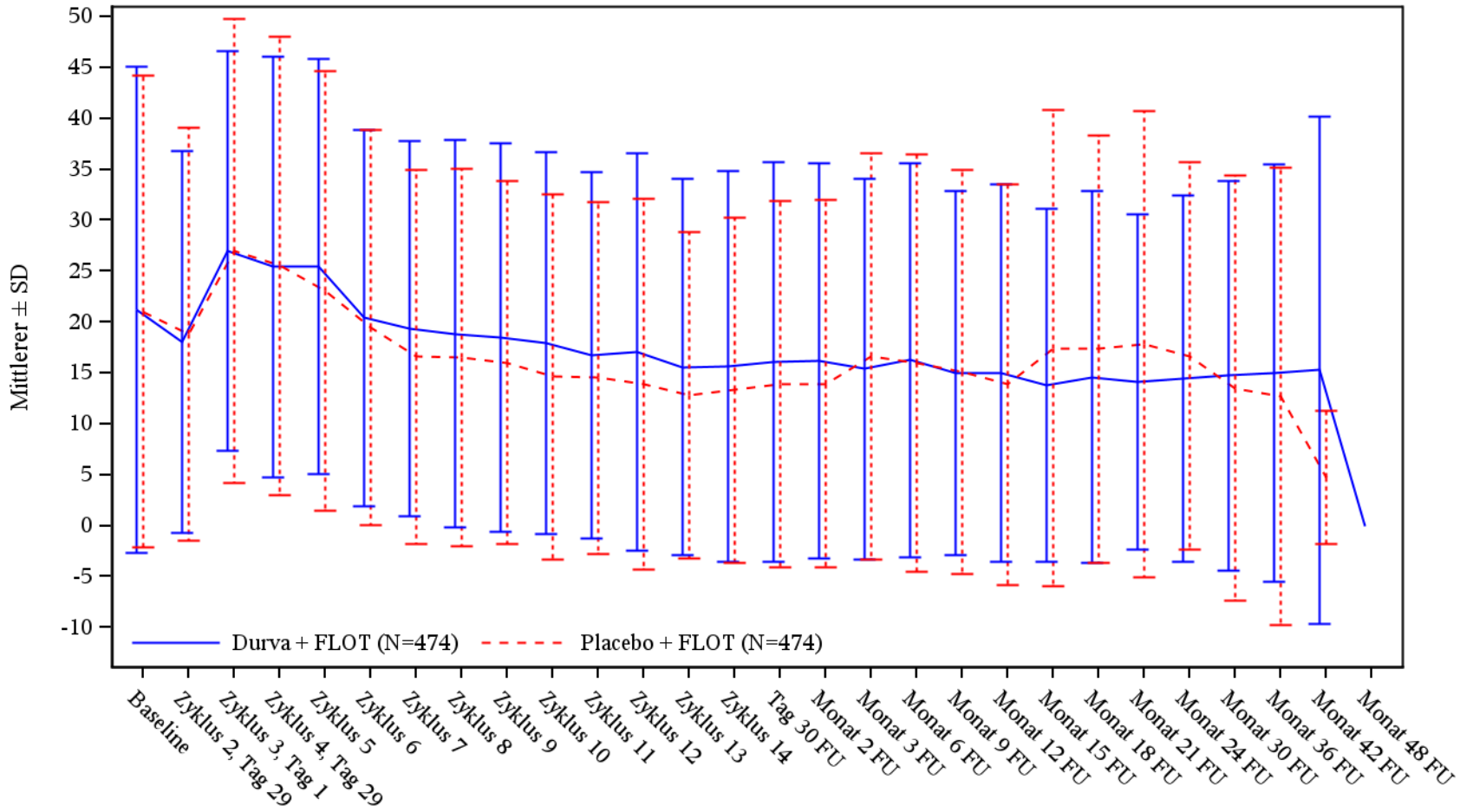


Anzahl an Patienten

423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.22 Mean (+/- SD) across timepoint, by treatment group for EORTC STO22 Eating Restrictions (Morbidity)
Full Analysis Set, DCO 01SEP2025



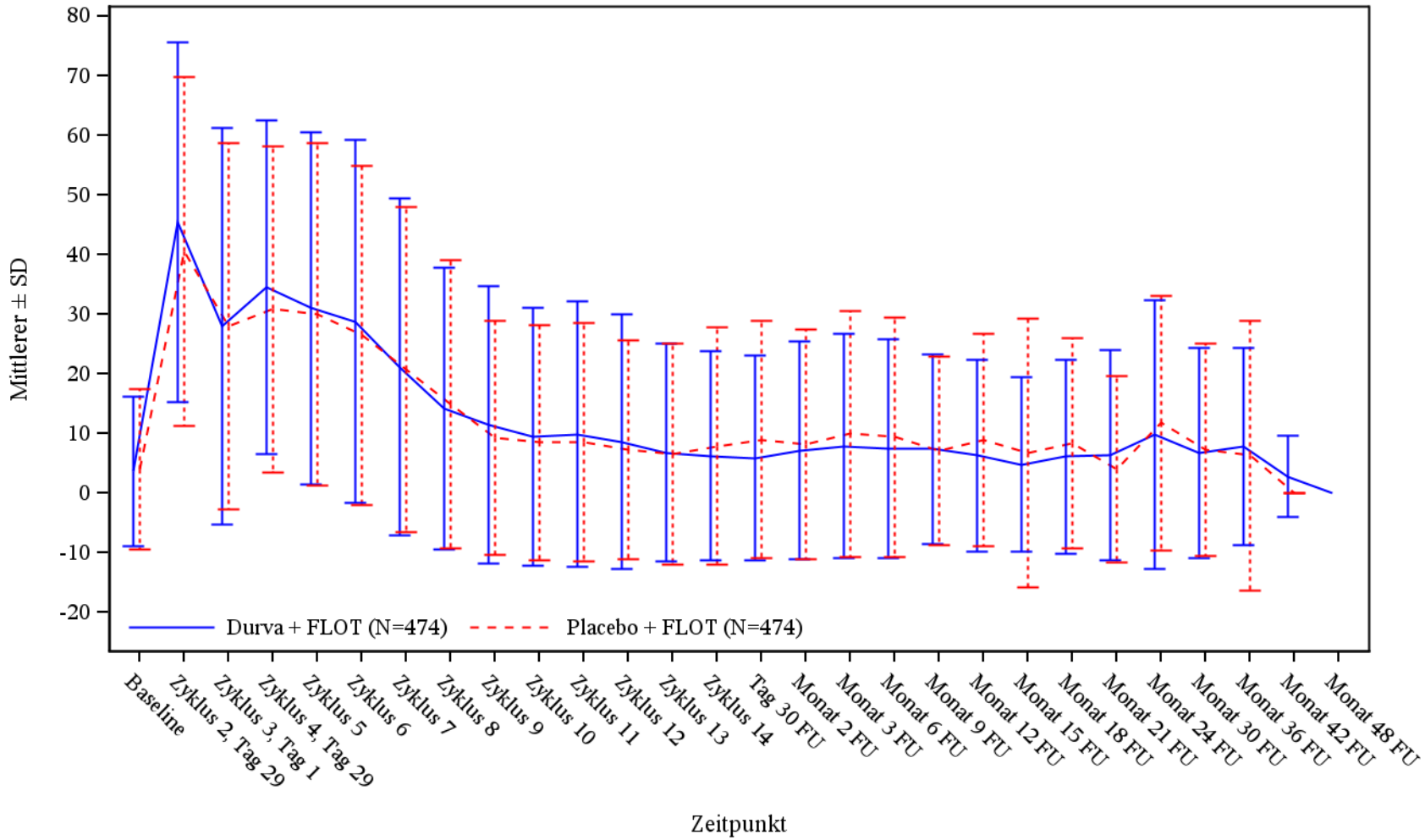
Anzahl an Patienten

423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.23 Mean (+/- SD) across timepoint, by treatment group for EORTC STO22 Hair Loss (Morbidity)
Full Analysis Set, DCO 01SEP2025

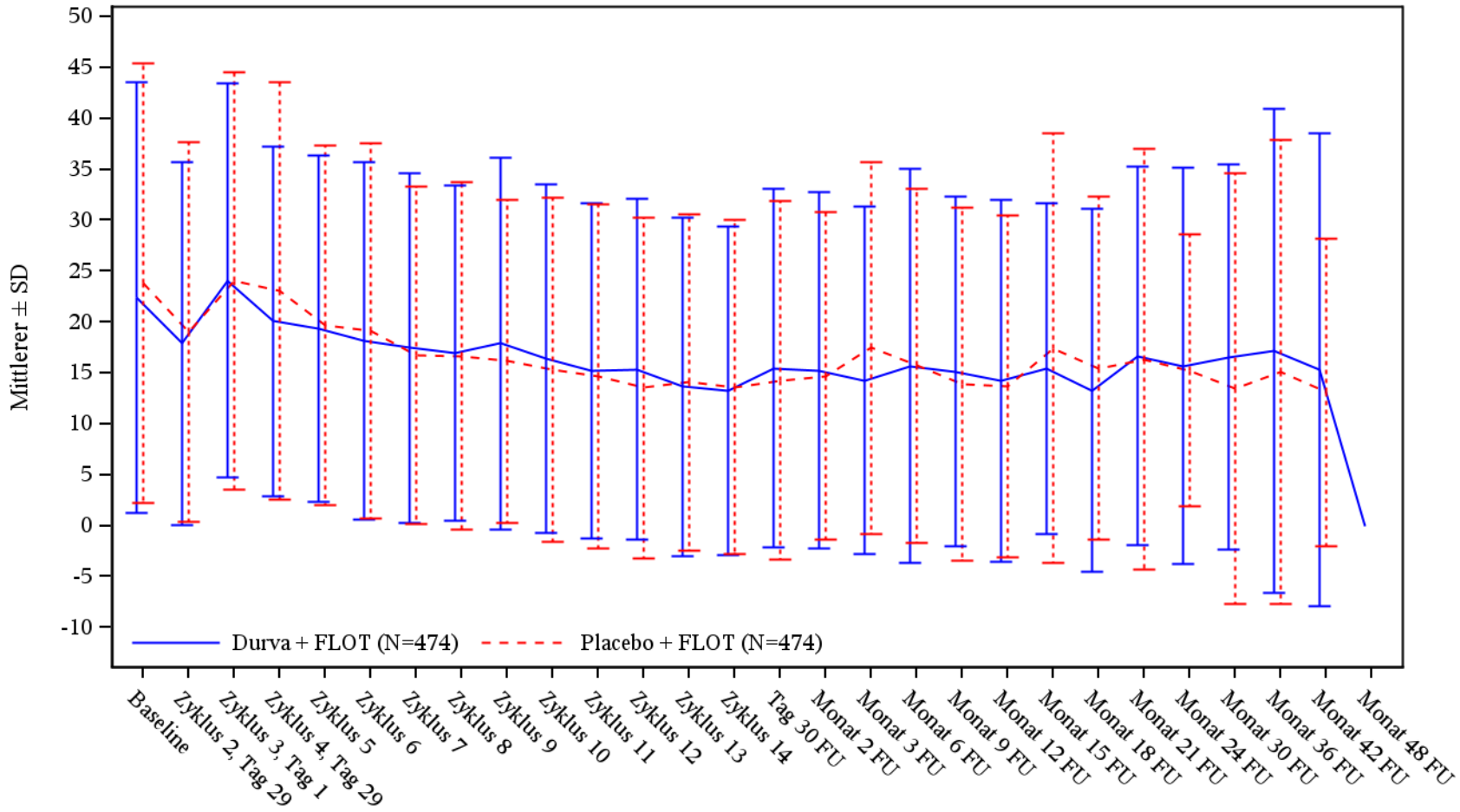


Anzahl an Patienten

423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.24 Mean (+/- SD) across timepoint, by treatment group for EORTC STO22 Pain (Morbidity)
Full Analysis Set, DCO 01SEP2025

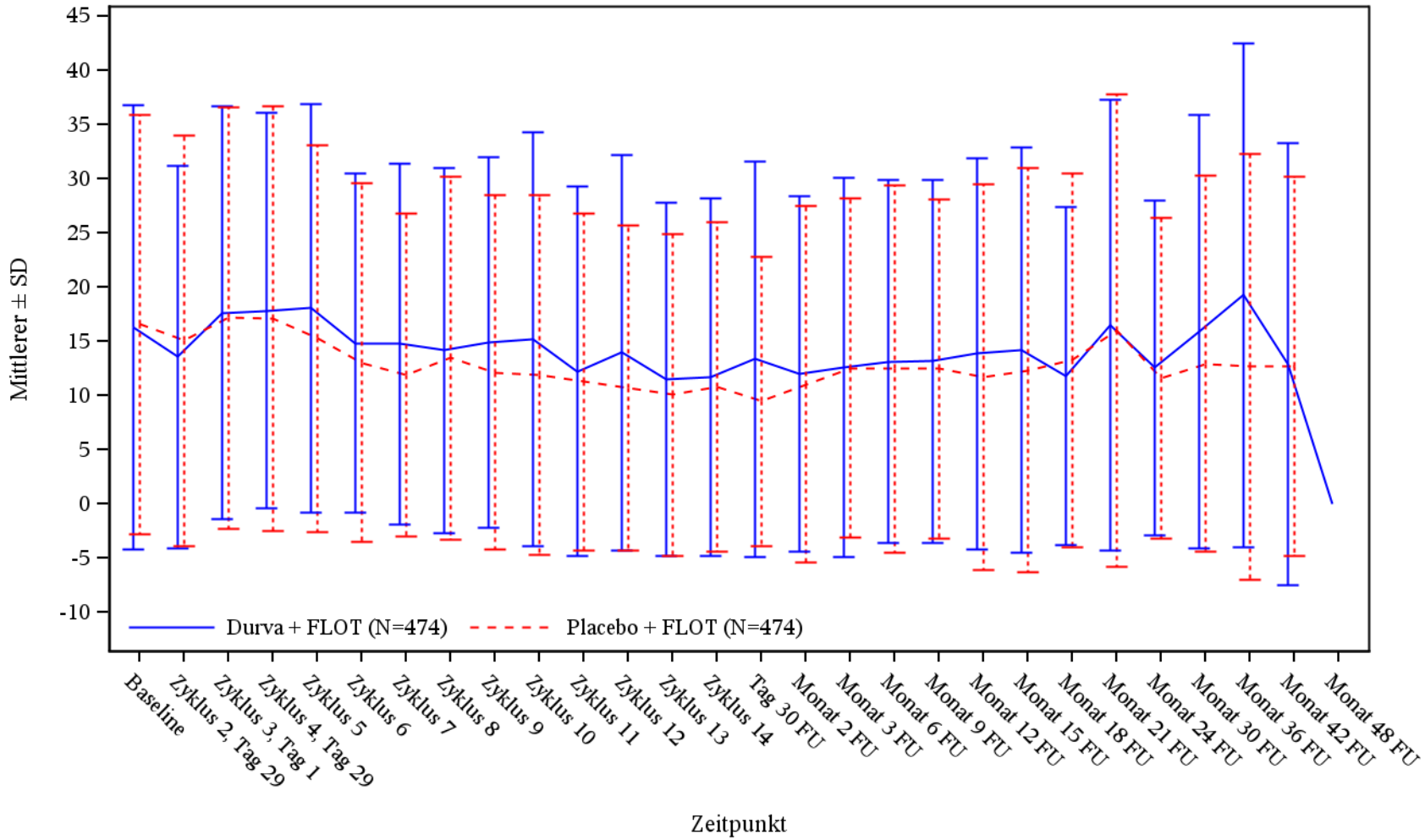


Anzahl an Patienten

423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraax 28JAN2026:09:28 khsk849

Figure 4.2.25 Mean (+/- SD) across timepoint, by treatment group for EORTC STO22 Reflux (Morbidity)
Full Analysis Set, DCO 01SEP2025



Anzahl an Patienten

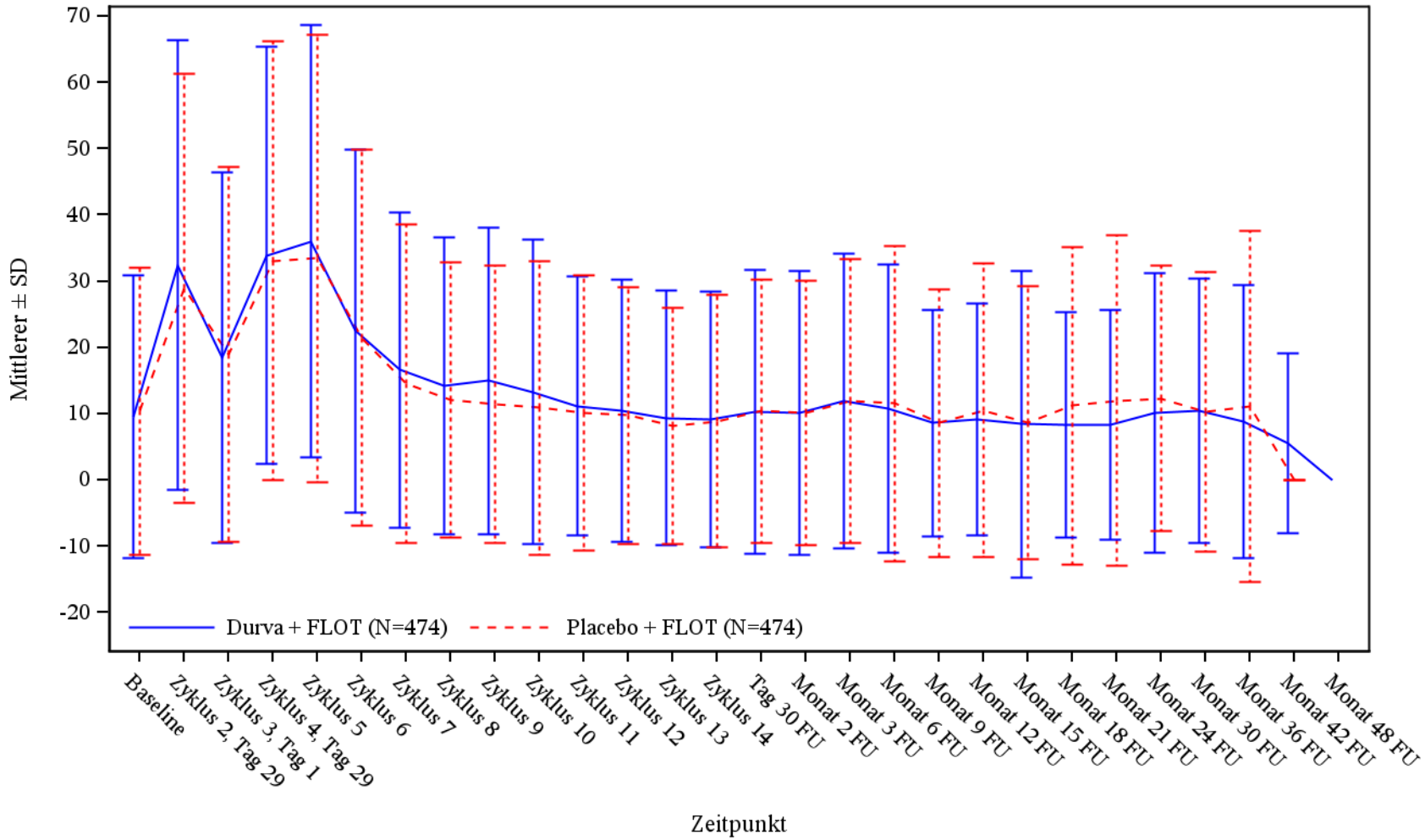
423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.

root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraay 28JAN2026:09:28 khsk849

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Figure 4.2.26 Mean (+/- SD) across timepoint, by treatment group for EORTC STO22 Taste (Morbidity)
Full Analysis Set, DCO 01SEP2025

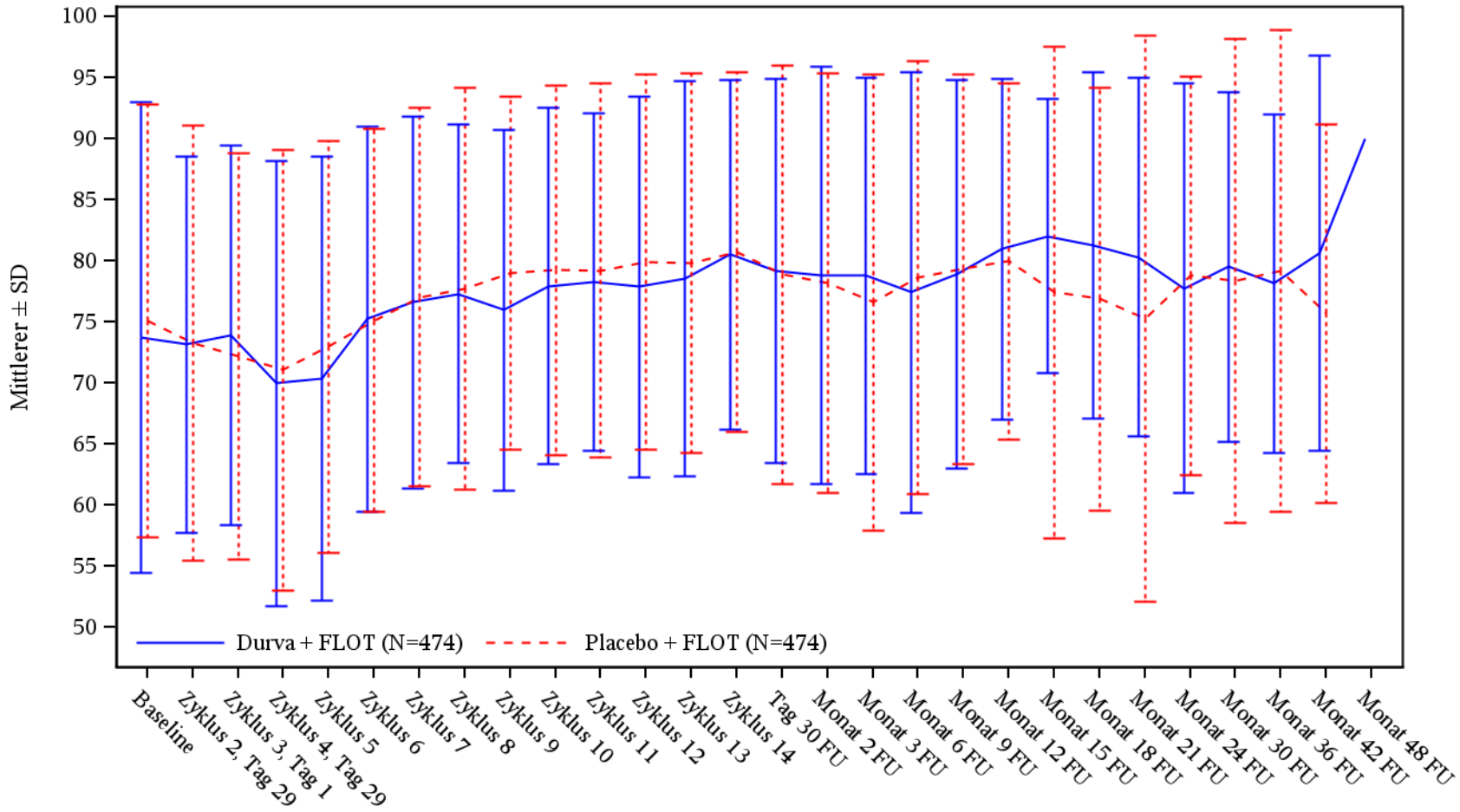


Anzahl an Patienten

423	419	285	285	257	283	279	283	267	258	256	250	232	251	245	237	252	206	198	161	83	116	76	76	86	34	6	1
430	406	272	276	259	273	266	268	259	257	240	232	220	232	231	237	254	185	162	117	54	98	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanpraaz 28JAN2026:09:28 khsk849

Figure 4.2.27 Mean (+/- SD) across timepoint, by treatment group for EQ-5D-5L Visual Analogue Scale (Morbidity)
Full Analysis Set, DCO 01SEP2025



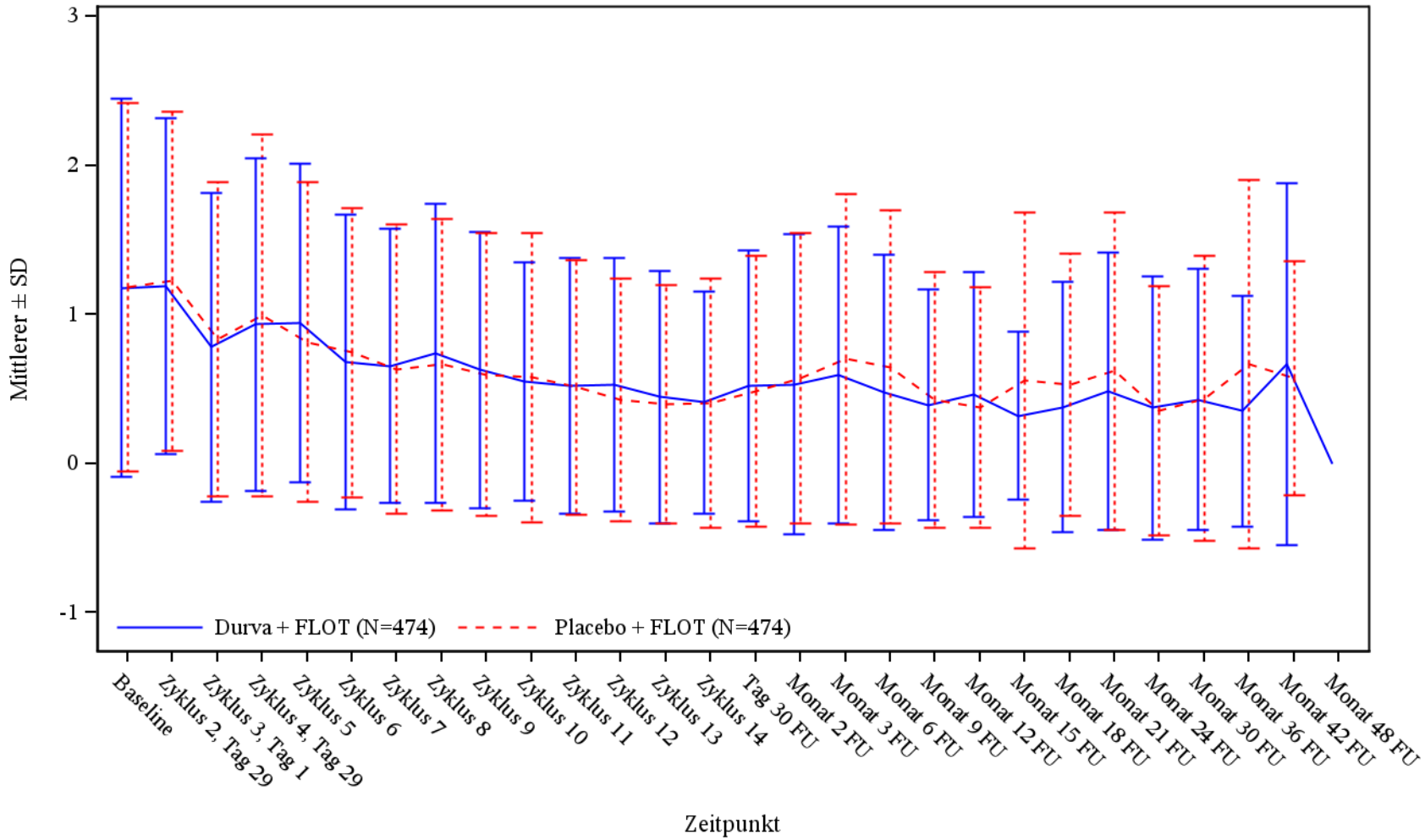
Anzahl an Patienten

423	416	282	285	255	282	278	283	266	257	256	250	232	249	245	237	252	206	195	161	82	116	76	76	86	34	6	1
429	405	270	275	259	271	266	267	258	256	240	232	219	232	230	237	253	185	161	117	54	97	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.28 Mean (+/- SD) across timepoint, by treatment group for Patient Global Impressions of Severity (PGIS) (Morbidity)
Full Analysis Set, DCO 01SEP2025

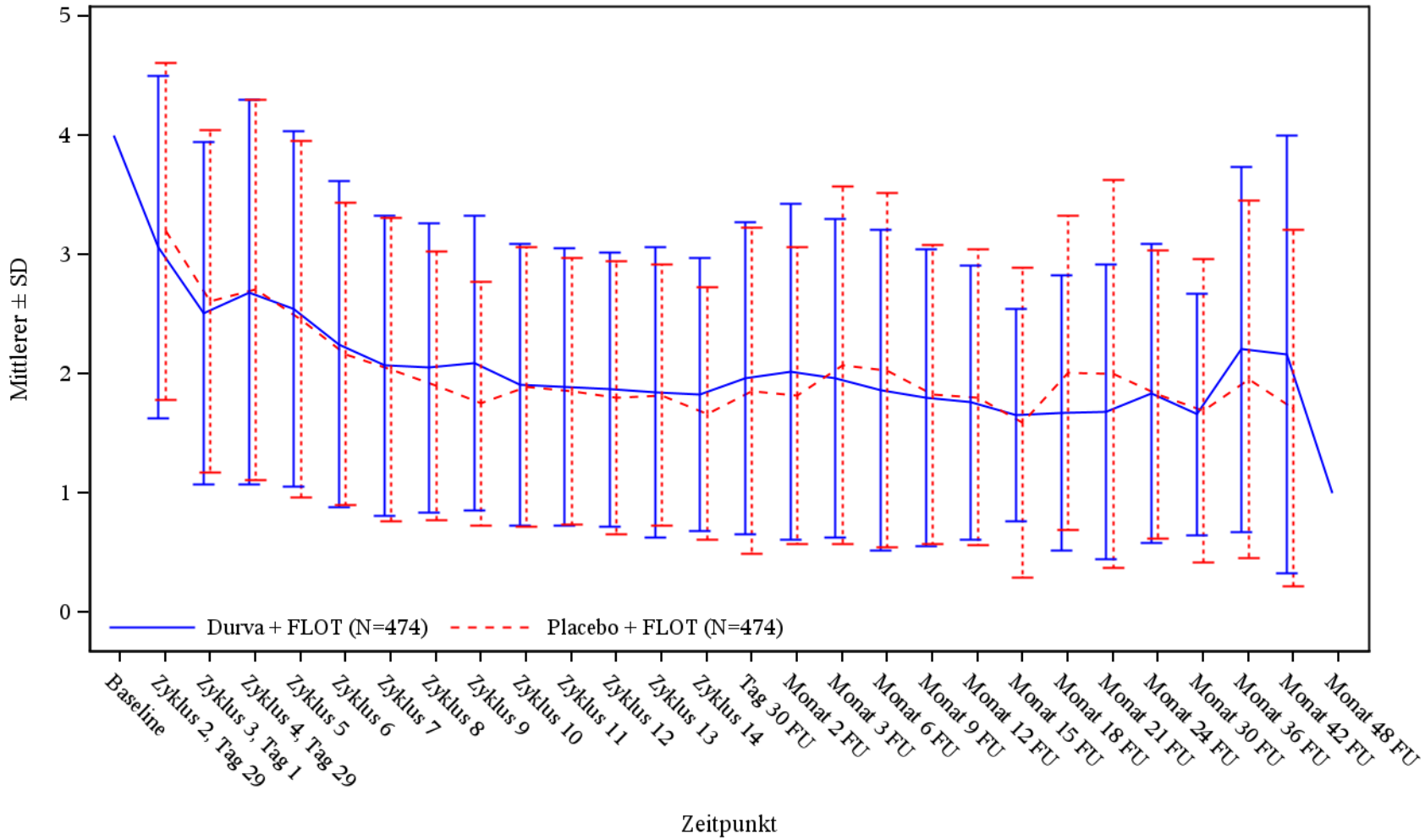


Anzahl an Patienten

421	412	281	282	250	279	275	280	264	257	256	248	231	249	243	237	250	205	193	161	81	116	76	75	86	34	6	1
427	404	268	273	258	269	266	263	258	255	240	231	219	232	230	233	252	182	160	117	54	97	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Figure 4.2.29 Mean (+/- SD) across timepoint, by treatment group for Patient Global Impression of Change (PGIC) (Morbidity)
Full Analysis Set, DCO 01SEP2025



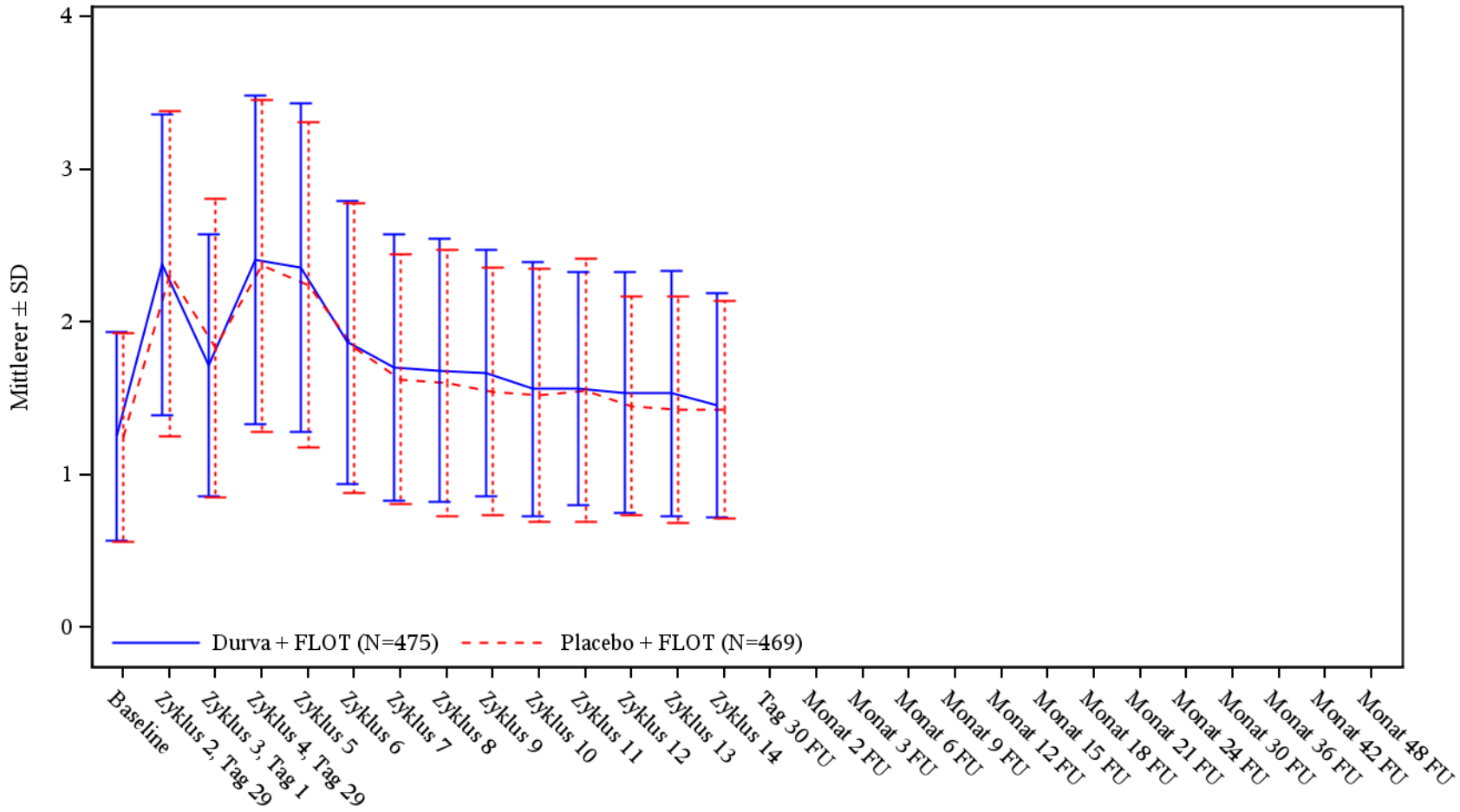
Anzahl an Patienten

1	408	280	281	252	279	276	282	265	257	256	248	232	249	243	237	252	205	195	161	82	116	76	75	86	34	6	1
0	400	269	273	259	269	266	263	258	255	240	232	219	232	230	234	252	185	160	117	54	97	50	65	55	21	7	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/fmeanpr.sas gfmeanprabc 28JAN2026:09:28 khsk849

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Figure 4.2.30 Mean (+/- SD) across timepoint, by treatment group for Patient Global Impression of Treatment Tolerability (PGITT) (Safety)
Safety Analysis Set, DCO 01SEP2025



Anzahl an Patienten

Durva + FLOT (N=475)	422	413	280	283	251	280	276	280	265	257	255	248	231	250	0	0	0	0	0	0	0	0	0	0	0	0
Placebo + FLOT (N=469)	426	403	267	269	256	268	265	262	257	254	237	229	218	231	0	0	0	0	0	0	0	0	0	0	0	0

Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.1 Summary of status at time of deterioration in EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EORTC QLQ-C30 Appetitverlust	Verschlechterung	Gesamt	269 [56,8]	256 [54,0]
	Zensiert	Gesamt	205 [43,2]	218 [46,0]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	72 [15,2]	94 [19,8]
		2 oder mehr aufeinanderfolgende fehlende Visiten	50 [10,5]	45 [9,5]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	19 [4,0]	18 [3,8]
EORTC QLQ-C30 Verstopfung	Verschlechterung	Gesamt	164 [34,6]	169 [35,7]
	Zensiert	Gesamt	310 [65,4]	305 [64,3]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	136 [28,7]	140 [29,5]
		2 oder mehr aufeinanderfolgende fehlende Visiten	83 [17,5]	83 [17,5]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	27 [5,7]	21 [4,4]
EORTC QLQ-C30 Diarrhö	Verschlechterung	Gesamt	314 [66,2]	293 [61,8]
	Zensiert	Gesamt	160 [33,8]	181 [38,2]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	56 [11,8]	76 [16,0]
		2 oder mehr aufeinanderfolgende fehlende Visiten	31 [6,5]	35 [7,4]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	9 [1,9]	9 [1,9]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.1 Summary of status at time of deterioration in EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EORTC QLQ-C30 Dyspnoe	Verschlechterung	Gesamt	206 [43,5]	210 [44,3]
	Zensiert	Gesamt	268 [56,5]	264 [55,7]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	109 [23,0]	116 [24,5]
		2 oder mehr aufeinanderfolgende fehlende Visiten	70 [14,8]	69 [14,6]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	25 [5,3]	18 [3,8]
EORTC QLQ-C30 Fatigue	Verschlechterung	Gesamt	335 [70,7]	322 [67,9]
	Zensiert	Gesamt	139 [29,3]	152 [32,1]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	42 [8,9]	57 [12,0]
		2 oder mehr aufeinanderfolgende fehlende Visiten	24 [5,1]	26 [5,5]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	9 [1,9]	8 [1,7]
EORTC QLQ-C30 Finanzielle Schwierigkeiten	Verschlechterung	Gesamt	175 [36,9]	188 [39,7]
	Zensiert	Gesamt	299 [63,1]	286 [60,3]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	132 [27,8]	132 [27,8]
		2 oder mehr aufeinanderfolgende fehlende Visiten	79 [16,7]	72 [15,2]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	24 [5,1]	21 [4,4]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.1 Summary of status at time of deterioration in EORTC QLQ-C30 (Morbidity)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EORTC QLQ-C30 Übelkeit und Erbrechen	Verschlechterung	Gesamt	285 [60,1]	282 [59,5]
	Zensiert	Gesamt	189 [39,9]	192 [40,5]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	65 [13,7]	73 [15,4]
		2 oder mehr aufeinanderfolgende fehlende Visiten	43 [9,1]	46 [9,7]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	17 [3,6]	12 [2,5]
EORTC QLQ-C30 Schmerzen	Verschlechterung	Gesamt	247 [52,1]	255 [53,8]
	Zensiert	Gesamt	227 [47,9]	219 [46,2]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	94 [19,8]	92 [19,4]
		2 oder mehr aufeinanderfolgende fehlende Visiten	52 [11,0]	51 [10,8]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	17 [3,6]	15 [3,2]
EORTC QLQ-C30 Schlaflosigkeit	Verschlechterung	Gesamt	228 [48,1]	204 [43,0]
	Zensiert	Gesamt	246 [51,9]	270 [57,0]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	103 [21,7]	123 [25,9]
		2 oder mehr aufeinanderfolgende fehlende Visiten	62 [13,1]	68 [14,3]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	17 [3,6]	18 [3,8]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.2 Summary of status at time of deterioration in EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EORTC QLQ-C30 Kognitive Funktion	Verschlechterung	Gesamt	245 [51,7]	243 [51,3]
	Zensiert	Gesamt	229 [48,3]	231 [48,7]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	102 [21,5]	102 [21,5]
		2 oder mehr aufeinanderfolgende fehlende Visiten	47 [9,9]	53 [11,2]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	16 [3,4]	15 [3,2]
EORTC QLQ-C30 Emotionale Funktion	Verschlechterung	Gesamt	178 [37,6]	190 [40,1]
	Zensiert	Gesamt	296 [62,4]	284 [59,9]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	133 [28,1]	127 [26,8]
		2 oder mehr aufeinanderfolgende fehlende Visiten	78 [16,5]	73 [15,4]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	21 [4,4]	23 [4,9]
EORTC QLQ-C30 Körperliche Funktion	Verschlechterung	Gesamt	274 [57,8]	279 [58,9]
	Zensiert	Gesamt	200 [42,2]	195 [41,1]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	77 [16,2]	82 [17,3]
		2 oder mehr aufeinanderfolgende fehlende Visiten	44 [9,3]	35 [7,4]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	15 [3,2]	17 [3,6]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.2 Summary of status at time of deterioration in EORTC QLQ-C30 (hrQoL)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EORTC QLQ-C30 Allgemeine Lebensqualität/Gesundheitszustand	Verschlechterung	Gesamt	253 [53,4]	259 [54,6]
	Zensiert	Gesamt	221 [46,6]	215 [45,4]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	92 [19,4]	87 [18,4]
		2 oder mehr aufeinanderfolgende fehlende Visiten	47 [9,9]	50 [10,5]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	18 [3,8]	17 [3,6]
EORTC QLQ-C30 Rollenfunktion	Verschlechterung	Gesamt	286 [60,3]	292 [61,6]
	Zensiert	Gesamt	188 [39,7]	182 [38,4]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	71 [15,0]	70 [14,8]
		2 oder mehr aufeinanderfolgende fehlende Visiten	38 [8,0]	37 [7,8]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	15 [3,2]	14 [3,0]
EORTC QLQ-C30 Soziale Funktion	Verschlechterung	Gesamt	271 [57,2]	262 [55,3]
	Zensiert	Gesamt	203 [42,8]	212 [44,7]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	64 [13,5]	61 [12,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	79 [16,7]	88 [18,6]
		2 oder mehr aufeinanderfolgende fehlende Visiten	42 [8,9]	47 [9,9]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	18 [3,8]	16 [3,4]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.3 Summary of status at time of deterioration in EORTC QLQ-IL38 (Morbidity)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EORTC IL38 Schwierigkeiten beim Schlucken	Verschlechterung	Gesamt	195 [41,1]	182 [38,4]
	Zensiert	Gesamt	279 [58,9]	292 [61,6]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	113 [23,8]	122 [25,7]
		2 oder mehr aufeinanderfolgende fehlende Visiten	77 [16,2]	84 [17,7]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	20 [4,2]	20 [4,2]
EORTC IL38 Gewichtsverlust	Verschlechterung	Gesamt	255 [53,8]	248 [52,3]
	Zensiert	Gesamt	219 [46,2]	226 [47,7]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	82 [17,3]	94 [19,8]
		2 oder mehr aufeinanderfolgende fehlende Visiten	48 [10,1]	50 [10,5]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	20 [4,2]	16 [3,4]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.4 Summary of status at time of deterioration in EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EORTC STO22 Angst	Verschlechterung	Gesamt	226 [47,7]	230 [48,5]
	Zensiert	Gesamt	248 [52,3]	244 [51,5]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	102 [21,5]	97 [20,5]
		2 oder mehr aufeinanderfolgende fehlende Visiten	60 [12,7]	62 [13,1]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	17 [3,6]	19 [4,0]
EORTC STO22 Körperbild	Verschlechterung	Gesamt	252 [53,2]	228 [48,1]
	Zensiert	Gesamt	222 [46,8]	246 [51,9]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	86 [18,1]	105 [22,2]
		2 oder mehr aufeinanderfolgende fehlende Visiten	52 [11,0]	58 [12,2]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	15 [3,2]	17 [3,6]
EORTC STO22 Mundtrockenheit	Verschlechterung	Gesamt	265 [55,9]	244 [51,5]
	Zensiert	Gesamt	209 [44,1]	230 [48,5]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	72 [15,2]	95 [20,0]
		2 oder mehr aufeinanderfolgende fehlende Visiten	50 [10,5]	50 [10,5]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	18 [3,8]	19 [4,0]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.4 Summary of status at time of deterioration in EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EORTC STO22 Dysphagie	Verschlechterung	Gesamt	253 [53,4]	240 [50,6]
	Zensiert	Gesamt	221 [46,6]	234 [49,4]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	89 [18,8]	94 [19,8]
		2 oder mehr aufeinanderfolgende fehlende Visiten	46 [9,7]	56 [11,8]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	17 [3,6]	18 [3,8]
EORTC STO22 Einschränkungen beim Essen	Verschlechterung	Gesamt	243 [51,3]	231 [48,7]
	Zensiert	Gesamt	231 [48,7]	243 [51,3]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	88 [18,6]	96 [20,3]
		2 oder mehr aufeinanderfolgende fehlende Visiten	53 [11,2]	59 [12,4]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	21 [4,4]	22 [4,6]
EORTC STO22 Haarverlust	Verschlechterung	Gesamt	377 [79,5]	367 [77,4]
	Zensiert	Gesamt	97 [20,5]	107 [22,6]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	14 [3,0]	22 [4,6]
		2 oder mehr aufeinanderfolgende fehlende Visiten	6 [1,3]	11 [2,3]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	8 [1,7]	8 [1,7]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.4 Summary of status at time of deterioration in EORTC QLQ-STO22 (Morbidity)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EORTC STO22 Schmerzen	Verschlechterung	Gesamt	210 [44,3]	193 [40,7]
	Zensiert	Gesamt	264 [55,7]	281 [59,3]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	103 [21,7]	121 [25,5]
		2 oder mehr aufeinanderfolgende fehlende Visiten	71 [15,0]	73 [15,4]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	21 [4,4]	21 [4,4]
EORTC STO22 Reflux	Verschlechterung	Gesamt	257 [54,2]	250 [52,7]
	Zensiert	Gesamt	217 [45,8]	224 [47,3]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	81 [17,1]	88 [18,6]
		2 oder mehr aufeinanderfolgende fehlende Visiten	51 [10,8]	51 [10,8]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	16 [3,4]	19 [4,0]
EORTC STO22 Geschmacksstörungen	Verschlechterung	Gesamt	310 [65,4]	278 [58,6]
	Zensiert	Gesamt	164 [34,6]	196 [41,4]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	69 [14,6]	66 [13,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	58 [12,2]	76 [16,0]
		2 oder mehr aufeinanderfolgende fehlende Visiten	25 [5,3]	39 [8,2]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	12 [2,5]	15 [3,2]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.5 Summary of status at time of deterioration in EQ-5D-5L Visual Analogue Scale (Morbidity)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
EQ-5D-5L Visuelle Analogskala	Verschlechterung	Gesamt	209 [44,1]	199 [42,0]
	Zensiert	Gesamt	265 [55,9]	275 [58,0]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	70 [14,8]	67 [14,1]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	107 [22,6]	128 [27,0]
		2 oder mehr aufeinanderfolgende fehlende Visiten	68 [14,3]	61 [12,9]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	20 [4,2]	19 [4,0]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.6 Summary of status at time of deterioration in Patient Global Impressions of Severity (PGIS) (Morbidity)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
Patient Global Impressions of Severity (PGIS)	Verschlechterung	Gesamt	228 [48,1]	234 [49,4]
	Zensiert	Gesamt	246 [51,9]	240 [50,6]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	73 [15,4]	69 [14,6]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	86 [18,1]	96 [20,3]
		2 oder mehr aufeinanderfolgende fehlende Visiten	72 [15,2]	57 [12,0]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	15 [3,2]	18 [3,8]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.7 Summary of status at time of deterioration in Patient Global Impression of Change (PGIC) (Morbidity)
Full Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=474)	Placebo + FLOT (N=474)
Patient Global Impression of Change (PGIC)	Verschlechterung	Gesamt	155 [32,7]	143 [30,2]
	Zensiert	Gesamt	319 [67,3]	331 [69,8]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	35 [7,4]	44 [9,3]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	157 [33,1]	172 [36,3]
		2 oder mehr aufeinanderfolgende fehlende Visiten	105 [22,2]	90 [19,0]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	22 [4,6]	25 [5,3]

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 4.3.8 Summary of status at time of deterioration in Patient Global Impression of Treatment Tolerability (PGITT) (Safety)
Safety Analysis Set, DCO 01SEP2025

		Grund	Durva + FLOT (N=475)	Placebo + FLOT (N=469)
Patient Global Impression of Treatment Tolerability (PGITT)	Verschlechterung	Gesamt	47 [9,9]	35 [7,5]
	Zensiert	Gesamt	428 [90,1]	434 [92,5]
		Kein auswertbarer Baselinewert oder kein auswertbarer Wert nach Baseline	74 [15,6]	70 [14,9]
		Letzte auswertbare Bewertung ohne Verschlechterung [a]	312 [65,7]	321 [68,4]
		2 oder mehr aufeinanderfolgende fehlende Visiten	40 [8,4]	43 [9,2]
		Tod innerhalb von 2 Visiten nach der letzten auswertbaren PRO-Bewertung	2 [0,4]	0

[a] Includes patients with baseline score too low/high to experience a deterioration.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
UE [a][d][h]	475	471[99,2]	469	463[98,7]	1,53[0,43; 6,00]	0,5105	1,00[0,99; 1,02]	0,5105	0,00[-0,01; 0,02]	0,5105
SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort [a][d][h]	475	307[64,6]	469	302[64,4]	1,01[0,77; 1,32]	0,9388	1,00[0,91; 1,10]	0,9388	0,00[-0,06; 0,06]	0,9388
PT: Asthenie [a][d][h]	475	95[20,0]	469	71[15,1]	1,40[1,001; 1,97]	0,0494 *	1,32[1,001; 1,75]	0,0494 *	0,05[0,0001; 0,10]	0,0494 *
PT: Brustkorbschmerz [a][d][h]	475	12[2,5]	469	16[3,4]	0,73[0,34; 1,56]	0,4221	0,74[0,35; 1,54]	0,4221	-0,01[-0,03; 0,01]	0,4221
PT: Ermuedung [a][d][h]	475	137[28,8]	469	146[31,1]	0,90[0,68; 1,18]	0,4430	0,93[0,76; 1,13]	0,4430	-0,02[-0,08; 0,04]	0,4430
PT: Fieber [a][d][h]	475	95[20,0]	469	71[15,1]	1,40[1,001; 1,97]	0,0494 *	1,32[1,001; 1,75]	0,0494 *	0,05[0,0001; 0,10]	0,0494 *
PT: Oedem peripher [a][d][h]	475	32[6,7]	469	30[6,4]	1,06[0,63; 1,78]	0,8329	1,05[0,65; 1,71]	0,8329	0,00[-0,03; 0,04]	0,8329
PT: Schleimhautentzuendung [a][d][h]	475	27[5,7]	469	23[4,9]	1,17[0,66; 2,08]	0,5924	1,16[0,67; 2,01]	0,5924	0,01[-0,02; 0,04]	0,5924
PT: Schmerz [a][d][h]	475	7[1,5]	469	11[2,3]	0,62[0,23; 1,60]	0,3256	0,63[0,23; 1,58]	0,3256	-0,01[-0,03; 0,01]	0,3256

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Schuettelfrost [a][d][h]	475	18[3,8]	469	10[2,1]	1,81[0,84; 4,11]	0,1307	1,78[0,85; 3,96]	0,1307	0,02[-0,01; 0,04]	0,1307
PT: Unwohlsein [a][d][h]	475	24[5,1]	469	26[5,5]	0,91[0,51; 1,61]	0,7362	0,91[0,53; 1,57]	0,7362	-0,00[-0,03; 0,02]	0,7362
SOC: Augenerkrankungen [a][d][h]	475	34[7,2]	469	45[9,6]	0,73[0,45; 1,15]	0,1758	0,75[0,48; 1,14]	0,1758	-0,02[-0,06; 0,01]	0,1758
PT: Traenensekretion verstaerkt [a][d][h]	475	11[2,3]	469	9[1,9]	1,21[0,50; 3,03]	0,6718	1,21[0,50; 2,97]	0,6718	0,00[-0,01; 0,02]	0,6718
PT: Trockenes Auge [a][d][h]	475	8[1,7]	469	10[2,1]	0,79[0,30; 2,01]	0,6145	0,79[0,30; 1,99]	0,6145	-0,00[-0,02; 0,01]	0,6145
SOC: Endokrine Erkrankungen [a][d][h]	475	67[14,1]	469	21[4,5]	3,50[2,14; 5,95]	<0,0001 *	3,15[2,00; 5,19]	<0,0001 *	0,10[0,06; 0,13]	<0,0001 *
PT: Hyperthyreose [a][d][h]	475	21[4,4]	469	8[1,7]	2,67[1,21; 6,46]	0,0139 *	2,59[1,21; 6,17]	0,0139 *	0,03[0,01; 0,05]	0,0139 *
PT: Hypothyreose [a][d][h]	475	37[7,8]	469	8[1,7]	4,87[2,36; 11,36]	<0,0001 *	4,57[2,27; 10,47]	<0,0001 *	0,06[0,03; 0,09]	<0,0001 *

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardae.sas gorrrardaeaaa 29JUN2026:08:36 khcs324

Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums [a][d][h]	475	155[32,6]	469	160[34,1]	0,94[0,71; 1,23]	0,6289	0,96[0,80; 1,15]	0,6289	-0,01[-0,07; 0,05]	0,6289
PT: Dysphonie [a][d][h]	475	13[2,7]	469	6[1,3]	2,17[0,85; 6,22]	0,1066	2,14[0,85; 6,05]	0,1066	0,01[-0,00; 0,03]	0,1066
PT: Dyspnoe [a][d][h]	475	26[5,5]	469	23[4,9]	1,12[0,63; 2,01]	0,6931	1,12[0,65; 1,94]	0,6931	0,01[-0,02; 0,03]	0,6931
PT: Epistaxis [a][d][h]	475	38[8,0]	469	51[10,9]	0,71[0,46; 1,10]	0,1302	0,74[0,49; 1,09]	0,1302	-0,03[-0,07; 0,01]	0,1302
PT: Husten [a][d][h]	475	42[8,8]	469	41[8,7]	1,01[0,64; 1,59]	0,9567	1,01[0,67; 1,53]	0,9567	0,00[-0,04; 0,04]	0,9567
PT: Lungenembolie [a][d][h]	475	20[4,2]	469	9[1,9]	2,25[1,04; 5,24]	0,0388 *	2,19[1,04; 5,02]	0,0388 *	0,02[0,001; 0,05]	0,0388 *
PT: Pleuraerguss [a][d][h]	475	14[2,9]	469	29[6,2]	0,46[0,23; 0,87]	0,0161 *	0,48[0,25; 0,87]	0,0161 *	-0,03[-0,06; -0,01]	0,0161 *
PT: Pneumonitis [a][d][h]	475	15[3,2]	469	5[1,1]	3,03[1,16; 9,36]	0,0224 *	2,96[1,16; 9,05]	0,0224 *	0,02[0,003; 0,04]	0,0224 *
PT: Schluckauf [a][d][h]	475	19[4,0]	469	22[4,7]	0,85[0,45; 1,59]	0,6025	0,85[0,46; 1,55]	0,6025	-0,01[-0,03; 0,02]	0,6025

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Schmerzen im Oropharynx [a][d][h]	475	9[1,9]	469	11[2,3]	0,80[0,32; 1,96]	0,6304	0,81[0,33; 1,93]	0,6304	-0,00[-0,02; 0,01]	0,6304
SOC: Erkrankungen der Geschlechtsorgane und der Brustdruese [a][d][h]	475	18[3,8]	469	18[3,8]	0,99[0,50; 1,93]	0,9690	0,99[0,52; 1,89]	0,9690	-0,00[-0,03; 0,02]	0,9690
SOC: Erkrankungen der Haut und des Unterhautgewebes [a][d][h]	475	257[54,1]	469	239[51,0]	1,13[0,88; 1,47]	0,3331	1,06[0,94; 1,20]	0,3331	0,03[-0,03; 0,09]	0,3331
PT: Alopezie [a][d][h]	475	145[30,5]	469	149[31,8]	0,94[0,72; 1,24]	0,6800	0,96[0,79; 1,16]	0,6800	-0,01[-0,07; 0,05]	0,6800
PT: Ausschlag [a][d][h]	475	65[13,7]	469	34[7,2]	2,03[1,32; 3,17]	0,0011 *	1,89[1,28; 2,83]	0,0011 *	0,06[0,03; 0,10]	0,0011 *
PT: Ausschlag makulo-papuloes [a][d][h]	475	15[3,2]	469	5[1,1]	3,03[1,16; 9,36]	0,0224 *	2,96[1,16; 9,05]	0,0224 *	0,02[0,003; 0,04]	0,0224 *
PT: Erythem [a][d][h]	475	12[2,5]	469	7[1,5]	1,71[0,68; 4,63]	0,2552	1,69[0,69; 4,51]	0,2552	0,01[-0,01; 0,03]	0,2552

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardae.sas gorrrardaeaaa 29JUN2026:08:36 khcs324

Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Palmar-plantares Erythrodysaesthesiesyndrom [a][d][h]	475	24[5,1]	469	22[4,7]	1,08[0,60; 1,97]	0,7963	1,08[0,61; 1,91]	0,7963	0,00[-0,02; 0,03]	0,7963
PT: Pruritus [a][d][h]	475	51[10,7]	469	25[5,3]	2,14[1,31; 3,56]	0,0021 *	2,01[1,28; 3,25]	0,0021 *	0,05[0,02; 0,09]	0,0021 *
PT: Trockene Haut [a][d][h]	475	36[7,6]	469	22[4,7]	1,67[0,97; 2,92]	0,0634	1,62[0,97; 2,75]	0,0634	0,03[-0,00; 0,06]	0,0634
SOC: Erkrankungen der Nieren und Harnwege [a][d][h]	475	44[9,3]	469	32[6,8]	1,39[0,87; 2,26]	0,1674	1,36[0,88; 2,12]	0,1674	0,02[-0,01; 0,06]	0,1674
SOC: Erkrankungen des Blutes und des Lymphsystems [a][d][h]	475	239[50,3]	469	254[54,2]	0,86[0,66; 1,11]	0,2373	0,93[0,82; 1,05]	0,2373	-0,04[-0,10; 0,03]	0,2373
PT: Anaemie [a][d][h]	475	119[25,1]	469	147[31,3]	0,73[0,55; 0,97]	0,0316 *	0,80[0,65; 0,98]	0,0316 *	-0,06[-0,12; -0,01]	0,0316 *
PT: Febrile Neutropenie [a][d][h]	475	17[3,6]	469	17[3,6]	0,99[0,49; 1,97]	0,9699	0,99[0,51; 1,92]	0,9699	-0,00[-0,02; 0,02]	0,9699

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Leukopenie [a][d][h]	475	27[5,7]	469	30[6,4]	0,88[0,51; 1,51]	0,6459	0,89[0,53; 1,47]	0,6459	-0,01[-0,04; 0,02]	0,6459
PT: Lymphopenie [a][d][h]	475	10[2,1]	469	10[2,1]	0,99[0,40; 2,43]	0,9771	0,99[0,41; 2,38]	0,9771	-0,00[-0,02; 0,02]	0,9771
PT: Neutropenie [a][d][h]	475	153[32,2]	469	155[33,0]	0,96[0,73; 1,26]	0,7835	0,97[0,81; 1,17]	0,7835	-0,01[-0,07; 0,05]	0,7835
PT: Thrombozytopenie [a][d][h]	475	31[6,5]	469	25[5,3]	1,24[0,72; 2,15]	0,4363	1,22[0,74; 2,06]	0,4363	0,01[-0,02; 0,04]	0,4363
SOC: Erkrankungen des Gastrointestinaltrakts [a][d][h]	475	409[86,1]	469	391[83,4]	1,24[0,87; 1,77]	0,2421	1,03[0,98; 1,09]	0,2421	0,03[-0,02; 0,07]	0,2421
PT: Abdominalschmerz [a][d][h]	475	82[17,3]	469	96[20,5]	0,81[0,58; 1,12]	0,2078	0,84[0,65; 1,10]	0,2078	-0,03[-0,08; 0,02]	0,2078
PT: Bauch aufgetrieben [a][d][h]	475	23[4,8]	469	17[3,6]	1,35[0,72; 2,60]	0,3523	1,34[0,73; 2,51]	0,3523	0,01[-0,01; 0,04]	0,3523
PT: Diarrhoe [a][d][h]	475	296[62,3]	469	270[57,6]	1,22[0,94; 1,58]	0,1366	1,08[0,98; 1,20]	0,1366	0,05[-0,02; 0,11]	0,1366
PT: Dyspepsie [a][d][h]	475	33[6,9]	469	27[5,8]	1,22[0,72; 2,08]	0,4531	1,21[0,74; 1,99]	0,4531	0,01[-0,02; 0,04]	0,4531

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Dysphagie [a][d][h]	475	47[9,9]	469	36[7,7]	1,32[0,84; 2,09]	0,2280	1,29[0,85; 1,96]	0,2280	0,02[-0,01; 0,06]	0,2280
PT: Erbrechen [a][d][h]	475	124[26,1]	469	120[25,6]	1,03[0,77; 1,38]	0,8555	1,02[0,82; 1,27]	0,8555	0,01[-0,05; 0,06]	0,8555
PT: Flatulenz [a][d][h]	475	11[2,3]	469	21[4,5]	0,51[0,23; 1,04]	0,0644	0,52[0,24; 1,04]	0,0644	-0,02[-0,05;0,001]	0,0644
PT: Gastrooesophageale Refluxerkrankung [a][d][h]	475	35[7,4]	469	41[8,7]	0,83[0,52; 1,33]	0,4378	0,84[0,54; 1,30]	0,4378	-0,01[-0,05; 0,02]	0,4378
PT: Haemorrhoiden [a][d][h]	475	7[1,5]	469	10[2,1]	0,69[0,25; 1,80]	0,4457	0,69[0,25; 1,78]	0,4457	-0,01[-0,02; 0,01]	0,4457
PT: Kolitis [a][d][h]	475	12[2,5]	469	6[1,3]	2,00[0,77; 5,79]	0,1572	1,97[0,77; 5,63]	0,1572	0,01[-0,01; 0,03]	0,1572
PT: Mundtrockenheit [a][d][h]	475	25[5,3]	469	14[3,0]	1,81[0,94; 3,61]	0,0766	1,76[0,94; 3,44]	0,0766	0,02[-0,00; 0,05]	0,0766
PT: Obstipation [a][d][h]	475	77[16,2]	469	81[17,3]	0,93[0,66; 1,30]	0,6626	0,94[0,71; 1,25]	0,6626	-0,01[-0,06; 0,04]	0,6626
PT: Oesophagitis [a][d][h]	475	5[1,1]	469	12[2,6]	0,41[0,13; 1,10]	0,0776	0,41[0,13; 1,10]	0,0776	-0,02[-0,03;0,002]	0,0776

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Schmerzen Oberbauch [a][d][h]	475	26[5,5]	469	27[5,8]	0,95[0,54; 1,65]	0,8501	0,95[0,56; 1,61]	0,8501	-0,00[-0,03; 0,03]	0,8501
PT: Stomatitis [a][d][h]	475	60[12,6]	469	44[9,4]	1,40[0,93; 2,12]	0,1101	1,35[0,94; 1,96]	0,1101	0,03[-0,01; 0,07]	0,1101
PT: Uebelkeit [a][d][h]	475	242[50,9]	469	238[50,7]	1,01[0,78; 1,30]	0,9507	1,00[0,89; 1,14]	0,9507	0,00[-0,06; 0,07]	0,9507
SOC: Erkrankungen des Immunsystems [a][d][h]	475	34[7,2]	469	28[6,0]	1,21[0,72; 2,05]	0,4610	1,20[0,74; 1,96]	0,4610	0,01[-0,02; 0,04]	0,4610
PT: Arzneimittelueberempfindlichkeit [a][d][h]	475	19[4,0]	469	12[2,6]	1,59[0,77; 3,40]	0,2121	1,56[0,78; 3,28]	0,2121	0,01[-0,01; 0,04]	0,2121
PT: Ueberempfindlichkeit [a][d][h]	475	11[2,3]	469	10[2,1]	1,09[0,45; 2,64]	0,8483	1,09[0,46; 2,58]	0,8483	0,00[-0,02; 0,02]	0,8483
SOC: Erkrankungen des Nervensystems [a][d][h]	475	280[58,9]	469	262[55,9]	1,13[0,88; 1,47]	0,3380	1,06[0,95; 1,18]	0,3380	0,03[-0,03; 0,09]	0,3380
PT: Dysaesthesie [a][d][h]	475	11[2,3]	469	8[1,7]	1,37[0,55; 3,56]	0,5036	1,36[0,55; 3,48]	0,5036	0,01[-0,01; 0,03]	0,5036

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Dysgeusie [a][d][h]	475	78[16,4]	469	61[13,0]	1,31[0,92; 1,89]	0,1383	1,26[0,93; 1,73]	0,1383	0,03[-0,01; 0,08]	0,1383
PT: Kopfschmerzen [a][d][h]	475	29[6,1]	469	25[5,3]	1,15[0,67; 2,02]	0,6081	1,15[0,68; 1,94]	0,6081	0,01[-0,02; 0,04]	0,6081
PT: Neurotoxizitaet [a][d][h]	475	20[4,2]	469	10[2,1]	2,02[0,96; 4,54]	0,0661	1,97[0,96; 4,36]	0,0661	0,02[-0,00; 0,04]	0,0661
PT: Paraesthesie [a][d][h]	475	38[8,0]	469	32[6,8]	1,19[0,73; 1,95]	0,4899	1,17[0,75; 1,85]	0,4899	0,01[-0,02; 0,05]	0,4899
PT: Periphere Neuropathie [a][d][h]	475	74[15,6]	469	70[14,9]	1,05[0,74; 1,50]	0,7800	1,04[0,77; 1,41]	0,7800	0,01[-0,04; 0,05]	0,7800
PT: Periphere sensorische Neuropathie [a][d][h]	475	96[20,2]	469	88[18,8]	1,10[0,79; 1,52]	0,5746	1,08[0,83; 1,40]	0,5746	0,01[-0,04; 0,07]	0,5746
PT: Polyneuropathie [a][d][h]	475	26[5,5]	469	23[4,9]	1,12[0,63; 2,01]	0,6931	1,12[0,65; 1,94]	0,6931	0,01[-0,02; 0,03]	0,6931
PT: Schwindelgefuehl [a][d][h]	475	31[6,5]	469	27[5,8]	1,14[0,67; 1,96]	0,6224	1,13[0,69; 1,88]	0,6224	0,01[-0,02; 0,04]	0,6224

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Synkope [a][d][h]	475	10[2,1]	469	6[1,3]	1,66[0,61; 4,91]	0,3230	1,65[0,62; 4,80]	0,3230	0,01[-0,01; 0,03]	0,3230
SOC: Erkrankungen des Ohrs und des Labyrinths [a][d][h]	475	8[1,7]	469	10[2,1]	0,79[0,30; 2,01]	0,6145	0,79[0,30; 1,99]	0,6145	-0,00[-0,02; 0,01]	0,6145
SOC: Gefaesserkrankungen [a][d][h]	475	75[15,8]	469	77[16,4]	0,95[0,67; 1,35]	0,7928	0,96[0,72; 1,29]	0,7928	-0,01[-0,05; 0,04]	0,7928
PT: Hypertonie [a][d][h]	475	19[4,0]	469	20[4,3]	0,94[0,49; 1,78]	0,8383	0,94[0,50; 1,74]	0,8383	-0,00[-0,03; 0,02]	0,8383
PT: Hypotonie [a][d][h]	475	13[2,7]	469	16[3,4]	0,80[0,37; 1,67]	0,5478	0,80[0,38; 1,65]	0,5478	-0,01[-0,03; 0,02]	0,5478
SOC: Herzerkrankungen [a][d][h]	475	41[8,6]	469	36[7,7]	1,14[0,71; 1,82]	0,5916	1,12[0,73; 1,73]	0,5916	0,01[-0,03; 0,04]	0,5916
PT: Vorhofflimmern [a][d][h]	475	10[2,1]	469	5[1,1]	2,00[0,70; 6,45]	0,1973	1,97[0,71; 6,30]	0,1973	0,01[-0,01; 0,03]	0,1973
SOC: Infektionen und parasitaere Erkrankungen [a][d][h]	475	239[50,3]	469	221[47,1]	1,14[0,88; 1,47]	0,3262	1,07[0,94; 1,22]	0,3262	0,03[-0,03; 0,10]	0,3262

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Aspirationspneumonie [a][d][h]	475	7[1,5]	469	11[2,3]	0,62[0,23; 1,60]	0,3256	0,63[0,23; 1,58]	0,3256	-0,01[-0,03; 0,01]	0,3256
PT: COVID-19 [a][d][h]	475	85[17,9]	469	74[15,8]	1,16[0,83; 1,64]	0,3848	1,13[0,85; 1,51]	0,3848	0,02[-0,03; 0,07]	0,3848
PT: Harnwegsinfektion [a][d][h]	475	28[5,9]	469	20[4,3]	1,41[0,78; 2,57]	0,2531	1,38[0,79; 2,45]	0,2531	0,02[-0,01; 0,04]	0,2531
PT: Infektion [a][d][h]	475	4[0,8]	469	11[2,3]	0,35[0,10; 1,04]	0,0599	0,36[0,10; 1,04]	0,0599	-0,02[-0,03;0,001]	0,0599
PT: Infektion der oberen Atemwege [a][d][h]	475	13[2,7]	469	12[2,6]	1,07[0,48; 2,41]	0,8646	1,07[0,49; 2,35]	0,8646	0,00[-0,02; 0,02]	0,8646
PT: Infektion im Zusammenhang mit einem Medizinprodukt [a][d][h]	475	13[2,7]	469	8[1,7]	1,62[0,68; 4,13]	0,2804	1,60[0,68; 4,02]	0,2804	0,01[-0,01; 0,03]	0,2804
PT: Pneumonie [a][d][h]	475	34[7,2]	469	32[6,8]	1,05[0,64; 1,74]	0,8401	1,05[0,66; 1,68]	0,8401	0,00[-0,03; 0,04]	0,8401
SOC: Leber- und Gallenerkrankungen [a][d][h]	475	46[9,7]	469	30[6,4]	1,57[0,98; 2,55]	0,0625	1,51[0,98; 2,38]	0,0625	0,03[-0,00; 0,07]	0,0625

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
SOC: Psychiatrische Erkrankungen [a][d][h]	475	66[13,9]	469	62[13,2]	1,06[0,73; 1,54]	0,7619	1,05[0,76; 1,45]	0,7619	0,01[-0,04; 0,05]	0,7619
PT: Angst [a][d][h]	475	13[2,7]	469	10[2,1]	1,29[0,56; 3,05]	0,5463	1,28[0,57; 2,98]	0,5463	0,01[-0,01; 0,03]	0,5463
PT: Depression [a][d][h]	475	7[1,5]	469	10[2,1]	0,69[0,25; 1,80]	0,4457	0,69[0,25; 1,78]	0,4457	-0,01[-0,02; 0,01]	0,4457
PT: Schlaflosigkeit [a][d][h]	475	34[7,2]	469	38[8,1]	0,87[0,54; 1,42]	0,5846	0,88[0,56; 1,38]	0,5846	-0,01[-0,04; 0,02]	0,5846
SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen [a][d][h]	475	120[25,3]	469	99[21,1]	1,26[0,93; 1,71]	0,1303	1,20[0,95; 1,51]	0,1303	0,04[-0,01; 0,10]	0,1303
PT: Arthralgie [a][d][h]	475	41[8,6]	469	31[6,6]	1,33[0,82; 2,18]	0,2412	1,31[0,84; 2,06]	0,2412	0,02[-0,01; 0,05]	0,2412
PT: Brustschmerzen die Skelettmuskulatur betreffend [a][d][h]	475	17[3,6]	469	7[1,5]	2,45[1,05; 6,39]	0,0387 *	2,40[1,05; 6,15]	0,0387 *	0,02[0,001; 0,04]	0,0387 *

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Myalgie [a][d][h]	475	19[4,0]	469	13[2,8]	1,46[0,72; 3,06]	0,2957	1,44[0,73; 2,96]	0,2957	0,01[-0,01; 0,04]	0,2957
PT: Rueckenschmerzen [a][d][h]	475	24[5,1]	469	29[6,2]	0,81[0,46; 1,41]	0,4502	0,82[0,48; 1,38]	0,4502	-0,01[-0,04; 0,02]	0,4502
PT: Schmerz in einer Extremitaet [a][d][h]	475	13[2,7]	469	12[2,6]	1,07[0,48; 2,41]	0,8646	1,07[0,49; 2,35]	0,8646	0,00[-0,02; 0,02]	0,8646
SOC: Stoffwechsel- und Ernaehrungsstoerungen [a][d][h]	475	219[46,1]	469	232[49,5]	0,87[0,68; 1,13]	0,3012	0,93[0,82; 1,07]	0,3012	-0,03[-0,10; 0,03]	0,3012
PT: Appetit vermindert [a][d][h]	475	145[30,5]	469	141[30,1]	1,02[0,77; 1,35]	0,8772	1,02[0,84; 1,23]	0,8772	0,00[-0,05; 0,06]	0,8772
PT: Dehydratation [a][d][h]	475	15[3,2]	469	13[2,8]	1,14[0,54; 2,47]	0,7265	1,14[0,55; 2,41]	0,7265	0,00[-0,02; 0,03]	0,7265
PT: Eisenmangel [a][d][h]	475	10[2,1]	469	8[1,7]	1,24[0,48; 3,27]	0,6533	1,23[0,49; 3,21]	0,6533	0,00[-0,01; 0,02]	0,6533
PT: Hypalbuminaemie [a][d][h]	475	31[6,5]	469	39[8,3]	0,77[0,47; 1,25]	0,2937	0,78[0,49; 1,23]	0,2937	-0,02[-0,05; 0,02]	0,2937

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Hyperglykaemie [a][d][h]	475	15[3,2]	469	9[1,9]	1,67[0,73; 4,00]	0,2241	1,65[0,74; 3,88]	0,2241	0,01[-0,01; 0,03]	0,2241
PT: Hypoglykaemie [a][d][h]	475	10[2,1]	469	5[1,1]	2,00[0,70; 6,45]	0,1973	1,97[0,71; 6,30]	0,1973	0,01[-0,01; 0,03]	0,1973
PT: Hypokaliaemie [a][d][h]	475	39[8,2]	469	53[11,3]	0,70[0,45; 1,08]	0,1089	0,73[0,49; 1,07]	0,1089	-0,03[-0,07; 0,01]	0,1089
PT: Hypokalzaemie [a][d][h]	475	14[2,9]	469	21[4,5]	0,65[0,32; 1,28]	0,2121	0,66[0,33; 1,27]	0,2121	-0,02[-0,04; 0,01]	0,2121
PT: Hypomagnesiaemie [a][d][h]	475	7[1,5]	469	20[4,3]	0,34[0,13; 0,77]	0,0087 *	0,35[0,14; 0,77]	0,0087 *	-0,03[-0,05; -0,01]	0,0087 *
PT: Hyponatriaemie [a][d][h]	475	11[2,3]	469	11[2,3]	0,99[0,42; 2,33]	0,9759	0,99[0,43; 2,28]	0,9759	-0,00[-0,02; 0,02]	0,9759
PT: Hypophosphataemie [a][d][h]	475	9[1,9]	469	10[2,1]	0,89[0,35; 2,22]	0,7950	0,89[0,36; 2,19]	0,7950	-0,00[-0,02; 0,02]	0,7950
SOC: Untersuchungen [a][d][h]	475	247[52,0]	469	255[54,4]	0,91[0,70; 1,17]	0,4654	0,96[0,85; 1,08]	0,4654	-0,02[-0,09; 0,04]	0,4654

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Alaninaminotransferase erhoeht [a][d][h]	475	33[6,9]	469	25[5,3]	1,33[0,78; 2,29]	0,3002	1,30[0,79; 2,18]	0,3002	0,02[-0,01; 0,05]	0,3002
PT: Alkalische Phosphatase im Blut erhoeht [a][d][h]	475	19[4,0]	469	19[4,1]	0,99[0,51; 1,90]	0,9681	0,99[0,53; 1,85]	0,9681	-0,00[-0,03; 0,03]	0,9681
PT: Amylase erhoeht [a][d][h]	475	18[3,8]	469	10[2,1]	1,81[0,84; 4,11]	0,1307	1,78[0,85; 3,96]	0,1307	0,02[-0,01; 0,04]	0,1307
PT: Aspartataminotransferase erhoeht [a][d][h]	475	26[5,5]	469	22[4,7]	1,18[0,66; 2,12]	0,5839	1,17[0,67; 2,05]	0,5839	0,01[-0,02; 0,04]	0,5839
PT: Gamma-Glutamyltransferase erhoeht [a][d][h]	475	21[4,4]	469	21[4,5]	0,99[0,53; 1,84]	0,9664	0,99[0,54; 1,79]	0,9664	-0,00[-0,03; 0,03]	0,9664
PT: Gewicht erniedrigt [a][d][h]	475	71[14,9]	469	88[18,8]	0,76[0,54; 1,07]	0,1170	0,80[0,60; 1,06]	0,1170	-0,04[-0,09; 0,01]	0,1170

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
PT: Laktatdehydrogenase im Blut erhoeht [a][d][h]	475	16[3,4]	469	13[2,8]	1,22[0,58; 2,61]	0,5950	1,22[0,59; 2,54]	0,5950	0,01[-0,02; 0,03]	0,5950
PT: Leukozytenzahl erniedrigt [a][d][h]	475	46[9,7]	469	62[13,2]	0,70[0,47; 1,05]	0,0875	0,73[0,51; 1,05]	0,0875	-0,04[-0,08; 0,01]	0,0875
PT: Lipase erhoeht [a][d][h]	475	16[3,4]	469	11[2,3]	1,45[0,67; 3,25]	0,3443	1,44[0,68; 3,15]	0,3443	0,01[-0,01; 0,03]	0,3443
PT: Lymphozytenzahl erniedrigt [a][d][h]	475	10[2,1]	469	5[1,1]	2,00[0,70; 6,45]	0,1973	1,97[0,71; 6,30]	0,1973	0,01[-0,01; 0,03]	0,1973
PT: Neutrophilenzahl erniedrigt [a][d][h]	475	119[25,1]	469	138[29,4]	0,80[0,60; 1,07]	0,1312	0,85[0,69; 1,05]	0,1312	-0,04[-0,10; 0,01]	0,1312
PT: Thrombozytenzahl vermindert [a][d][h]	475	34[7,2]	469	27[5,8]	1,26[0,75; 2,14]	0,3808	1,24[0,76; 2,04]	0,3808	0,01[-0,02; 0,05]	0,3808

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.1 Summary of analysis (odds ratio, relative risk and risk differences) of AE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen [a][d][h]	475	113[23,8]	469	108[23,0]	1,04[0,77; 1,41]	0,7823	1,03[0,82; 1,30]	0,7823	0,01[-0,05; 0,06]	0,7823
PT: Reaktion im Zusammenhang mit einer Infusion [a][d][h]	475	33[6,9]	469	17[3,6]	1,99[1,10; 3,69]	0,0215 *	1,92[1,10; 3,47]	0,0215 *	0,03[0,005; 0,06]	0,0215 *
PT: Schmerzen waehrend eines Eingriffes [a][d][h]	475	34[7,2]	469	31[6,6]	1,09[0,66; 1,81]	0,7394	1,08[0,68; 1,74]	0,7394	0,01[-0,03; 0,04]	0,7394

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardae.sas gorrrardaeaaa 29JUN2026:08:36 khcs324

Table 5.1.2 Summary of analysis (odds ratio, relative risk and risk differences) of AE max CTCAE grade>=3 (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
UE mit CTCAE Grad >=3 [a][d][h]	475	367[77,3]	469	354[75,5]	1,10[0,82; 1,49]	0,5189	1,02[0,95; 1,10]	0,5189	0,02[-0,04; 0,07]	0,5189
G>=3 SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort [a][d][h]	475	34[7,2]	469	36[7,7]	0,93[0,57; 1,51]	0,7613	0,93[0,59; 1,47]	0,7613	-0,01[-0,04; 0,03]	0,7613
G>=3 PT: Asthenie [a][d][h]	475	15[3,2]	469	12[2,6]	1,24[0,58; 2,73]	0,5803	1,23[0,58; 2,66]	0,5803	0,01[-0,02; 0,03]	0,5803
G>=3 PT: Ermuedung [a][d][h]	475	9[1,9]	469	13[2,8]	0,68[0,28; 1,59]	0,3706	0,68[0,28; 1,57]	0,3706	-0,01[-0,03; 0,01]	0,3706
G>=3 SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums [a][d][h]	475	25[5,3]	469	26[5,5]	0,95[0,54; 1,67]	0,8488	0,95[0,55; 1,62]	0,8488	-0,00[-0,03; 0,03]	0,8488
G>=3 PT: Lungenembolie [a][d][h]	475	13[2,7]	469	5[1,1]	2,61[0,98; 8,19]	0,0561	2,57[0,98; 7,95]	0,0561	0,02[-0,00; 0,04]	0,0561

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardae.sas gorrrardaeaab 29JUN2026:08:36 khcs324

Table 5.1.2 Summary of analysis (odds ratio, relative risk and risk differences) of AE max CTCAE grade>=3 (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
G>=3 SOC: Erkrankungen der Nieren und Harnwege [a][d][h]	475	12[2,5]	469	7[1,5]	1,71[0,68; 4,63]	0,2552	1,69[0,69; 4,51]	0,2552	0,01[-0,01; 0,03]	0,2552
G>=3 SOC: Erkrankungen des Blutes und des Lymphsystems [a][d][h]	475	134[28,2]	469	138[29,4]	0,94[0,71; 1,25]	0,6806	0,96[0,78; 1,17]	0,6806	-0,01[-0,07; 0,05]	0,6806
G>=3 PT: Anaemie [a][d][h]	475	24[5,1]	469	24[5,1]	0,99[0,55; 1,77]	0,9639	0,99[0,57; 1,72]	0,9639	-0,00[-0,03; 0,03]	0,9639
G>=3 PT: Febrile Neutropenie [a][d][h]	475	17[3,6]	469	17[3,6]	0,99[0,49; 1,97]	0,9699	0,99[0,51; 1,92]	0,9699	-0,00[-0,02; 0,02]	0,9699
G>=3 PT: Neutropenie [a][d][h]	475	101[21,3]	469	104[22,2]	0,95[0,70; 1,29]	0,7341	0,96[0,75; 1,22]	0,7341	-0,01[-0,06; 0,04]	0,7341
G>=3 SOC: Erkrankungen des Gastrointestinaltrakts [a][d][h]	475	110[23,2]	469	84[17,9]	1,38[1,01; 1,90]	0,0458 *	1,29[1,005; 1,67]	0,0458 *	0,05[0,001; 0,10]	0,0458 *

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.2 Summary of analysis (odds ratio, relative risk and risk differences) of AE max CTCAE grade>=3 (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
G>=3 PT: Diarrhoe [a][d][h]	475	30[6,3]	469	28[6,0]	1,06[0,62; 1,81]	0,8250	1,06[0,64; 1,75]	0,8250	0,00[-0,03; 0,03]	0,8250
G>=3 PT: Erbrechen [a][d][h]	475	9[1,9]	469	14[3,0]	0,63[0,26; 1,45]	0,2755	0,63[0,27; 1,43]	0,2755	-0,01[-0,03; 0,01]	0,2755
G>=3 PT: Uebelkeit [a][d][h]	475	13[2,7]	469	7[1,5]	1,86[0,75; 4,98]	0,1809	1,83[0,76; 4,84]	0,1809	0,01[-0,01; 0,03]	0,1809
G>=3 SOC: Erkrankungen des Immunsystems [a][d][h]	475	13[2,7]	469	13[2,8]	0,99[0,45; 2,17]	0,9738	0,99[0,46; 2,13]	0,9738	-0,00[-0,02; 0,02]	0,9738
G>=3 SOC: Erkrankungen des Nervensystems [a][d][h]	475	35[7,4]	469	25[5,3]	1,41[0,84; 2,42]	0,1984	1,38[0,84; 2,30]	0,1984	0,02[-0,01; 0,05]	0,1984
G>=3 SOC: Gefaesserkrankungen [a][d][h]	475	14[2,9]	469	20[4,3]	0,68[0,33; 1,36]	0,2764	0,69[0,35; 1,34]	0,2764	-0,01[-0,04; 0,01]	0,2764
G>=3 SOC: Herzerkrankungen [a][d][h]	475	13[2,7]	469	13[2,8]	0,99[0,45; 2,17]	0,9738	0,99[0,46; 2,13]	0,9738	-0,00[-0,02; 0,02]	0,9738

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.2 Summary of analysis (odds ratio, relative risk and risk differences) of AE max CTCAE grade>=3 (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
G>=3 SOC: Infektionen und parasitaere Erkrankungen [a][d][h]	475	75[15,8]	469	58[12,4]	1,33[0,92; 1,93]	0,1302	1,28[0,93; 1,76]	0,1302	0,03[-0,01; 0,08]	0,1302
G>=3 PT: Pneumonie [a][d][h]	475	16[3,4]	469	14[3,0]	1,13[0,55; 2,38]	0,7370	1,13[0,56; 2,32]	0,7370	0,00[-0,02; 0,03]	0,7370
G>=3 SOC: Leber- und Gallenerkrankungen [a][d][h]	475	16[3,4]	469	14[3,0]	1,13[0,55; 2,38]	0,7370	1,13[0,56; 2,32]	0,7370	0,00[-0,02; 0,03]	0,7370
G>=3 SOC: Stoffwechsel- und Ernaehrungsstoerungen [a][d][h]	475	50[10,5]	469	31[6,6]	1,66[1,05; 2,68]	0,0309 *	1,59[1,04; 2,47]	0,0309 *	0,04[0,004; 0,08]	0,0309 *
G>=3 PT: Appetit vermindert [a][d][h]	475	15[3,2]	469	9[1,9]	1,67[0,73; 4,00]	0,2241	1,65[0,74; 3,88]	0,2241	0,01[-0,01; 0,03]	0,2241
G>=3 PT: Hypokaliaemie [a][d][h]	475	9[1,9]	469	10[2,1]	0,89[0,35; 2,22]	0,7950	0,89[0,36; 2,19]	0,7950	-0,00[-0,02; 0,02]	0,7950
G>=3 SOC: Untersuchungen [a][d][h]	475	125[26,3]	469	135[28,8]	0,88[0,66; 1,18]	0,3959	0,91[0,74; 1,12]	0,3959	-0,02[-0,08; 0,03]	0,3959

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.2 Summary of analysis (odds ratio, relative risk and risk differences) of AE max CTCAE grade>=3 (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
G>=3 PT: Gewicht erniedrigt [a][d][h]	475	10[2,1]	469	16[3,4]	0,61[0,26; 1,34]	0,2182	0,62[0,27; 1,33]	0,2182	-0,01[-0,04; 0,01]	0,2182
G>=3 PT: Leukozytenzahl erniedrigt [a][d][h]	475	25[5,3]	469	28[6,0]	0,88[0,50; 1,52]	0,6370	0,88[0,52; 1,49]	0,6370	-0,01[-0,04; 0,02]	0,6370
G>=3 PT: Neutrophilenzahl erniedrigt [a][d][h]	475	93[19,6]	469	105[22,4]	0,84[0,62; 1,15]	0,2891	0,87[0,68; 1,12]	0,2891	-0,03[-0,08; 0,02]	0,2891
G>=3 SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen [a][d][h]	475	33[6,9]	469	25[5,3]	1,33[0,78; 2,29]	0,3002	1,30[0,79; 2,18]	0,3002	0,02[-0,01; 0,05]	0,3002

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.3 Summary of analysis (odds ratio, relative risk and risk differences) of SAE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
SUE [a][d][h]	475	231[48,6]	469	207[44,1]	1,20[0,93; 1,55]	0,1661	1,10[0,96; 1,27]	0,1661	0,04[-0,02; 0,11]	0,1661
SUE SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort [a][d][h]	475	19[4,0]	469	15[3,2]	1,26[0,63; 2,55]	0,5081	1,25[0,64; 2,47]	0,5081	0,01[-0,02; 0,03]	0,5081
SUE SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums [a][d][h]	475	16[3,4]	469	18[3,8]	0,87[0,44; 1,74]	0,6986	0,88[0,45; 1,70]	0,6986	-0,00[-0,03; 0,02]	0,6986
SUE SOC: Erkrankungen der Nieren und Harnwege [a][d][h]	475	11[2,3]	469	6[1,3]	1,83[0,69; 5,35]	0,2276	1,81[0,69; 5,22]	0,2276	0,01[-0,01; 0,03]	0,2276
SUE SOC: Erkrankungen des Blutes und des Lymphsystems [a][d][h]	475	26[5,5]	469	25[5,3]	1,03[0,58; 1,82]	0,9225	1,03[0,60; 1,76]	0,9225	0,00[-0,03; 0,03]	0,9225

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.3 Summary of analysis (odds ratio, relative risk and risk differences) of SAE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
SUE PT: Febrile Neutropenie [a][d][h]	475	10[2,1]	469	15[3,2]	0,65[0,28; 1,45]	0,2942	0,66[0,29; 1,43]	0,2942	-0,01[-0,03; 0,01]	0,2942
SUE PT: Neutropenie [a][d][h]	475	10[2,1]	469	4[0,9]	2,50[0,83; 9,16]	0,1056	2,47[0,83; 8,95]	0,1056	0,01[-0,00; 0,03]	0,1056
SUE SOC: Erkrankungen des Gastrointestinaltrakts [a][d][h]	475	83[17,5]	469	72[15,4]	1,17[0,83; 1,65]	0,3787	1,14[0,85; 1,52]	0,3787	0,02[-0,03; 0,07]	0,3787
SUE PT: Diarrhoe [a][d][h]	475	9[1,9]	469	12[2,6]	0,74[0,30; 1,75]	0,4886	0,74[0,30; 1,73]	0,4886	-0,01[-0,03; 0,01]	0,4886
SUE PT: Erbrechen [a][d][h]	475	10[2,1]	469	10[2,1]	0,99[0,40; 2,43]	0,9771	0,99[0,41; 2,38]	0,9771	-0,00[-0,02; 0,02]	0,9771
SUE SOC: Gefaesserkrankungen [a][d][h]	475	5[1,1]	469	11[2,3]	0,44[0,14; 1,23]	0,1196	0,45[0,14; 1,22]	0,1196	-0,01[-0,03;0,003]	0,1196
SUE SOC: Herzerkrankungen [a][d][h]	475	11[2,3]	469	13[2,8]	0,83[0,36; 1,88]	0,6561	0,84[0,37; 1,85]	0,6561	-0,00[-0,03; 0,02]	0,6561

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardae.sas gorrrardaeaac 29JUN2026:08:36 khcs324

Table 5.1.3 Summary of analysis (odds ratio, relative risk and risk differences) of SAE (total, and by SOC and PT occurring with frequency >=10 patients and 1% in either arm) (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt								
					Odds Ratio		Relatives Risiko			Risikodifferenz			
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert		Schätzer [95%-KI]		2-seitiger p-Wert
SUE SOC: Infektionen und parasitaere Erkrankungen [a][d][h]	475	71[14,9]	469	64[13,6]	1,11[0,77; 1,60]	0,5679	1,10[0,80; 1,50]	0,5679		0,01[-0,03; 0,06]		0,5679
SUE PT: Pneumonie [a][d][h]	475	14[2,9]	469	16[3,4]	0,86[0,41; 1,79]	0,6843	0,86[0,42; 1,75]	0,6843		-0,00[-0,03; 0,02]		0,6843
SUE SOC: Leber- und Gallenerkrankungen [a][d][h]	475	8[1,7]	469	11[2,3]	0,71[0,27; 1,78]	0,4687	0,72[0,28; 1,76]	0,4687		-0,01[-0,03; 0,01]		0,4687
SUE SOC: Stoffwechsel- und Ernaehrungsstoerungen [a][d][h]	475	22[4,6]	469	10[2,1]	2,23[1,07; 4,97]	0,0317 *	2,17[1,07; 4,75]	0,0317 *		0,02[0,002; 0,05]		0,0317 *
SUE SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen [a][d][h]	475	26[5,5]	469	26[5,5]	0,99[0,56; 1,73]	0,9624	0,99[0,58; 1,68]	0,9624		-0,00[-0,03; 0,03]		0,9624

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.4 Summary of analysis (odds ratio, relative risk and risk differences) of AE leading to discontinuation of (>=1 component) of treatment (Safety)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Therapieabbruch aufgrund von UE [a][d][h]	475	143[30,1]	469	107[22,8]	1,46[1,09; 1,95]	0,0110 *	1,32[1,07; 1,64]	0,0110 *	0,07[0,02; 0,13]	0,0110 *

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. All models include treatment only.
[a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b].
[d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression.
[f] RR, 95% CI, p-value via modified Wald method. [g] RR NC via [d], [e] or [f]. [h] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [i] RD, 95% CI, p-value via Agresti-Caffo method. [j] RD NC via [h] or [i].
OR and RR<1, and RD <0 favours Durva. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardae.sas gorrrardaeaad 29JUN2026:08:36 khcs324

Table 5.1.5 Summary of adverse events leading to discontinuation of study treatment (Safety)
Safety Analysis Set, DCO 01SEP2025

System organ class / MedDRA Preferred term	Number (%) of patients	
	Durva + FLOT (N=475)	Placebo + FLOT (N=469)
Patienten mit Abbruch wegen UE	143 [30,1]	107 [22,8]
SOC: Allgemeine Erkrankungen und Beschwerden am Verabreichungsort	24 [5,1]	16 [3,4]
PT: Arzneimittelunvertraeglichkeit	2 [0,4]	1 [0,2]
PT: Asthenie	7 [1,5]	3 [0,6]
PT: Ermuedung	8 [1,7]	2 [0,4]
PT: Fieber	0	3 [0,6]
PT: Generelle Verschlechterung des physischen Gesundheitszustandes	3 [0,6]	2 [0,4]
PT: Polyserositis	0	1 [0,2]
PT: Schleimhautentzuendung	1 [0,2]	0
PT: Schuettelfrost	1 [0,2]	1 [0,2]
PT: Unwohlsein	2 [0,4]	2 [0,4]
PT: Zustand verschlimmert	0	1 [0,2]
SOC: Endokrine Erkrankungen	3 [0,6]	0
PT: Hypopituitarismus	2 [0,4]	0
PT: Nebenniereninsuffizienz	1 [0,2]	0
SOC: Erkrankungen der Atemwege, des Brustraums und Mediastinums	5 [1,1]	4 [0,9]
PT: Dyspnoe	0	1 [0,2]
PT: Interstitielle Lungenerkrankung	0	1 [0,2]
PT: Lungenembolie	1 [0,2]	0
PT: Pneumonitis	4 [0,8]	2 [0,4]
SOC: Erkrankungen der Haut und des Unterhautgewebes	9 [1,9]	4 [0,9]
PT: Ausschlag	4 [0,8]	0
PT: Ausschlag makulo-papuloes	0	1 [0,2]
PT: Hauthyperpigmentierung	0	1 [0,2]

Includes adverse events with onset date after first dose of study treatment until 28 days following the date of last dose of study treatment.
All AEs are coded using MedDRA version 28.0.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.5 Summary of adverse events leading to discontinuation of study treatment (Safety)
Safety Analysis Set, DCO 01SEP2025

System organ class / MedDRA Preferred term	Number (%) of patients	
	Durva + FLOT (N=475)	Placebo + FLOT (N=469)
PT: Medikamentenausschlag	1 [0,2]	0
PT: Nageldystrophie	0	1 [0,2]
PT: Palmar-plantares Erythrodysaesthesiesyndrom	2 [0,4]	1 [0,2]
PT: Pruritus	1 [0,2]	0
PT: Stevens-Johnson-Syndrom	1 [0,2]	0
PT: Urtikaria	1 [0,2]	0
PT: Xeroderma	0	1 [0,2]
SOC: Erkrankungen der Nieren und Harnwege	5 [1,1]	0
PT: Akute Nierenschaedigung	1 [0,2]	0
PT: Autoimmune Nephritis	1 [0,2]	0
PT: Immunvermittelte Nephritis	2 [0,4]	0
PT: Nierenversagen	1 [0,2]	0
SOC: Erkrankungen des Blutes und des Lymphsystems	17 [3,6]	6 [1,3]
PT: Anaemie	1 [0,2]	0
PT: Febrile Neutropenie	2 [0,4]	1 [0,2]
PT: Leukopenie	1 [0,2]	0
PT: Neutropenie	14 [2,9]	5 [1,1]
SOC: Erkrankungen des Gastrointestinaltrakts	19 [4,0]	17 [3,6]
PT: Bauch aufgetrieben	0	1 [0,2]
PT: Diaphragmahernie	0	1 [0,2]
PT: Diarrhoe	6 [1,3]	7 [1,5]
PT: Duenndarmfistel	1 [0,2]	0
PT: Dysphagie	1 [0,2]	0
PT: Erbrechen	3 [0,6]	2 [0,4]
PT: Intraabdominelle Fluessigkeitsansammlung	1 [0,2]	1 [0,2]
PT: Kolitis	2 [0,4]	2 [0,4]

Includes adverse events with onset date after first dose of study treatment until 28 days following the date of last dose of study treatment.
All AEs are coded using MedDRA version 28.0.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.5 Summary of adverse events leading to discontinuation of study treatment (Safety)
Safety Analysis Set, DCO 01SEP2025

System organ class / MedDRA Preferred term	Number (%) of patients	
	Durva + FLOT (N=475)	Placebo + FLOT (N=469)
PT: Magenstenose	1 [0,2]	0
PT: Mundtrockenheit	1 [0,2]	0
PT: Obstruktion des Magens	1 [0,2]	0
PT: Stomatitis	1 [0,2]	1 [0,2]
PT: Thrombose einer Mesenterialarterie	1 [0,2]	0
PT: Uebelkeit	6 [1,3]	4 [0,9]
SOC: Erkrankungen des Immunsystems	14 [2,9]	9 [1,9]
PT: Anaphylaktische Reaktion	2 [0,4]	1 [0,2]
PT: Anaphylaktischer Schock	1 [0,2]	1 [0,2]
PT: Arzneimittelueberempfindlichkeit	6 [1,3]	5 [1,1]
PT: Ueberempfindlichkeit	5 [1,1]	2 [0,4]
SOC: Erkrankungen des Nervensystems	34 [7,2]	34 [7,2]
PT: Apoplektischer Insult	0	1 [0,2]
PT: Dysaesthesie	0	1 [0,2]
PT: Dysarthrie	1 [0,2]	0
PT: Dysgeusie	0	1 [0,2]
PT: Gleichgewichtsstoerung	1 [0,2]	0
PT: Guillain-Barré-Syndrom	1 [0,2]	0
PT: Hypoaesthesie	0	1 [0,2]
PT: Ischaemischer Schlaganfall	1 [0,2]	0
PT: Neurotoxizitaet	3 [0,6]	0
PT: Paraesthesie	4 [0,8]	3 [0,6]
PT: Periphere Neuropathie	10 [2,1]	8 [1,7]
PT: Periphere sensorische Neuropathie	12 [2,5]	16 [3,4]
PT: Polyneuropathie	3 [0,6]	3 [0,6]
SOC: Gefaesserkrankungen	1 [0,2]	1 [0,2]

Includes adverse events with onset date after first dose of study treatment until 28 days following the date of last dose of study treatment.
All AEs are coded using MedDRA version 28.0.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/aediscsum.sas gaediscsuma 12FEB2026:09:39 khsk849

Table 5.1.5 Summary of adverse events leading to discontinuation of study treatment (Safety)
Safety Analysis Set, DCO 01SEP2025

System organ class / MedDRA Preferred term	Number (%) of patients	
	Durva + FLOT (N=475)	Placebo + FLOT (N=469)
PT: Haemorrhagischer Schock	1 [0,2]	0
PT: Hypotonie	0	1 [0,2]
SOC: Gutartige, boesartige und nicht spezifizierte Neubildungen (einschl. Zysten und Polypen)	1 [0,2]	0
PT: Gemischtes adenoneuroendokrines Karzinom	1 [0,2]	0
SOC: Herzerkrankungen	1 [0,2]	2 [0,4]
PT: Herzinsuffizienz	1 [0,2]	1 [0,2]
PT: Perikarderguss	0	1 [0,2]
SOC: Infektionen und parasitaere Erkrankungen	11 [2,3]	7 [1,5]
PT: Aspirationspneumonie	1 [0,2]	0
PT: Infektioese Enterokolitis	1 [0,2]	0
PT: Infektion der oberen Atemwege	1 [0,2]	0
PT: Infektion im Zusammenhang mit einem Medizinprodukt	1 [0,2]	1 [0,2]
PT: Leberabszess	0	2 [0,4]
PT: Pneumonie	2 [0,4]	2 [0,4]
PT: Reaktivierung einer Hepatitis B	0	1 [0,2]
PT: Sepsis	2 [0,4]	0
PT: Sepsis durch Staphylokokken	1 [0,2]	0
PT: Septischer Schock	2 [0,4]	0
PT: Wundinfektion	0	1 [0,2]
SOC: Leber- und Gallenerkrankungen	8 [1,7]	8 [1,7]
PT: Arzneimittelbedingter Leberschaden	1 [0,2]	1 [0,2]
PT: Autoimmune Hepatitis	0	1 [0,2]
PT: Gallenblasenvergroesserung	1 [0,2]	0
PT: Hepatitis	1 [0,2]	2 [0,4]

Includes adverse events with onset date after first dose of study treatment until 28 days following the date of last dose of study treatment.
All AEs are coded using MedDRA version 28.0.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.5 Summary of adverse events leading to discontinuation of study treatment (Safety)
Safety Analysis Set, DCO 01SEP2025

System organ class / MedDRA Preferred term	Number (%) of patients	
	Durva + FLOT (N=475)	Placebo + FLOT (N=469)
PT: Immunvermittelte Hepatitis	3 [0,6]	1 [0,2]
PT: Immunvermittelte Leberkrankheit	0	1 [0,2]
PT: Leberfunktion anomal	0	1 [0,2]
PT: Lebertoxizitaet	1 [0,2]	1 [0,2]
PT: Leberzirrhose	1 [0,2]	0
SOC: Psychiatrische Erkrankungen	0	1 [0,2]
PT: Depression	0	1 [0,2]
SOC: Skelettmuskulatur-, Bindegewebs- und Knochenerkrankungen	3 [0,6]	1 [0,2]
PT: Arthritis	0	1 [0,2]
PT: Myalgie	1 [0,2]	0
PT: Myositis	1 [0,2]	0
PT: Polyarthritis	1 [0,2]	0
PT: Tenosynovitis	1 [0,2]	0
SOC: Stoffwechsel- und Ernaehrungsstoerungen	7 [1,5]	2 [0,4]
PT: Appetit vermindert	5 [1,1]	2 [0,4]
PT: Diabetes mellitus Typ 1	1 [0,2]	0
PT: Diabetische Ketoazidose	2 [0,4]	0
SOC: Untersuchungen	2 [0,4]	8 [1,7]
PT: Alaninaminotransferase erhoeht	0	1 [0,2]
PT: Aspartataminotransferase erhoeht	1 [0,2]	1 [0,2]
PT: Gewicht erniedrigt	0	2 [0,4]
PT: Kreatinin im Blut erhoeht	0	1 [0,2]
PT: Neutrophilenzahl erniedrigt	1 [0,2]	3 [0,6]
SOC: Verletzung, Vergiftung und durch Eingriffe bedingte Komplikationen	15 [3,2]	7 [1,5]

Includes adverse events with onset date after first dose of study treatment until 28 days following the date of last dose of study treatment.
All AEs are coded using MedDRA version 28.0.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.1.5 Summary of adverse events leading to discontinuation of study treatment (Safety)
Safety Analysis Set, DCO 01SEP2025

System organ class / MedDRA Preferred term	Number (%) of patients	
	Durva + FLOT (N=475)	Placebo + FLOT (N=469)
PT: Anastomose misslungen	1 [0,2]	1 [0,2]
PT: Fistel nach einem Eingriff	1 [0,2]	0
PT: Reaktion im Zusammenhang mit einer Infusion	13 [2,7]	5 [1,1]
PT: Wunddehiszenz	0	1 [0,2]

Includes adverse events with onset date after first dose of study treatment until 28 days following the date of last dose of study treatment.
All AEs are coded using MedDRA version 28.0.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.1 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of AE (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [b][e][h]	90	89[98,9]	88	88[100]	0,34[0,00; 6,41]	0,4766	0,99[0,97; 1,01]	0,3160	NC	NC
Nicht-Asien [a][d][g]	385	382[99,2]	381	375[98,4]	2,04[0,53; 9,71]	0,3025	1,01[0,99; 1,03]	0,3025	0,01[-0,01; 0,03]	0,3025
Int. p-Wert [b][e][h]						0,7786		0,1593		NC
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	328[99,4]	325	321[98,8]	2,04[0,40; 14,81]	0,3972	1,01[0,99; 1,02]	0,3972	0,01[-0,01; 0,02]	0,3972
Negativ [a][d][g]	145	143[98,6]	144	142[98,6]	1,01[0,12; 8,48]	0,9944	1,00[0,97; 1,03]	0,9944	0,00[-0,03; 0,03]	0,9944
Int. p-Wert [a][d][g]						0,5932		0,6965		0,6953
PD-L1-Status										
TAP >= 1% [a][d][g]	427	424[99,3]	422	417[98,8]	1,69[0,41; 8,30]	0,4649	1,00[0,99; 1,02]	0,4649	0,00[-0,01; 0,02]	0,4649
TAP < 1% [a][d][g]	48	47[97,9]	47	46[97,9]	1,02[0,04; 26,33]	0,9880	1,00[0,93; 1,08]	0,9880	0,00[-0,07; 0,08]	0,9880
Int. p-Wert [a][d][g]						0,7532		0,8865		0,8851

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.1 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of AE (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	289[99,3]	264	261[98,9]	1,66[0,27; 12,68]	0,5756	1,00[0,99; 1,02]	0,5756	0,00[-0,01; 0,02]	0,5756
>=65 [a][d][g]	184	182[98,9]	205	202[98,5]	1,35[0,22; 10,34]	0,7410	1,00[0,98; 1,03]	0,7410	0,00[-0,02; 0,03]	0,7410
Int. p-Wert [a][d][g]						0,8738		0,9594		0,9585
Geschlecht										
Männlich [a][d][g]	327	324[99,1]	351	346[98,6]	1,56[0,38; 7,66]	0,5386	1,01[0,99; 1,02]	0,5386	0,01[-0,01; 0,02]	0,5386
Weiblich [a][d][g]	148	147[99,3]	118	117[99,2]	1,26[0,05; 31,97]	0,8724	1,00[0,98; 1,03]	0,8724	0,00[-0,02; 0,03]	0,8724
Int. p-Wert [a][d][g]						0,8921		0,8064		0,8072
Tumorlokalisation										
GC [a][d][g]	325	323[99,4]	313	308[98,4]	2,62[0,56; 18,39]	0,2271	1,01[0,99; 1,03]	0,2271	0,01[-0,01; 0,03]	0,2271
GEJC [a][d][g]	150	148[98,7]	156	155[99,4]	0,48[0,02; 5,03]	0,5355	0,99[0,96; 1,02]	0,5355	-0,01[-0,04; 0,02]	0,5355
Int. p-Wert [a][d][g]						0,2357		0,2314		0,2313

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.2 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Asthenia (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	8[8,9]	88	4[4,5]	2,05[0,62; 7,92]	0,2434	1,96[0,64; 7,11]	0,2434	0,04[-0,03; 0,12]	0,2434
Nicht-Asien [a][d][g]	385	87[22,6]	381	67[17,6]	1,37[0,96; 1,96]	0,0832	1,29[0,97; 1,72]	0,0832	0,05[-0,01; 0,11]	0,0832
Int. p-Wert [a][d][g]						0,5330		0,4834		0,8875
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	68[20,6]	325	44[13,5]	1,66[1,10; 2,52]	0,0159 *	1,52[1,08; 2,17]	0,0159 *	0,07[0,01; 0,13]	0,0159 *
Negativ [a][d][g]	145	27[18,6]	144	27[18,8]	0,99[0,55; 1,80]	0,9775	0,99[0,61; 1,61]	0,9775	-0,00[-0,09; 0,09]	0,9775
Int. p-Wert [a][d][g]						0,1632		0,1581		0,1862
PD-L1-Status										
TAP >= 1% [a][d][g]	427	80[18,7]	422	64[15,2]	1,29[0,90; 1,85]	0,1655	1,24[0,92; 1,67]	0,1655	0,04[-0,01; 0,09]	0,1655
TAP < 1% [a][d][g]	48	15[31,3]	47	7[14,9]	2,60[0,97; 7,51]	0,0565	2,10[0,98; 5,07]	0,0565	0,16[-0,00; 0,33]	0,0565
Int. p-Wert [a][d][g]						0,1922		0,2105		0,1514

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.2 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Asthenia (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	60[20,6]	264	44[16,7]	1,30[0,85; 2,01]	0,2325	1,24[0,87; 1,77]	0,2325	0,04[-0,03; 0,10]	0,2325
>=65 [a][d][g]	184	35[19,0]	205	27[13,2]	1,55[0,90; 2,69]	0,1156	1,44[0,91; 2,31]	0,1156	0,06[-0,01; 0,13]	0,1156
Int. p-Wert [a][d][g]						0,6202		0,6004		0,7029
Geschlecht										
Männlich [a][d][g]	327	64[19,6]	351	53[15,1]	1,37[0,92; 2,05]	0,1236	1,30[0,93; 1,81]	0,1236	0,04[-0,01; 0,10]	0,1236
Weiblich [a][d][g]	148	31[20,9]	118	18[15,3]	1,47[0,78; 2,83]	0,2313	1,37[0,82; 2,38]	0,2313	0,06[-0,04; 0,15]	0,2313
Int. p-Wert [a][d][g]						0,8492		0,8559		0,8257
Tumorlokalisation										
GC [a][d][g]	325	69[21,2]	313	55[17,6]	1,26[0,85; 1,88]	0,2425	1,21[0,88; 1,67]	0,2425	0,04[-0,02; 0,10]	0,2425
GEJC [a][d][g]	150	26[17,3]	156	16[10,3]	1,83[0,95; 3,64]	0,0711	1,69[0,96; 3,09]	0,0711	0,07[-0,01; 0,15]	0,0711
Int. p-Wert [a][d][g]						0,3444		0,3169		0,4955

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.3 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Pyrexia (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	34[37,8]	88	27[30,7]	1,37[0,74; 2,57]	0,3182	1,23[0,82; 1,88]	0,3182	0,07[-0,07; 0,21]	0,3182
Nicht-Asien [a][d][g]	385	61[15,8]	381	44[11,5]	1,44[0,95; 2,20]	0,0833	1,37[0,96; 1,98]	0,0833	0,04[-0,01; 0,09]	0,0833
Int. p-Wert [a][d][g]						0,8959		0,6985		0,7096
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	67[20,3]	325	49[15,1]	1,43[0,96; 2,16]	0,0793	1,35[0,97; 1,89]	0,0793	0,05[-0,01; 0,11]	0,0793
Negativ [a][d][g]	145	28[19,3]	144	22[15,3]	1,33[0,72; 2,47]	0,3643	1,26[0,76; 2,13]	0,3643	0,04[-0,05; 0,13]	0,3643
Int. p-Wert [a][d][g]						0,8351		0,8385		0,8233
PD-L1-Status										
TAP >= 1% [a][d][g]	427	83[19,4]	422	65[15,4]	1,33[0,93; 1,90]	0,1209	1,26[0,94; 1,70]	0,1209	0,04[-0,01; 0,09]	0,1209
TAP < 1% [a][d][g]	48	12[25,0]	47	6[12,8]	2,28[0,80; 7,12]	0,1250	1,96[0,83; 5,23]	0,1250	0,12[-0,03; 0,28]	0,1250
Int. p-Wert [a][d][g]						0,3427		0,3485		0,3261

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.3 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Pyrexia (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	64[22,0]	264	40[15,2]	1,58[1,02; 2,46]	0,0382 *	1,45[1,02; 2,10]	0,0382 *	0,07[0,004; 0,13]	0,0382 *
>=65 [a][d][g]	184	31[16,8]	205	31[15,1]	1,14[0,66; 1,96]	0,6426	1,11[0,70; 1,76]	0,6426	0,02[-0,06; 0,09]	0,6426
Int. p-Wert [a][d][g]						0,3555		0,3707		0,3041
Geschlecht										
Männlich [a][d][g]	327	68[20,8]	351	56[16,0]	1,38[0,94; 2,05]	0,1033	1,30[0,95; 1,80]	0,1033	0,05[-0,01; 0,11]	0,1033
Weiblich [a][d][g]	148	27[18,2]	118	15[12,7]	1,53[0,78; 3,10]	0,2155	1,44[0,81; 2,65]	0,2155	0,06[-0,03; 0,14]	0,2155
Int. p-Wert [a][d][g]						0,7985		0,7759		0,8968
Tumorlokalisation										
GC [a][d][g]	325	63[19,4]	313	51[16,3]	1,24[0,82; 1,86]	0,3079	1,19[0,85; 1,67]	0,3079	0,03[-0,03; 0,09]	0,3079
GEJC [a][d][g]	150	32[21,3]	156	20[12,8]	1,84[1,01; 3,44]	0,0468 *	1,66[1,01; 2,83]	0,0468 *	0,09[0,001; 0,17]	0,0468 *
Int. p-Wert [a][d][g]						0,2826		0,2790		0,3007

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.4 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of SOC: Endocrine disorders (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	11[12,2]	88	4[4,5]	2,92[0,96; 10,89]	0,0603	2,69[0,96; 9,42]	0,0603	0,08[-0,00; 0,16]	0,0603
Nicht-Asien [a][d][g]	385	56[14,5]	381	17[4,5]	3,64[2,12; 6,58]	<0,0001 *	3,26[1,98; 5,68]	<0,0001 *	0,10[0,06; 0,14]	<0,0001 *
Int. p-Wert [a][d][g]						0,7445		0,7604		0,6046
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	46[13,9]	325	16[4,9]	3,13[1,77; 5,81]	<0,0001 *	2,83[1,68; 5,06]	<0,0001 *	0,09[0,05; 0,14]	<0,0001 *
Negativ [a][d][g]	145	21[14,5]	144	5[3,5]	4,71[1,85; 14,43]	0,0007 *	4,17[1,76; 12,23]	0,0007 *	0,11[0,05; 0,18]	0,0007 *
Int. p-Wert [a][d][g]						0,4844		0,4787		0,6156
PD-L1-Status										
TAP >= 1% [a][d][g]	427	55[12,9]	422	21[5,0]	2,82[1,70; 4,86]	<0,0001 *	2,59[1,62; 4,30]	<0,0001 *	0,08[0,04; 0,12]	<0,0001 *
TAP < 1% [b][f][h]	48	12[25,0]	47	0	32,54[4,04;4219,22]	<0,0001 *	NC	NC	NC	NC
Int. p-Wert [b][f][h]						0,0152 *		NC		NC

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.4 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of SOC: Endocrine disorders (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	45[15,5]	264	9[3,4]	5,18[2,60; 11,53]	<0,0001 *	4,54[2,38; 9,76]	<0,0001 *	0,12[0,07; 0,17]	<0,0001 *
>=65 [a][d][g]	184	22[12,0]	205	12[5,9]	2,18[1,07; 4,68]	0,0327 *	2,04[1,06; 4,15]	0,0327 *	0,06[0,01; 0,12]	0,0327 *
Int. p-Wert [a][d][g]						0,1008		0,1037		0,1173
Geschlecht										
Männlich [a][d][g]	327	40[12,2]	351	17[4,8]	2,74[1,54; 5,05]	0,0005 *	2,53[1,49; 4,49]	0,0005 *	0,07[0,03; 0,12]	0,0005 *
Weiblich [a][d][g]	148	27[18,2]	118	4[3,4]	6,36[2,39; 22,01]	<0,0001 *	5,38[2,18; 17,83]	<0,0001 *	0,15[0,08; 0,22]	<0,0001 *
Int. p-Wert [a][d][g]						0,1598		0,1768		0,0727
Tumorlokalisation										
GC [a][d][g]	325	46[14,2]	313	13[4,2]	3,80[2,07; 7,48]	<0,0001 *	3,41[1,94; 6,46]	<0,0001 *	0,10[0,06; 0,15]	<0,0001 *
GEJC [a][d][g]	150	21[14,0]	156	8[5,1]	3,01[1,34; 7,45]	0,0072 *	2,73[1,30; 6,39]	0,0072 *	0,09[0,02; 0,16]	0,0072 *
Int. p-Wert [a][d][g]						0,6669		0,6603		0,7794

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaad 29JUN2026:08:39 khcs324

Table 5.2.5 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Hyperthyroidism (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [b][f][h]	90	0	88	1[1,1]	0,32[0,00; 6,12]	0,4577	NC	NC	NC	NC
Nicht-Asien [b][d][g]	385	21[5,5]	381	7[1,8]	2,95[1,32; 7,33]	0,0074 *	2,97[1,34; 7,46]	0,0064 *	0,04[0,01; 0,06]	0,0064 *
Int. p-Wert [b][f][h]						0,3365		NC		NC
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	15[4,5]	325	5[1,5]	3,05[1,17; 9,46]	0,0222 *	2,95[1,16; 9,00]	0,0222 *	0,03[0,004; 0,06]	0,0222 *
Negativ [a][d][g]	145	6[4,1]	144	3[2,1]	2,03[0,52; 9,76]	0,3101	1,99[0,53; 9,27]	0,3101	0,02[-0,02; 0,07]	0,3101
Int. p-Wert [a][d][g]						0,6487		0,6482		0,6978
PD-L1-Status										
TAP >= 1% [b][d][g]	427	17[4,0]	422	8[1,9]	2,08[0,93; 5,02]	0,0750	2,10[0,94; 5,10]	0,0691	0,02[-0,00; 0,04]	0,0691
TAP < 1% [b][f][h]	48	4[8,3]	47	0	9,61[0,98;1286,87]	0,0522	NC	NC	NC	NC
Int. p-Wert [b][f][h]						0,3038		NC		NC

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.5 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Hyperthyroidism (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	15[5,2]	264	4[1,5]	3,53[1,26; 12,52]	0,0147 *	3,40[1,25; 11,82]	0,0147 *	0,04[0,01; 0,07]	0,0147 *
>=65 [a][d][g]	184	6[3,3]	205	4[2,0]	1,69[0,48; 6,71]	0,4148	1,67[0,48; 6,45]	0,4148	0,01[-0,02; 0,05]	0,4148
Int. p-Wert [a][d][g]						0,3959		0,4002		0,2987
Geschlecht										
Männlich [a][d][g]	327	13[4,0]	351	7[2,0]	2,03[0,82; 5,47]	0,1256	1,99[0,83; 5,25]	0,1256	0,02[-0,01; 0,05]	0,1256
Weiblich [a][d][g]	148	8[5,4]	118	1[0,8]	6,69[1,20;124,92]	0,0274 *	6,38[1,19;117,46]	0,0274 *	0,05[0,01; 0,09]	0,0274 *
Int. p-Wert [a][d][g]						0,2648		0,2658		0,2797
Tumorlokalisation										
GC [a][d][g]	325	9[2,8]	313	4[1,3]	2,20[0,71; 8,19]	0,1766	2,17[0,71; 7,93]	0,1766	0,01[-0,01; 0,04]	0,1766
GEJC [a][d][g]	150	12[8,0]	156	4[2,6]	3,30[1,12; 12,04]	0,0294 *	3,12[1,11; 10,97]	0,0294 *	0,05[0,01; 0,11]	0,0294 *
Int. p-Wert [a][d][g]						0,6306		0,6574		0,1481

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaae 29JUN2026:08:39 khcs324

Table 5.2.6 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Hypothyroidism (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	4[4,4]	88	1[1,1]	4,05[0,58; 79,96]	0,1669	3,91[0,59; 75,65]	0,1669	0,03[-0,02; 0,09]	0,1669
Nicht-Asien [a][d][g]	385	33[8,6]	381	7[1,8]	5,01[2,32; 12,47]	<0,0001 *	4,67[2,22; 11,38]	<0,0001 *	0,07[0,04; 0,10]	<0,0001 *
Int. p-Wert [a][d][g]						0,8616		0,8830		0,2696
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	28[8,5]	325	7[2,2]	4,21[1,91; 10,61]	0,0002 *	3,94[1,85; 9,69]	0,0002 *	0,06[0,03; 0,10]	0,0002 *
Negativ [a][d][g]	145	9[6,2]	144	1[0,7]	9,46[1,74;175,63]	0,0061 *	8,94[1,71;163,70]	0,0061 *	0,06[0,02; 0,10]	0,0061 *
Int. p-Wert [a][d][g]						0,4478		0,4323		0,7669
PD-L1-Status										
TAP >= 1% [a][d][g]	427	32[7,5]	422	8[1,9]	4,19[2,00; 9,87]	<0,0001 *	3,95[1,94; 9,13]	<0,0001 *	0,06[0,03; 0,09]	<0,0001 *
TAP < 1% [b][f][h]	48	5[10,4]	47	0	12,01[1,30;1594,14]	0,0247 *	NC	NC	NC	NC
Int. p-Wert [b][f][h]						0,5597		NC		NC

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.6 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Hypothyroidism (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	24[8,2]	264	2[0,8]	11,78[3,45; 73,71]	<0,0001 *	10,89[3,28; 67,32]	<0,0001 *	0,07[0,04; 0,11]	<0,0001 *
>=65 [a][d][g]	184	13[7,1]	205	6[2,9]	2,52[0,97; 7,31]	0,0568	2,41[0,98; 6,75]	0,0568	0,04[-0,00; 0,09]	0,0568
Int. p-Wert [a][d][g]						0,0662		0,0650		0,2376
Geschlecht										
Männlich [a][d][g]	327	22[6,7]	351	6[1,7]	4,15[1,76; 11,38]	0,0008 *	3,94[1,72; 10,58]	0,0008 *	0,05[0,02; 0,08]	0,0008 *
Weiblich [a][d][g]	148	15[10,1]	118	2[1,7]	6,54[1,80; 42,05]	0,0027 *	5,98[1,73; 37,46]	0,0027 *	0,08[0,03; 0,14]	0,0027 *
Int. p-Wert [a][d][g]						0,6021		0,6223		0,2723
Tumorlokalisation										
GC [a][d][g]	325	24[7,4]	313	6[1,9]	4,08[1,75; 11,14]	0,0007 *	3,85[1,71; 10,29]	0,0007 *	0,05[0,02; 0,09]	0,0007 *
GEJC [a][d][g]	150	13[8,7]	156	2[1,3]	7,31[1,97; 47,25]	0,0017 *	6,76[1,91; 42,76]	0,0017 *	0,07[0,03; 0,13]	0,0017 *
Int. p-Wert [a][d][g]						0,5038		0,5074		0,5117

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.7 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Pulmonary embolism (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [c][f][h]	90	0	88	0	NC	NC	NC	NC	NC	NC
Nicht-Asien [b][d][g]	385	20[5,2]	381	9[2,4]	2,20[1,03; 5,03]	0,0410 *	2,20[1,05; 5,02]	0,0376 *	0,03[0,002; 0,06]	0,0376 *
Int. p-Wert [b][f][h]						0,1894		NC		NC
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	14[4,2]	325	7[2,2]	2,01[0,83; 5,37]	0,1255	1,97[0,83; 5,14]	0,1255	0,02[-0,01; 0,05]	0,1255
Negativ [a][d][g]	145	6[4,1]	144	2[1,4]	3,06[0,69; 21,15]	0,1452	2,98[0,70; 20,10]	0,1452	0,03[-0,01; 0,07]	0,1452
Int. p-Wert [a][d][g]						0,6526		0,6499		0,7783
PD-L1-Status										
TAP >= 1% [b][d][g]	427	20[4,7]	422	9[2,1]	2,19[1,03; 5,00]	0,0418 *	2,20[1,04; 5,02]	0,0383 *	0,03[0,001; 0,05]	0,0383 *
TAP < 1% [c][f][h]	48	0	47	0	NC	NC	NC	NC	NC	NC
Int. p-Wert [b][f][h]						0,1881		NC		NC

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.7 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Pulmonary embolism (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	7[2,4]	264	5[1,9]	1,28[0,40; 4,36]	0,6781	1,27[0,41; 4,25]	0,6781	0,01[-0,02; 0,03]	0,6781
>=65 [a][d][g]	184	13[7,1]	205	4[2,0]	3,82[1,32; 13,76]	0,0120 *	3,62[1,31; 12,68]	0,0120 *	0,05[0,01; 0,10]	0,0120 *
Int. p-Wert [a][d][g]						0,1836		0,1916		0,0537
Geschlecht										
Männlich [a][d][g]	327	12[3,7]	351	7[2,0]	1,87[0,74; 5,09]	0,1848	1,84[0,75; 4,89]	0,1848	0,02[-0,01; 0,04]	0,1848
Weiblich [a][d][g]	148	8[5,4]	118	2[1,7]	3,31[0,81; 22,24]	0,0993	3,19[0,82; 20,87]	0,0993	0,04[-0,01; 0,09]	0,0993
Int. p-Wert [a][d][g]						0,5309		0,5353		0,4232
Tumorlokalisation										
GC [a][d][g]	325	14[4,3]	313	3[1,0]	4,65[1,50; 20,32]	0,0062 *	4,49[1,48; 19,36]	0,0062 *	0,03[0,01; 0,06]	0,0062 *
GEJC [a][d][g]	150	6[4,0]	156	6[3,8]	1,04[0,32; 3,40]	0,9448	1,04[0,33; 3,26]	0,9447	0,00[-0,04; 0,05]	0,9447
Int. p-Wert [a][d][g]						0,0758		0,0738		0,2166

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.8 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Pleural effusion (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [b][d][g]	90	1[1,1]	88	1[1,1]	0,98[0,08; 12,21]	0,9845	0,98[0,04; 24,45]	0,9872	-0,00[-0,04; 0,04]	0,9872
Nicht-Asien [b][d][g]	385	13[3,4]	381	28[7,3]	0,45[0,22; 0,86]	0,0147 *	0,46[0,23; 0,85]	0,0136 *	-0,04[-0,07; -0,01]	0,0136 *
Int. p-Wert [b][d][g]						0,6706		0,6046		0,1053
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	10[3,0]	325	25[7,7]	0,38[0,17; 0,77]	0,0071 *	0,39[0,18; 0,78]	0,0071 *	-0,05[-0,08; -0,01]	0,0071 *
Negativ [a][d][g]	145	4[2,8]	144	4[2,8]	0,99[0,23; 4,27]	0,9921	0,99[0,24; 4,13]	0,9921	-0,00[-0,04; 0,04]	0,9921
Int. p-Wert [a][d][g]						0,2337		0,2433		0,0808
PD-L1-Status										
TAP >= 1% [a][d][g]	427	13[3,0]	422	25[5,9]	0,50[0,24; 0,97]	0,0409 *	0,51[0,26; 0,97]	0,0409 *	-0,03[-0,06; -0,00]	0,0409 *
TAP < 1% [a][d][g]	48	1[2,1]	47	4[8,5]	0,23[0,01; 1,62]	0,1478	0,24[0,01; 1,58]	0,1478	-0,06[-0,17; 0,03]	0,1478
Int. p-Wert [a][d][g]						0,4893		0,4930		0,4430

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.8 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Pleural effusion (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	11[3,8]	264	13[4,9]	0,76[0,33; 1,73]	0,5084	0,77[0,34; 1,69]	0,5084	-0,01[-0,05; 0,02]	0,5084
>=65 [a][d][g]	184	3[1,6]	205	16[7,8]	0,20[0,05; 0,60]	0,0030 *	0,21[0,05; 0,61]	0,0030 *	-0,06[-0,11; -0,02]	0,0030 *
Int. p-Wert [a][d][g]						0,0603		0,0610		0,0628
Geschlecht										
Männlich [a][d][g]	327	11[3,4]	351	23[6,6]	0,50[0,23; 1,01]	0,0544	0,51[0,24; 1,01]	0,0544	-0,03[-0,07;0,001]	0,0544
Weiblich [a][d][g]	148	3[2,0]	118	6[5,1]	0,39[0,08; 1,50]	0,1706	0,40[0,09; 1,48]	0,1706	-0,03[-0,08; 0,01]	0,1706
Int. p-Wert [a][d][g]						0,7550		0,7448		0,9635
Tumorlokalisation										
GC [a][d][g]	325	2[0,6]	313	6[1,9]	0,32[0,05; 1,39]	0,1316	0,32[0,05; 1,38]	0,1316	-0,01[-0,03;0,004]	0,1316
GEJC [a][d][g]	150	12[8,0]	156	23[14,7]	0,50[0,23; 1,03]	0,0617	0,54[0,27; 1,03]	0,0617	-0,07[-0,14;0,003]	0,0617
Int. p-Wert [a][d][g]						0,6005		0,5393		0,1425

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaah 29JUN2026:08:39 khcs324

Table 5.2.9 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Pneumonitis (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [b][d][g]	90	2[2,2]	88	2[2,3]	0,98[0,15; 6,46]	0,9799	0,98[0,12; 8,00]	0,9819	-0,00[-0,05; 0,05]	0,9819
Nicht-Asien [b][d][g]	385	13[3,4]	381	3[0,8]	3,92[1,33; 15,27]	0,0120 *	4,29[1,40; 18,59]	0,0093 *	0,03[0,01; 0,05]	0,0093 *
Int. p-Wert [b][d][g]						0,2589		0,2119		0,2965
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	9[2,7]	325	3[0,9]	3,01[0,89; 13,65]	0,0782	2,95[0,89; 13,23]	0,0782	0,02[-0,00; 0,04]	0,0782
Negativ [a][d][g]	145	6[4,1]	144	2[1,4]	3,06[0,69; 21,15]	0,1452	2,98[0,70; 20,10]	0,1452	0,03[-0,01; 0,07]	0,1452
Int. p-Wert [a][d][g]						0,9863		0,9936		0,6622
PD-L1-Status										
TAP >= 1% [b][d][g]	427	15[3,5]	422	3[0,7]	4,50[1,56; 17,36]	0,0042 *	4,94[1,65; 21,22]	0,0031 *	0,03[0,01; 0,05]	0,0031 *
TAP < 1% [b][f][h]	48	0	47	2[4,3]	0,19[0,00; 2,39]	0,2145	NC	NC	NC	NC
Int. p-Wert [b][f][h]						0,0386 *		NC		NC

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaai 29JUN2026:08:39 khcs324

Table 5.2.9 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Pneumonitis (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	9[3,1]	264	3[1,1]	2,78[0,82; 12,61]	0,1043	2,72[0,82; 12,17]	0,1043	0,02[-0,00; 0,05]	0,1043
>=65 [a][d][g]	184	6[3,3]	205	2[1,0]	3,42[0,78; 23,54]	0,1068	3,34[0,78; 22,61]	0,1068	0,02[-0,01; 0,06]	0,1068
Int. p-Wert [a][d][g]						0,8437		0,8438		0,8627
Geschlecht										
Männlich [b][d][g]	327	13[4,0]	351	4[1,1]	3,31[1,21; 11,01]	0,0189 *	3,49[1,25; 12,29]	0,0159 *	0,03[0,01; 0,05]	0,0159 *
Weiblich [b][d][g]	148	2[1,4]	118	1[0,8]	1,34[0,18; 14,75]	0,7780	1,59[0,15; 34,04]	0,6953	0,01[-0,03; 0,04]	0,6953
Int. p-Wert [b][d][g]						0,8190		0,5736		0,1953
Tumorlokalisation										
GC [a][d][g]	325	11[3,4]	313	4[1,3]	2,71[0,91; 9,85]	0,0731	2,65[0,92; 9,48]	0,0731	0,02[-0,00; 0,05]	0,0731
GEJC [a][d][g]	150	4[2,7]	156	1[0,6]	4,25[0,62; 83,53]	0,1493	4,16[0,62; 80,82]	0,1493	0,02[-0,01; 0,06]	0,1493
Int. p-Wert [a][d][g]						0,7162		0,7119		0,9657

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.10 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Rash (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	21[23,3]	88	12[13,6]	1,93[0,89; 4,32]	0,0942	1,71[0,91; 3,39]	0,0942	0,10[-0,02; 0,21]	0,0942
Nicht-Asien [a][d][g]	385	44[11,4]	381	22[5,8]	2,11[1,25; 3,65]	0,0049 *	1,98[1,23; 3,30]	0,0049 *	0,06[0,02; 0,10]	0,0049 *
Int. p-Wert [a][d][g]						0,8548		0,7259		0,5082
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	48[14,5]	325	23[7,1]	2,23[1,34; 3,83]	0,0019 *	2,06[1,30; 3,36]	0,0019 *	0,07[0,03; 0,12]	0,0019 *
Negativ [a][d][g]	145	17[11,7]	144	11[7,6]	1,61[0,73; 3,66]	0,2387	1,53[0,75; 3,27]	0,2387	0,04[-0,03; 0,11]	0,2387
Int. p-Wert [a][d][g]						0,4981		0,5096		0,4247
PD-L1-Status										
TAP >= 1% [a][d][g]	427	58[13,6]	422	32[7,6]	1,92[1,22; 3,05]	0,0043 *	1,79[1,20; 2,73]	0,0043 *	0,06[0,02; 0,10]	0,0043 *
TAP < 1% [a][d][g]	48	7[14,6]	47	2[4,3]	3,84[0,87; 26,77]	0,0775	3,43[0,88; 22,22]	0,0775	0,10[-0,01; 0,23]	0,0775
Int. p-Wert [a][d][g]						0,3994		0,3936		0,4821

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.10 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Rash (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	39[13,4]	264	18[6,8]	2,12[1,19; 3,88]	0,0097 *	1,97[1,17; 3,44]	0,0097 *	0,07[0,02; 0,12]	0,0097 *
>=65 [a][d][g]	184	26[14,1]	205	16[7,8]	1,94[1,02; 3,82]	0,0444 *	1,81[1,01; 3,34]	0,0444 *	0,06[0,002; 0,13]	0,0444 *
Int. p-Wert [a][d][g]						0,8509		0,8394		0,9493
Geschlecht										
Männlich [a][d][g]	327	52[15,9]	351	27[7,7]	2,27[1,40; 3,76]	0,0008 *	2,07[1,35; 3,26]	0,0008 *	0,08[0,03; 0,13]	0,0008 *
Weiblich [a][d][g]	148	13[8,8]	118	7[5,9]	1,53[0,60; 4,18]	0,3764	1,48[0,63; 3,83]	0,3764	0,03[-0,04; 0,09]	0,3764
Int. p-Wert [a][d][g]						0,4740		0,5141		0,1841
Tumorlokalisation										
GC [a][d][g]	325	46[14,2]	313	25[8,0]	1,90[1,15; 3,22]	0,0126 *	1,77[1,13; 2,86]	0,0126 *	0,06[0,01; 0,11]	0,0126 *
GEJC [a][d][g]	150	19[12,7]	156	9[5,8]	2,37[1,06; 5,67]	0,0348 *	2,20[1,06; 4,95]	0,0348 *	0,07[0,01; 0,14]	0,0348 *
Int. p-Wert [a][d][g]						0,6551		0,6347		0,8589

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.11 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Rash maculo-papular (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [b][d][g]	90	2[2,2]	88	1[1,1]	1,65[0,21; 18,27]	0,6270	1,96[0,19; 41,61]	0,5698	0,01[-0,03; 0,06]	0,5698
Nicht-Asien [b][d][g]	385	13[3,4]	381	4[1,0]	3,04[1,11; 10,09]	0,0298 *	3,22[1,15; 11,34]	0,0249 *	0,02[0,003; 0,05]	0,0249 *
Int. p-Wert [b][d][g]						0,6118		0,7163		0,5828
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	9[2,7]	325	4[1,2]	2,25[0,72; 8,37]	0,1642	2,22[0,73; 8,11]	0,1642	0,01[-0,01; 0,04]	0,1642
Negativ [a][d][g]	145	6[4,1]	144	1[0,7]	6,17[1,04;117,34]	0,0451 *	5,96[1,04;111,79]	0,0451 *	0,03[0,001; 0,08]	0,0451 *
Int. p-Wert [a][d][g]						0,3914		0,3936		0,3379
PD-L1-Status										
TAP >= 1% [b][d][g]	427	13[3,0]	422	5[1,2]	2,47[0,95; 7,36]	0,0630	2,57[0,98; 7,95]	0,0556	0,02[-0,00; 0,04]	0,0556
TAP < 1% [b][f][h]	48	2[4,2]	47	0	5,11[0,40;711,94]	0,2276	NC	NC	NC	NC
Int. p-Wert [b][f][h]						0,4523		NC		NC

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.11 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Rash maculo-papular (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	12[4,1]	264	3[1,1]	3,74[1,17; 16,55]	0,0244 *	3,63[1,17; 15,80]	0,0244 *	0,03[0,004; 0,06]	0,0244 *
>=65 [a][d][g]	184	3[1,6]	205	2[1,0]	1,68[0,28; 12,88]	0,5667	1,67[0,28; 12,58]	0,5667	0,01[-0,02; 0,03]	0,5667
Int. p-Wert [a][d][g]						0,4813		0,4886		0,1962
Geschlecht										
Männlich [a][d][g]	327	10[3,1]	351	3[0,9]	3,66[1,11; 16,43]	0,0325 *	3,58[1,11; 15,85]	0,0325 *	0,02[0,002; 0,05]	0,0325 *
Weiblich [a][d][g]	148	5[3,4]	118	2[1,7]	2,03[0,43; 14,33]	0,3841	1,99[0,44; 13,74]	0,3841	0,02[-0,02; 0,06]	0,3841
Int. p-Wert [a][d][g]						0,5870		0,5836		0,8120
Tumorlokalisation										
GC [a][d][g]	325	5[1,5]	313	4[1,3]	1,21[0,32; 4,92]	0,7800	1,20[0,32; 4,82]	0,7800	0,00[-0,02; 0,02]	0,7800
GEJC [a][d][g]	150	10[6,7]	156	1[0,6]	11,07[2,08;204,40]	0,0024 *	10,40[2,03;189,62]	0,0024 *	0,06[0,02; 0,11]	0,0024 *
Int. p-Wert [a][d][g]						0,0497 *		0,0523		0,0079 *

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.12 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Pruritus (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	13[14,4]	88	10[11,4]	1,32[0,55; 3,26]	0,5395	1,27[0,59; 2,83]	0,5395	0,03[-0,07; 0,13]	0,5395
Nicht-Asien [a][d][g]	385	38[9,9]	381	15[3,9]	2,67[1,47; 5,09]	0,0010 *	2,51[1,43; 4,63]	0,0010 *	0,06[0,02; 0,10]	0,0010 *
Int. p-Wert [a][d][g]						0,1988		0,1699		0,5937
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	33[10,0]	325	15[4,6]	2,30[1,24; 4,43]	0,0075 *	2,17[1,22; 4,03]	0,0075 *	0,05[0,01; 0,09]	0,0075 *
Negativ [a][d][g]	145	18[12,4]	144	10[6,9]	1,90[0,86; 4,42]	0,1137	1,79[0,87; 3,90]	0,1137	0,05[-0,01; 0,12]	0,1137
Int. p-Wert [a][d][g]						0,7175		0,6907		0,9831
PD-L1-Status										
TAP >= 1% [a][d][g]	427	44[10,3]	422	23[5,5]	1,99[1,19; 3,41]	0,0082 *	1,89[1,18; 3,13]	0,0082 *	0,05[0,01; 0,09]	0,0082 *
TAP < 1% [a][d][g]	48	7[14,6]	47	2[4,3]	3,84[0,87; 26,77]	0,0775	3,43[0,88; 22,22]	0,0775	0,10[-0,01; 0,23]	0,0775
Int. p-Wert [a][d][g]						0,4341		0,4435		0,3667

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaal 29JUN2026:08:39 khcs324

Table 5.2.12 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Pruritus (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	36[12,4]	264	15[5,7]	2,34[1,28; 4,51]	0,0056 *	2,18[1,25; 4,01]	0,0056 *	0,07[0,02; 0,12]	0,0056 *
>=65 [a][d][g]	184	15[8,2]	205	10[4,9]	1,73[0,77; 4,08]	0,1882	1,67[0,78; 3,76]	0,1882	0,03[-0,02; 0,08]	0,1882
Int. p-Wert [a][d][g]						0,5675		0,5927		0,3293
Geschlecht										
Männlich [a][d][g]	327	37[11,3]	351	17[4,8]	2,51[1,40; 4,65]	0,0017 *	2,34[1,37; 4,18]	0,0017 *	0,06[0,02; 0,11]	0,0017 *
Weiblich [a][d][g]	148	14[9,5]	118	8[6,8]	1,44[0,59; 3,71]	0,4270	1,40[0,62; 3,39]	0,4270	0,03[-0,04; 0,09]	0,4270
Int. p-Wert [a][d][g]						0,3184		0,3192		0,3349
Tumorlokalisation										
GC [a][d][g]	325	28[8,6]	313	20[6,4]	1,38[0,76; 2,54]	0,2854	1,35[0,78; 2,38]	0,2854	0,02[-0,02; 0,06]	0,2854
GEJC [a][d][g]	150	23[15,3]	156	5[3,2]	5,47[2,18; 16,65]	0,0001 *	4,78[2,03; 13,96]	0,0001 *	0,12[0,06; 0,19]	0,0001 *
Int. p-Wert [a][d][g]						0,0141 *		0,0151 *		0,0089 *

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.13 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Anaemia (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	17[18,9]	88	18[20,5]	0,91[0,43; 1,90]	0,7927	0,92[0,50; 1,68]	0,7927	-0,02[-0,13; 0,10]	0,7927
Nicht-Asien [a][d][g]	385	102[26,5]	381	129[33,9]	0,70[0,52; 0,96]	0,0263 *	0,78[0,63; 0,97]	0,0263 *	-0,07[-0,14; -0,01]	0,0263 *
Int. p-Wert [a][d][g]						0,5388		0,6085		0,3955
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	86[26,1]	325	103[31,7]	0,76[0,54; 1,07]	0,1116	0,82[0,64; 1,05]	0,1116	-0,06[-0,13; 0,01]	0,1116
Negativ [a][d][g]	145	33[22,8]	144	44[30,6]	0,67[0,39; 1,13]	0,1334	0,74[0,50; 1,09]	0,1334	-0,08[-0,18; 0,02]	0,1334
Int. p-Wert [a][d][g]						0,6925		0,6709		0,7301
PD-L1-Status										
TAP >= 1% [a][d][g]	427	110[25,8]	422	135[32,0]	0,74[0,55; 0,99]	0,0451 *	0,81[0,65;0,995]	0,0451 *	-0,06[-0,12; -0,00]	0,0451 *
TAP < 1% [a][d][g]	48	9[18,8]	47	12[25,5]	0,67[0,25; 1,78]	0,4252	0,73[0,33; 1,57]	0,4252	-0,07[-0,24; 0,10]	0,4252
Int. p-Wert [a][d][g]						0,8603		0,8195		0,9513

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.13 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Anaemia (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	69[23,7]	264	70[26,5]	0,86[0,59; 1,27]	0,4466	0,89[0,67; 1,19]	0,4466	-0,03[-0,10; 0,04]	0,4466
>=65 [a][d][g]	184	50[27,2]	205	77[37,6]	0,62[0,40; 0,95]	0,0287 *	0,72[0,53; 0,97]	0,0287 *	-0,10[-0,20; -0,01]	0,0287 *
Int. p-Wert [a][d][g]						0,2641		0,3120		0,2062
Geschlecht										
Männlich [a][d][g]	327	69[21,1]	351	105[29,9]	0,63[0,44; 0,89]	0,0084 *	0,71[0,54; 0,92]	0,0084 *	-0,09[-0,15; -0,02]	0,0084 *
Weiblich [a][d][g]	148	50[33,8]	118	42[35,6]	0,92[0,56; 1,54]	0,7580	0,95[0,68; 1,33]	0,7580	-0,02[-0,13; 0,10]	0,7580
Int. p-Wert [a][d][g]						0,2178		0,1677		0,3004
Tumorlokalisation										
GC [a][d][g]	325	88[27,1]	313	99[31,6]	0,80[0,57; 1,13]	0,2066	0,86[0,67; 1,09]	0,2066	-0,05[-0,12; 0,03]	0,2066
GEJC [a][d][g]	150	31[20,7]	156	48[30,8]	0,59[0,35; 0,98]	0,0428 *	0,67[0,45; 0,99]	0,0428 *	-0,10[-0,20; -0,00]	0,0428 *
Int. p-Wert [a][d][g]						0,3216		0,2987		0,3658

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.14 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Musculoskeletal chest pain (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [b][f][h]	90	0	88	1[1,1]	0,32[0,00; 6,12]	0,4577	NC	NC	NC	NC
Nicht-Asien [b][d][g]	385	17[4,4]	381	6[1,6]	2,74[1,15; 7,38]	0,0216 *	2,80[1,18; 7,70]	0,0187 *	0,03[0,005; 0,05]	0,0187 *
Int. p-Wert [b][f][h]						0,3723		NC		NC
Klinischer Lymphknotenstatus										
Positiv [b][d][g]	330	14[4,2]	325	6[1,8]	2,25[0,91; 6,18]	0,0782	2,30[0,93; 6,42]	0,0707	0,02[-0,00; 0,05]	0,0707
Negativ [b][d][g]	145	3[2,1]	144	1[0,7]	2,35[0,38; 24,46]	0,3643	2,98[0,39; 59,81]	0,3063	0,01[-0,01; 0,05]	0,3063
Int. p-Wert [b][d][g]						0,6445		0,8324		0,5990
PD-L1-Status										
TAP >= 1% [b][d][g]	427	14[3,3]	422	6[1,4]	2,25[0,92; 6,15]	0,0779	2,31[0,93; 6,46]	0,0704	0,02[-0,00; 0,04]	0,0704
TAP < 1% [b][d][g]	48	3[6,3]	47	1[2,1]	2,38[0,37; 25,31]	0,3642	2,94[0,39; 58,20]	0,3062	0,04[-0,04; 0,14]	0,3062
Int. p-Wert [b][d][g]						0,6242		0,8424		0,5831

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.14 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Musculoskeletal chest pain (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	12[4,1]	264	5[1,9]	2,23[0,81; 7,08]	0,1214	2,18[0,82; 6,77]	0,1214	0,02[-0,01; 0,05]	0,1214
>=65 [a][d][g]	184	5[2,7]	205	2[1,0]	2,84[0,60; 19,96]	0,1919	2,79[0,61; 19,28]	0,1919	0,02[-0,01; 0,05]	0,1919
Int. p-Wert [a][d][g]						0,8084		0,8007		0,8073
Geschlecht										
Männlich [a][d][g]	327	12[3,7]	351	3[0,9]	4,42[1,39; 19,52]	0,0103 *	4,29[1,38; 18,72]	0,0103 *	0,03[0,01; 0,05]	0,0103 *
Weiblich [a][d][g]	148	5[3,4]	118	4[3,4]	1,00[0,26; 4,11]	0,9959	1,00[0,27; 3,95]	0,9959	-0,00[-0,05; 0,05]	0,9959
Int. p-Wert [a][d][g]						0,1102		0,1082		0,2579
Tumorlokalisation										
GC [a][d][g]	325	5[1,5]	313	3[1,0]	1,61[0,39; 7,92]	0,5079	1,61[0,40; 7,77]	0,5079	0,01[-0,01; 0,03]	0,5079
GEJC [a][d][g]	150	12[8,0]	156	4[2,6]	3,30[1,12; 12,04]	0,0294 *	3,12[1,11; 10,97]	0,0294 *	0,05[0,01; 0,11]	0,0294 *
Int. p-Wert [a][d][g]						0,4498		0,4730		0,0658

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaan 29JUN2026:08:39 khcs324

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Table 5.2.15 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Hypomagnesaemia (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [c][f][h]	90	0	88	0	NC	NC	NC	NC	NC	NC
Nicht-Asien [b][d][g]	385	7[1,8]	381	20[5,2]	0,35[0,14; 0,78]	0,0100 *	0,35[0,14; 0,77]	0,0086 *	-0,03[-0,06; -0,01]	0,0086 *
Int. p-Wert [b][f][h]						0,1893		NC		NC
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	4[1,2]	325	11[3,4]	0,35[0,10; 1,04]	0,0583	0,36[0,10; 1,04]	0,0583	-0,02[-0,05;0,001]	0,0583
Negativ [a][d][g]	145	3[2,1]	144	9[6,3]	0,32[0,07; 1,09]	0,0687	0,33[0,07; 1,08]	0,0687	-0,04[-0,09;0,003]	0,0687
Int. p-Wert [a][d][g]						0,9112		0,9283		0,4362
PD-L1-Status										
TAP >= 1% [b][d][g]	427	6[1,4]	422	18[4,3]	0,34[0,13; 0,79]	0,0119 *	0,33[0,12; 0,78]	0,0102 *	-0,03[-0,05; -0,01]	0,0102 *
TAP < 1% [b][d][g]	48	1[2,1]	47	2[4,3]	0,57[0,05; 4,49]	0,5932	0,49[0,02; 4,95]	0,5415	-0,02[-0,11; 0,06]	0,5415
Int. p-Wert [b][d][g]						0,6085		0,7640		0,8567

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.15 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Hypomagnesaemia (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	4[1,4]	264	9[3,4]	0,39[0,11; 1,23]	0,1103	0,40[0,11; 1,22]	0,1103	-0,02[-0,05;0,005]	0,1103
>=65 [a][d][g]	184	3[1,6]	205	11[5,4]	0,29[0,07; 0,95]	0,0410 *	0,30[0,07; 0,96]	0,0410 *	-0,04[-0,08; -0,00]	0,0410 *
Int. p-Wert [a][d][g]						0,7364		0,7460		0,4485
Geschlecht										
Männlich [a][d][g]	327	3[0,9]	351	15[4,3]	0,21[0,05; 0,64]	0,0044 *	0,21[0,05; 0,64]	0,0044 *	-0,03[-0,06; -0,01]	0,0044 *
Weiblich [a][d][g]	148	4[2,7]	118	5[4,2]	0,63[0,15; 2,42]	0,4934	0,64[0,16; 2,36]	0,4934	-0,02[-0,07; 0,03]	0,4934
Int. p-Wert [a][d][g]						0,2300		0,2258		0,4907
Tumorlokalisation										
GC [a][d][g]	325	5[1,5]	313	12[3,8]	0,39[0,12; 1,07]	0,0682	0,40[0,13; 1,07]	0,0682	-0,02[-0,05;0,002]	0,0682
GEJC [a][d][g]	150	2[1,3]	156	8[5,1]	0,25[0,04; 1,02]	0,0532	0,26[0,04; 1,02]	0,0532	-0,04[-0,08;0,001]	0,0532
Int. p-Wert [a][d][g]						0,6355		0,6398		0,5229

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaao 29JUN2026:08:39 khcs324

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Table 5.2.16 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Infusion related reaction (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	3[3,3]	88	2[2,3]	1,48[0,24; 11,46]	0,6674	1,47[0,25; 10,94]	0,6674	0,01[-0,04; 0,07]	0,6674
Nicht-Asien [a][d][g]	385	30[7,8]	381	15[3,9]	2,06[1,11; 4,00]	0,0220 *	1,98[1,10; 3,72]	0,0220 *	0,04[0,01; 0,07]	0,0220 *
Int. p-Wert [a][d][g]						0,7391		0,7551		0,3627
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	17[5,2]	325	9[2,8]	1,91[0,86; 4,54]	0,1154	1,86[0,86; 4,31]	0,1154	0,02[-0,01; 0,06]	0,1154
Negativ [a][d][g]	145	16[11,0]	144	8[5,6]	2,11[0,90; 5,36]	0,0886	1,99[0,90; 4,76]	0,0886	0,05[-0,01; 0,12]	0,0886
Int. p-Wert [a][d][g]						0,8703		0,9102		0,3833
PD-L1-Status										
TAP >= 1% [a][d][g]	427	29[6,8]	422	13[3,1]	2,29[1,20; 4,62]	0,0116 *	2,20[1,19; 4,33]	0,0116 *	0,04[0,01; 0,07]	0,0116 *
TAP < 1% [a][d][g]	48	4[8,3]	47	4[8,5]	0,98[0,22; 4,37]	0,9752	0,98[0,24; 3,93]	0,9752	-0,00[-0,12; 0,12]	0,9752
Int. p-Wert [a][d][g]						0,2973		0,2838		0,5115

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.16 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of PT: Infusion related reaction (AE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	24[8,2]	264	12[4,5]	1,89[0,94; 3,98]	0,0738	1,81[0,95; 3,69]	0,0738	0,04[-0,00; 0,08]	0,0738
>=65 [a][d][g]	184	9[4,9]	205	5[2,4]	2,06[0,70; 6,80]	0,1933	2,01[0,71; 6,43]	0,1933	0,02[-0,01; 0,07]	0,1933
Int. p-Wert [a][d][g]						0,8984		0,8768		0,6586
Geschlecht										
Männlich [a][d][g]	327	22[6,7]	351	8[2,3]	3,09[1,41; 7,50]	0,0042 *	2,95[1,39; 6,98]	0,0042 *	0,04[0,01; 0,08]	0,0042 *
Weiblich [a][d][g]	148	11[7,4]	118	9[7,6]	0,97[0,39; 2,49]	0,9523	0,97[0,42; 2,34]	0,9523	-0,00[-0,07; 0,06]	0,9523
Int. p-Wert [a][d][g]						0,0645		0,0603		0,1973
Tumorlokalisation										
GC [a][d][g]	325	22[6,8]	313	13[4,2]	1,68[0,84; 3,48]	0,1445	1,63[0,85; 3,27]	0,1445	0,03[-0,01; 0,06]	0,1445
GEJC [a][d][g]	150	11[7,3]	156	4[2,6]	3,01[1,003; 11,05]	0,0494 *	2,86[1,002; 10,14]	0,0494 *	0,05[0,0001; 0,10]	0,0494 *
Int. p-Wert [a][d][g]						0,3917		0,3888		0,4771

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.17 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of AE max CTCAE grade>=3 (AE max CTCAE grade>=3)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	79[87,8]	88	77[87,5]	1,03[0,42; 2,53]	0,9551	1,00[0,89; 1,13]	0,9551	0,00[-0,10; 0,10]	0,9551
Nicht-Asien [a][d][g]	385	288[74,8]	381	277[72,7]	1,11[0,81; 1,54]	0,5085	1,03[0,95; 1,12]	0,5085	0,02[-0,04; 0,08]	0,5085
Int. p-Wert [a][d][g]						0,8639		0,7213		0,7561
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	255[77,3]	325	246[75,7]	1,09[0,76; 1,57]	0,6334	1,02[0,94; 1,11]	0,6334	0,02[-0,05; 0,08]	0,6334
Negativ [a][d][g]	145	112[77,2]	144	108[75,0]	1,13[0,66; 1,95]	0,6549	1,03[0,90; 1,17]	0,6549	0,02[-0,08; 0,12]	0,6549
Int. p-Wert [a][d][g]						0,9149		0,9114		0,9124
PD-L1-Status										
TAP >= 1% [a][d][g]	427	330[77,3]	422	326[77,3]	1,00[0,73; 1,38]	0,9911	1,00[0,93; 1,08]	0,9911	0,00[-0,06; 0,06]	0,9911
TAP < 1% [a][d][g]	48	37[77,1]	47	28[59,6]	2,28[0,95; 5,70]	0,0652	1,29[0,98; 1,75]	0,0652	0,18[-0,01; 0,36]	0,0652
Int. p-Wert [a][d][g]						0,0844		0,0753		0,0780

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.17 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of AE max CTCAE grade>=3 (AE max CTCAE grade>=3)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	214[73,5]	264	193[73,1]	1,02[0,70; 1,49]	0,9082	1,01[0,91; 1,11]	0,9082	0,00[-0,07; 0,08]	0,9082
>=65 [a][d][g]	184	153[83,2]	205	161[78,5]	1,35[0,81; 2,26]	0,2480	1,06[0,96; 1,17]	0,2480	0,05[-0,03; 0,12]	0,2480
Int. p-Wert [a][d][g]						0,3908		0,4723		0,4455
Geschlecht										
Männlich [a][d][g]	327	251[76,8]	351	261[74,4]	1,14[0,80; 1,62]	0,4676	1,03[0,95; 1,13]	0,4676	0,02[-0,04; 0,09]	0,4676
Weiblich [a][d][g]	148	116[78,4]	118	93[78,8]	0,97[0,54; 1,75]	0,9315	0,99[0,88; 1,13]	0,9315	-0,00[-0,10; 0,10]	0,9315
Int. p-Wert [a][d][g]						0,6560		0,6327		0,6395
Tumorlokalisation										
GC [a][d][g]	325	254[78,2]	313	240[76,7]	1,09[0,75; 1,58]	0,6556	1,02[0,94; 1,11]	0,6556	0,01[-0,05; 0,08]	0,6556
GEJC [a][d][g]	150	113[75,3]	156	114[73,1]	1,13[0,67; 1,88]	0,6520	1,03[0,90; 1,18]	0,6520	0,02[-0,08; 0,12]	0,6520
Int. p-Wert [a][d][g]						0,9175		0,8871		0,8965

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.18 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of G>=3 SOC: Gastrointestinal disorders (AE max CTCAE grade>=3)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	17[18,9]	88	10[11,4]	1,82[0,79; 4,36]	0,1595	1,66[0,82; 3,58]	0,1595	0,08[-0,03; 0,18]	0,1595
Nicht-Asien [a][d][g]	385	93[24,2]	381	74[19,4]	1,32[0,94; 1,87]	0,1123	1,24[0,95; 1,64]	0,1123	0,05[-0,01; 0,11]	0,1123
Int. p-Wert [a][d][g]						0,4910		0,4568		0,6475
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	73[22,1]	325	57[17,5]	1,34[0,91; 1,97]	0,1410	1,26[0,93; 1,73]	0,1410	0,05[-0,02; 0,11]	0,1410
Negativ [a][d][g]	145	37[25,5]	144	27[18,8]	1,48[0,85; 2,62]	0,1652	1,36[0,88; 2,14]	0,1652	0,07[-0,03; 0,16]	0,1652
Int. p-Wert [a][d][g]						0,7606		0,7816		0,7053
PD-L1-Status										
TAP >= 1% [a][d][g]	427	96[22,5]	422	75[17,8]	1,34[0,96; 1,88]	0,0868	1,27[0,97; 1,66]	0,0868	0,05[-0,01; 0,10]	0,0868
TAP < 1% [a][d][g]	48	14[29,2]	47	9[19,1]	1,74[0,68; 4,66]	0,2528	1,52[0,74; 3,34]	0,2528	0,10[-0,07; 0,27]	0,2528
Int. p-Wert [a][d][g]						0,6154		0,6393		0,5621

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaar 29JUN2026:08:39 khcs324

Table 5.2.18 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of G>=3 SOC: Gastrointestinal disorders (AE max CTCAE grade>=3)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	62[21,3]	264	48[18,2]	1,22[0,80; 1,86]	0,3559	1,17[0,84; 1,65]	0,3559	0,03[-0,04; 0,10]	0,3559
>=65 [a][d][g]	184	48[26,1]	205	36[17,6]	1,66[1,02; 2,71]	0,0413 *	1,49[1,02; 2,20]	0,0413 *	0,09[0,003; 0,17]	0,0413 *
Int. p-Wert [a][d][g]						0,3489		0,3628		0,3147
Geschlecht										
Männlich [a][d][g]	327	69[21,1]	351	64[18,2]	1,20[0,82; 1,75]	0,3476	1,16[0,85; 1,57]	0,3476	0,03[-0,03; 0,09]	0,3476
Weiblich [a][d][g]	148	41[27,7]	118	20[16,9]	1,88[1,04; 3,48]	0,0363 *	1,63[1,03; 2,70]	0,0363 *	0,11[0,01; 0,21]	0,0363 *
Int. p-Wert [a][d][g]						0,2130		0,2255		0,1842
Tumorlokalisation										
GC [a][d][g]	325	77[23,7]	313	50[16,0]	1,63[1,10; 2,44]	0,0143 *	1,48[1,08; 2,06]	0,0143 *	0,08[0,02; 0,14]	0,0143 *
GEJC [a][d][g]	150	33[22,0]	156	34[21,8]	1,01[0,59; 1,74]	0,9654	1,01[0,66; 1,55]	0,9654	0,00[-0,09; 0,10]	0,9654
Int. p-Wert [a][d][g]						0,1620		0,1548		0,1863

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaar 29JUN2026:08:39 khcs324

Table 5.2.19 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of G>=3 SOC: Metabolism and nutrition disorders (AE max CTCAE grade>=3)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	12[13,3]	88	6[6,8]	2,10[0,78; 6,29]	0,1457	1,96[0,80; 5,41]	0,1457	0,07[-0,02; 0,16]	0,1457
Nicht-Asien [a][d][g]	385	38[9,9]	381	25[6,6]	1,56[0,93; 2,67]	0,0945	1,50[0,93; 2,47]	0,0945	0,03[-0,01; 0,07]	0,0945
Int. p-Wert [a][d][g]						0,6093		0,6219		0,5111
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	36[10,9]	325	23[7,1]	1,61[0,94; 2,81]	0,0855	1,54[0,94; 2,58]	0,0855	0,04[-0,01; 0,08]	0,0855
Negativ [a][d][g]	145	14[9,7]	144	8[5,6]	1,82[0,75; 4,68]	0,1862	1,74[0,77; 4,23]	0,1862	0,04[-0,02; 0,10]	0,1862
Int. p-Wert [a][d][g]						0,8199		0,8090		0,9442
PD-L1-Status										
TAP >= 1% [a][d][g]	427	41[9,6]	422	28[6,6]	1,49[0,91; 2,49]	0,1127	1,45[0,92; 2,32]	0,1127	0,03[-0,01; 0,07]	0,1127
TAP < 1% [a][d][g]	48	9[18,8]	47	3[6,4]	3,38[0,93; 16,07]	0,0640	2,94[0,94; 12,64]	0,0640	0,12[-0,01; 0,26]	0,0640
Int. p-Wert [a][d][g]						0,2563		0,2722		0,1717

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaas 29JUN2026:08:39 khcs324

Table 5.2.19 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of G>=3 SOC: Metabolism and nutrition disorders (AE max CTCAE grade>=3)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	25[8,6]	264	17[6,4]	1,37[0,72; 2,63]	0,3367	1,33[0,74; 2,46]	0,3367	0,02[-0,02; 0,07]	0,3367
>=65 [a][d][g]	184	25[13,6]	205	14[6,8]	2,15[1,09; 4,37]	0,0262 *	1,99[1,08; 3,82]	0,0262 *	0,07[0,01; 0,13]	0,0262 *
Int. p-Wert [a][d][g]						0,3452		0,3619		0,2231
Geschlecht										
Männlich [a][d][g]	327	36[11,0]	351	19[5,4]	2,16[1,23; 3,92]	0,0073 *	2,03[1,21; 3,55]	0,0073 *	0,06[0,02; 0,10]	0,0073 *
Weiblich [a][d][g]	148	14[9,5]	118	12[10,2]	0,92[0,41; 2,11]	0,8466	0,93[0,45; 1,97]	0,8466	-0,01[-0,08; 0,06]	0,8466
Int. p-Wert [a][d][g]						0,0953		0,0926		0,1339
Tumorlokalisation										
GC [a][d][g]	325	32[9,8]	313	22[7,0]	1,44[0,82; 2,57]	0,1998	1,40[0,84; 2,39]	0,1998	0,03[-0,02; 0,07]	0,1998
GEJC [a][d][g]	150	18[12,0]	156	9[5,8]	2,23[0,99; 5,36]	0,0529	2,08[0,99; 4,72]	0,0529	0,06[-0,00; 0,13]	0,0529
Int. p-Wert [a][d][g]						0,3966		0,3993		0,3812

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.20 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of SAE (SAE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	44[48,9]	88	36[40,9]	1,38[0,76; 2,51]	0,2843	1,20[0,86; 1,67]	0,2843	0,08[-0,07; 0,22]	0,2843
Nicht-Asien [a][d][g]	385	187[48,6]	381	171[44,9]	1,16[0,87; 1,54]	0,3061	1,08[0,93; 1,26]	0,3061	0,04[-0,03; 0,11]	0,3061
Int. p-Wert [a][d][g]						0,6016		0,5895		0,6039
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	165[50,0]	325	151[46,5]	1,15[0,85; 1,57]	0,3648	1,08[0,92; 1,26]	0,3648	0,04[-0,04; 0,11]	0,3648
Negativ [a][d][g]	145	66[45,5]	144	56[38,9]	1,31[0,82; 2,10]	0,2538	1,17[0,89; 1,54]	0,2538	0,07[-0,05; 0,18]	0,2538
Int. p-Wert [a][d][g]						0,6477		0,6001		0,6585
PD-L1-Status										
TAP >= 1% [a][d][g]	427	206[48,2]	422	187[44,3]	1,17[0,89; 1,54]	0,2507	1,09[0,94; 1,26]	0,2507	0,04[-0,03; 0,11]	0,2507
TAP < 1% [a][d][g]	48	25[52,1]	47	20[42,6]	1,47[0,65; 3,32]	0,3519	1,22[0,80; 1,92]	0,3519	0,10[-0,11; 0,29]	0,3519
Int. p-Wert [a][d][g]						0,6043		0,6106		0,6035

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.20 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of SAE (SAE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	126[43,3]	264	110[41,7]	1,07[0,76; 1,50]	0,6976	1,04[0,86; 1,26]	0,6976	0,02[-0,07; 0,10]	0,6976
>=65 [a][d][g]	184	105[57,1]	205	97[47,3]	1,48[0,99; 2,21]	0,0545	1,21[0,996; 1,46]	0,0545	0,10[-0,00; 0,20]	0,0545
Int. p-Wert [a][d][g]						0,2232		0,2843		0,2170
Geschlecht										
Männlich [a][d][g]	327	161[49,2]	351	162[46,2]	1,13[0,84; 1,53]	0,4221	1,07[0,91; 1,25]	0,4221	0,03[-0,04; 0,11]	0,4221
Weiblich [a][d][g]	148	70[47,3]	118	45[38,1]	1,46[0,89; 2,39]	0,1333	1,24[0,94; 1,67]	0,1333	0,09[-0,03; 0,21]	0,1333
Int. p-Wert [a][d][g]						0,3915		0,3621		0,3982
Tumorlokalisation										
GC [a][d][g]	325	155[47,7]	313	126[40,3]	1,35[0,99; 1,85]	0,0584	1,18[0,99; 1,42]	0,0584	0,07[-0,00; 0,15]	0,0584
GEJC [a][d][g]	150	76[50,7]	156	81[51,9]	0,95[0,61; 1,49]	0,8260	0,98[0,78; 1,21]	0,8260	-0,01[-0,12; 0,10]	0,8260
Int. p-Wert [a][d][g]						0,2064		0,1753		0,2097

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.21 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of SAE SOC: Metabolism and nutrition disorders (SAE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	6[6,7]	88	3[3,4]	2,02[0,52; 9,83]	0,3166	1,96[0,53; 9,04]	0,3166	0,03[-0,03; 0,10]	0,3166
Nicht-Asien [a][d][g]	385	16[4,2]	381	7[1,8]	2,32[0,98; 6,09]	0,0567	2,26[0,98; 5,83]	0,0567	0,02[-0,00; 0,05]	0,0567
Int. p-Wert [a][d][g]						0,8751		0,8602		0,7869
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	18[5,5]	325	9[2,8]	2,03[0,92; 4,79]	0,0810	1,97[0,92; 4,54]	0,0810	0,03[-0,00; 0,06]	0,0810
Negativ [a][d][g]	145	4[2,8]	144	1[0,7]	4,06[0,59; 79,83]	0,1639	3,97[0,60; 77,15]	0,1639	0,02[-0,01; 0,06]	0,1639
Int. p-Wert [a][d][g]						0,5436		0,5324		0,7766
PD-L1-Status										
TAP >= 1% [a][d][g]	427	18[4,2]	422	8[1,9]	2,28[1,01; 5,60]	0,0469 *	2,22[1,01; 5,37]	0,0469 *	0,02[0,0003; 0,05]	0,0469 *
TAP < 1% [a][d][g]	48	4[8,3]	47	2[4,3]	2,05[0,38; 15,29]	0,4095	1,96[0,40; 13,65]	0,4095	0,04[-0,06; 0,15]	0,4095
Int. p-Wert [a][d][g]						0,9139		0,8930		0,7285

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.21 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of SAE SOC: Metabolism and nutrition disorders (SAE)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Alter bei Randomisierung (Jahre)										
<65 [a][d][g]	291	11[3,8]	264	5[1,9]	2,03[0,73; 6,53]	0,1785	2,00[0,74; 6,27]	0,1785	0,02[-0,01; 0,05]	0,1785
>=65 [a][d][g]	184	11[6,0]	205	5[2,4]	2,54[0,91; 8,20]	0,0770	2,45[0,91; 7,66]	0,0770	0,04[-0,00; 0,08]	0,0770
Int. p-Wert [a][d][g]						0,7735		0,7845		0,5021
Geschlecht										
Männlich [a][d][g]	327	17[5,2]	351	6[1,7]	3,15[1,29; 8,83]	0,0108 *	3,04[1,28; 8,34]	0,0108 *	0,03[0,01; 0,06]	0,0108 *
Weiblich [a][d][g]	148	5[3,4]	118	4[3,4]	1,00[0,26; 4,11]	0,9959	1,00[0,27; 3,95]	0,9959	-0,00[-0,05; 0,05]	0,9959
Int. p-Wert [a][d][g]						0,1716		0,1722		0,1833
Tumorlokalisation										
GC [a][d][g]	325	14[4,3]	313	7[2,2]	1,97[0,81; 5,25]	0,1386	1,93[0,81; 5,02]	0,1386	0,02[-0,01; 0,05]	0,1386
GEJC [a][d][g]	150	8[5,3]	156	3[1,9]	2,87[0,81; 13,31]	0,1035	2,77[0,82; 12,48]	0,1035	0,03[-0,01; 0,08]	0,1035
Int. p-Wert [a][d][g]						0,6462		0,6487		0,5973

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
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Table 5.2.22 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of AE leading to discontinuation of treatment (AE leading to discontinuation of treatment)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt					
					Odds Ratio		Relatives Risiko		Risikodifferenz	
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert	Schätzer [95%-KI]	2-seitiger p-Wert
Region										
Asien [a][d][g]	90	20[22,2]	88	20[22,7]	0,97[0,48; 1,97]	0,9357	0,98[0,56; 1,70]	0,9357	-0,01[-0,13; 0,12]	0,9357
Nicht-Asien [a][d][g]	385	123[31,9]	381	87[22,8]	1,59[1,15; 2,19]	0,0046 *	1,40[1,11; 1,78]	0,0046 *	0,09[0,03; 0,15]	0,0046 *
Int. p-Wert [a][d][g]						0,2145		0,2387		0,1716
Klinischer Lymphknotenstatus										
Positiv [a][d][g]	330	95[28,8]	325	75[23,1]	1,35[0,95; 1,92]	0,0952	1,25[0,96; 1,63]	0,0952	0,06[-0,01; 0,12]	0,0952
Negativ [a][d][g]	145	48[33,1]	144	32[22,2]	1,73[1,03; 2,94]	0,0382 *	1,49[1,02; 2,21]	0,0382 *	0,11[0,01; 0,21]	0,0382 *
Int. p-Wert [a][d][g]						0,4343		0,4516		0,4079
PD-L1-Status										
TAP >= 1% [a][d][g]	427	130[30,4]	422	99[23,5]	1,43[1,05; 1,94]	0,0217 *	1,30[1,04; 1,63]	0,0217 *	0,07[0,01; 0,13]	0,0217 *
TAP < 1% [a][d][g]	48	13[27,1]	47	8[17,0]	1,81[0,68; 5,06]	0,2354	1,59[0,74; 3,69]	0,2354	0,10[-0,07; 0,27]	0,2354
Int. p-Wert [a][d][g]						0,6525		0,6206		0,7317

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaav 29JUN2026:08:39 khcs324

Table 5.2.22 Summary of subgroup analysis (odds ratio, relative risk and risk differences) of AE leading to discontinuation of treatment (AE leading to discontinuation of treatment)
Safety Analysis Set, DCO 01SEP2025

	Durva + FLOT (N=475)		Placebo + FLOT (N=469)		Behandlungseffekt								
					Odds Ratio			Relatives Risiko			Risikodifferenz		
Subgruppen	n	Anzahl (%) der Patienten mit Ereignis	n	Anzahl (%) der Patienten mit Ereignis	Schätzer [95%-KI]		2-seitiger p-Wert	Schätzer [95%-KI]		2-seitiger p-Wert	Schätzer [95%-KI]		2-seitiger p-Wert
Alter bei Randomisierung (Jahre)													
<65 [a][d][g]	291	84[28,9]	264	56[21,2]	1,51[1,02;	2,23]	0,0375 *	1,36[1,02;	1,84]	0,0375 *	0,08[0,004;	0,15]	0,0375 *
>=65 [a][d][g]	184	59[32,1]	205	51[24,9]	1,43[0,92;	2,22]	0,1162	1,29[0,94;	1,78]	0,1162	0,07[-0,02;	0,16]	0,1162
Int. p-Wert [a][d][g]							0,8525			0,8057			0,9365
Geschlecht													
Männlich [a][d][g]	327	94[28,7]	351	81[23,1]	1,34[0,95;	1,90]	0,0919	1,25[0,96;	1,61]	0,0919	0,06[-0,01;	0,12]	0,0919
Weiblich [a][d][g]	148	49[33,1]	118	26[22,0]	1,75[1,01;	3,08]	0,0446 *	1,50[1,01;	2,31]	0,0446 *	0,11[0,003;	0,22]	0,0446 *
Int. p-Wert [a][d][g]							0,4259			0,4431			0,3995
Tumorlokalisation													
GC [a][d][g]	325	97[29,8]	313	65[20,8]	1,62[1,13;	2,34]	0,0083 *	1,44[1,10;	1,90]	0,0083 *	0,09[0,02;	0,16]	0,0083 *
GEJC [a][d][g]	150	46[30,7]	156	42[26,9]	1,20[0,73;	1,97]	0,4695	1,14[0,80;	1,63]	0,4695	0,04[-0,06;	0,14]	0,4695
Int. p-Wert [a][d][g]							0,3355			0,3076			0,3898

NC=not calculable. CI=confidence interval. PL=profile likelihood. LR=likelihood ratio test. ID=insufficient data. Interaction p-values from models including treatment, subgroup and treatment by subgroup, rest of models include treatment only. An interaction model is only used when >=10 patients for all subgroup levels and >=10 events for one subgroup level. For subgroups with >2 levels, levels with ID were dropped and if appropriate, interaction model re-fitted. If interaction model conditions not met ID is presented. [a] Odds ratio (OR), 95% PL CI, LR p-value via logistic regression. [b] As [a] but with Firth method. [c] OR NC via [a] or [b]. [d] Relative risk (RR), 95% PL CI, LR p-value via log-binomial regression. [e] RR, 95% CI, p-value via modified Poisson regression. [f] RR NC via [d] or [e]. [g] Risk difference (RD), 95% PL CI, LR p-value via binomial regression. [h] RD NC via [g]. OR and RR<1, and RD <0 favours Durva + FLOT. *p<0.05.
Durva = Durvalumab. FLOT = Fluorouracil + Leucovorin + Oxaliplatin + Docetaxel.
root/cdar/d419/d910gc00001/ar/pay_germany2/restricted_tlf/prod/program/orrrardsubae.sas gorrrardsubaeaav 29JUN2026:08:39 khcs324

Table 6.1.1 Post-discontinuation disease-related anti-cancer therapy
Full Analysis Set, DCO 01SEP2025

Antineoplastische Folgetherapien [a]	Durva + FLOT (N=474)	Placebo + FLOT (N=474)	Total (N=948)
Anzahl der Patient:innen mit nachfolgender krankheitsspezifischer antineoplastischer Therapie	116 [24,5]	161 [34,0]	277 [29,2]
Systemische Therapie	111 [23,4]	154 [32,5]	265 [28,0]
Zytotoxische Chemotherapie	109 [23,0]	148 [31,2]	257 [27,1]
Antiangiogene Therapie	22 [4,6]	32 [6,8]	54 [5,7]
Zielgerichtete Therapie	13 [2,7]	16 [3,4]	29 [3,1]
Immuntherapie	18 [3,8]	50 [10,5]	68 [7,2]
Ausschließlich Immuntherapie	2 [0,4]	5 [1,1]	7 [0,7]
Immuntherapie + zytotoxische Chemotherapie	10 [2,1]	24 [5,1]	34 [3,6]
Immuntherapie + zielgerichtete Therapie + zytotoxische Chemotherapie	3 [0,6]	4 [0,8]	7 [0,7]
Immuntherapie + andere	3 [0,6]	17 [3,6]	20 [2,1]
Andere	2 [0,4]	7 [1,5]	9 [0,9]
Radiotherapie	19 [4,0]	28 [5,9]	47 [5,0]
Begleitende Chemoradiotherapie	6 [1,3]	8 [1,7]	14 [1,5]
Palliative Therapie	9 [1,9]	18 [3,8]	27 [2,8]
Folgetherapie Regime			
1. Folgetherapie	110 [23,2]	150 [31,6]	260 [27,4]
2. Folgetherapie	39 [8,2]	50 [10,5]	89 [9,4]
>/= 3. Folgetherapie	12 [2,5]	19 [4,0]	31 [3,3]

[a] Therapies post discontinuation of study treatment. Subjects can be counted in more than one anti-cancer therapy.
Durva = Durvalumab. FLOT = 5-FU + Leucovorin + Oxaliplatin + Docetaxel. N = Number of subjects in treatment group.
WHODrug Dictionary version March 2025.
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Table 6.1.2 First post-discontinuation disease-related anti-cancer therapy
Full Analysis Set, DCO 01SEP2025

Antineoplastische Folgetherapien [a]	Durva + FLOT (N=474)	Placebo + FLOT (N=474)	Total (N=948)
Anzahl der Patient:innen mit nachfolgender krankheitsspezifischer antineoplastischer Therapie	116 [24,5]	161 [34,0]	277 [29,2]
Systemische Therapie	106 [22,4]	146 [30,8]	252 [26,6]
Zytotoxische Chemotherapie	103 [21,7]	140 [29,5]	243 [25,6]
Antiangiogene Therapie	9 [1,9]	15 [3,2]	24 [2,5]
Zielgerichtete Therapie	8 [1,7]	9 [1,9]	17 [1,8]
Immuntherapie	13 [2,7]	29 [6,1]	42 [4,4]
Ausschließlich Immuntherapie	2 [0,4]	5 [1,1]	7 [0,7]
Immuntherapie + zytotoxische Chemotherapie	8 [1,7]	16 [3,4]	24 [2,5]
Immuntherapie + zielgerichtete Therapie + zytotoxische Chemotherapie	1 [0,2]	2 [0,4]	3 [0,3]
Immuntherapie + andere	2 [0,4]	6 [1,3]	8 [0,8]
Andere	0	1 [0,2]	1 [0,1]
Radiotherapie	12 [2,5]	18 [3,8]	30 [3,2]
Begleitende Chemoradiotherapie	3 [0,6]	5 [1,1]	8 [0,8]
Palliative Therapie	5 [1,1]	11 [2,3]	16 [1,7]
Folgetherapie Regime			
1. Folgetherapie	104 [21,9]	142 [30,0]	246 [25,9]
2. Folgetherapie	2 [0,4]	3 [0,6]	5 [0,5]
>/= 3. Folgetherapie	0	1 [0,2]	1 [0,1]

[a] Therapies post discontinuation of study treatment. Subjects can be counted in more than one anti-cancer therapy.
Durva = Durvalumab. FLOT = 5-FU + Leucovorin + Oxaliplatin + Docetaxel. N = Number of subjects in treatment group.
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